NPWomensHealthcare.com September 2018 • Volume 6 • Number 3

Women's Healthcare

A CLINICAL JOURNAL FOR NPs

The official journal of NPWH NURSE PRACTITIONERS IN WOMEN'S HEALTH Caring for Women

CONTINUING EDUCATION

Managing women's health issues across a lifespan

Challenges of preconception and interconception care: Environmental toxic exposures

Developing and implementing PrEP at your local health center

NPWH POSITION STATEMENT
Men with breast conditions: The role of the WHNP specializing in breast care

A HEALTHCOM MEDIA Publication

INDICATION AND IMPORTANT SAFETY INFORMATION INCLUDING **BOXED WARNING**

INDICATION

Osphena® (ospemifene) is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

WARNING: Endometrial Cancer and Cardiovascular Disorders

Osphena® is an estrogen agonist/antagonist with tissue selective effects. In the endometrium Osphena® has estrogen agonistic effects. There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen therapy. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

The Women's Health Initiative (WHI) estrogen-alone substudy reported an increased risk of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg], relative to placebo. Osphena® 60 mg had thromboembolic and hemorrhagic stroke incidence rates of 0.72 and 1.45 per thousand women vs. 1.04 and 0 per thousand women for placebo and a DVT incidence rate of 1.45 vs. 1.04 per thousand women for placebo. Osphena® should be prescribed for the shortest duration consistent with treatment goals and risks for the individual woman.

IMPORTANT SAFETY INFORMATION FOR OSPHENA®

CONTRAINDICATIONS

- Undiagnosed abnormal genital bleeding
- Known or suspected estrogen-dependent neoplasia
- Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions
- Active arterial thromboembolic disease (for example, stroke and myocardial infarction), or a history of these conditions
- Hypersensitivity (for example, angioedema, urticaria, rash, pruritus) to Osphena® or any of its ingredients
- Women who are or may become pregnant. Osphena® may cause fetal harm when administered to a pregnant woman. Ospemifene was embryo-fetal lethal with labor difficulties and increased pup deaths in rats at doses below clinical exposures, and embryo-fetal lethal in rabbits at 10 times the clinical exposure based on mg/m2. If this drug is used during pregnancy, or if a woman becomes pregnant while taking this drug, she should be apprised of the potential hazard to a fetus.

WARNINGS AND PRECAUTIONS

In Osphena® clinical trials of up to 15 months, the incidence rates compared to placebo for thromboembolic and hemorrhagic stroke were 0.72 Osphena® 60 mg vs. 1.04 placebo and 1.45 Osphena® 60 mg vs. 0 placebo per thousand women. Should thromboembolic or hemorrhagic stroke occur or be suspected, Osphena® should be discontinued immediately. In clinical trials, a single MI occurred in a woman receiving Osphena® 60 mg.

Incidence rate of DVT was 1.45 Osphena® vs. 1.04 placebo per thousand women. Should a VTE occur or be suspected, Osphena® should be discontinued immediately. Osphena® should be discontinued at least 4 to 6 weeks before surgery with increased risk of thromboembolism or during periods of prolonged immobilization.

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen therapy. The risk appears dependent on duration of treatment and estrogen dose. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. However, studies suggest a possible increased risk for breast cancer in patients receiving estrogen plus progestin therapy.

Osphena® is an estrogen agonist/antagonist with tissue selective effects. In the endometrium, Osphena® has agonistic effects. In Osphena® clinical trials, no cases of endometrial cancer were seen with exposure up to 52 weeks. There was a single case of simple hyperplasia without atypia. Endometrial thickening equal to 5mm or greater was reported at a rate of 60.1 Osphena® vs. 21.2 placebo per 1000 women. Uterine polyps occurred at an incidence of 5.9 Osphena® vs. 1.8 placebo per 1000 women, and any type of proliferative endometrium (weakly plus active plus disordered) was 86.1 Osphena® vs. 13.3 placebo per 1000 women.

Osphena® has not been adequately studied in women with breast cancer; therefore it should not be used in women with known or suspected breast cancer or with a history of breast cancer.

Osphena® should not be used in women with severe hepatic impairment as it has not been studied.

In clinical trials the more commonly reported adverse reactions in ≥1 percent of patients treated with Osphena® 60 mg compared to placebo were: hot flush (7.5% vs. 2.6%), vaginal discharge (3.8% vs. 0.3%), muscle spasms (3.2% vs. 0.9%), hyperhidrosis (1.6% vs. 0.6%), and genital discharge (1.3% vs. 0.1%).

The following adverse reactions have been identified during post-approval use of ospemifene: Immune System Disorders: allergic conditions including hypersensitivity, angioedema. Skin and Subcutaneous Tissue Disorders: rash, rash erythematous, rash generalized, pruritus, urticaria.

Drug interactions: Do not use estrogens or estrogen agonists/antagonists, fluconazole, or rifampin concomitantly with Osphena®. Co-administration of Osphena® with drugs that inhibit CYP3A4 and CYP2C9 may increase the risk of Osphena®-related adverse reactions. Osphena® is highly protein bound. Use cautiously with highly protein bound drugs as use with other highly protein-bound drugs may lead to increase exposure of that drug or ospemifene.

Please see U.S. Full Prescribing Information for Osphena® (ospemifene) tablets, including **Boxed Warning**, and Patient Information on www.Osphena.com.

DUCHESNAY USA

Osphena®
(ospemifene) tablets
60 mg

ARE YOUR PATIENTS SUFFERING FROM MODERATE TO SEVERE PAINFUL SEX DUE TO MENOPAUSE?

PRESCRIBE THE ORAL OPTION.

WHAT IS OSPHENA®?

Osphena® is the only oral selective estrogen receptor modulator (SERM) indicated for the treatment of moderate to severe dyspareunia, a symptom of VVA (vulvar and vaginal atrophy) due to menopause.[1]

HOW OSPHENA® WORKS

Osphena® provides relief of moderate to severe dyspareunia associated with VVA due to menopause in as little as 12 weeks by improving the specific vaginal tissue causing the pain:[1]

- Increases superficial cells
- Decreases parabasal cells
- Reduces vaginal pH

SAFETY AND EFFICACY

Osphena® is a Level A treatment recommended by ACOG and NAMS, based on its safety and efficacy profile.[2,4]

Osphena® has robust clinical and safety data: [1,3]

- Largest population of post-menopausal women with dyspareunia (~1900)
- Nine phase 2/3 trials
- Well-tolerated safety profile
- Long-term safety data up to 52 weeks in duration[3]
  - [3] 409 postmenopausal women were studied for up to 52 weeks in safety studies.
- Unlike clinical trials involving estrogen-based products, Osphena® clinical trials were performed without adding a progestin, either in women with or without an intact uterus.[1,6]

Left untreated, dyspareunia may worsen.[3,4,5]

Prescribe Osphena® for your appropriate patients today

Patients can pay as little as $0/prescription!
Please see Osphena.com/HCP for details

References

1. Osphena® [package insert]. Florham Park, NJ: Shionogi Inc.; 2015.
2. ACOG Practice Bulletin Number 141: Management of menopausal symptoms. Practice Bulletin No. 141. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2014:123(1):202-216.
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6. The Women's Health Initiative Study Group. Design of the Women's Health Initiative clinical trial and observational study. Control Clin Trials. 1998; 19(1):61–109.

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Editorial Mission: *Women's Healthcare*, the official journal of the National Association of Nurse Practitioners in Women's Health, provides NPs and other advanced practice nurses providing healthcare to women with comprehensive, timely, useful, evidence-based information to empower them to set a new standard for women's healthcare throughout the continuum of a patient's life; to maximize their educational foundation of best practices; and to assist them in the advancement of their professional practice and career.

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features


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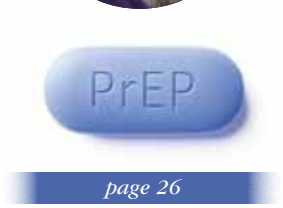

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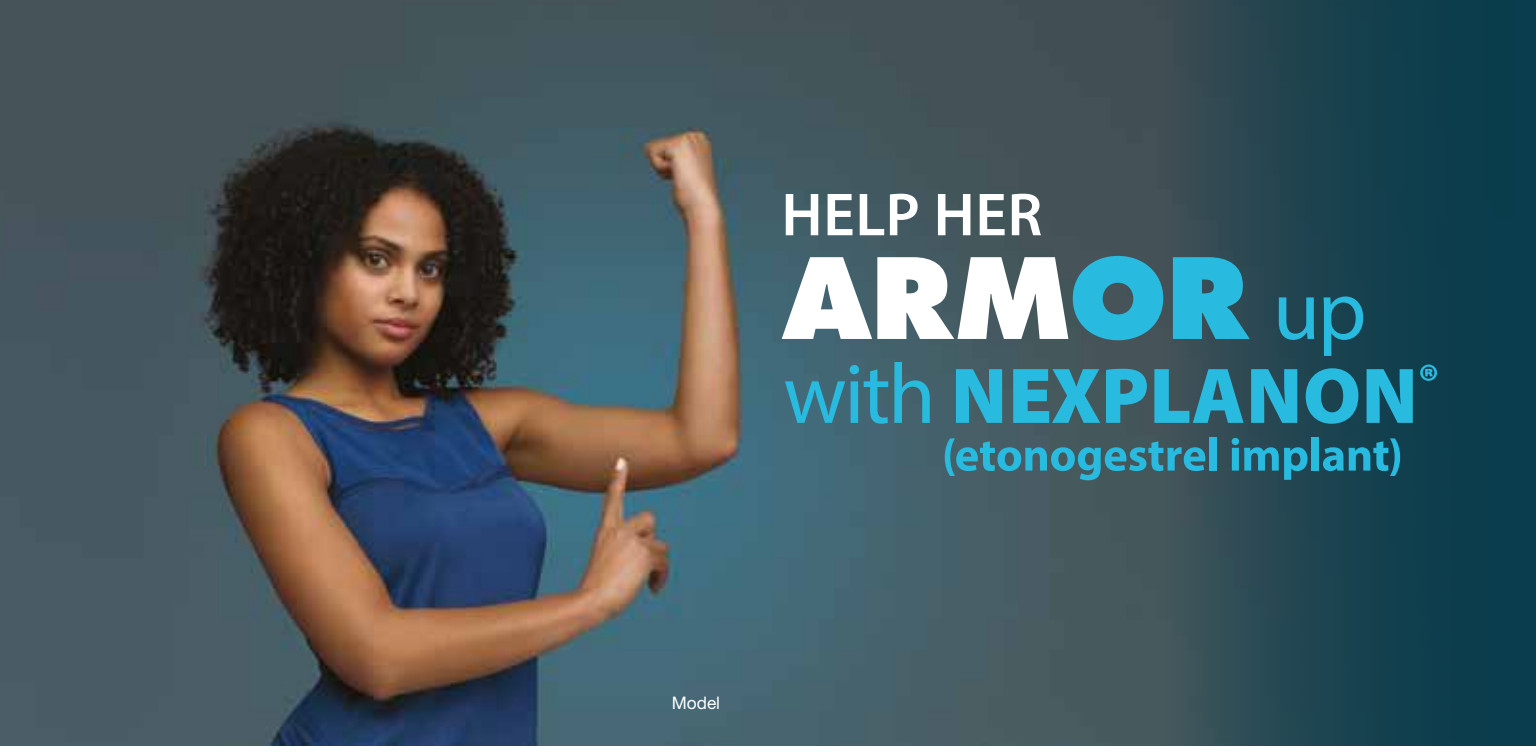


NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

- NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; and/or allergic reaction to any of the components of NEXPLANON.

WARNINGS and PRECAUTIONS

Complications of insertion and removal

- NEXPLANON should be inserted subdermally and be palpable after insertion. Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.
- Insertion and removal-related complications may include pain, paresthesias, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removal is recommended.
- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Endovascular or surgical procedures may be needed for removal.

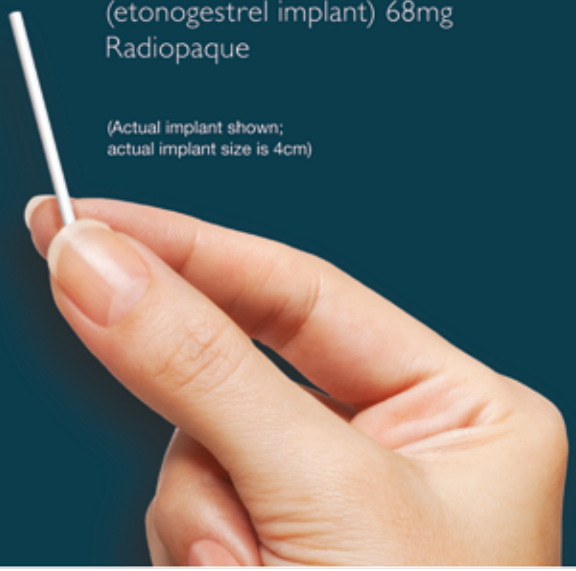
NEXPLANON and pregnancy

- Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.
- **Rule out pregnancy before inserting NEXPLANON.**

Educate her about the risk of serious vascular events

- The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events [stroke and myocardial infarction (MI)] or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis (DVT), retinal vein thrombosis, and pulmonary embolism). Women with risk factors known to increase the risk of these events should be carefully assessed. Postmarketing reports in women using the nonradiopaque etonogestrel implant have included pulmonary emboli (some fatal), DVT, MI, and stroke. NEXPLANON should be removed if thrombosis occurs.

NEXPLANON — 1 ARM IMPLANT provides up to 3 years of pregnancy prevention*



>99% effective†

Placed subdermally in the inner upper arm just under the skin

***NEXPLANON must be removed by the end of the third year and may be replaced by another NEXPLANON at the time of removal, if continued contraceptive protection is desired.**

†Less than 1 pregnancy per 100 women who used NEXPLANON for 1 year.

SELECTED SAFETY INFORMATION (*continued*)

- Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removing the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

Counsel her about changes in bleeding patterns

- Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, changes in bleeding pattern were the most common reason reported for stopping treatment (11.1%). Counsel women regarding potential changes they may experience.

Be aware of other serious complications, adverse reactions, and drug interactions

- Remove NEXPLANON if jaundice occurs.
- Remove NEXPLANON if blood pressure rises significantly and becomes uncontrolled.
- Prediabetic and diabetic women using NEXPLANON should be carefully monitored.
- Carefully observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.
- The most common adverse reactions (≥10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).
- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- The efficacy of NEXPLANON in women weighing more than 130% of their ideal body weight has not been studied. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, NEXPLANON may be less effective in overweight women.
- Counsel women to contact their health care provider immediately if, at any time, they are unable to palpate the implant.
- NEXPLANON does not protect against HIV or other STDs.

Please read the adjacent Brief Summary of the Prescribing Information

MERCK

Nexplanon®

(etonogestrel implant) 68mg

BRIEF SUMMARY (For full Prescribing Information, see package insert.)

Women should be informed that this product does not protect against HIV infection (the virus that causes AIDS) or other sexually transmitted diseases.

INDICATION AND USAGE

NEXPLANON is indicated for use by women to prevent pregnancy.

DOSAGE AND ADMINISTRATION

The efficacy of NEXPLANON does not depend on daily, weekly or monthly administration. All healthcare providers should receive instruction and training prior to performing insertion and/or removal of NEXPLANON. A single NEXPLANON implant is inserted subdermally in the upper arm. To reduce the risk of neural or vascular injury, the implant should be inserted at the inner side of the non-dominant upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus. The implant should be inserted subdermally just under the skin, avoiding the sulcus (groove) between the biceps and triceps muscles and the large blood vessels and nerves that lie there in the neurovascular bundle deeper in the subcutaneous tissues. An implant inserted more deeply than subdermally (deep insertion) may not be palpable and the localization and/or removal can be difficult or impossible *[see Dosage and Administration and Warnings and Precautions]*. NEXPLANON must be inserted by the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method. The implant must be removed by the end of the third year and may be replaced by a new implant at the time of removal, if continued contraceptive protection is desired.

CONTRAINDICATIONS

NEXPLANON should not be used in women who have

- Known or suspected pregnancy
- Current or past history of thrombosis or thromboembolic disorders
- Liver tumors, benign or malignant, or active liver disease
- Undiagnosed abnormal genital bleeding
- Known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past
- Allergic reaction to any of the components of NEXPLANON *[see Adverse Reactions]*

WARNINGS AND PRECAUTIONS

The following information is based on experience with the etonogestrel implants (IMPLANON® [etonogestrel implant] and/or NEXPLANON), other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives.

1. **Complications of Insertion and Removal**

   NEXPLANON should be inserted subdermally so that it is palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert NEXPLANON properly may go unnoticed unless it is palpated immediately after insertion. Undetected failure to insert the implant may lead to an unintended pregnancy. Complications related to insertion and removal procedures, such as pain, paresthesias, bleeding, hematoma, scarring or infection, may occur.

   If NEXPLANON is inserted deeply (intramuscular or in the fascia), neural or vascular injury may occur. To reduce the risk of neural or vascular injury, NEXPLANON should be inserted at the inner side of the non-dominant upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus. NEXPLANON should be inserted subdermally just under the skin avoiding the sulcus (groove) between the biceps and triceps muscles and the large blood vessels and nerves that lie there in the neurovascular bundle deeper in the subcutaneous tissues. Deep insertions of NEXPLANON have been associated with paraesthesia (due to neural injury), migration of the implant (due to intramuscular or fascial insertion), and intravascular insertion. If infection develops at the insertion site, start suitable treatment. If the infection persists, the implant should be removed. Incomplete insertions or infections may lead to expulsion.

   Implant removal may be difficult or impossible if the implant is not inserted correctly, is inserted too deeply, not palpable, encased in fibrous tissue, or has migrated.

   There have been reports of migration of the implant within the arm from the insertion site, which may be related to deep insertion. There also have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.

   If at any time the implant cannot be palpated, it should be localized and removal is recommended.

   Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged. Removal of deeply inserted implants should be conducted with caution in order to prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare providers familiar with the anatomy of the arm. If the implant is located in the chest, healthcare providers familiar with the anatomy of the chest should be consulted. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

2. **Changes in Menstrual Bleeding Patterns**

   After starting NEXPLANON, women are likely to have a change from their normal menstrual bleeding pattern. These may include changes in bleeding frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or duration. In clinical trials of the non-radiopaque etonogestrel implant (IMPLANON), bleeding patterns ranged from amenorrhea (1 in 5 women) to frequent and/or prolonged bleeding (1 in 5 women). The bleeding pattern experienced during the first three months of NEXPLANON use is broadly predictive of the future bleeding pattern for many women. Women should be counseled regarding the bleeding pattern changes they may experience so that they know what to expect. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy.

   In clinical studies of the non-radiopaque etonogestrel implant, reports of changes in bleeding pattern were the most common reason for stopping treatment (11.1%). Irregular bleeding (10.8%) was the single most common reason women stopped treatment, while amenorrhea (0.3%) was cited less frequently. In these studies, women had an average of 17.7 days of bleeding or spotting every 90 days (based on 3,315 intervals of 90 days recorded by 780 patients). The percentages of patients having 0, 1-7, 8-21, or >21 days of spotting or bleeding over a 90-day interval while using the non-radiopaque etonogestrel implant are shown in Table 1.

Table 1: Percentages of Patients With 0, 1-7, 8-21, or >21 Days of Spotting or Bleeding Over a 90-Day Interval While Using the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Total Days of Spotting or Bleeding	Percentage of Patients		
	Treatment Days 91-180 (N = 745)	Treatment Days 271-360 (N = 657)	Treatment Days 631-720 (N = 547)
0 Days	19%	24%	17%
1-7 Days	15%	13%	12%
8-21 Days	30%	30%	37%
>21 Days	35%	33%	35%

Bleeding patterns observed with use of the non-radiopaque etonogestrel implant for up to 2 years, and the proportion of 90-day intervals with these bleeding patterns, are summarized in Table 2.

Table 2: Bleeding Patterns Using the Non-Radiopaque Etonogestrel Implant (IMPLANON) During the First 2 Years of Use*

Bleeding Patterns	Definitions	%†
Infrequent	Less than three bleeding and/or spotting episodes in 90 days (excluding amenorrhea)	33.6
Amenorrhea	No bleeding and/or spotting in 90 days	22.2
Prolonged	Any bleeding and/or spotting episode lasting more than 14 days in 90 days	17.7
Frequent	More than 5 bleeding and/or spotting episodes in 90 days	6.7

* Based on 3315 recording periods of 90 days duration in 780 women, excluding the first 90 days after implant insertion

† % = Percentage of 90-day intervals with this pattern

In case of undiagnosed, persistent, or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy.

3. **Ectopic Pregnancies**

   As with all progestin-only contraceptive products, be alert to the possibility of an ectopic pregnancy among women using NEXPLANON who become pregnant or complain of lower abdominal pain. Although ectopic pregnancies are uncommon among women using NEXPLANON, a pregnancy that occurs in a woman using NEXPLANON may be more likely to be ectopic than a pregnancy occurring in a woman using no contraception.

4. **Thrombotic and Other Vascular Events**

   The use of combination hormonal contraceptives (progestin plus estrogen) increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism). NEXPLANON is a progestin-only contraceptive. It is unknown whether this increased risk is applicable to etonogestrel alone. It is recommended, however, that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed. There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. NEXPLANON should be removed in the event of a thrombosis.

   Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

5. **Ovarian Cysts**

   If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. On rare occasion, surgery may be required.

6. **Carcinoma of the Breast and Reproductive Organs**

   Women who currently have or have had breast cancer should not use hormonal contraception because breast cancer may be hormonally sensitive *[see Contraindications]*. Some studies suggest that the use of combination hormonal contraceptives might increase the incidence of breast cancer; however, other studies have not confirmed such findings. Some studies suggest that the use of combination hormonal contraceptives is associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors. Women with a family history of breast cancer or who develop breast nodules should be carefully monitored.

7. **Liver Disease**

   Disturbances of liver function may necessitate the discontinuation of hormonal contraceptive use until markers of liver function return to normal. Remove NEXPLANON if jaundice develops. Hepatic adenomas are associated with combination hormonal contraceptives use. An estimate of the attributable risk is 3.3 cases per 100,000 for combination hormonal contraceptives users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON. The progestin in NEXPLANON may be poorly metabolized in women with liver impairment. Use of NEXPLANON in women with active liver disease or liver cancer is contraindicated *[see Contraindications]*.

8. **Weight Gain**

   In clinical studies, mean weight gain in U.S. non-radiopaque etonogestrel implant (IMPLANON) users was 2.8 pounds after one year and 3.7 pounds after two years. How much of the weight gain was related to the non-radiopaque etonogestrel implant is unknown. In studies, 2.3% of the users reported weight gain as the reason for having the non-radiopaque etonogestrel implant removed.

9. **Elevated Blood Pressure**

   Women with a history of hypertension-related diseases or renal disease should be discouraged from using hormonal contraception. For women with well-controlled hypertension, use of NEXPLANON can be considered. Women with hypertension using NEXPLANON should be closely monitored. If sustained hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed.

10. **Gallbladder Disease**

    Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON.

11. **Carbohydrate and Lipid Metabolic Effects**

    Use of NEXPLANON may induce mild insulin resistance and small changes in glucose concentrations of unknown clinical significance. Carefully monitor prediabetic and diabetic women using NEXPLANON. Women who are being treated for hyperlipidemia should be followed closely if they elect to use NEXPLANON. Some progestins may elevate LDL levels and may render the control of hyperlipidemia more difficult.

12. **Depressed Mood**

    Women with a history of depressed mood should be carefully observed. Consideration should be given to removing NEXPLANON in patients who become significantly depressed.

13. **Return to Ovulation**

    In clinical trials with the non-radiopaque etonogestrel implant (IMPLANON), the etonogestrel levels in blood decreased below sensitivity of the assay by one week after removal of the implant. In addition, pregnancies were observed to occur as early as 7 to 14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired.

14. **Fluid Retention**
Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention.
15. **Contact Lenses**
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.
16. ***In Situ* Broken or Bent Implant**
There have been reports of broken or bent implants while in the patient's arm. Based on *in vitro* data, when an implant is broken or bent, the release rate of etonogestrel may be slightly increased. When an implant is removed, it is important to remove it in its entirety *[see Dosage and Administration]*.
17. **Monitoring**
A woman who is using NEXPLANON should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated health care.
18. **Drug-Laboratory Test Interactions**
Sex hormone-binding globulin concentrations may be decreased for the first six months after NEXPLANON insertion followed by gradual recovery. Thyroxine concentrations may initially be slightly decreased followed by gradual recovery to baseline.

ADVERSE REACTIONS

In clinical trials involving 942 women who were evaluated for safety, change in menstrual bleeding patterns (irregular menses) was the most common adverse reaction causing discontinuation of use of the non-radiopaque etonogestrel implant (IMPLANON® [etonogestrel implant]) (11.1% of women).

Adverse reactions that resulted in a rate of discontinuation of ≥1% are shown in Table 3.

Table 3: Adverse Reactions Leading to Discontinuation of Treatment in 1% or More of Subjects in Clinical Trials of the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Adverse Reactions	All Studies N = 942
Bleeding Irregularities*	11.1%
Emotional Lability†	2.3%
Weight Increase	2.3%
Headache	1.6%
Acne	1.3%
Depression‡	1.0%

*Includes "frequent", "heavy", "prolonged", "spotting", and other patterns of bleeding irregularity.
† Among US subjects (N=330), 6.1% experienced emotional lability that led to discontinuation.
‡ Among US subjects (N=330), 2.4% experienced depression that led to discontinuation.

Other adverse reactions that were reported by at least 5% of subjects in the non-radiopaque etonogestrel implant clinical trials are listed in Table 4.

Table 4: Common Adverse Reactions Reported by ≥5% of Subjects in Clinical Trials With the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Adverse Reactions	All Studies N = 942
Headache	24.9%
Vaginitis	14.5%
Weight increase	13.7%
Acne	13.5%
Breast pain	12.8%
Abdominal pain	10.9%
Pharyngitis	10.5%
Leukorrhea	9.6%
Influenza-like symptoms	7.6%
Dizziness	7.2%
Dysmenorrhea	7.2%
Back pain	6.8%
Emotional lability	6.5%
Nausea	6.4%
Pain	5.6%
Nervousness	5.6%
Depression	5.5%
Hypersensitivity	5.4%
Insertion site pain	5.2%

In a clinical trial of NEXPLANON, in which investigators were asked to examine the implant site after insertion, implant site reactions were reported in 8.6% of women. Erythema was the most frequent implant site complication, reported during and/or shortly after insertion, occurring in 3.3% of subjects. Additionally, hematoma (3.0%), bruising (2.0%), pain (1.0%), and swelling (0.7%) were reported.

Effects of Other Drugs on Hormonal Contraceptives

Substances decreasing the plasma concentrations of hormonal contraceptives (HCs) and potentially diminishing the efficacy of HCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and potentially diminish the effectiveness of HCs or ncrease breakthrough bleeding.

Some drugs or herbal products that may decrease the effectiveness of HCs include efavirenz, phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, topiramate, rifabutin, rufinamide, aprepitant, and products containing St. John's wort. Interactions between HCs and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when enzyme inducers are used with HCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Substances increasing the plasma concentrations of HCs: Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the serum concentrations of progestins, including etonogestrel.

Human Immunodeficiency Virus (HIV)/Hepatitis C Virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma concentrations of progestin have been noted in cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir] or increase [e.g., indinavir and atazanavir/ritonavir])/HCV protease inhibitors (decrease [e.g., boceprevir and telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine, efavirenz] or increase [e.g., etravirene]). These changes may be clinically relevant in some cases. Consult the prescribing information of anti-viral and anti-retroviral concomitant medications to identify potential interactions.

Effects of Hormonal Contraceptives on Other Drugs

Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporine) or decrease (for example, lamotrigine). Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

USE IN SPECIFIC POPULATIONS

1. **Pregnancy**
Risk Summary
NEXPLANON is contraindicated during pregnancy because there is no need for pregnancy prevention in a woman who is already pregnant *[see Contraindications]*. Epidemiologic studies and meta-analyses have not shown an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following maternal exposure to low dose CHCs prior to conception or during early pregnancy. No adverse development outcomes were observed in pregnant rats and rabbits with the administration of etonogestrel during organogenesis at doses of 315 or 781 times the anticipated human dose (60 µg/day). NEXPLANON should be removed if maintaining a pregnancy.
2. **Nursing Mothers**
Lactation
Risk Summary
Small amounts of contraceptive steroids and/or metabolites, including etonogestrel are present in human milk. No significant adverse effects have been observed in the production or quality of breast milk, or on the physical and psychomotor development of breastfed infants. Hormonal contraceptives, including etonogestrel, can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. When possible, advise the nursing mother about both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEXPLANON and any potential adverse effects on the breastfed child from NEXPLANON or from the underlying maternal condition.
3. **Pediatric Use**
Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON are expected to be the same for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.
4. **Geriatric Use**
This product has not been studied in women over 65 years of age and is not indicated in this population.
5. **Hepatic Impairment**
No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated *[see Contraindications]*.
6. **Overweight Women**
The effectiveness of the etonogestrel 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. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. It is therefore possible that NEXPLANON may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations such as concomitant use of hepatic enzyme inducers.

OVERDOSAGE

Overdosage may result if more than one implant is inserted. In case of suspected overdose, the implant should be removed.

NONCLINICAL TOXICOLOGY

In a 24-month carcinogenicity study in rats with subdermal implants releasing 10 and 20 mcg etonogestrel per day (equal to approximately 1.8-3.6 times the systemic steady state exposure in women using NEXPLANON), no drug-related carcinogenic potential was observed. Etonogestrel was not genotoxic in the *in vitro* Ames/Salmonella reverse mutation assay, the chromosomal aberration assay in Chinese hamster ovary cells or in the *in vivo* mouse micronucleus test. Fertility in rats returned after withdrawal from treatment.

PATIENT COUNSELING INFORMATION *See FDA-Approved Patient Labeling.*

- Counsel women about the insertion and removal procedure of the NEXPLANON implant. Provide the woman with a copy of the Patient Labeling and ensure that she understands the information in the Patient Labeling before insertion and removal. A USER CARD and consent form are included in the packaging. Have the woman complete a consent form and retain it in your records. The USER CARD should be filled out and given to the woman after insertion of the NEXPLANON implant so that she will have a record of the location of the implant in the upper arm and when it should be removed.
- Counsel women to contact their healthcare provider immediately if, at any time, they are unable to palpate the implant.
- Counsel women that NEXPLANON does not protect against HIV or other STDs.
- Counsel women that the use of NEXPLANON may be associated with changes in their normal menstrual bleeding patterns so that they know what to expect.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA.

For more detailed information, please read the Prescribing Information.

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MERCK

Editor-in-chief's message

Dear Colleagues,

The National Association of Nurse Practitioners in Women's Health (NPWH) strives to continuously improve the accessibility and quality of healthcare for women. This improvement is accomplished by promoting innovation and excellence in continuing education and professional development; leadership in policy, practice, and research areas; and support and services for our members. Achieving all these goals is our organization's vision.

If you are a women's health nurse practitioner (WHNP), I urge you to help NPWH learn more about you and your professional role so that we can realize this vision. In particular, I ask you to consider participating in the 2018 NPWH WHNP Workforce Demographics and Compensation Survey. To assist you in deciding whether to participate in this survey, I have answered some questions you might have.

How is this survey being conducted?

This survey is being conducted by NPWH. The National Certification Corporation (NCC) is providing assistance in distributing the survey to all nationally certified WHNPs. NPWH is *the* national organization representing WHNPs. NCC is *the* national certification body for WHNPs.

Why is this survey important to WHNPs?

NPWH strives to support and advocate for WHNPs so that their role is fully appreciated and that it thrives into the future. Having detailed demographic information is especially important to fully understand who today's WHNPs are, where these WHNPs work, what they do, and which

(continued on page 10)

A survey focused on WHNPs would allow for better representation and a more complete picture of the demographics and employment characteristics of this important group of NPs.

NPWH Presents

2018 Women's Health Nurse Practitioner Certification Exam Review Course & Women's Health Update

Whether you're a student/recent graduate preparing to take your NCC WHNP certification exam, or a practicing NP looking for CE to stay up-to-date on women's health issues, this updated version of our popular *WHNP Certification Exam Review Course and Women's Health Update* offers you a convenient, affordable format to meet your learning needs.

How does the Course prepare WHNP students and new graduates for the NCC WHNP certification exam?

- The 23 modules are based on **NCC's content outline** and **test blueprint** for individuals preparing to take the certification examination
- One module is solely dedicated to helpful **test-taking strategies**
- More than **200 review questions** are written in NCC question format
- Modules can be used to **supplement course content** as current students progress through their academic programs

How does the Course promote the continuing competence and life-long learning of working nurse practitioners?

- Individual modules can be purchased to address **specific continuing education needs**
- The entire course can be purchased for a **complete high-quality, evidence-based women's health update**
- Titles and codes reflecting the NCC certification maintenance competency areas, contact hours, pharmacology hours, and objectives are listed in each module

Purchase the Complete Course or Individual Modules: http://bit.ly/NPWH2018ReviewCourse

PRICING

Complete Course		Individual Modules	
Members	$310	Members	$15
Students	$310	Students	$15
Non-Members	$389	Non-Members	$20

The NPWH Women's Health Nurse Practitioner Certification Exam Review Course and Women's Health Update was created and presented by 15 NCC certified WHNPs. All presenters teach or have taught in WHNP programs or were chosen specifically because they specialize in the module topic. This unique feature of the Review Course provides variety in presenting styles that will keep you engaged as you move through each module.

(continued from page 8)

populations they serve. It is also crucial for the future of the WHNP role to have information about compensation/benefits and employment/role satisfaction specific to WHNPs so that NPWH can advocate for both fair compensation and favorable working environments. Finally, we seek information about the role of the WHNP as a preceptor for future generations of WHNPs.

Why should I participate in this survey?

Success of this survey depends on a high response rate from WHNPs so that we can gather as much information as possible in order to draw as many conclusions as possible and to make as many reasonable recommendations as possible. At the beginning of the survey, you will be asked a few preliminary questions to see if you qualify to complete the entire survey. Once you have completed the preliminary questions, if you qualify, you will have access to the remainder of the survey. The survey is fully voluntary; there is no penalty for not participating and no penalty for opting to skip answering any specific questions.

How does this workforce survey differ from other NP workforce surveys?

In the American Association of Nurse Practitioners (AANP) 2017 national NP survey overview, it was reported that there are more than 222,000 licensed NPs in the United States, with the majority certified as family nurse practitioners (FNPs).[1] A random sample of 47,540 NPs was used for the AANP survey. Among the 6,784 respondents, 60.6% were FNPs. Data were presented on compensation and benefits for respondents working full-time. Of the 4,344 full-time primary care NP respondents, 2,964 (68.2%) were FNPs and 957 (22.0%) were adult or adult-gerontology NPs. Of those 4,344 full-time primary care NP respondents, only 137 (2.7%) were WHNPs.[1] Because the WHNP participation rate was quite small, it may not have been representative. *A survey focused on WHNPs would allow for better representation and a more complete picture of the demographics and employment characteristics of this important group of NPs.*

Who will see the information I provide on the survey?

First, the survey is anonymous. No individual identifying information will be collected. All responses will be reported only at the aggregate level. NPWH will use the data internally to guide development of support and services for WHNPs. The data also will be shared through a variety of venues with other stakeholders to include our membership, faculty and directors for WHNP programs, current WHNP students, prospective WHNP students, NCC, other NP organizations, and relevant policy makers. *NPWH hopes to have a robust response to the survey to make the data meaningful and useful—for all of us.*

All certified WHNPs should receive an email from NCC with an invitation and link to the NPWH WHNP Workforce Demographics and Compensation Survey by the end of September. If you do not receive your invitation by September 30, 2018, please contact Julia Knox at jknox@npwh.org so that she can send it to you.

Thank you in advance for your participation in this important survey.

Beth Kelsey, EdD, APRN, WHNP-BC, FAANP

Reference

1. American Association of Nurse Practitioners. 2017 National Nurse Practitioner Sample Survey: An Overview. Austin, TX: American Association of Nurse Practitioners; March 2018.

Gay Johnson, CEO

Message from the CEO

Some of you may know about NPWH's Well Woman Visit Mobile App and have downloaded it already, but other readers may not be familiar with it.

Several years ago, we decided to develop this app as a helpful tool for the well woman visit. The app is designed for healthcare providers (HCPs) to facilitate and guide the evaluation and treatment of patients. First, the HCP enters the patient's age. This information then generates age-appropriate avenues of investigation in the following categories: sexual history taking, physical exam, STD screening, immunizations, preventative health screening, and anticipatory guidance.

After the initial launch of the app, we added several new categories, including cardiovascular assessment, irritable bowel syndrome, and menopause. And because our app is always evolving and expanding, we are now developing another new category that will be extremely helpful in assessing a patient's brain health, which should be an integral component of the well woman visit. The brain health portion of the app will include a definition of a healthy brain and then cover cognitive impairment, symptoms, diagnosis, treatment, special considerations, caregiver resources, and web resources.

In 2017, NPWH released the findings of a joint survey of more than 1,000 nurse practitioners that we conducted with the organization Women Against Alzheimer's. Our goal was to determine whether NPs have the information and tools they need to evaluate patients at risk for Alzheimer's disease and other dementias, to make timely diagnoses of these diseases, to manage these diseases, and to counsel patients and their families once the risk or actual disease is identified. The survey results suggested that NPs want more information about the symptoms of Alzheimer's and other dementias. They want help starting the conversation about brain health with their patients, and they want and need greater access to diagnostic tools. As the number of U.S. women aged 65+ years with Alzheimer's continues to grow (this number now stands at more than 3.3 million), the assessment of memory and brain health belongs at the forefront of women's healthcare.

We believe that this new portion of our Well Woman Visit Mobile App will become the "go to" for HCPs seeking more information and guidance on brain health. Watch for the release of this new iteration of our mobile app, which should be available in late September. Until then, download the app now for other valuable guidance. This free app is available for download from NPWH or the Apple Store.

– Gay Johnson
Chief Executive Officer, NPWH

Managing women's health issues across a lifespan: NPWH 2017-2018 regional meetings

By Beth Kelsey, EdD, APRN, WHNP-BC, FAANP

To participate in this CE program, click *here*[A].

Faculty:
Beth Kelsey, EdD, APRN, WHNP-BC, FAANP is Assistant Professor at Ball State University School of Nursing in Muncie, Indiana.

Intended audience: This continuing education (CE) activity has been designed to meet the educational needs of nurse practitioners who provide care for women across the lifespan.

CE approval period: Now through September 30, 2019

Estimated time to complete this activity: 1 hour

CE approval hours: 1.0 contact hour of CE credit

Goal statement: To use current evidence and guidelines in shared decision making with women to develop treatment/management plans for unscheduled bleeding with hormonal contraception, recurrent bacterial vaginitis (BV), postmenopausal hypoactive sexual desire disorder (HSDD), and postmenopausal osteoporosis—according to each woman's needs, desires, and preferences.

Needs assessment: This activity for *Women's Healthcare* is based on a CE presentation developed by the NPWH Education Committee and presented at the four NPWH regional meetings in 2017-2018. In this article, the author used clinical scenarios to describe current recommendations/guidelines for management of unscheduled bleeding with hormonal contraception, recurrent BV, postmenopausal HSDD, and postmenopausal osteoporosis. The author used data shared at the NPWH regional meetings in which the presenters provided updates on issues related to contraception, BV, HSDD, and osteoporosis.

Educational objectives: At the conclusion of this educational activity, participants should be able to:

1. Describe potential causes of and management options for unscheduled bleeding associated with hormonal contraception use.
2. Describe potential causes of and management options for recurrent BV.
3. Discuss assessment and management of postmenopausal HSDD.
4. Describe assessment and management of postmenopausal osteoporosis.

Accreditation statement: This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH), and has been approved for 1.0 contact hour of CE credit.

Faculty disclosures: NPWH policy requires all faculty to disclose any affiliation or relationship with a commercial interest that may cause a potential, real, or apparent conflict of interest with the content of a CE program. NPWH does not imply that the affiliation or relationship will affect the content of the CE program. Disclosure provides participants with information that may be important to their evaluation of an activity. Faculty are also asked to identify any unlabeled/unapproved uses of drugs or devices made in their presentation.
Beth Kelsey, EdD, APRN, WHNP-BC, FAANP, has no actual or potential conflicts of interest in relation to this presentation.

Disclosure of unlabeled use: NPWH policy requires authors to disclose to participants when they are presenting information about unlabeled use of a commercial product or device or an investigational use of a drug or device not yet approved for any use.

Disclaimer: Participating faculty members determine the editorial content of the CE activity; this content does not necessarily represent the views of NPWH. This content has undergone a blinded peer review process for validation of clinical content. Although every effort has been made to ensure that the information is accurate, clinicians are responsible for evaluating this information in relation to generally accepted standards in their own communities and integrating the information in this activity with that of established recommendations of other authorities, national guidelines, FDA-approved package inserts, and individual patient characteristics.

Successful completion of the activity: Successful completion of this activity, J-18-03, requires participants to:

1. Log on to npwh.org/courses/home/details/1155 and "Sign In" at the top right-hand corner of the page if you have an NPWH account. You must be signed in to receive credit for this course. If you do not remember your username or password, please follow the "Forgot Password" link and instructions on the sign-in page. If you do not have an account, please click on "Create an Account."*
2. Read the learning objectives, disclosures, and disclaimers on the previous page.
3. Study the material in the learning activity during the approval period (now through September 30, 2019).
4. Complete the post-test and evaluation. You must earn a score of 70% or better on the post-test to receive CE credit.
5. Print out the CE certificate if successfully completed.

*If you are an NPWH member, were once a member, or have taken CE activities with NPWH in the past, you have a username and password in our system. Please do not create a new account. Creation of multiple accounts could result in loss of CE credits as well as other NPWH services. If you do not remember your username or password, please either click on the "Forgot Username" or "Forgot Password" link or call the NPWH office at (202) 543-9693, ext. 1.

Commercial support: The content for this article was supported by educational grants from Lupin Pharmaceuticals; Merck & Co., Inc.; Radius Health, Inc.; and Valeant Pharmaceuticals North America, LLC.

Before reading the article, click *here*[A] to take the pretest.

Over the past year, NPWH sponsored four regional meetings highlighting updates on the management of women's health issues across a lifespan. The meetings were presented to live audiences using an interactive learning strategy, with several clinical scenarios illustrating issues within four topic areas: contraception, bacterial vaginosis, hypoactive sexual desire disorder, and postmenopausal osteoporosis. The author of this article has chosen one scenario for each topic to demonstrate how this learning strategy can cover important health areas in a way that intrigues and challenges, in this case, our readers.

Scenario #1: Contraception

Long-acting reversible contraceptives (LARC), the most effective of all reversible contraceptives, are becoming more widely used by reproductive-aged women and adolescents. LARC include intrauterine contraceptives (IUCs) and the etonogestrel (ENG) implant. Fewer than 1% of LARC users become pregnant, and their continuation rates at 1 year are significantly higher than those of short-acting birth-control method users (86% vs. 55%).[1] LARC have a good safety profile, with very few contraindications; most women are eligible for either IUCs or the ENG implant.[2] In fact, for women with conditions that might make pregnancy an unacceptable health risk, LARC might be the best choice to avoid unintended pregnancy. Likewise, LARC might be the best choice for women taking teratogenic drugs for a health condition. The American College of Obstetricians and Gynecologists recommends that LARC be offered as first-line contraceptives and encouraged as options for most females, including adolescents and nulliparous women.[1,3] Scenario #1 depicts assessment and management of unscheduled bleeding associated with use of the ENG implant.

Ava is 17 years old. She is brought to the clinic by her mother, who just

learned that her daughter is sexually active. Ava has never been pregnant. Her last menstrual period started 3 days ago. The nurse practitioner (NP) reviews contraceptive methods with Ava, who decides she would like an implant, which is placed at that visit. Ten weeks later, Ava calls the clinic to report that she has been bleeding or spotting every day. She tells the NP, *I am sick of the bleeding and I want this thing out*. The NP recommends that Ava come to the clinic for evaluation of her bleeding and to discuss how to proceed from there.

Unscheduled bleeding is a common side effect of all the progestin-only methods (i.e., progestin-only pills, depot medroxyprogesterone acetate, ENG implant, levonorgestrel [LNG] IUCs). Two recent studies have shown that unpredictable or irregular bleeding is one of the most common reasons cited for early discontinuation of these methods.[4,5]

What else would be helpful for the NP to know?

Ava tells the NP that she has a new boyfriend. They had sex 6 weeks ago and again 2 weeks ago, without using a condom. She has no pain with sex or abnormal vaginal discharge. She describes her bleeding as lighter than a period *(Sometimes it is only spotting)* that has occurred on most days since the implant was placed.

Are laboratory tests or a physical examination needed?

Another possible cause of Ava's irregular bleeding is infection with *Chlamydia*, especially because she has a new sex partner who does not use a condom. A urine sample is collected for a *Chlamydia* test. Because Ava uses a highly effective contraceptive, the NP is reasonably certain that she is not pregnant. Unscheduled bleeding is not indicative of decreased efficacy of the method.[6] A pregnancy test could be done if there is concern. A pelvic exam is not needed.

What options are available to manage Ava's bleeding?

The etiology of unscheduled bleeding with use of progestin-only contraceptives is not fully understood. The bleeding may be due in part to rapid endometrial thinning initially. With sustained use, the endometrium may become more fragile and prone to bleed.[6] Studies of various therapies to decrease bleeding have shown mixed results.

The U.S. Selected Practice Recommendations for Contraceptive Use, 2016[B] (SPR) provides an algorithm to guide management of bleeding irregularities in women using hormonal contraceptives.[7] Options to manage bothersome bleeding associated with an implant include a 5- to 7-day course of a nonsteroidal anti-inflammatory drug (NSAID) or a 10- to 20-day course of estrogen (via a combination oral contraceptive [COC], oral conjugated estrogen 1.25 mg, or oral estradiol 2 mg) if medically eligible. Although several studies have shown that treatment with NSAIDs or estrogen controls bleeding associated with various progestin-only contraceptives, these results are not consistently sustained. Moreover, these studies evaluated different NSAIDs and different lengths of time on estrogen, making it difficult to draw firm conclusions.[6]

After the NP and Ava discuss the options and their possible but uncertain effectiveness, Ava decides to try the COC. The NP prescribes a low-dose COC for 21 days. Two months after treatment, Ava remains without bleeding or spotting. She does have a positive *Chlamydia* test result and is treated along with her partner.

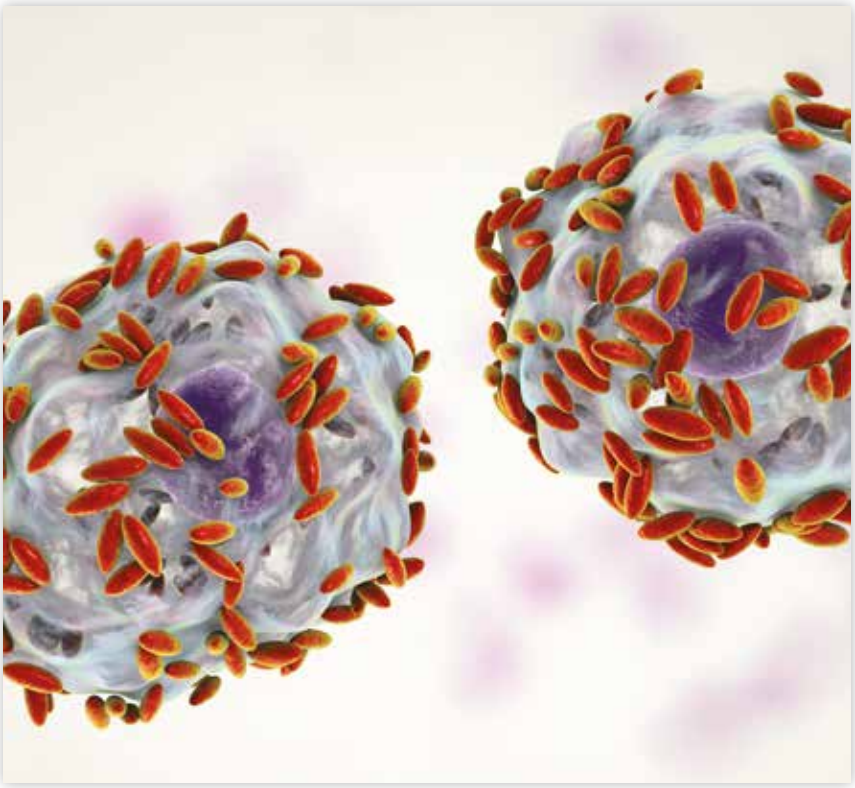
Nurse practitioners providing care for reproductive-aged women can help them choose contraceptives that fit their individual lifestyles and preferences. Evidence-based guidelines such as the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016[C] and the SPR can assist in appropriate assessment and management for safe and effective contraception.[2,7] Strategies to reduce barriers and promote consistent contraceptive use should be individually tailored, and should provide women with knowledge and tools that empower them to prevent unintended pregnancies.

Scenario #2: Recurrent bacterial vaginosis

Factors that alter the vaginal microbiome increase the risk for bacterial vaginosis (BV) by causing a shift in the vaginal microbiota from lactobacillus-dominated bacteria to a variable mixture of anaerobic and facultative bacteria.[8,9] These factors include, but are not limited to, sexual behaviors (e.g., frequent vaginal intercourse, multiple male or female sex partners, new sex partner, lack of condom use), hormonal fluctuations, smoking, douching, and antibiotic use. Protective factors may include having a male partner who is circumcised and use of hormonal contraceptives.[8-10]

Recent studies have detected a polymicrobial biofilm in the vaginal epithelial cells of some women with BV that aids in bacterial persistence and enhances resistance to host defense mechanisms and antibiotics.[8,9] This biofilm also may inhibit normal shedding of vaginal epithelial cells needed to provide glycogen as a nutrient source of lactobacilli, further disrupting the healthy vaginal microbiota. The trigger for the change in the vaginal microbiota and the development of the biofilm remains elusive, but it may contribute to persistent or recurrent BV.[8,9] BV is typically defined as recurrent if three or more episodes occur per year. Scenario #2 portrays assessment and management of a woman with recurrent BV.

Bea, a 35-year-old woman, presents at the clinic as a new patient with a complaint of bad smelling vaginal discharge again. She states that she just wants a cure that lasts. She tells the NP that she has been treated countless times for BV over the past several years, with temporary relief before the odor and discharge return.



What additional information would be helpful for the NP to obtain?

Bea tells the NP that she has been treated for BV 3 times in the past year, each time with oral metronidazole for 7 days. Her symptoms resolve for a month and then recur when she has a period. The odor is worse after sex. Bea is married and in a monogamous relationship with her husband of 10 years and knows that BV is not a sexually transmitted infection (STI), but she wonders whether he should be treated. Bea admits to douching after sex sometimes to try to eliminate the odor. She is in good health overall, is of normal weight, does not smoke, and is on no medications. She has had no abnormal Pap test results and has never had an STI. Her husband had a vasectomy 3 years ago. They do not use condoms.

A pelvic exam reveals a malodorous thin gray discharge at the vaginal introitus and adhering to the vaginal walls. No erythema or lesions are noted. Vaginal pH is >5.0 and a wet prep shows clue cells, no yeast buds/hyphae, no trichomonads, and no lactobacilli. A potassium hydroxide (KOH) whiff test result is positive. A diagnosis of BV is made based on the presence of at least three Amsel's criteria: homogeneous thin gray/white discharge, positive whiff test result with 10% KOH, vaginal pH >4.5, and clue cells on microscopy.[11] A confirmatory test is not needed. Diagnosis based on identification of *Gardnerella vaginalis* on vaginal culture is insufficient; *G. vaginalis* is detected in up to 55% of healthy asymptomatic women.[12] Based on Bea's history and exam findings, the NP does not order any STI tests.

What is the recommended treatment plan?

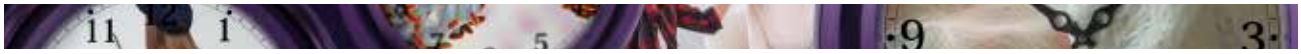
The NP acknowledges Bea's frustration with her recurring symptoms. The NP explains that although data on treatment for recurrent BV are not conclusive, several options have been cited in the literature

based on limited studies. The NP and Bea develop a treatment plan but agree that they will consider other options as needed. The plan is to treat the current BV infection with metronidazole 500 mg orally twice daily for 7 days, followed by 0.75% metronidazole gel intravaginally twice weekly for 4 months to reduce the risk for recurrence, with cessation of vaginal douching.

In addition to oral metronidazole, the CDC recommends intravaginal metronidazole gel 0.75% once daily for 5 days or intravaginal clindamycin cream 2% at bedtime for 7 days to treat BV.[11] Alternative regimens are tinidazole 2 g orally once daily for 2 days, tinidazole 1 g orally once daily for 5 days, or clindamycin 300 mg orally twice daily for 7 days. Secnidazole, a single-dose granule formulation with no warning to avoid alcohol consumption, was approved by the FDA in 2017 for treatment of BV and is not yet included in the CDC recommendations.[13] The granules are mixed with soft food such as applesauce, yogurt, or pudding and then consumed within 30 minutes.

Limited studies support the use of 0.75% metronidazole gel twice weekly for 4-6 months after completion of treatment for the current infection to reduce recurrences. The benefit may not persist after discontinuation.[9,11]

Several interventions to reduce or eradicate bacteria associated with BV and to restore and maintain a normal vaginal microbiome have been proposed based on limited and sometimes conflicting studies. Among these interventions are the use of biofilm-disruptive agents such as intravaginal boric acid; probiotics to boost favorable lactobacilli species; hormonal contraception to improve the genital microenvironment through increased glycogen production in vaginal epithelial cells, promoting lactobacilli species growth as well as reduction of menstrual bleeding; male and female partner treatment; condom use; and suppressive antimicrobial therapy.[8-11,14]



Scenario #3: Hypoactive sexual desire disorder

Whether called low libido, hypoactive sexual desire disorder (HSDD), or female sexual interest/arousal disorder, this condition is common across the adult lifespan. Scenario #3 illustrates assessment and management of HSDD in a postmenopausal woman.

Cass, a 58-year-old female, presents at the office as a new patient with concerns about low libido that she first noticed a year ago. She tells the NP that she worries about its effect on her relationship with her partner. She and Ellen have been in a monogamous relationship for 20 years and have always enjoyed their sexual relationship. She notes that Ellen is understanding but also sometimes frustrated with her recent lack of interest in sex. Both women have fast-paced, time-consuming jobs that have recently required them to work on weekends, which had always been time for them to relax, reconnect, and share intimacy.

What additional information would be helpful for the NP to obtain?

Cass is 8 years postmenopausal. She was on oral estrogen-progestogen therapy to manage hot flashes until last year, when she stopped treatment at the recommendation of her previous healthcare provider. The hot flashes recurred, so about 6 months ago, she started the selective serotonin reuptake inhibitor (SSRI) paroxetine 7.5 mg, which has been helpful. However, she has noticed vaginal dryness that has made penetrative sex play painful. Cass has suffered from severe arthritis in her hips for the past few years, causing

certain sex positions to be uncomfortable. In this context, the vaginal dryness and pain with penetration are even more distressing. Cass has had a recent normal Pap test result, and she has had no urinary tract problems. She has never been pregnant or had any pelvic surgery. She denies any current or past history of physical, emotional, or sexual abuse; depression; or substance abuse.

The NP uses the Female Sexual Function Index[D] questionnaire to guide further assessment of six domains of sexual health: desire, arousal, lubrication, orgasm, satisfaction, and pain.[15] She confirms that Cass's main concerns are related to decreased desire and pain with penetrative sex. Cass is able to achieve arousal and orgasm with a vibrator and oral sex, but it takes longer now. Use of an over-the-counter (OTC) vaginal lubricant is minimally helpful.

A physical exam reveals bilateral hip range-of-motion limitation consistent with osteoarthritis. The NP conducts a systematic vulvovaginal/pelvic exam to determine the location of Cass's pain and to evaluate skin/tissue integrity and vaginal/pelvic floor muscle (PFM) strength. Inspection and palpation of vulvar structures reveal no lesions or tenderness. The vaginal walls are pale and dry with decreased rugae. PFM strength is moderate, and no pelvic organ prolapse is noted. Vaginal pH is >5.0 and a wet prep shows presence of parabasal cells and no lactobacilli.

Other lab tests are performed only when a clinical indication exists and if results will affect treatment decisions. Measurement of various hormone levels may be considered in specific circumstances by clinicians well versed in the use of results to guide therapy.[16] The NP determines from Cass's assessment that no other lab tests are indicated.

What is an appropriate management strategy for Cass?

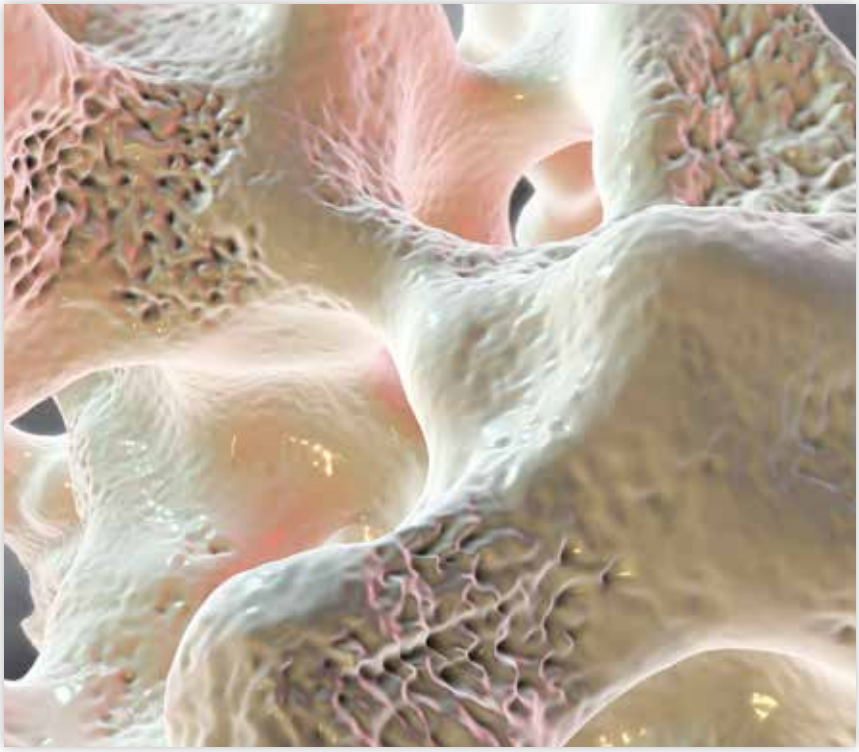
Cass's assessment indicates that she has HSDD. Contributing factors to this diagnosis include genitourinary syndrome of menopause (GSM), which can lead to dyspareunia (or pain with any vaginal penetration); the potential dampening effect of an SSRI on sexual desire and arousal; positioning discomfort related to hip arthritis; and a change in work schedules that has decreased time for Cass and her partner to share relaxation and intimacy.

OTC lubricants have been only minimally helpful. Three FDA-approved medications are available to treat GSM-related dyspareunia: local vaginal estrogen, ospemifene, and prasterone.[17] Ospemifene, a selective estrogen reuptake modulator, has an estrogen agonist effect on vaginal tissue. However, hot flashes are a common side effect, making it a less than optimal choice for Cass. Prasterone is an intravaginal DHEA converted locally inside vaginal cells into active estrogens and androgens.[17]

SSRIs are among the most common medications linked to low libido, decreased arousal, and orgasmic dysfunction in women. The specific relationship between SSRI use and sexual dysfunction is not known but appears to be dose dependent.[18] Cass is taking the SSRI to help relieve hot flashes, not for depression. She can decrease the SSRI dosage to see if hot flashes are still relieved or consider nonpharmacologic management strategies.

Control of arthritis pain may include physical therapy (PT), application of heat or cold, and use of OTC analgesics. Other strategies include planning sexual activity for times of day when pain severity is typically low, taking an analgesic about 30 minutes in advance, judicious use of pillows for positioning and joint support, and incorporating a warm shower or bath.[19]

The NP and Cass discuss these approaches. Cass considers local vaginal estrogen and discontinuation of paroxetine, along with nondrug management of her hot flashes. She also plans to discuss what she has learned at this visit with Ellen. She believes that the two of them can be creative in planning time for relaxation and intimacy if they work on it together. She agrees to a referral to PT to start exercises for mobility and strength building. She also asks if any medication is available specifically to treat HSDD. The NP explains that one medication, flibanserin, is FDA approved for treatment of HSDD in premenopausal women. This agent acts on the central nervous system to improve sexual desire and satisfying sexual events.[16]



Scenario #4: Postmenopausal osteoporosis

The American Association of Clinical Endocrinologists and the American College of Endocrinology list four criteria, any one of which indicates a diagnosis of osteoporosis in postmenopausal women[20]:

- a T-score of –2.5 or lower in the lumbar spine, femoral neck, total, and/or one-third of radius;
- low-trauma spine or hip fracture, regardless of bone mineral density (BMD);
- osteopenia/low bone mass (T-score, –1 to –2.5) with a fragility fracture of the proximal humerus, pelvis, or possibly distal forearm; or
- osteopenia/low bone mass and high fracture probability based on a Fracture Risk Assessment Tool (FRAX) score and country-specific thresholds.

BMD is measured most commonly with dual-energy x-ray absorptiometry (DXA) of the hip and spine. FRAX uses 10 risk factors to calculate the 10-year risk of a major osteoporotic fracture. An algorithm based on FRAX score places an individual at low, moderate, or high risk for fracture.[21] Scenario #4 reflects assessment and management of a woman with postmenopausal osteoporosis.

Dot, a 63-year-old female, presents at the office with a complaint of mid-back pain that started 2 weeks ago. Acetaminophen has helped, but the pain remains.

What additional information will be helpful for the NP to obtain?

Dot tells the NP that the current back pain started after strenuous gardening and it worsens when she takes a deep breath and with certain movements. She has no urinary tract signs or symptoms. In reviewing Dot's health history, the NP learns that she suffered a wrist fracture 3 years ago when she slipped on her bathroom floor and stretched out her arm to brace the fall. Dot tells the NP that her mother sustained a hip fracture at age 72 as the result of a fall. Given this information, the NP wants to assess Dot for osteoporosis and other bone fractures risks. Dot reached menopause at age 50 and has never used hormonal treatment to manage menopause symptoms. She does not smoke or drink alcohol and admits she gets very little exercise. She does not consume dairy products because she is lactose intolerant. She occasionally takes a multivitamin but is not on any prescription medications. She is 5'6" tall and weighs 140 lb.

Lab tests show normal results for her urinalysis, complete blood cell count, and metabolic panel. The only abnormal lab test result is a low 25-hydroxyvitamin D (25[OH] D) level. A spinal radiograph shows a T12 wedge compression fracture "age indeterminate" and mild degenerative changes in the L2-L5 area. DXA shows T-scores of –2.3 at L1-L4 and –1.9 at the left femoral neck. Her FRAX score is 17% for major osteoporotic fracture and 2.2% for hip fracture in the next 10 years, placing her at moderate risk.

Does Dot have a diagnosis of osteopenia or osteoporosis?

Dot is diagnosed with osteoporosis based on her BMD scores (indicating osteopenia) and her history of a fragility fracture of the distal forearm. The most common areas of fragility fractures are the wrist, hip, and spine; in women, more than 50% of these fractures occur in those with T-scores in the osteopenia range.[20]

What is the best treatment plan for Dot?

Recommended initial pharmacotherapy for postmenopausal osteoporosis in women at moderate risk for fracture includes medications in the antiresorptive drug class. These

medications slow or suppress osteoclast-mediated bone resorption, resulting in increased BMD. Drugs in this class that have been shown to reduce the risk for hip, nonvertebral, and spine fractures include bisphosphonates (BPs) such as alendronate, risedronate, and zoledronic acid and the RANK ligand inhibitor denosumab.[20,22] Two other drugs in the antiresorptive class, the BP ibandronate and the estrogen agonist/antagonist raloxifene, have been shown to reduce vertebral fracture risk but not that of nonvertebral or hip fracture.[20]

The NP and Dot discuss the implications of her test results and her risk for future fractures. Dot says that the fall and wrist fracture scared her, and that she does not want to endure a hip fracture as her mother did. Her main treatment goals are to improve and/or stabilize her T-scores and to decrease her fracture risk. She agrees to start an oral BP.

Oral BPs are taken on a daily, weekly, or monthly basis. These medications may cause dysphagia, esophagitis, and esophageal ulcers. Patients with esophageal abnormalities that delay esophageal emptying or who cannot stand or sit upright for at least 30-60 minutes after ingesting medication should not use oral BPs. Hypocalcemia is a possible adverse effect. Serum calcium and serum creatinine should be measured before beginning treatment; BPs should not be used in individuals with renal impairment. Rare but serious adverse effects with long-term and high-dose BP therapy include osteonecrosis of the jaw and atypical femur fracture.[20,22]

Zoledronic acid is a BP given by intravenous infusion once yearly and denosumab is given by subcutaneous injection every 6 months. Either of these two drugs may be appropriate as initial treatment for postmenopausal women at high fracture risk, those who cannot tolerate oral agents, those with lower gastrointestinal problems that may inhibit absorption, and those who have difficulty remembering to take or adhering to instructions for oral medications.[20]

Attention is given to Dot's deficiency in vitamin D, which is essential for efficient intestinal absorption of calcium and may enhance response to BP therapy. In Dot's case, the likely cause of the vitamin D deficiency is lack of dietary vitamin D and age-related decline in cutaneous production.[22] Pharmacologic management options include 50,000 IU of vitamin D_2 or D_3 once weekly or 5,000 IU of vitamin D_2 or D_3 daily for 8-12 weeks to achieve a blood 25(OH)D level >30 ng/mL. Maintenance therapy is 1,000-2,000 IU of vitamin D_3 daily or an appropriate dose to maintain a blood 25(OH)D level ≥30 ng/mL.[20,22]

Other components of an osteoporosis treatment and fracture prevention program for Dot include adequate calcium intake (recommendation for women aged 50+ years, 1,200 mg/day), including supplements as needed, an exercise program to include weight-bearing activities as well as strength and balance training, and fall prevention strategies.[20,22]

What follow-up is important for Dot?

Dot should undergo BMD testing every 1-2 years, with stable or increasing T-scores indicating a satisfactory response. If she has no new fractures during 5 years on oral BPs, a drug holiday can be considered. BPs accumulate in bone and continue to have a protective effect. Optimal duration of therapy and length of a holiday are not established and should be based on ongoing assessment for fracture risk.[20,22]

When are anabolic medications considered?

Two anabolic medications, teriparatide and abaloparatide, are approved for treatment of osteoporosis in postmenopausal women who are at high risk for fracture or have failed or been intolerant of treatment with antiresorptive drugs.[23,24] These parathyroid analogs are self-administered subcutaneously daily and work by increasing new bone formation through stimulation of osteoblastic activity.[22] Their use is not recommended beyond 2 years' duration. Unlike BPs, anabolic medications do not accumulate in bone; BMD declines quickly after discontinuation. Use of an antiresorptive drug following discontinuation may prevent this loss and further increase BMD. Research is ongoing to determine when combination therapies might be beneficial and which treatment sequence is optimal for patients with osteoporosis.[25]

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Web resources

A. npwh.org/courses/home/details/1155
B. cdc.gov/mmwr/volumes/65/rr/rr6504a1.htm
C. cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm?s_cid=rr6503a1_w
D. fsfi-questionnaire.com

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INDICATIONS AND USAGE

Balcoltra is a progestin/estrogen combination oral contraceptive (COC) indicated for use by females of reproductive potential to prevent pregnancy.

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.

CONTRAINDICATIONS

Balcoltra is contraindicated in women with a high risk of arterial or venous thrombotic diseases, liver tumors (benign or malignant) or liver disease, undiagnosed abnormal uterine bleeding, during pregnancy, with breast cancer or other estrogen- or progestin-sensitive cancer (now or in the past), hypersensitivity to any of the components, or in women who are currently taking Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir (with or without dasabuvir).

WARNINGS AND PRECAUTIONS

- Discontinue Balcoltra if an arterial thrombotic event or venous thromboembolic event (VTE) occurs, and at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during prolonged immobilization. Balcoltra should not be started any earlier than 4 weeks after delivery, in women who are not breastfeeding. The use of COCs increases the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions. Use COCs with caution in women with cardiovascular disease risk factors.
- If jaundice occurs, treatment should be discontinued.
- Balcoltra should not be prescribed for women with uncontrolled hypertension or hypertension with vascular disease. An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. If Balcoltra is used in women with well-controlled hypertension, monitor blood pressure and stop treatment if blood pressure rises significantly.
- Women who are prediabetic or diabetic should be monitored while using Balcoltra. Alternate contraceptive methods should be considered for women with uncontrolled dyslipidemia.
- Patients using Balcoltra who have a significant change in headaches or who develop new headaches that are recurrent, persistent, or severe should be evaluated, and Balcoltra should be discontinued if indicated.
- Irregular bleeding and spotting sometimes occurs in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles on Balcoltra, check for causes such as pregnancy or malignancy.
- This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Sensitivity to tartrazine is frequently seen in patients who have aspirin hypersensitivity.

ADVERSE REACTIONS

In a clinical trial with levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg, the most common adverse reactions (incidence ≥ 2%) were headache (14%), metrorrhagia (8%), dysmenorrhea (7%), nausea (7%), abdominal pain (4%), breast pain (4%), emotional lability (3%), acne (3%), depression (2%), amenorrhea (2%), and vaginal moniliasis (2%).

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the effectiveness of COCs or increase breakthrough bleeding.

Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Please see full Prescribing Information, including BOXED WARNING, for Balcoltra.

References: 1. Balcoltra [package insert]. Alpharetta, GA: Avion Pharmaceuticals LLC; 2018.

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Balcoltra™ (levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets and ferrous bisglycinate 36.5 mg tablets) for oral administration

Brief Summary of Prescribing Information

For additional information, refer to the full Prescribing Information.

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.

INDICATIONS AND USAGE

Balcoltra is indicated for use by females of reproductive potential to prevent pregnancy.

DOSAGE AND ADMINISTRATION

Patients should take one tablet by mouth at the same time every day in the order directed on the blister pack.

CONTRAINDICATIONS

Balcoltra is contraindicated in individuals with:

- A high risk of arterial or venous thrombotic diseases, including in women who:
  - -Smoke, if over age 35
  - -Have deep vein thrombosis or pulmonary embolism, now or in the past
  - -Have inherited or acquired hypercoagulopathies
  - -Have cerebrovascular disease
  - -Have coronary artery disease
  - -Have thrombogenic valvular or rhythm diseases of the heart
  - -Have uncontrolled hypertension
  - -Have diabetes mellitus with vascular disease
  - -Have headaches with focal neurological symptoms or have migraine headaches with aura
- Women over age 35 with any migraine headaches
- Liver tumors or liver disease
- Undiagnosed abnormal uterine bleeding
- Pregnancy
- Breast cancer or other estrogen- or progestin-sensitive cancer or history of these cancers
- Hypersensitivity of any of the components
- Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir

WARNINGS AND PRECAUTIONS

Thrombotic Disorders and Other Vascular Problems

Stop Balcoltra if an arterial thrombotic event or venous thromboembolic (VTE) event occurs, or if unexplained visual loss, proptosis, diplopia, papilledema or retinal vascular lesions occur. If possible, stop at least 4 weeks before through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during the following prolonged immobilization. Start no earlier than 4 weeks after delivery, in women who are not breastfeeding.

The use of COCs increases the risk of VTE; however, pregnancy increases the risk of VTE as much or more than the use of COCs. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. The risk of thromboembolic disease due to COCs gradually disappears after use is discontinued. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes). This risk increases with age, particularly in women over 35 years of age who smoke. Use COCs with caution in women with cardiovascular disease risk factors.

Liver Disease

Do not use Balcoltra in women with liver disease, such as acute viral hepatitis or severe (decompensated) cirrhosis of liver. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded. Discontinue Balcoltra if jaundice develops. Balcoltra is contraindicated in women with benign and malignant liver tumors. Hepatic adenomas are associated with COC use. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that contains ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN), including some cases greater than 20 times the ULN, were significantly more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue Balcoltra prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Balcoltra can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

High Blood Pressure

Balcoltra is contraindicated in women with uncontrolled hypertension or hypertension with vascular disease.

If used in women with well-controlled hypertension, monitor blood pressure and stop Balcoltra if blood pressure rises significantly.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. The incidence of hypertension increases with increasing concentrations of progestin.

Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users. COCs may worsen existing gallbladder disease. A history of COC-related cholestasis predicts an increased risk with subsequent COC use. Women with a history of pregnancy-related cholestasis may be at an increased risk for COC related cholestasis.

Carbohydrate and Lipid Metabolic Effects

Monitor prediabetic and diabetic women taking Balcoltra, as COCs may decrease glucose tolerance. Consider an alternative contraceptive method for women with uncontrolled dyslipidemia. Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

Headache

If a woman taking Balcoltra develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue Balcoltra if indicated. Consider discontinuation of Balcoltra in the case of increased frequency or severity of migraine during COC use.

Bleeding Irregularities and Amenorrhea

Evaluate irregular bleeding or amenorrhea.

Unscheduled (breakthrough or intracyclic) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different contraceptive product.

Women who use Balcoltra may experience amenorrhea. In the clinical trial, 2.6% of the evaluable cycles were amenorrheic. Some women may experience amenorrhea or oligomenorrhea after discontinuation of COCs, especially when such a condition was preexistent.

If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more active tablets or started taking them on a day later than she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

FD&C Yellow No. 5 Allergic-type Reaction

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Depression

Carefully observe women with a history of depression and discontinue Balcoltra if depression recurs to a serious degree.

Carcinoma of the Breast and Cervix

Balcoltra is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive.

Effect on Binding Globulins

The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

Monitoring

A woman who is taking COCs should have her blood pressure checked periodically with her healthcare provider.

Hereditary Angioedema

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

Chloasma

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking Balcoltra.

ADVERSE REACTIONS

In a clinical trial with levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets, a total of 1477 healthy women of child-bearing potential were enrolled and had 7870 cycles of exposure. Of these, 792 subjects had completed 6 cycles of treatment. The women ranged in age from 17 to 49 years and 87% were Caucasian.

Common Adverse Reactions (≥ 2% of women):

Headache (14%), metrorrhagia (8%), dysmenorrhea (7%), nausea (7%), abdominal pain (4%), breast pain (4%), emotional lability (3%), acne (3%), depression (2%), amenorrhea (2%), and vaginal moniliasis (2%).

At the time of the report, 133 (9%) subjects had withdrawn from the study due to adverse events. The most frequent were due to headache and metrorrhagia (1% each). Other adverse events occurring in < 1% of those who discontinued included amenorrhea, depression, emotional lability, hypertension, acne, menorrhagia, nausea, hypercholesterolemia, weight gain, dysmenorrhea, and flatulence. All other reasons for discontinuation were reported by 3 or fewer subjects. These are not all of the possible adverse reactions of Balcoltra.

DRUG INTERACTIONS

Consult the labeling of concurrently used drugs to obtain more information about interactions with hormonal contraceptives. Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of COCs or increase breakthrough bleeding. Counsel women to use an alternative method of contraception or a back-up method when enzyme inducers are used with COCs, and to continue back-up contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Colesevelam: Colesevelam, a bile acid sequestrant, given together with a COC, has been shown to significantly decrease the AUC of ethinyl estradiol (EE). The drug interaction between the contraceptive and colesevelam was decreased when the two drug products were given 4 hours apart.

Co-administration of atorvastatin or rosuvastatin and certain COCs containing EE increase AUC values for EE by approximately 20-25%. Ascorbic acid and acetaminophen may increase plasma EE concentrations, possibly by inhibition of conjugation. CYP3A4 inhibitors, such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations.

Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin have been noted in some cases of co-administration with HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir, boceprevir, telaprevir, nevirapine and efavirenz] or increase [e.g., indinavir, atazanavir/ritonavir and etravirine]).

Combined oral contraceptives containing EE may inhibit the metabolism of other compounds (e.g., cyclosporine, prednisolone, theophylline, tizanidine, and voriconazole) and increase their plasma concentrations. Combined oral contraceptives have been shown to decrease plasma concentrations of acetaminophen, clofibric acid, morphine, salicylic acid, temazepam and lamotrigine. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because the serum concentration of thyroid-binding globulin increases with use of COCs.

Do not co-administer Balcoltra with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations.

The use of contraceptive steroids may influence the results of certain laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins.

USE IN SPECIFIC POPULATIONS

Pregnant Women

Balcoltra is contraindicated in pregnancy because there is no reason to use combined hormonal contraceptives (CHCs) in pregnancy. Discontinue Balcoltra if pregnancy occurs. Based on epidemiologic studies and meta-analyses, there is little or no increased risk of birth defects in the children of females who inadvertently use COCs during early pregnancy.

Epidemiologic studies and meta-analyses have not found an increased risk of genital or nongenital birth defects (including cardiac anomalies and limb-reduction defects) following exposure to COCs before conception or during early pregnancy.

Nursing Mothers

Combined hormonal contraceptives (CHCs) and/or metabolites are present in human milk and in breast-fed infants. CHCs, including Balcoltra, can reduce milk production in breast-feeding females. This reduction can occur at any time but is less likely to occur once breast-feeding is well established. When possible, advise the nursing female to use other methods of contraception until she discontinues breast-feeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Balcoltra and any potential adverse effects on the breast-fed child from Balcoltra or from the underlying maternal condition.

Pediatric Use

Safety and efficacy of Balcoltra have been established in women of reproductive age. Efficacy is expected to be the same in post-pubertal adolescents under the age of 18 years as for users 18 years and older. Use of this product before menarche is not indicated.

Geriatric Use

Balcoltra has not been studied in postmenopausal women and is not indicated in this population.

Hepatic Impairment

The pharmacokinetics of Balcoltra has not been studied in women with hepatic impairment. However, steroid hormones may be poorly metabolized in patients with hepatic impairment. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded.

OVERDOSAGE

There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.

The FDA-approved product labeling can be found at www.balcoltra.com, or call 1-888-612-8466.

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Avion PHARMACEUTICALS

Men with breast conditions: The role of the WHNP specializing in breast care

NPWH
NURSE PRACTITIONERS IN WOMEN'S HEALTH
Caring for Women

The National Association of Nurse Practitioners in Women's Health (NPWH) affirms the role of the women's health nurse practitioner (WHNP), as a member of a multidisciplinary breast care specialty team, in providing specialized breast care for women and men. Furthermore, NPWH supports the removal of any restrictions to the provision of male breast care that are based on the WHNP credential.

WHNPs are educationally prepared to provide care for both women and men with benign and malignant breast conditions. The WHNP program curriculum includes breast pathophysiology, genomics/genetics, assessment and management of breast disorders, and risk assessment for hereditary breast cancers—all applicable to men as well as women.[1] The national WHNP certification examination through the National Certification Corporation (NCC) includes content on breast cancer and other breast disorders.[2] WHNPs choosing to specialize in breast care may expand their knowledge and skills in this area through on-the-job training in the clinical setting and through continuing education (CE) programs.

As of now, some states and healthcare institutions restrict WHNPs from providing care for male patients with breast cancer or other breast conditions. Given that the diagnostic procedures and treatment are the same for women and men, this restriction is unwarranted. WHNPs specializing in breast care are qualified to provide this care for all individuals.

Background

The majority of individuals who develop breast cancer are women. Nevertheless, breast cancer is not exclusively a female disease. Current knowledge concerning breast cancer risks, statistics, diagnosis, and treatment in men provides a background to understand the role of the WHNP specializing in breast care as it applies to male patients. Although the background information in this section focuses on breast cancer, it is important to keep in mind that specialized breast care encompasses both malignant and benign breast conditions.

Risk factors

An individual may present to a breast specialist not because of signs or symptoms that could indicate breast cancer but, rather, because of an identified potentially increased risk for breast cancer. For men, well-established breast cancer risk factors include family history and *BRCA1/2* mutations, primarily those of *BRCA2*. In fact, 5%-10% of men with *BRCA2* mutations eventually develop breast cancer.[3,4] In addition, conditions that alter the estrogen-to-androgen ratio (e.g., Klinefelter syndrome, obesity, cirrhosis, history of prostate cancer treated with estrogen) are associated with an increased risk of breast cancer in men.[3,5,6] Although some of these risk factors apply only to men, the principles of risk assessment and counseling are the same for women and men. The National Comprehensive Cancer Network provides detailed guidelines for risk assessment, criteria for offering genetic counseling and testing, and recommendations for surveillance of individuals identified as being at increased risk for breast cancer.[7]

Incidence

The American Cancer Society predicts that 2,550 men will develop breast cancer in 2018.[3] By comparison, an estimated 266,120 new cases of breast cancer in women are expected in 2018.[8] Consistent with these statistics, male breast cancer comprises fewer than 1% of all breast cancer cases, as well as fewer than 1% of overall male cancer cases. Although these numbers and percentages in men are small compared with those in women, many men with breast disease will present to a breast care center at some point during diagnosis and treatment.

Diagnosis

Diagnostic tests used when an individual presents with a breast mass or other breast changes that may indicate a malignancy are the same for women and men. These tests include clinical breast examination; imaging modalities such as mammography, ultrasound, and magnetic resonance imaging, as indicated; and biopsy of the mass.[5,9] The most common type of breast cancer diagnosed in men (80%-90% of cases) is infiltrating ductal carcinoma. This breast cancer type is also the most common type in women (80%). About 10% of breast cancers

in men are ductal carcinoma *in situ*. Fewer than 2% of male breast cancers are lobular carcinomas, primarily because most men have minimal lobular tissue.[3] Estrogen-, progesterone-, and HER2-receptor testing of breast cancer cells is part of the evaluation for both women and men. Many breast cancers in men demonstrate receptors for the hormones estrogen and progesterone.[3,10,11]

Staging

Histologic staging of breast cancer is the same for women and men. Staging is defined according to tumor size, nodal involvement, metastasis, and pathologic characteristics of the cancer, including receptor status and tumor grade.[3,6,9,12] The pathophysiology of breast cancer metastasis is the same in women and men.[3] Studies do suggest that men, compared with women, are diagnosed with higher-stage tumors and have a poorer prognosis overall. The poorer prognosis correlates with delay in diagnosis and treatment—thought to occur in part because of lack of awareness of breast cancer in men.[5,6,10]

Treatment

Four modalities are used either as single therapies or in combination for the treatment of breast cancer in both women and men. These modalities are surgery, radiation, chemotherapy, and hormone therapy.[3,6,12] In the absence of randomized controlled trials of the treatment of breast cancer in men, current guidelines are based for the most part on treatment of breast cancer in women.[13]

Follow-up care and concerns

The care provided by healthcare professionals specializing in breast cancer goes beyond initial diagnosis and treatment. The needs of both male and female breast cancer survivors are multifaceted and ongoing. Genetic counseling/testing, as appropriate, is one component of this care (if not done prior to treatment). Just as for females, genetic testing for male breast cancer survivors can provide information relevant to their surveillance needs and those of their family members.[6,7,12,14] Surveillance recommendations for both male and female breast cancer survivors include clinical breast/chest wall examination twice yearly for the first 5 years and then annually thereafter.[13,14] Although only limited data support the use of breast imaging as part of surveillance for male breast cancer survivors, it may be offered.[14]

Care for both male and female breast cancer survivors also includes management of side effects of treatment. Men treated with hormone therapies may experience side effects similar to those in women, including hot flashes, weight gain, and sexual dysfunction. In fact, approximately one in four men discontinues therapy prematurely because of bothersome symptoms.[6,14] Although management of breast cancer treatment-related side effects in men is less well studied than that in women, similar lifestyle and medication approaches are used.[14]

Because any type of cancer, as well as its treatment, can affect sexual functioning in men and women, WHNPs should ask patients about their sexual health at follow-up visits and refer them to specialists when needed.[14-17] The WHNP curriculum includes specific content on male sexual health that prepares WHNPs to assess sexual health conditions, to address psychosocial factors and conditions that affect sexual health, and to collaborate or refer appropriately for male sexual dysfunction treatment.[1] The NCC WHNP certification examination includes content on male sexuality and sexual dysfunction.[2]

Both men and women with a diagnosis of breast cancer may experience body image disruption, anxiety, and depression.[14,15] Although similarities between male and female breast cancer survivors exist in terms of psychological and quality-of-life (QOL) concerns, certain concerns are more likely to affect men. For example, some men may feel stigmatized by having a diagnosis so strongly associated with women.[6,14,15] They may feel embarrassed to talk with their healthcare provider and feel isolated because they cannot find other male breast cancer survivors to whom then can relate.[14,15] WHNPs are prepared in educational and clinical environments that emphasize attention to psychological, social, and cultural factors that influence healthcare and health outcomes. This holistic and individualized care extends across genders.

Gaps in knowledge

More research is needed regarding all aspects of male breast cancer. Biological differences between male breast cancers and female breast cancers may have implications for treatment strategies.[11,12,14] Men with breast cancer should have an opportunity to participate in clinical trials and/or be added to a tumor registry to provide data on the care and outcomes of a rare disease. Studies conducted to better understand psychological and QOL problems for men with breast cancer could lead to improved care. All healthcare professionals specializing in breast cancer care for women and men are expected to stay current on evidence for best practice.

Implications for WHNP practice

WHNPs who choose to specialize in breast care have a strong foundation to prepare them for this role. The WHNP curriculum and the WHNP certification examination reflect the knowledge base needed to provide care in this specialty area, which includes benign and malignant breast conditions in women and men. On-the-job training and CE programs further expand the knowledge and skills appropriate to providing this care.

Principles of breast cancer risk assessment and counseling are the same for women and men. Diagnostic testing, hormone-receptor evaluation, and staging for breast cancer are the same. Treatment modalities are the same. Management for treatment-related side effects and surveillance strategies for breast cancer survivors are similar for women and men. Holistic and individualized care is a cornerstone for all WHNPs. And those WHNPs who specialize in breast care are qualified to provide care for women *and* men.

NPWH will:

- Educate employers and state boards of nursing as needed concerning the qualifications of WHNPs to specialize in breast care; and
- Advocate for removal of any current restrictions to WHNPs providing breast care for men.

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Approved by the NPWH Board of Directors: May 2018

Developing and implementing PrEP at your local health center

By Brenda A. Wolfe, MSN, APN, ACRN; Elizabeth Higgins, MSN, WHNP; Michelle Vos, MA; and Amy Whitaker, MD

Pre-exposure prophylaxis (PrEP) is an effective tool in the prevention of HIV acquisition. Advanced practice registered nurses are ideally positioned to introduce and prescribe PrEP, but some may not know how to integrate it into their practice. In this article, the authors describe the logistics of developing and implementing a PrEP program at multiple Planned Parenthood of Illinois (PPIL) health centers. They also discuss the training and support offered to PPIL clinicians during implementation of the program, the evaluation process, and the results. The process from development to implementation and evaluation can be easily adapted to other clinical settings.

KEY WORDS: **Pre-exposure prophylaxis, PrEP, women, HIV prevention, outpatient health services, reproductive health**

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medication by HIV-negative individuals to reduce their risk of acquiring HIV. Emtricitabine/tenofovir disoproxil fumarate (ETDF), the only FDA-approved medication for PrEP, is more than 92% effective in preventing HIV acquisition when taken as directed.[1] Information about PrEP should be offered to suitable candidates, as described in the CDC's Clinical Practice Guideline, **Preexposure Prophylaxis for the Prevention of HIV Infection in the United States**[A].[2] Advanced practice registered nurses (APRNs) working in reproductive health clinics, sexually transmitted infection clinics, obstetrics and gynecology (Ob/Gyn) practices, and other primary healthcare settings are particularly well positioned to discuss PrEP with their patients and prescribe the medication when indicated.

Many clinicians are reluctant to implement PrEP in their practices—for a variety of reasons. A major concern is the time needed to obtain sexual histories, provide counseling, and complete required paperwork for patients needing financial assistance (mainly for medication provision). Clinical concerns related to prescribing PrEP include drug side effects, a potential lack of adher-

ence to the regimen by patients, and the possibility that patients might engage in riskier sexual behavior[3] because, by taking PrEP, they may feel less vulnerable to harm.

Even though ETDF has proved to be highly effective in preventing HIV acquisition, clinicians working in certain types of practices are unlikely to prescribe it. For example, according to a PrEP utilization review, only 3% of PrEP regimens prescribed between 2013 and 2016 were provided in Ob/Gyn offices.[4] According to this same review, most women accessed PrEP through family medicine and emergency department providers, whereas most men accessed it through family medicine and internal medicine providers.[4]

With the hope of encouraging APRNs to be more proactive in prescribing PrEP and, even more, helping them set up a PrEP program in their own practice venue—the authors share their experience in developing and implementing a PrEP program at 16 affiliates of Planned Parenthood of Illinois (PPIL). They describe the training and support provided to the PPIL clinicians during implementation of the program and discuss the evaluation process and results.

Developing and implementing a PrEP program

Integrating a new service into a private or multispecialty practice requires planning. One of the first steps is to anticipate barriers that may (1) prevent administrators, clinicians, and staff members from fully embracing the program or (2) deter patients from returning for services. The next step is figuring out how to avoid or overcome these barriers as the program is designed and then launched. A host of other decisions about the program must be made and numerous details regarding its implementation must be addressed.

Based on their experience at PPIL, the authors recommend these steps for developing and implementing a PrEP program:

- Ensure that top administrators (e.g., CEO, county commissioners, board of directors) are well versed about PrEP.
- Obtain support from the senior leadership team.
- Determine whether clinicians perceive that PrEP is an appropriate intervention and whether they have concerns about the screening process or the PrEP protocol itself. Provide information and address concerns as needed.
- Train and support clinicians on how to provide PrEP.
- Create a PrEP algorithm for screening and prescribing.
- Train medical assistant staff to screen for and educate about PrEP.
- Inform support staff, schedulers, educators, and administrative staff about PrEP services.
- Include PrEP education in the new-hire orientation program.
- Designate a champion to provide support and on-call assistance. (A clinician can become a PrEP champion via continuing education, experience in prescribing PrEP, or both.)
- Determine whether rapid HIV testing will be performed onsite or outsourced.
- Identify patient visit and laboratory test costs.
- Ascertain whether ETDF will be stocked in-house and/or acquired by patients from offsite pharmacies.
- Identify appropriate diagnostic codes for PrEP services to ensure optimal reimbursement and ability to track visits for program evaluation (at PPIL, the PrEP program developers gave clinicians one specific diagnostic code to use when ordering PrEP in order to make the evaluation process easier).
- Create standing orders for laboratory tests and medications.
- Configure standing laboratory test and medication orders into electronic health records (EHRs).
- Create educational phrases in the EHR for efficient comprehensive documentation.
- Include PrEP services in marketing materials and messages, including those on social media.
- Inform stakeholders and community agencies about available PrEP services.
- Pre-populate and print patient medication assistance forms and co-pay cards for efficient application processing. The **Gilead Advancing Access®program**[B] provides information for clinicians and patients to help ensure access to medication.
- Add your clinic and/or clinicians to the **PrEP Locator National Directory**[C].
- Evaluate the effectiveness of program implementation.
- Address concerns recognized during the evaluation process.

PrEP training and support for clinicians

Written protocols are an important resource for training and supporting clinicians as they implement a new service within their practice setting. Examples of available resources for PrEP protocols and checklists are provided in the *Box*. Planned Parenthood's Medical Standards and Guidelines (MS&Gs) include comprehensive PrEP protocols and algorithms that were used for this purpose at PPIL.

As part of the training at PPIL, the clinicians were asked to review these MS&Gs and attend a 90-minute pre-

(continued on page 31)

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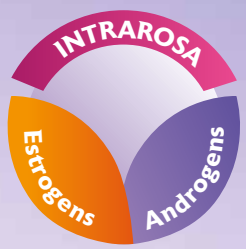

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Indication

INTRAROSA is a steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Important Safety Information

INTRAROSA is contraindicated in women with undiagnosed abnormal genital bleeding.

Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

In four 12-week randomized, placebo-controlled clinical trials, the most common adverse reaction with an incidence ≥2 percent was vaginal discharge. In one 52-week open-label clinical trial, the most common adverse reactions with an incidence ≥2 percent were vaginal discharge and abnormal Pap smear.

Please see the following page for a Brief Summary of full Prescribing Information.

References: 1. Intrarosa [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2018. **2.** Archer DF, Labrie F, Bouchard C, et al. *Menopause*. 2015;22(9):950-963. **3.** Labrie F, Archer DF, Koltun W, et al. *Menopause*. 2016;23(3):243-256.

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Prasterone VAGINAL INSERTS 6.5 mg

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INTRAROSA® (prasterone) vaginal inserts

Brief Summary: Consult full Prescribing Information for complete product information.

INDICATION
INTRAROSA is a steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

CONTRAINDICATIONS
Undiagnosed abnormal genital bleeding: Any postmenopausal woman with undiagnosed, persistent or recurring genital bleeding should be evaluated to determine the cause of the bleeding before consideration of treatment with INTRAROSA.

WARNINGS AND PRECAUTIONS Current or Past History of Breast Cancer
Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

ADVERSE REACTIONS Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In four (4) placebo-controlled, 12-week clinical trials [91% - White Caucasian non-Hispanic women, 7% - Black or African American women, and 2% - "Other" women, average age 58.8 years of age (range 40 to 80 years of age)], vaginal discharge is the most frequently reported treatment-emergent adverse reaction in the INTRAROSA treatment group with an incidence of ≥ 2 percent and greater than reported in the placebo treatment group. There were 38 cases in 665 participating postmenopausal women (5.71 percent) in the INTRAROSA treatment group compared to 17 cases in 464 participating postmenopausal women (3.66 percent) in the placebo treatment group.

In a 52-week non-comparative clinical trial [92% - White Caucasian non-Hispanic women, 6% - Black or African American women, and 2% - "Other" women, average age 57.9 years of age (range 43 to 75 years of age)], vaginal discharge and abnormal Pap smear at 52 weeks were the most frequently reported treatment-emergent adverse reaction in women receiving INTRAROSA with an incidence of ≥ 2 percent. There were 74 cases of vaginal discharge (14.2 percent) and 11 cases of abnormal Pap smear (2.1 percent) in 521 participating postmenopausal women. The eleven (11) cases of abnormal Pap smear at 52 weeks include one (1) case of low-grade squamous intraepithelial lesion (LSIL), and ten (10) cases of atypical squamous cells of undetermined significance (ASCUS).

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(continued from page 27)

sentation on PrEP. The presentation was provided by PPIL's PrEP champion. The presentation included a case study with multiple-choice questions that generated discussion and allowed the clinicians to apply information from the protocols and algorithms. PrEP education included identifying candidates for PrEP, counseling, prescribing, and required follow-up. Information about PrEP-Ception, the utilization of PrEP for HIV sero-discordant couples wanting to conceive, was included in the training.

The clinicians were reminded that most patients are unaware of PrEP; as clinicians, they are responsible for discussing PrEP as part of a comprehensive HIV prevention strategy. Clinicians involved in reproductive healthcare practices are already experienced in taking sexual histories and discussing safer sex practices. Adding PrEP to the conversation simply expands the prevention messages and options for patient protection.

Statistics on HIV prevalence within the communities in which the clinicians practice were provided during the presentation as well. The clinicians were encouraged to share this information with their patients—a strategy aimed at increasing patients' awareness of the level of risk of acquiring HIV based on its prevalence within their community. Too often, patients perceive PrEP candidates as persons who have engaged in promiscuous or dangerous behavior. Clinicians' emphasis on HIV prevalence in the community—as opposed to certain behaviors—as being a factor in acquiring HIV can reduce the stigma.

Upon completion of the PrEP presentation, the clinicians were free to implement PrEP into their practice. Providing routine education about and screening for PrEP was encouraged. However, the clinicians exercised their own judgment and comfort level in terms of whether they chose to prescribe PrEP themselves or refer patients to another PPIL provider to do so. The PrEP champion was always available to answer questions and provide support. Most questions posed to the champion concerned laboratory tests, co-morbidities, and potential drug interactions, and were typified by the following:

- When monitoring kidney function, which test panel or test (complete metabolic profile, basic metabolic profile, blood urea nitrogen, or creatinine) is the most cost effective?
- How should I proceed if a patient has a slightly low or high creatinine level?
- How often should a hepatitis B antigen be drawn on a patient who wants to restart PrEP?
- Can PrEP be started in a patient with a positive syphilis test result?
- Can use of PrEP be affected by the presence of certain health conditions?
- Can PrEP be prescribed prior to the return of baseline lab test results in a patient with a negative rapid HIV test result?
- Which drugs can potentially interact with PrEP?

Evaluation process and results

Short- and long-term evaluations are important components of a successful change in practice. Barriers can be identified and addressed, lessons can be learned and shared to improve processes, and factors needed to sustain the change can be assessed. Each clinical setting implementing PrEP services can decide how best to implement the evaluation component. However, having an evaluation plan in place from the beginning will help ensure that it occurs.

PPIL implemented evaluations at 4, 12, and 18 months using EHR data, one-on-one meetings between the clinicians and the PrEP champion, and clinician surveys. Along the way, these evaluations provided valuable insights. Early on, some clinicians needed and were provided with more information about the PrEP protocol, as well as guidance on initiating the conversation about PrEP with patients who might not con-

Box. PrEP resources

New York State Department of Health AIDS Institute. Clinical Guidelines Program. PREP FOR HIV PREVENTION

- Purpose of this guideline: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_0
- Updates to this guideline: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_1
- PrEP efficacy: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_2
- Candidates for PrEP: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_3
- Pre–prescription counseling and assessment: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_5
- Prescribing PrEP: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_7
- PrEP follow–up: https://www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/#tab_8

sider themselves vulnerable to HIV. One year after implementing PrEP services, the clinicians reported that they had received appropriate training but that they gained complete confidence in themselves and the process only after seeing a patient for whom they prescribed PrEP. They reported that the more times they prescribed PrEP, the easier it became to do so. During the first year, 18 (75%) of the 24 PPIL clinicians reported prescribing PrEP and all 24 expressed interest in prescribing PrEP.

The PrEP champion used information from one-on-one meetings with the clinicians, as well as the 4-month and 1-year evaluations, to provide a second presentation on PrEP that was focused on common questions about abnormal lab test results and drug interactions, strategies for increasing PrEP use specifically for women at risk for HIV acquisition, PrEP use during pregnancy and breastfeeding, use of PrEP for patients with co-morbidities, and use of an iPhone app, NefroCalc[D], for easy calculation of estimated creatinine clearance. A chart audit conducted at 18 months post-implementation (4 months after the second presentation) identified a significant increase in the number of new patients receiving PrEP, demonstrating the importance of ongoing education and discussion with staff when implementing a new program.

Summary

At PPIL, PrEP services were implemented immediately following an initial educational presentation. A system-wide approach to implementation was utilized rather than executing the service one health center at a time. Clinicians did not find screening and prescribing PrEP during routine visits problematic. Ongoing education, support, evaluation, and dialogue resulted in clinicians prescribing PrEP for an increased number of patients. Staff continue to look at strategies to remove barriers to medication adherence crucial to PrEP efficacy and to better facilitate PrEP follow-up visits.

Clinical implications

According to the CDC, a total of 1,232,000 persons in the U.S. would benefit from PrEP.[1] Among this group are 492,000 men who have sex with men, 115,000 adults who inject drugs, and 624,000 heterosexually active adults, *of whom 468,000 are women*.[1] Information about PrEP should be included routinely when APRNs caring for women are discussing reproductive and sexual health. Women should be informed if they reside in areas with high HIV prevalence and should be helped in identifying their own individual risk factors. APRNs caring for women should consider implementing PrEP services as an HIV prevention strategy. The steps described by the authors for developing, implementing, and evaluating PrEP services at PPIL provide guidance that can be adapted to a variety of clinical settings. ●

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2. CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. cdc/gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
3. Monthly Prescribing Reference. Why are Clinicians Reluctant to Prescribe PrEP to High-Risk Patients? April 6, 2015. empr.com/news/why-are-clinicians-reluctant-to-prescribe-prep-to-high-risk-patients/article/407448/
4. Truvada for PrEP Utilization by Gender and Provider Specialty. November 2016. Email communication with Staci Bush.

Web resources

A. cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
B. gileadadvancingaccess.com/hcp
C. preplocator.org/about-us/
D. download.cnet.com/NefroCalc/3000-2129_4-75598175.html

ASK HER IF SHE WANTS A birth control that's HORMONE FREE

PARAGARD®
(intrauterine copper contraceptive)—
the only highly effective, reversible birth control that is
completely hormone free[1]

56% of women reported that they had **concerns with hormones** in their birth control‡[3]

Tell her she has a hormone-free choice—tell her about PARAGARD.

INDICATION

PARAGARD is indicated for intrauterine contraception for up to 10 years.

IMPORTANT SAFETY INFORMATION

- **PARAGARD does not protect against HIV/AIDS or other sexually transmitted infections (STI).**
- PARAGARD must not be used by women who are pregnant or may be pregnant as this can be life threatening and may result in loss of pregnancy or fertility.
- PARAGARD must not be used by women who have acute pelvic inflammatory disease (PID) or current behavior suggesting a high risk of PID; have had a postpregnancy or postabortion uterine infection in the past 3 months; have cancer of the uterus or cervix; have an infection of the cervix; have an allergy to any component; or have Wilson's disease.
- The most common side effects of PARAGARD are heavier and longer periods and spotting between periods; for most women, these typically subside after 2 to 3 months.
- If a woman misses her period, she must be promptly evaluated for pregnancy.
- Some possible serious complications that have been associated with intrauterine contraceptives, including PARAGARD, are PID, embedment, perforation of the uterus, and expulsion.

Please see the following page for a brief summary of full Prescribing Information.

*Data are from the Contraceptive CHOICE Project. The study evaluated 3- and 6-month self-reported bleeding and cramping patterns in 5011 long-acting reversible contraceptive (LARC) users (n=826, PARAGARD), and the association of these symptoms with method satisfaction. Study participants rated satisfaction with their LARC method as "very satisfied," "somewhat satisfied," or "not satisfied." For the data analyses, "satisfied" and "very satisfied" were grouped together as "satisfied."[2]

†PARAGARD must be removed by a healthcare professional.

‡Based on a September 2017 web-based survey of US women aged 18-45 years (N=300), where participants were asked about their attitudes about birth control that contains hormones. Respondents were required to be currently using birth control or have plans to use birth control in the next year. Repeat respondents within the previous 6 months were not permitted.

References: 1. Kaneshiro B, Aeby T. Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device. *Int J Womens Health*. 2010;2:211-220. **2.** Diedrich JT, Desai S, Zhao Q, Secura G, Madden T, Peipert JF. Association of short-term bleeding and cramping patterns with long-acting reversible contraceptive method satisfaction. *Am J Obstet Gynecol*. 2015;212(1):50.e1-50.e8. **3.** Data on File. CooperSurgical, Inc., September 2017.

PARAGARD® T380A
intrauterine copper contraceptive
Life on *Her* Terms.

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CooperSurgical

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
ParaGard® T 380A Intrauterine Copper Contraceptive

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

ParaGard® is indicated for intrauterine contraception for up to 10 years. The pregnancy rate in clinical studies has been less than 1 pregnancy per 100 women each year.

CONTRAINDICATIONS

ParaGard® should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
2. Abnormalities of the uterus resulting in distortion of the uterine cavity
3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard®
10. A previously placed IUD that has not been removed

WARNINGS

1. Intrauterine Pregnancy

If intrauterine pregnancy occurs with ParaGard® in place and the string is visible, ParaGard® should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard® is in her uterus (for example, by ultrasound). If ParaGard® is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. Ectopic Pregnancy

Women who become pregnant while using ParaGard® should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard® in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard® prevents most pregnancies, women who use ParaGard® have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has *symptoms* of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

4. Immunocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. Embedment

Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard® promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. Wilson's Disease

Theoretically, ParaGard® can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Information for patients

Before inserting ParaGard® discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. Insertion precautions, continuing care, and removal.

3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard®, menstrual changes were the most common medical reason for discontinuation of ParaGard®. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard® because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2 % in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard®.

4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. Expulsion following placement after a birth or abortion

ParaGard® has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard® is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard® can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard®. One study examined the effect of MRI on the CU-7® Intrauterine Copper Contraceptive and Lippes Loop™ intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard® was subjected to MRI.

7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. Pregnancy

ParaGard® is contraindicated during pregnancy.

9. Nursing mothers

Nursing mothers may use ParaGard®. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. Pediatric use

ParaGard® is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in **WARNINGS** and **PRECAUTIONS**. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

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This brief summary is based on the ParaGard full prescribing information dated September 2014.

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Challenges of preconception and interconception care: Environmental toxic exposures

By Diane Schadewald, DNP, MSN, RN, FNP-BC, WHNP-BC and Ursula A. Pritham, PhD, WHNP-BC, FNP-BC, SANE

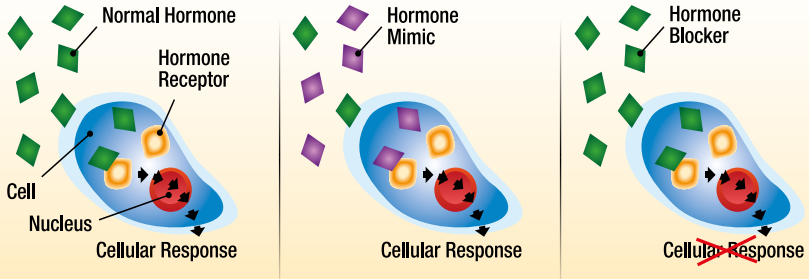
This article provides healthcare providers with up-to-date information about the impact of a variety of potentially toxic environmental exposures on reproductive health, specifically with respect to preconception care (PC) and interconception care (IC). PC/IC should include education regarding environmental risks and a discussion about ways to minimize a woman's exposure to environmental toxins in order to optimize both pregnancy and infant outcomes.

KEY WORDS: **preconception care, interconception care, environmental toxic exposures, reproductive health**

A major focus of preconception care (PC) and interconception care (IC) is identification and mitigation/management of risk factors to improve health outcomes for women, newborns, and children.[1] The importance of providing information about environmental toxins, as part of PC/IC to decrease risks of exposure, was recently highlighted by the International Federation of Gynecology and Obstetrics (FIGO).[2] The American College of Obstetricians and Gynecologists (ACOG) includes information about environmental risks in its Good Health Before Pregnancy: Preconception Care patient guide.[3] In this article, the authors describe what is known about some common environmental toxins and recommend strategies that healthcare providers (HCPs) can implement to help patients mitigate their risks of exposure.

Nearly all HCPs are aware of the dangers of smoking and drinking alcoholic beverages both prior to conception and during pregnancy, and counsel patients to avoid these practices. Also, before and after pregnancy is achieved, nearly all HCPs review patients' medications to identify any potential teratogens and make adjustments as needed. Most HCPs advise pregnant patients to avoid eating fish high in mercury (e.g., shark, tilefish, swordfish, king mackerel).[4] It also is common knowledge to

Figure. Effects of endocrine disruptors on cells



When absorbed in the body, an endocrine disruptor can decrease or increase normal hormone levels (*left*), mimic the body's natural hormones (*middle*), or alter the natural production of hormones (*right*).

Source: NIH, National Institute of Environmental Health Sciences. niehs.nih.gov/health/topics/agents/endocrine/index.cfm

recommend against consumption of soft cheeses and deli meats to decrease risk of exposure to listeria, and to remind patients to avoid exposure to toxins such as radiation, radon, and lead. Therefore, this article focuses on environmental risks about which HCPs may be less well informed.[5]

Environmental toxins are found in the air, in water, and in animals and plants that are consumed as food, as well as in products and furnishings in people's homes. Adverse effects of exposure to high concentrations of such toxins in humans have been reported. It remains unclear, however, whether the lower concentrations of such toxins in the surrounding environment can potentially have the same adverse effects as do higher concentrations that are ingested or inhaled directly and on a regular basis.[6]

Endocrine disruptors

Many of these environmental toxins can act as *endocrine disruptors*; that is, they can interfere with endocrine system function at multiple levels and in multiple ways (*Figure*). During highly sensitive stages of human development, even small disturbances in endocrine function can have profound effects. With regard to the reproductive system and pregnancy outcomes, potential effects of endocrine disruption include fertility problems for both females and males, fetal growth restriction, physical malformations, neurologic/cognitive developmental disruptions, preterm birth, and increased future cancer risk.[2,4,6-8] Many different categories of substances in the environment can serve as endocrine disruptors.

Pesticides/herbicides/fertilizers

Certain pesticides and herbicides may adversely affect fertility or they may have teratogenic effects if conception does occur. In addition, exposure to detectable amounts of pesticides has been linked to childhood leukemia and to neurologic and cardiovascular abnormalities in offspring.[7] For example, exposure to organophosphate pesticides such as chlorpyrifos and diazinon has been associated with abnormal cognitive development in offspring.[2,4,8]

Consuming organically grown produce may limit one's exposure to organophosphates used to control weeds and pests.[7] Some non-organically grown produce is safer to consume than others. Readers are advised to check the **Environmental Working Group's (EWG's) Shopper's Guide to Pesticides in Produce**[A], which has information on non-organic fruits and vegetables with low or high residues of organophosphates. Of note, residue from these organophosphates becomes embedded in the skin of the produce and/or penetrates into the produce and cannot be washed off.

Agricultural runoff from pesticides, herbicides, and fertilizers seeps into ground water. Exposure to the herbicide atrazine has been associated with reduced fetal growth.[9] Nitrates in groundwater coming from fertilizers, manure, and human sewage have been associated with methemoglobinemia (blue baby syndrome) in infants and thyroid dysfunction in pregnant women.[9] Although public water systems are tested for these contaminants and must meet safety standards, individuals who get drinking water from wells should be advised to have the water tested. Likewise, individuals whose drinking water comes from a public water system should ask for the latest test results for these substances.[9] If test results are positive, home water filtration and/or reverse osmosis systems are recommended.

Personal care products/cleaning products/paints

Many personal care products such as fragrances, cosmetics, soaps, lotions, and deodorants contain phthalates, which can act as endocrine disruptors.[5,7] Phthalate exposure both prior to and during pregnancy has been linked to a risk for preterm birth and to neurodevelopmental and executive function problems in offspring.[2,4] Males are more likely than females to be adversely affected by prenatal exposure to phthalates.[4] In particular, male reproductive development abnormalities have been noted from *in utero* exposure to these compounds.[4,10] Best practice is to check the labels on personal care products and use only those that are phthalate free.

Triclosan, parabens, and triclocarbans, which are added to personal care products to provide antibacterial and antifungal effects, have been identified as endocrine disruptors

(continued on page 38)

(continued from page 36)

that have been associated with preterm birth and low birth weight (LBW). In addition, exposure to triclosan may have thyrotoxic effects on the mother, which would have an adverse impact on the fetus.[10] The **EWG's web page on Consumer Products**[B] is a good resource for information on high- and low-risk personal care and cleaning products.

Some organic compounds are not tightly chemically bound to the products containing them and can be released into the atmosphere in a process called *off-gassing*. Off-gassed compounds can be inhaled directly from the atmosphere, but they also may settle on surfaces and be absorbed through the dermis by contact with such contaminated surfaces, or they may be ingested by hand-to-mouth transfer. This phenomenon is a concern when using latex-based paints and enamels. Exposure to these volatile organic compounds (VOCs) has been associated with increased allergy-related conditions in offspring such as rhinitis, asthma, and eczema.[7] Use of low VOC-containing paints—recognizable by labels indicating this status—is recommended.

Housewares/furnishings/ flame retardants

Many hard plastic containers contain bisphenol A (BPA), which acts as an endocrine disruptor and which has been associated with LBW in newborns and persistent wheezing, behavioral problems, and neurodevelopmental abnormalities, including problems with executive function, in offspring.[2,4,7] Heating may increase release of BPA from these containers. Best practice is to not use these hard plastic containers or at least not use them to heat food in a microwave oven. Containers marked with a triangle containing the number 3 or the number 7 are made of soft plastics containing phthalates and pose the same risks as do personal care products containing phthalates.[11]

Perfluorochemicals (PFCs) are used to make fluoropolymer coatings and products that resist heat, oil, stains, grease, and water. Fluoropolymer coatings can be used in products such as clothing, furniture, adhesives, food packaging, heat-resistant non-stick cooking surfaces, and the insulation of electrical wire. PFCs have been voluntarily eliminated from the market. However, because of their long half-lives, they persist in the environment and in wildlife and humans previously exposed to them. PFCs have been linked to thyroid problems and to adverse pregnancy outcomes related to prenatal exposure, although study results are inconsistent.[9] As a health advisory, the Environmental Protection Agency has recommended that drinking water be evaluated for presence of perfluoroalkyl substances (PFASs), including PFCs such as perfluorooctanoic acid and perfluorooctanesulfonic acid.[12] These PFASs can be removed from drinking water by carbon filtration and/or reverse osmosis.[12]

Additive flame retardants such as polybrominated diphenyl ethers (PBDEs), widely used in furniture starting in the 1960s and 1970s, have been linked to endocrine disruption, impaired neurodevelopment, and increased risk for papillary thyroid cancer.[2,7] Exposure to organophosphate flame retardants (PFRs), as quantified by urinary concentration of PFR metabolites in a study sample of 211 women, was shown to significantly impede the success of *in vitro* fertilization.[13] Because of PBDEs' long half-lives, any accumulation remains in the body for years.[14]

PBDEs were banned in Europe and voluntarily taken off the market in the United States in 2004. They were replaced by the flame retardant tris(1,3-dichloro-2-propyl)phosphate (TDCPP), which also disrupts endocrine function and has carcinogenic properties. TDCPP was voluntarily withdrawn from the market in 2015. However, both products—PBDE and TDCPP—were widely used in the foam of upholstered furniture, as well as in other foam cushion products (e.g., foam mattresses, pillows, bumper pads, automobile seats) and electronics. These chemicals are unstable in the foam and are released into the atmosphere via off-gassing, enabling them to be inhaled. In addition, these gases settle into household dust and create pathways for accumulation in the body through dermal absorption.

TDCPP is included in California Proposition 65's list of carcinogenic products. Good hand washing can decrease exposure to this compound.[14,15] Another recommended practice is to check the tag on upholstered furniture to determine whether it meets California TB117 fire safety standards and then *avoid* such furniture to limit exposure to these flame retardants.[16,17] Finally, if possible, polyurethane foam should be avoided in favor of products that use polyester fiber filling for cushioning. Polyester fiber fillings are not treated with flame-retardant chemicals.

Polycyclic aromatic hydrocarbons and particulate matter

Living near a highway, which increases one's exposure to polycyclic aromatic hydrocarbons (byproducts of fuel burning) and high levels of particulate matter (PM), is associated with increased risk for preterm labor and the development of autism spectrum disorder (ASD) and other cognitive problems in offspring.[4,7,18] Preterm labor and ASD have also been associated with spending a lot

of time driving in internal combustion engine-powered vehicles, with resultant higher exposure to exhaust containing benzene and other volatile gases such as polycyclic aromatic hydrocarbons.[4,7,18] Traffic-related exposure to nitrogen dioxide and to PM <2.5 micrometers in diameter ($PM_{2.5}$) and <10 micrometers in diameter (PM_{10}) is also associated with ASD development.[18] The risk related to long commutes or an occupation involving driving an internal combustion engine-powered vehicle can be mitigated by having a good filtration system in the vehicle.[7]

Exposure to ozone and fine PM ($PM_{2.5}$ and PM_{10}) in the air also is associated with preterm delivery and risk for pregnancy-related hypertension.[7] Therefore, paying attention to low-quality air alerts and staying indoors in a setting with a good filtration system for cooling and heating systems is a prudent practice for every woman of childbearing age, not just those with chronic respiratory conditions.

Solvents

In its Good Health Before Pregnancy: Preconception Care patient guide, ACOG advises women to check with their employers about potential exposure to solvents.[3] Prenatal exposure to solvents such as toluene has long been known to be harmful to offspring. Exposure to chlorinated solvents has been associated with increased risk for ASD.[18] Presence in drinking water of a product used in dry cleaning, tetrachoroethylene (perchlorethylene or PERC), has been linked to neurologic problems and the development of neurodegenerative disorders such as Parkinson's disease later in life.[4] Although many dry cleaners are replacing PERC with safer chemicals, long-term exposure remains a concern and is associated with adverse pregnancy outcomes.[7,19]

Box. Preconception care and interconception care: Resources regarding environmental toxic exposures

- CDC. Planning for Pregnancy: cdc.gov/preconception/planning.html
- Wisconsin Association for Perinatal Care. Resources for Parents and Consumers: perinatalweb.org/for-parents-and-consumers/other-resourses
- Wisconsin Environmental Health Network. Prenatal Environmental Health: WEHNonline.org/prenatal
- Wisconsin Association for Perinatal Care. Planning for a Healthy Future. Algorithm for Providers Caring for Women of Childbearing Age: beforeandbeyond.org/uploads/wapc_pcc_algorithm.pdf
- Environmental Working Group website: ewg.org/
- Duke University Foam Project: foam.pratt.duke.edu/
- Preconception Health + Healthcare Initiative: Before, Between & Beyond Pregnancy: beforeandbeyond.org/

Potential emerging environmental risks

Concern exists regarding the possibility that banned substances such as polychlorinated biphenyls (PCBs), which have been associated with adverse neurodevelopmental effects, may increase again in the environment.[9] The return of PCBs is related to melting of the polar ice caps in which they may be trapped. Information is also emerging about possible harms from electromagnetic radiation exposures, nanoparticles, and genetically modified organisms.[7] These risks need further study before inclusion in PC/IC recommendations.

Resources and recommendations

Preconception care and interconception care should include the provision to patients of evidence-based information on potential environmental toxins and how to reduce risks of exposure. In today's often time-limited visits, HCPs may have difficulty covering everything important in PC/IC. Written materials such as ACOG's Good Health Before Pregnancy: Preconception Care and websites such as those listed in the *Box* can be helpful.

Healthcare providers are encouraged by FIGO to engage in advocacy to decrease the widespread use of identified environmental toxins.[2] In 2015, scientists, health professionals, and children's health advocates joined together in Project TENDR: Targeting Environmental Neuro-Developmental Risks. Project TENDR developed a consensus statement supporting assessment, monitoring, and reduction of exposures to environmental toxins in order to promote health for children in the U.S.[20] The seriousness of the risks to the current generation and the potential intergenerational risks related to possible epigenetic changes associated with toxic environmental exposures make providing information to patients about these risks imperative. ●

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A complete list of references cited in this article is available at **npwomenshealthcare.com/?p=6706**.

Web resources

A. ewg.org/foodnews/

B. ewg.org/key-issues/consumer-products#.WX9RrYTyuJA

Effects of environmental toxins on reproductive health and pregnancy*

By Diane Schadewald, DNP, MSN, RN, FNP-BC, WHNP-BC and Ursula A. Pritham, PhD, WHNP-BC, FNP-BC, SANE

Women who want to become pregnant or who are already pregnant need to be aware of toxins (poisons) in the environment. These toxins may be in their homes, their neighborhoods, their workplaces, or in their world at large. The toxins may affect their fertility (their ability to become pregnant) or they may harm the women and/or the baby growing inside them. This chart lists agents (that is, the toxins or poisons) that may be harmful in this way. It explains the type of damage the agents can cause, lists the sources of these agents, and suggests how to avoid exposure to these agents.

*Readers are invited to photocopy this table for their own use and/or for their patients' use.

Agent	Risk to woman/offspring	Source	Suggestions
Tobacco	• Infertility • Fetal growth restriction • Placental previa (a condition in which the placenta partly or fully covers the cervix) or insufficiency	Smoking, chewing tobacco, secondhand smoke	Quit use of tobacco prior to and during pregnancy.
Alcohol	Fetal alcohol spectrum disorders	Drinking alcoholic beverages	Avoid all alcoholic beverages if you could become pregnant and during pregnancy.
Mercury (high exposure)	Irreversible brain and nerve damage, hearing loss, poor vision in offspring	• Large fish such as shark, tilefish, swordfish, king mackerel, white or albacore tuna • Thimerosal, a topical disinfectant and preservative used in some vaccines • Household items such as fluorescent lightbulbs, batteries, items that glow	Limit exposure. Avoid consumption of large fish listed on this chart and limit intake of tuna to one 6-oz serving per week.
Lead	Harmful effects on developing brain, leading to lower intelligence quotient (IQ) and behavior problems in offspring	• Paint in homes built before 1978 • Tap water from old lead pipes, well-water	Have home and water inspected and tested for lead. If the test result is positive, have lead paint removed and get home water filtration or reverse osmosis system that filters for lead.
Radiation (ionizing; large doses)	Cell damage, contributing to early pregnancy loss or increased risk for childhood leukemia	X-rays, computed tomography (CT) scan, positron emission tomography (PET) scan	Compare risks and benefits of such imaging tests. Use proper shielding when dental X-rays are done. Undergo screening mammograms as recommended by your health-care provider (they pose little risk).
Radon	Birth defects	Igneous rock and soil (radon may seep into house through cracks in concrete basement floors or slabs, floor drains, sump pumps, construction joints, or cracks/pores in hollow-block walls)	Test your house for radon. If present, do proper remediation.
Air pollutants	• Preterm labor/delivery, pregnancy-induced hypertension in mother • Autism spectrum disorders in offspring	• Exhaust from cars, trucks, power plants, wildfires, wood-burning stoves • Traffic-related exposure to nitrogen dioxide from long commutes or an occupation involving driving	When possible, avoid going outdoors when local air quality index report is poor or smog/haze is visible. Use a high-filtration filter in your heating and air conditioning system for your home and vehicle.
Solvents	• Adverse pregnancy outcomes (long-term exposure) • Neurologic problems, autism spectrum disorders (chlorinated solvent exposure) in offspring • Neurodegenerative disorders (e.g., Parkinson's disease) later in life	• Prenatal exposure to toluene (found in nail polish) • Tetrachloroethylene or perchloroethylene (PERC) used in dry cleaning	Avoid known exposures. Make sure your nail polish or nail polish remover does not contain toluene. Look for dry cleaners who use newer, more environmentally friendly (green) solvents.

Agent	Risk to woman/offspring	Source	Suggestions
All of the following environmental toxins are in a category of endocrine disruptors. The endocrine system is a collection of glands that secrete hormones.			
Pesticides and herbicides	• Infertility • Thyroid dysfunction in pregnancy • Fetal growth restriction • Birth defects, childhood leukemia, neurologic and cardiovascular defects, blue baby syndrome in offspring	• Organophosphate pesticides and herbicides on food and in groundwater • Atrazine pesticide (fetal growth restriction) • Nitrates from fertilizers, manure, and human sewage (thyroid dysfunction in pregnancy, blue baby syndrome in infants)	When possible, buy organic fruits and vegetables to limit exposure to organophosphates. See Environmental Working Group website[A] for nonorganic fruits and vegetables with low and high residues. Check public water reports or well-water for contaminants; if result is positive, get home water filtration or reverse osmosis system.
Personal care and cleaning products with phthalates, triclosan, parabens, or triclocarbans	• Preterm birth, neurodevelopmental and executive function problems • Males more adversely affected by *in utero* exposure, with potential reproductive development abnormalities	Fragrances, cosmetics, soaps, lotions, and deodorants (some products contain phthalates)	Check labels on products and avoid those with phthalates, triclosan, parabens, or triclocarbans. See Environmental Working Group website[B] for product safety ratings.
Latex-based paints or enamels with volatile organic compounds (VOCs)	Allergy-related conditions (rhinitis, asthma, and eczema) in offspring	Organic compounds in some latex-based paints/enamels (can seep from the product, a process known as off-gassing)	Use paints/enamels with low VOCs. Such products are labeled as low VOC.
Plastic containers with bisphenol A (BPA)	Low birth weight, wheezing, behavioral problems, neurodevelopmental abnormalities	• Hard plastic containers (many contain BPA; heating increases release of BPA from container) • Soft plastics (may contain phthalates; see information above on phthalates)	Avoid use of plastic containers to heat food in the microwave. Soft plastic containers marked with #3 or #7 in a triangle contain phthalates (see information above on phthalates).
Perfluorochemicals (PFCs)	Thyroid problems	Stain-resistant treatments, carpet cleaning solutions, non-stick cookware, some food-contact packaging (especially microwave popcorn bags)	Removed from market, but PFCs persist in the environment and in those previously exposed. Check drinking water. If PFCs are present, remove them by carbon filtration and/or reverse osmosis system.
Polybrominated diphenyl ethers (PBDEs)	Impaired neurodevelopment, increased risk for thyroid cancer	Additive flame retardants used in furniture starting in 1960s	Removed from market in U.S. in 2004. However, PBDE accumulation remains in bodies of those exposed for years.
Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)	Cancer-causing properties	• Flame retardant used in foam upholstered furniture, foam mattresses, pillows, bumper pads, automobile seats, electronics • TDCPP releases into atmosphere, allowing it to be inhaled and settle into household dust and absorbed through skin	Removed in 2015. Decrease exposure by good hand washing. Avoid upholstered furniture flame retardants. Buy products that use polyester fiber filling for cushioning, which is not treated with flame retardants. If desired, submit a small sample of the foam for analysis to the Duke University Foam Project[C].

Web resources

A. ewg.org/foodnews/

B. ewg.org/key-issues/consumer-products#.WX9RrYTyuJA

C. foam.pratt.duke.edu/

Educational interventions to increase Tdap vaccination rates among pregnant women

By Cari McAlister, DNP, MSN, WHNP-BC; Ginny Moore Wurttemberg, DNP, MSN, CNM; Donna Dunn, PhD, CNM, FNP-BC; and Tedra Smith, DNP, CPNP-PC, CNE

The highly contagious respiratory infection pertussis remains a public health problem for the United States.[1] Infants have the highest morbidity and mortality rates from pertussis because of a lack of immunity at birth and an immature immune system. In 2015, a total of 20,762 cases of pertussis were reported in the U.S., with infants accounting for 1,960 cases (9.5% of the total cases).[2]

In 2013, the CDC and the American Congress of Obstetricians and Gynecologists recommended that pregnant women receive the tetanus/diphtheria/acellular pertussis (Tdap) vaccination at 27-36 weeks' gestation during each pregnancy.[1] Tdap vaccine given to women at this point in pregnancy provides passive immunity to infants until 6 months of age, by which time most will have completed the recommended three-dose vaccination series.[3]

Despite this evidence-based recommendation, the rate of gestational Tdap vaccination remains low.[3] According to obstetricians surveyed, a major barrier to recommending the vaccination is lack of patient interest.[4] Many pregnant women do not view pertussis as an infection they can acquire and pass to their infants.[5] Some women choose not to obtain the Tdap vaccine during pregnancy because of misinformation about vaccine safety.[6] Lack of knowledge about the importance of Tdap vaccination during pregnancy and lack of healthcare provider (HCP) recommendation are reasons pregnant women have noted for not receiving the vaccine.[7] Nitsch-Osuch et al[1] reported that 80% of women would be willing to receive the Tdap vaccine if their HCP recommended it.

Purpose

The purpose of the project was to implement an evidence-based educational intervention to increase knowledge about the importance of Tdap vaccination during pregnancy and provide information about the vaccine's safety. The goal was to increase Tdap vaccination rates among pregnant women seen for care at two obstetrics settings.

Method

The university's institutional review board approved the project. Criteria to participate in the project included being pregnant, having the ability to speak English or Spanish, and being 19-44 years old. The educational intervention included the CDC's Tdap vaccination handout, a 5-minute educational video created by the project directors (PDs), and a PD-led patient education session. Each educational intervention was available in English and Spanish. Information provided in the handout, video, and education session was identical and included the purpose, importance, and safety of Tdap vaccination during pregnancy and current recommendations in this regard.

The PDs conducted education at their respective practice locations (Clinic A and Clinic B) during a 12-week period. All three educational interventions were implemented with each participant. Education took place at the first obstetric visit or at the 1-hour glucose-tolerance test appointment. Review of the CDC handout, viewing of the video, and the education session took approximately 10 minutes altogether.

Each participant received an evaluation form to complete after watching the video. Completion of this form,

which addressed participants' understanding of the video and its impact on their vaccination decision, was optional. The form was completed by all participants in Clinic A but by only 38% of those in Clinic B, mainly because of time constraints and literacy barriers. If participants chose not to obtain the Tdap vaccine, the PDs asked in a non-judgmental manner about factors that affected their decision.

Cultural awareness and acknowledging the importance of education in the participants' primary language are keys to increasing Tdap vaccination rates in pregnancy.

Outcomes

A total of 75 pregnant women participated in the educational intervention in Clinic A or Clinic B. Each participant's chart included documentation of the decision to obtain or decline the Tdap vaccination on the problem list and the medication list.

Because Clinic A's population comprised patients with private insurance or Medicaid, the clinic was able to receive reimbursement for vaccinations. Prior to this intervention, Clinic A provided education, albeit not consistently, in the form of handouts and HCP conversation. A retrospective chart audit showed that among 468 pregnant women seen in the clinic, 186 (40%) received the Tdap vaccination in the year before the intervention.

Thirty-one women in Clinic A participated in the Tdap educational intervention. Of these women, 28 (90%) received the vaccine. Of the 3 who refused the vaccine, 2 stated that they did not feel that pertussis was a threat and 1 was concerned about vaccine safety. Data from the Clinic A participants' completed evaluation forms indicated that HCP conversations superseded the need for an educational video about the importance of Tdap vaccination during pregnancy.

Clinic B's population was composed of mainly underserved Hispanic women without health insurance. Clinic staff did not routinely administer vaccines because of cost, nor did they provide any education on Tdap vaccination to pregnant women prior to this project. No Tdap vaccinations were given in the year before the intervention. The authors received a grant from the CDC, which provided vaccines for Clinic B. Prior to the grant, patients at this clinic needed to go to the local health department or primary care clinic to obtain the vaccine.

Forty-four women in Clinic B participated in the Tdap educational intervention. Of this group, 33 (75%) received the vaccine. Eleven participants did not receive the vaccine because they believed that everything would be fine. Data from these participants' completed evaluation forms indicated two factors affecting vaccination rates in a culturally diverse population: (1) The participants understood more clearly the importance of the Tdap vaccination after viewing the educational video in their native language and (2) the participants desired family input with regard to the decision for maternal Tdap vaccination. Although the conversations with the HCP were helpful, these participants indicated a greater understanding after watching the video. Family members were allowed to view the video with participants, thereby clarifying any additional concerns.

Limitations

Limitations included the short time interval and the inability to see all women meeting inclusion criteria. PDs were not able to follow up with all participants who were undecided about receiving the Tdap vaccine because of the short time frame and the inability to make contact with every participant between 27 and 36 weeks' gestation.

Implications for practice

In this project, 66 (81%) of 75 participants received the Tdap vaccination. The vaccination rate remained higher in Clinic A than in Clinic B. Participants in Clinic A, more so than those in Clinic B, were willing to receive the Tdap vaccination after HCP discussion prior to viewing the video. At Clinic B, the language barrier was an obstacle for HCPs in explaining the importance of Tdap vaccination during pregnancy. This obstacle was overcome using an educational video in Spanish. Cultural awareness and acknowledging the importance of education in the participants' primary language are keys to increasing Tdap vaccination rates in pregnancy.

Understanding specific barriers to and concerns about vaccination within an HCP's particular patient popula-

tion is important. Vaccination rates can be improved by having a protocol in place to ensure that education is provided, vaccination recommendation is made, and the vaccine is available in the clinical setting.

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Diana M. Drake

Health policy and the female caregiver: The impact on women's health

By Diana M. Drake, DNP, MSN, APRN, WHNP-BC

As healthcare providers (HCPs), we are aware of the demographic shift and increased longevity that have resulted in a rise of the aging population in the United States and in many other countries around the world.[1] These changes have increased the need for "informal" caregivers, usually partners or relatives, to provide assistance to individuals at varying levels of healthcare need. Unpaid caregiving by partners, family members, or even friends remains the main source of long-term care for older persons worldwide.[1] This caregiving, usually provided by women, can have an adverse impact on caregivers' health, quality of life, economic stability, and longevity.[2,3]

Rising need for caregivers

Increasing longevity, the aging of the large Baby Boomer generation, and a decline in fertility and subsequent family sizes of younger generations have all contributed to the rising need for informal caregivers amidst a shrinking pool of prospective younger caregivers. The 65-and-older population in the U.S. is projected to nearly double over the next three decades, ballooning from 48 million to 88 million by 2050.[1] Declining fertility levels have been one of the main propellers of a demographic shift to an older population; the global fertility rate is near or below the 2.1 replacement level in all world regions except Africa.[1] In 2030, the first wave of Baby Boomers will turn 85, an age when people are twice as likely as those even a decade younger to need help getting through the day. However, because of shrinking family sizes over the past few decades, fewer young or even middle-aged adults will be available to care for their older relatives in the years ahead.[1]

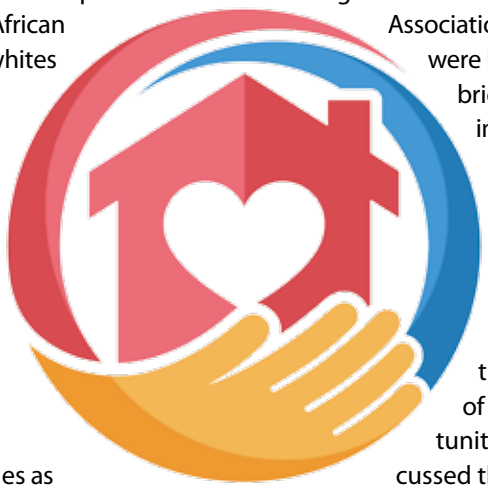
Caregiver role as a policy concern

The caregiver role has become a significant public policy issue that affects healthcare costs, personal losses of wages and benefits, and stability of the workforce. Of note:

- Women provide the majority of informal care to spouses, parents, parents-in-law, friends, and neighbors, and they play many roles while caregiving: hands-on care provider, care manager, friend, companion, surrogate decision-maker, and advocate.[4]
- Sixty-five percent of care recipients are female, with an average age of 69.4 years.[4]
- The typical caregiver is a woman who works outside the home and provides 20 hours per week of unpaid care to her mother.[2]
- Although men do provide assistance in this regard, female caregivers may spend as much as 50% more time than their male counterparts do in providing care.[5]
- Nearly 60% of today's family members perform tasks that were previously handled by nurses, including giving injections, providing wound care, and operating special medical equipment. These individuals spend an average of $7,000 a year of their own money.[2]
- Family caregivers aged 50+ years who leave the workforce to care for a parent lose, on average, nearly

$304,000 in wages and benefits over their lifetime. For women, this amount—$324,044—is even higher.[2]

- Family caregivers have been described as *America's other Social Security*. The nation's healthcare system would go broke if it had to pay for their work, valued at $470 billion a year in free care.[2]
- Workers with eldercare responsibilities comprise all racial and ethnic groups, including African Americans (21%), Hispanics (20%), whites (17%), and Asians (14%).[2]
- Compared with other demographic groups, low-income workers, minorities, and women are more likely to reduce their work hours or leave the workforce because of their caregiving role.[2]



Impact on women's health

Female caregivers are more likely than male caregivers to report poor health, especially when they perceive their roles as difficult or life changing.[6] Female caregivers are less likely than male caregivers to see HCPs for their *own* preventive healthcare needs. According to the U.S. Department of Health and Human Services, female caregivers are at increased risk for[7]:

- depression and anxiety;
- a weak immune system;
- obesity;
- chronic disease;
- problems with short-term memory or paying attention; and
- heart disease.

NPWH leadership and policy work: Caring for the female caregiver

NPWH is providing leadership by participating in two coalitions in Washington, DC, that aim to increase awareness of the impact of the female caregiver role: the Coalition for Women's Health Equity[8] and Healthy at Any Age: Women's Health over 50.

Coalition for Women's Health Equity

As a key member of this coalition, which comprises about 20 organizations, NPWH participated on the steering committee for its 2nd Annual Women's Health Empowerment Summit. On May 16, 2018, more than 300 women from across the country met in Washington, DC, to highlight actionable steps to address inequities that endanger women's health and safety. The summit featured National Women's Law Center President & CEO Fatima Goss Graves, whose organization administers the TIME'S UP Legal Defense Fund, and Rep. Raul Ruiz, MD (CA-36). Samantha Abrams, Executive Director of the March on Washington Film Festival, served as summit emcee. In addition to lead sponsor Hadassah, the Women's Zionist Organization of America, Inc., the American Heart Association and Women Against Alzheimer's were key in focusing attention on policy briefings, scientific advances, financial implications of disease, and the direct impact of policy and advocacy work.

As a participating organization on the steering committee for the summit, NPWH helped organize a speaker panel, Caregiving Across the Lifespan: the Disparate Impact of Caregiving on Women and Opportunities for Change. Panel members discussed the burden and opportunities presented by caregiving and legislation that would require the government to develop strategies to recognize and support family caregivers. As a panel member representing NPWH, I was honored to speak as both a women's health nurse practitioner who provides healthcare to many informal caregivers and a daughter of two 96-year-old parents living in partially assisted care. As an NPWH member, I was able to speak directly to the impact on the female caregiver, the invisibility of the issue, and the gap in our healthcare system to recognize and assess the caregiver status of patients, as well as the impact that being a caregiver has on women's health. The importance of advocating for our patients who are caregivers to practice self-care and disease prevention was stressed. All women who serve as caregivers were encouraged to describe their caregiver roles to their HCPs at health visits.

This event was streamed live on Facebook and generated a lot of Twitter activity among the organizations (#HealthEquity4Her and #NWHW). More information about the other speakers and the summit itself is available here[A].

Healthy at Any Age: Women's Health over 50 Coalition

Gay Johnson, CEO of NPWH, described the second Healthy at Any Age summit in her message[B] in the June 2018 issue of *Women's Healthcare*. The Healthy at Any Age: Women's Health over 50 Coalition takes a broad

In 2030, the first wave of Baby Boomers will turn 85, an age when people are twice as likely as those even a decade younger to need help getting through the day.

view of women's health issues as they age, and is launching the National Older Women's Health Agenda. This agenda includes health issues related to women as caregivers and the adverse impact of caregivers' long-term neglect of their own health.[9] Caregiver-related topics of pay, respite care, mental and physical health, and medication management are considered opportunities for improving healthcare for older women. NPWH will lead the coalition's communications and meetings and will recruit select public, private, and nonprofit organizations to join the founders. The ongoing journey of the coalition is to unite diverse sectors, share resources, and create strategies that advance the health and well-being of older U.S. women for decades to come.

Taking steps from policy to action

Healthcare providers are encouraged to bring the caregiver role into the health assessment visit with a few simple steps:

1) Ask questions. Listen to their stories.
- During health exams, ask women about their caregiver role and its effects on their physical and mental health.
- Be aware of the known increased health risks for caregivers.
- Inquire about the number of hours per week that they spend in caregiving.
- Assess their stress level and quality of life.
- Assess their support system.
- Be aware that caregiving does not necessarily exert an adverse impact on every caregiver's life.

2) Promote and support caregivers' self-care.
- Teach self-care practices and the signs of caregiver burnout.
- Encourage maintaining regular healthcare visits and preventive screenings.
- Utilize patient education tools and community resources:
  - Family Caregiver Alliance: caregiver.org
  - Office on Women's Health. Caregiver Stress fact sheet: womenshealth.gov/files/documents/caregiver-fact-sheet.pdf
  - American Heart Association. Caregivers: Be Realistic, Think Positive: heart.org/HEARTORG/Support/Caregivers-Be-Realistic-Think-Positive_UCM_301771_Article.jsp#.Wz1k0S2ZNhF

3) Increase your knowledge of health policy and the role of caregivers.
- Become familiar with the Concentrating on High-Value Alzheimer's Needs to Get to an End (CHANGE) Act of 2018, which, if passed, would address the care needs of patients *and* their caretakers, including creating a coverage and payment model that offers family caregivers evidence-based training and certification specific to dementia care.
- Learn about the newly enacted Recognize, Assist, Include, Support and Engage (RAISE) Family Caregivers Act, which provides a framework for public and private sector stakeholders to develop and execute a national caregiving strategic action plan.
  - As family caregiver advocates for 40 years, the Family Caregiver Alliance recognizes passage of the federal RAISE Family Caregivers Act as critical to the creation of a strategy to acknowledge and aid unpaid family caregivers on a national level.
  - The RAISE Act is an important step toward more fully recognizing the impending crisis in caregiving as the aging population continues to grow. As improved guidelines and policies develop from the legislation, funding will be required to relieve the 2015 AARP estimate of $470 billion in unpaid care and the 2016 AARP estimate of $7,000 in out-of-pocket expenses provided annually by family caregivers.
- Understand that better federal coordination across agencies and initiatives can further the recognition and support of unpaid family caregivers and has the possibility of large-scale change in payment and service delivery systems.

Conclusion

Research and public discourse on the caregiver role and its specific impact on women must remain a focus of national and local community attention. Women's

(continued on page 50)


Caitlyn E. Hull


Randee L. Masciola

WHNPs in specialty positions: My experience in breast surgical oncology

By Caitlyn E. Hull, MS, APRN-CNP, WHNP-BC and Randee L. Masciola, DNP, APRN-CNP, WHNP-BC

When I, Caitlyn E. Hull, sought to become a women's health nurse practitioner (WHNP), I had not considered the variety of roles that might be available. I had imagined myself working as a generalist in an obstetrics/gynecology (Ob/Gyn) private practice or federally funded clinic like many of my professors and preceptors, and I was thrilled with the possibilities that lay ahead of me in this field. When I was offered a position as a WHNP in surgical oncology at the Stefanie Spielman Comprehensive Breast Center (*Photograph*), which is affiliated with The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital (The James) and Richard J. Solove Research Institute, I had several questions and hesitations. I was curious about how my education and training would be utilized in breast oncology, particularly as a new NP.

Excluding non-melanoma skin cancers, breast cancer is the most common cancer in women in the United States; as of January 2018, more than 3.1 million U.S. women are breast cancer survivors.[1] Owing to advances in the field of breast oncology over the past several decades, overall outcomes are much better today. The decreasing breast cancer mortality rate combined with a demographic shift toward an aging population has led to a large increase in the number of breast cancer survivors. In fact, these women represent 41% of *all* female cancer survivors.[2]

The growing number of breast cancer survivors, whose healthcare needs become even more complex as they age, has presented an opportunity for WHNPs to play a more important role in their care. Physicians who work in the field of breast oncology have perceived an increased need to deliver survivorship care to their patients and are increasingly looking to NPs to address these specialized needs.[3]

During our initial interview, the surgeon who would become my primary collaborating physician said that, for him, working with a WHNP would enhance his ability to both run his practice and provide quality care to his patients. Because he needs to spend so much time in the operating room, the surgeon said that he, not to mention his patients, could benefit from having a WHNP work in the clinic, seeing patients either in collaboration with him or independently. In addition, he emphasized the meaningful provider–patient relationships that would evolve from caring for patients through their cancer journeys. He felt that a WHNP was particularly well equipped, by virtue of this provider's educational background, experience, and nursing philosophy, to fill this role and achieve these goals.

I acknowledge that my entrance into breast oncology as a novice NP posed a steep learning curve. My entrance was facilitated by my orientation at the Stefanie Spielman Comprehensive Breast Center, which was structured to expose me to the evidence-based multidisciplinary team approach that is highly regarded within most healthcare delivery systems to improve patient outcomes. This orientation included observation experiences in the operating room and exposure to the various departments comprising the multidisciplinary team: reconstructive surgery, radiation oncology, medical oncology, radiology, and physical therapy. I spent a good deal of time reviewing breast pathology, as well as the National Comprehensive Cancer Network breast cancer guidelines that are the standard of care for practice in breast oncology.

My role in the surgical oncology clinic began by serving as an "extension" of the breast surgeon. During his three clinic days each week, I joined him in seeing both women with newly diagnosed breast cancer and breast cancer survivors coming in for follow-up visits. My main responsibility entailed performing a history and physical examination in women needing a breast biopsy or breast surgery. I also ordered and managed pre-operative laboratory testing and imaging, making referrals as needed, and I prepared patients for their breast procedures.

The decreasing breast cancer mortality rate combined with a demographic shift toward an aging population has led to a large increase in the number of breast cancer survivors.

Over time, I have become even more deeply involved in the coordination of care of our patients, managing their treatment trajectory and seeing them in clinic for acute problems, most commonly postoperative complications, breast infections, and new breast lumps. In addition, I return patients' phone calls; notify them of test results, including the pathology reports from biopsies and surgeries; and manage follow-up and case management problems as they arise.

Of note, our institution and physician colleagues, in addition to supporting WHNPs in their role in providing care for women with breast cancer, support WHNPs' provision of care for men with benign and malignant breast conditions. Our standard-of-care arrangement states that we can care for men with breast diseases or conditions warranting our specialty expertise. Although breast cancer in men represents only 1% of all breast cancers, many of these men present at a more advanced stage of disease than do women.[4] In 2018, approximately 2,500 men in the U.S. will be diagnosed with breast cancer and 500 will die of it.[4] Utilization of WHNPs to see males with breast conditions enables us to differentiate benign breast conditions such as gynecomastia or breast abscess from breast cancer and expedite those with a malignancy to the appropriate care teams for treatment and support. Because male breast cancer is far less common than female breast cancer, I strongly encourage WHNPs to seek out continuing education (CE) resources to support their knowledge base and clinical experience in male breast cancer. In 2017, as an expert in our healthcare system because of my education and training, I organized a CE event for our advanced practice providers and registered nursing staff members that featured a journal club on the topic of male breast cancer to improve our awareness as an institution about caring for men with this disease.

Since I started in my position in 2012, the number of NPs in our organization has soared. We now have 23 NPs, including 7 WHNPs, caring for patients at the Stefanie Spielman Comprehensive Breast Center. The role that we play in caring for patients with breast cancer has expanded too. We now perform both independent and shared visits. In addition, the growing number of long-term breast cancer survivors has created a demand for WHNP-driven follow-up clinics to provide surveillance and to address the long-term physical and emotional sequelae of breast cancer treatments, as well as the increased need for survivorship care. Furthermore, WHNPs lead benign breast disease and high-risk breast disease clinics within the breast center.

In addition to the advancement of WHNPs within the breast center since I started in 2012, I have witnessed the implementation and accreditation of The James Oncology Advanced Practice Provider fellowship program. This 12-month, highly competitive program, initiated in 2013, offers NPs, including WHNPs, an opportunity to rotate within mentored subspecialty clinical experiences. These clinical experiences are supplemented by weekly educational sessions and training in evidence-based practice (EBP). This yearlong fellowship serves as a gateway for new WHNPs to enter the field of oncology at The James. WHNPs who have completed this program are now successfully caring for patients within the multiple specialty disciplines at The James, including gynecology/oncology, breast surgical/oncology, medical/oncology, and radiation/oncology.

Beyond the fellowship, The James offers its own version of a clinical ladder program to continue to enhance WHNPs' professional development. This yearly opportunity allows all advanced practice providers to create five goals within the categories of leadership, education, clinical practice, EBP, and community service. Since its inception, this project has encouraged WHNPs to participate in numerous activities, including joining action committees, implementing unit improvement projects, presenting research projects, and providing women's health services

to underserved members of the community. This program has enriched my career by affording me the opportunity to guest-lecture on the WHNP role in survivorship care. My lectures are presented to graduate students in women's health and nurse midwifery at our affiliated College of Nursing at The Ohio State University.

When I started my WHNP education, I did not imagine myself as a WHNP in breast oncology; now I am very proud to serve in this capacity. My WHNP education—particularly my training in breast pathophysiology, breast health assessment and risk assessment, management of breast disorders, pharmacology, EBP, and patient-centered care—provided the foundation I needed to navigate this specialty role. I have learned so much, both personally and professionally, since I started in my position, and I am humbled by the fact that I have a lot of learning left to do in this fast-paced, information-exploding specialty.

I admit that working in oncology can sometimes be emotionally taxing. However, the privilege of being a part of my patients' journeys and helping them through some of the toughest moments of their lives is what makes my job so rewarding. I am passionate about taking care of these patients and I cherish the relationships I have built with them.

These connections are the threads that tie *all* of us together as WHNPs. Whether we work in a general Ob/Gyn practice or a breast cancer clinic, at the end of the day, caring for our patients is what we all have in common and why we keep doing what we do.

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(continued from page 47)

healthcare providers can increase the visibility of the issue through comprehensive assessment in health exams, promotion of education, and provision of support resources for their caregiving patients, as well as increase public policy awareness and action.

Diana M. Drake is Clinical Associate Professor and Specialty Coordinator of the DNP WHNP Program at the University of Minnesota School of Nursing and Program Director for Integrative Women's Health at the Women's Health Specialists Clinic, both in Minneapolis. She is Chair of the NPWH Policy Committee and Chair Elect of the NPWH Board of Directors.

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Web resources

A. hadassah.org/advocate/womens-health-empowerment-2018.html
B. npwomenshealthcare.com/wp-content/uploads/2018/06/WHNP0618_NPWH_News.pdf

NPWH 2017 Conference Abstracts

This issue of *Women's Healthcare: A Clinical Journal for NPs* features abstracts presented at the 20th annual NPWH conference in Seattle in October 2017. These abstracts include those of the podium presenters and the first- and second-place poster award winners. My heartiest congratulations to all! Each year, the NPWH conference is enriched by these podium presentations and the poster sessions. Please take time to review the abstracts that provide state-of-the-science information about women's health, and please consider submitting your work for 2019!

Lorraine Byrnes, PhD, CNM, FNP-BC, PMHNP-BC, FAANP
2017 NPWH Research Committee Chair

Counseling patients on medication use during pregnancy: Why you need to be talking about pregnancy exposure registries

By Robin D. Johnson, Public Health Advisor, and Kimberly A. Thomas, MPH

Objectives:

1. **To provide pregnant women's top five preferred sources of information on medication use during pregnancy and methods for teaching patients how to assess the credibility of these sources.**
2. **To provide four tips to help pregnant women learn more about how prescription and over-the counter medicines might affect them and their babies.**
3. **To describe how to use the FDA pregnancy exposure registries' website to identify a registry and how pregnancy registries can help improve product safety information and labeling.**

Purpose: Fifty percent of pregnant women report taking at least one medication. First-trimester use of prescription medications increased by more than 60% between 1976 and 2008. Pregnancy exposure registries gather information about drug effects on a pregnant woman and her developing fetus. In 2015, the FDA Office of Women's Health (OWH) conducted focus groups to learn about women's knowledge and opinions about medication use during pregnancy and participation in pregnancy exposure registries. The aim of the project was to better understand women's attitudes about registries to help improve FDA resources for patient–provider counseling.

Summary: Four 90-minute focus group sessions were conducted in Chicago, Miami, and the Washington, DC, area. Twenty-six participants ranged in age from 21 to 41 years. Among the participants, 92% took prescription medications or received a vaccine during pregnancy. Participants engaged in a guided group discussion and completed a verbal and written review of FDA medicine and pregnancy materials.

Outcomes: Participants viewed the healthcare provider (HCP) as the primary information source. Decisions about medication use were also influenced by online searches via social media, pregnancy websites, and hospital or health insurance websites. None of the participants, including those currently pregnant and on medication had heard of a pregnancy exposure registry prior to the group. However, they were open to participating in order to help other women have more information on drug effects. Based on these findings, OWH conducted an outreach campaign targeting patients and health professionals. Phase I of the campaign included distribution of new Medicine and Pregnancy factsheets for patient counseling and a digital ad campaign to raise awareness about pregnancy registries. The campaign reached more than 1 million individuals throughout the United States, including Puerto Rico.

Implications for women's healthcare: Enrolling patients in a pregnancy exposure registry can help improve safety information for medicines used during pregnancy. The focus groups demonstrated that HCPs are important information sources about registries and that discussions about registries and online pregnancy resources should be added to patient counseling about medication choices during pregnancy.

An examination of three Indiana ethnically and racially diverse populations' knowledge and perceptions of human papillomavirus infection and HPV prevention, screening, and vaccination

By Juanita M. Brand, EdD, MSN, RN, WHNPc; Sam Colbert, BS; Millicent Fleming Moran, PhD; Anita Ohmit, MPH; and Virginia A. Caine, MD

Juanita M. Brand

Objectives:

1. **To describe study participants' knowledge of HPV infection and their understanding of HPV prevention through vaccination.**
2. **To summarize participants' personal and cultural beliefs regarding HPV vaccination uptake in children and young adults.**
3. **To identify community members' support of HPV vaccination for the medically recommended populations in the communities identified.**

Purpose: This qualitative study examined three Indiana ethnically/racially diverse populations' knowledge of HPV infection and their perceptions of HPV prevention, screening, and vaccination.

Methodology: A study group of 90 men and women was selected by purposeful sampling among persons who self-identified as African American (AA; n = 30) Native American (NA)/Alaska Native (n = 30), or Hispanic/Latino (n = 30). Recruitment occurred at statewide Indiana Minority Health Coalition sites and powwows from May 2016 through November 2016. Twenty-minute open-ended interviews covered demographics, self-identity, cultural influences, health, understanding of HPV, HPV vaccination uptake, and access/confidence in healthcare. Interviews were conducted, recorded, and transcribed verbatim in Spanish or English.

Results: The three groups generally self-identified racially/ethnically as singular AA, Hispanic, or NA (90%+ for each group). More than 80% of the participants were female. Mean age overall was 45 years, with Hispanics being an average of 10 years younger than the other groups (AAs, 51 years; NAs, 46 years; Hispanics, 38.3 years). Three key themes emerged: level of trust in healthcare, vaccine beliefs, and access to care. Although most participants trusted healthcare providers (HCPs), some mistrusted messaging regarding vaccination uptake and outcomes. Vaccination beliefs were not consistent. Some participants related "anecdotal" stories heard regarding injury, sterilization, post-vaccination increase in sexual activity (in youth), and dire vaccination outcomes. Other participants reported or perceived no difficulties with vaccination or its uptake. Overall, 77% viewed vaccination opportunities as "valuable" at community events and more than 80% would encourage teen participation in HPV immunization and information events.

Regarding access to care, 75% of participants had regular care access, and a similar proportion reported good-to-excellent health, whereas 24.7% reported very poor or fair health status. NAs and Hispanics (27%-30%) were more likely than AAs to report fair-poor health. Twenty-one percent reported financial barriers to care, and 31% had difficulty paying for prescription medications (no significant differences by racial/ethnic group).

Implications for women's health: HCPs should be aware that trust and access concerns may influence racial/ethnic communities' acceptance of HPV vaccination. Crafting culturally relevant healthcare messaging and respect for cultural beliefs concerning HPV vaccine safety and acceptance among young persons are key elements for HCPs in caring for culturally diverse populations.

FIRST-PLACE POSTER AWARD WINNER

Improving quality of care during gynecologic examinations by reducing anxiety and discomfort

By Kristen Leigh Ransone, DNP, APRN, FNP-C

Objectives:

1. **To describe the evidence underlying the project development.**
2. **To identify two interventions effective at decreasing anxiety and discomfort during gynecologic examinations.**
3. **To discuss implications of the outcomes for women's health and patient-centered care.**

Purpose: The purpose of this poster presentation was to describe the development, implementation, and outcomes of a quality improvement project undertaken to address anxiety and discomfort felt by women during gynecologic exams.

Summary: This project was conducted in a single-setting military family practice clinic over a period of 2 months. All the women who presented for a routine gynecologic exam were offered a choice of music to be played throughout their visits and their pelvic exams were conducted without the use of stirrups. At the end of the visit, they completed an 8-question survey about the experience.

Outcomes: The following results were collected from 17 women, who used a Likert-type survey tool. Average scores were (1) physical discomfort, 1.47 (1 = no discomfort to 5 = complete discomfort), (2) sense of vulnerability, 1.41 (1 = no vulnerability to 5 = completely vulnerable), (3) sense of control, 1.35 (1 = fully in control to 5 = total lack of control), (4) sense of anxiety, 1.58 (1 = no anxiety to 5 = highly anxious), and (5) overall quality of care, 1.17 (1 = excellent to 5 = poor). Ninety-four percent of the women reported that this experience made them more likely to return for a wellness exam in the future. Open-ended survey comments supported that the experience was extremely positive.

Implications for women's healthcare:

Many women of all ages and backgrounds feel anxiety and discomfort during gynecologic exams, which can lead to delays in screening and treatment of disease. This clinical project successfully demonstrated how simple interventions can be applied to the gynecologic visit to improve a patient's experience and overall quality of patient-centered care. By having a more positive experience, women may be more likely to return for future routine screening and disease treatment.

SECOND-PLACE POSTER AWARD WINNER

Implementation of a universal screening program to increase identification and treatment of perinatal mood and anxiety disorders among pregnant and postpartum women*

Laura Bartlett

Terrie H. Platt

By Laura Bartlett, DNP, RN, WHNP-BC and Terrie H. Platt, DNP, RN, WHNP-BC, NCMP

Purpose: The purpose of this project was to evaluate whether consistent implementation of a valid and reliable screening tool for perinatal mood and anxiety disorders in the clinic setting, as well as follow-up care, would result in better identification and treatment.

Summary: From January 2017 to May 2017, clinicians at the Ob/Gyn clinic implemented use of the Edinburgh Postnatal Depression Scale (EPDS) to screen patients for perinatal mood and anxiety disorders at the initial obstetric visit, the 24-week visit, the 36-week visit, the 2-week postpartum visit (if applicable), and the 6-week postpartum visit. For women with EPDS scores ≥10, the clinician performed risk assessment and referred them to a local perinatal mental health clinic if indicated. To assess for overall effectiveness of the project, chart reviews of all eligible participants were performed. Data, including EPDS scores and *ICD-10* codes, were extracted from the electronic health record to determine the number of women with symptoms of perinatal mood and anxiety disorders identified by the clinician.

Outcomes: Of 836 women who met eligibility criteria, 619 were included in the QI project. A 494% increase in identification of women with perinatal mood and anxiety disorders was seen with implementation of the screening protocol. More than 87.4% of women with EPDS scores ≥10 were given education about perinatal mood and anxiety disorders and were offered behavioral referrals and local resources. More than 65% of participants with perinatal mood and anxiety disorders were provided with referrals to behavioral health; 42% of them completed an appointment with a behavioral health specialist to address symptoms.

Implications for women's health: Standardized, universal screening for perinatal mood and anxiety disorders improves the detection rate. Screening for perinatal mood and anxiety disorders during pregnancy, especially at the initial prenatal visit, can result in earlier identification. Earlier identification of women with perinatal mood and anxiety disorders can result in more prompt intervention and management of symptoms. Screening with the EPDS in the Ob/Gyn clinic is cost effective, efficacious, and easily reproducible. Although screening is important, ensuring adequate behavioral health follow-up is crucial in the management of women with perinatal mood and anxiety disorders.

*The initial abstract for this study was submitted while the project was still in process. This updated version of the abstract, which has all of the results and outcomes of the project, was submitted to NPWH following its completion.

Brooke M. Faught

Pessary use for pelvic organ prolapse in sexually active women

By Brooke M. Faught, MSN, WHNP-BC, IF

Pelvic organ prolapse (POP), a common condition in women, increases in prevalence with advancing age. Treatment for POP may include pelvic floor exercises, surgery, and/or use of pessaries. Pessaries offer women a nonsurgical, cost-effective, low-risk option for treating symptomatic prolapse. This column focuses on what healthcare providers need to know when caring for sexually active women with POP who choose to use a pessary.

Approximately 3% of women in the United States have pelvic organ prolapse (POP).[1] POP prevalence in U.S. women is projected to reach 5% by 2050 because of changing demographics.[2] POP may involve the bladder (cystocele), rectum (rectocele), small bowel (enterocele), urethra (urethrocele), and/or uterus (uterovaginal prolapse). Although many women with POP remain asymptomatic, some report vaginal pressure, sensation of a vaginal bulge, vulvovaginal irritation, bowel or bladder dysfunction, and/or a disruption in sexual functioning. Healthcare providers (HCPs) should perform a pelvic examination on all patients with known or suspected prolapse and document the type and stage of prolapse.[3] The POP quantification system (POP-Q) is commonly used to stage the condition.[4]

A nonsurgical alternative

Not all women with POP are surgical candidates. And even among those who are candidates, many prefer to avoid surgery for a variety of reasons. These women may benefit from a nonsurgical treatment that is effective and that poses minimal risk: a pessary.[3] A pessary is a soft-yet-firm, medical-grade silicone device that comes in various sizes and shapes and that is placed in the vagina to support the prolapsed area. Up to 90% of women with POP can be successfully fitted for a pessary.[5] The pessary shape recommended for an individual woman depends on the type, location, and severity of prolapse, as well as the presence or absence of stress urinary incontinence. The most frequently used pessary shapes for women with POP are the ring, oval, donut, Shaatz, and dish. Less commonly used shapes for this indication are the Gehrung, Mar-Land, Hodge, and cube.

Special considerations for sexually active women

When HCPs consider prescribing a pessary for a sexually active woman, they need to ascertain the types and frequency of sexual activity in which the woman is engaging. Most pessaries must be removed before penetrative sex play (e.g., intercourse, use of sexual aids or toys inserted within the vagina); HCPs should know that the ring, oval, and Shaatz pessaries are easiest for a patient to self-manage. At the time of the pessary fitting, the HCP should teach the patient how to remove and replace the pessary so that it does not interfere with sex play. At this

same visit, the patient should demonstrate to her HCP that she has learned the proper techniques. A woman who finds that she is not capable of pessary self-maintenance may opt for nonpenetrative sex play or have her partner learn to remove and replace the pessary. Another option is for the HCP to remove the pessary before a planned penetrative event (e.g., during a trip or vacation). The woman may then return at a later date for pessary replacement. This option is particularly suitable for a woman with mild prolapse who infrequently partakes in penetrative sex play.

Many postmenopausal women experience urogenital tissue changes related to vulvovaginal atrophy (VVA).[6] If VVA is suspected during a pessary fitting, HCPs should consider prescribing treatment with local vaginal estrogen or other FDA-approved products for VVA symptoms. This treatment may prevent vaginal tissue breakdown while the pessary is being worn, as well as potentially improve other manifestations of VVA, including dyspareunia and vaginal dryness.[7-11] All pessary users, but particularly those with VVA, should be encouraged to use a water-based, glycerin-free lubricant with removal and replacement of the pessary.

Some women may complain of vaginal odor and discharge with prolonged pessary use. Presence of ejaculate in the vagina may increase the potential for a temporary shift in vaginal pH. Women who engage in sexual activity that involves internal ejaculation may want to douche with a diluted hydrogen peroxide solution *before* replacing the pessary. Although postcoital douching is not necessary, many women report that this practice diminishes vaginal discharge and odor. Over-the-counter, prepared douche solutions are not advised because of the presence of harsh ingredients that may disrupt the normal vaginal ecosystem.

Conclusion

Pessaries are a suitable alternative to more invasive and expensive treatments for symptomatic POP. HCPs should assess women's sexual health history at the time of the pessary fitting in order to preserve their desired type and frequency of sexual activity. Additional thoughts when considering a pessary include the presence of bowel and bladder dysfunction, VVA, and tendency for vaginal discharge and odor.

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