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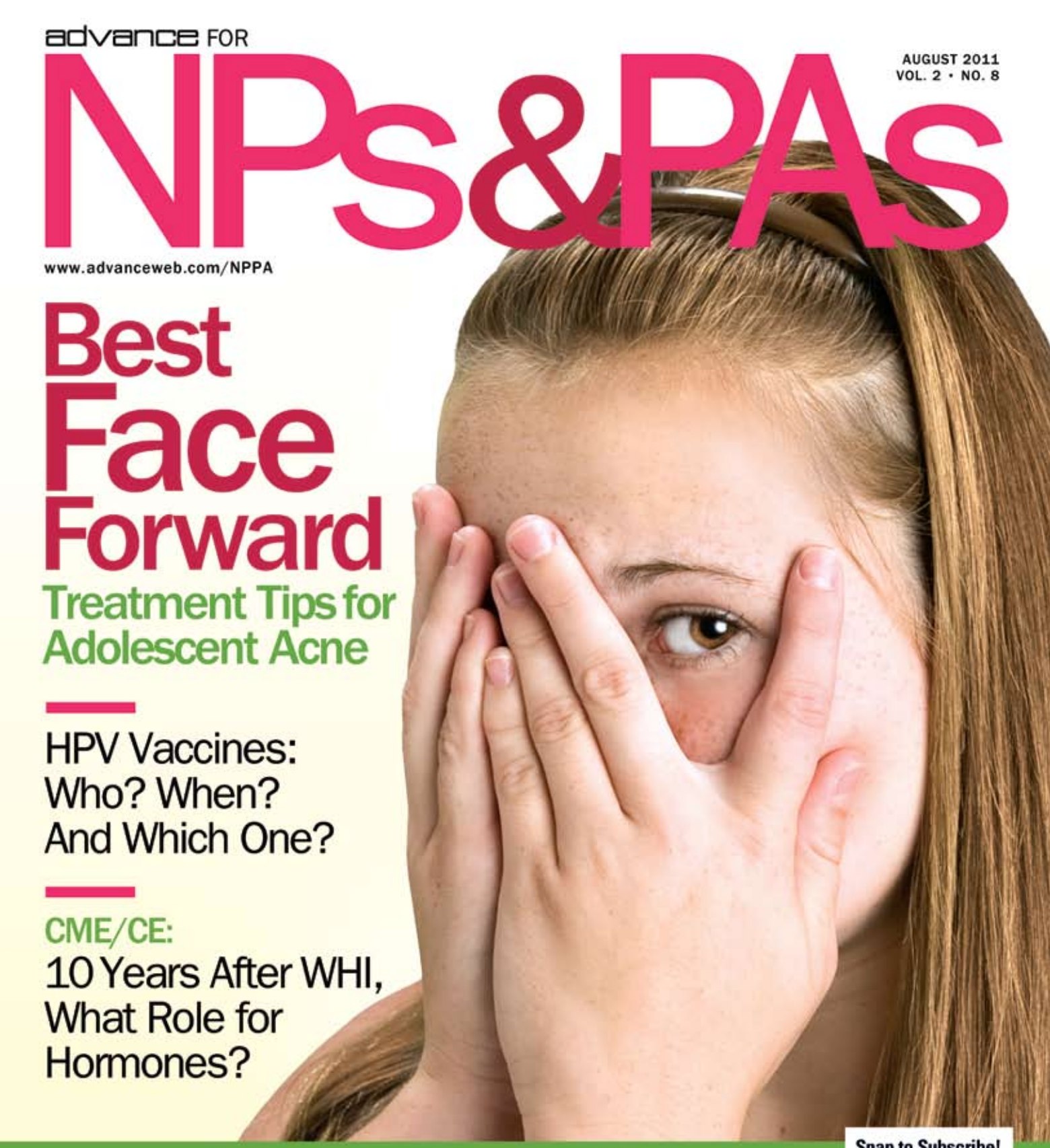

Best Face Forward
Treatment Tips for Adolescent Acne

HPV Vaccines: Who? When? And Which One?

CME/CE:
10 Years After WHI, What Role for Hormones?

factor in folate

The Centers for Disease Control and Prevention (CDC) recommends daily folate supplementation for women of childbearing age*

Beyaz is the only oral contraceptive (OC) with 4 FDA-approved indications for women who choose an OC for contraception

- Prevention of pregnancy
  - — 99% contraceptive efficacy when taken as directed
- Treatment of the symptoms of premenstrual dysphoric disorder (PMDD)
  - — The effectiveness of Beyaz for PMDD when used for more than 3 menstrual cycles has not been evaluated. Beyaz has not been evaluated for the treatment of premenstrual syndrome (PMS)
- Treatment of moderate acne for women at least 14 years of age who have achieved menarche

ALSO, indicated for women who choose an OC for contraception to

- Raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product

Beyaz is not indicated during pregnancy

Plasma folate levels are likely to return to baseline ~20 weeks after discontinuation

Important Safety Information about Beyaz, including boxed warning

Patients who should not take Beyaz

Women over 35 years old who smoke should not use Beyaz. Smoking increases the risk of serious cardiovascular side effects from Beyaz use. This risk increases with age and the number of cigarettes smoked.

- Beyaz is contraindicated in women with a high risk of arterial or venous thrombotic diseases, undiagnosed abnormal uterine bleeding, breast cancer or other hormone-sensitive cancer, liver tumors (benign or malignant) or liver disease, conditions that predispose to hyperkalemia (ie, renal impairment, hepatic dysfunction, and adrenal insufficiency), or who are pregnant

Know serious risks with Beyaz

- **Thromboembolic and Other Vascular Events:** Stop Beyaz if an arterial or deep venous thrombotic event occurs. The risk of venous thromboembolism is highest during the first year of use of combination oral contraceptives (COCs). COC use also increases risk of arterial thromboses (eg, stroke and myocardial infarction), especially in women with risk factors for these events. Use COCs with caution in women with cardiovascular disease risk factors. If feasible, stop Beyaz at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism. Start Beyaz no earlier than 4 weeks after delivery in women not breastfeeding
- **Hyperkalemia:** Beyaz contains drospirenone that has the potential for hyperkalemia in high-risk patients and is contraindicated in patients with conditions that predispose to hyperkalemia. Check serum potassium level during the first treatment cycle in women who receive long-term treatment with medications that may increase serum potassium (eg, ACE inhibitors, angiotensin-II receptor antagonists, potassium-sparing diuretics, potassium supplementation, heparin, aldosterone antagonists, and NSAIDs)
- **Liver Disease:** Discontinue Beyaz if jaundice develops

*The CDC does not endorse specific products or brands.

Bayer HealthCare Pharmaceuticals

170-10-0011-11 Printed in USA May 2011

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BEYAZ (drospirenone/ethinyl estradiol/ levomefolate calcium tablets and levomefolate calcium tablets)

Initial U.S. Approval: 2010

BRIEF SUMMARY OF PRESCRIBING INFORMATION
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (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 should not be used by women who are over 35 years of age and smoke. *[See Contraindications (4)]*.

1 INDICATIONS AND USAGE

1.1 Oral Contraceptive

Beyaz is indicated for use by women to prevent pregnancy.

1.2 Premenstrual Dysphoric Disorder (PMDD)

Beyaz is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception. The effectiveness of Beyaz for PMDD when used for more than three menstrual cycles has not been evaluated.

Beyaz has not been evaluated for the treatment of premenstrual syndrome (PMS).

1.3 Acne

Beyaz is indicated for the treatment of moderate acne vulgaris in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche. Beyaz should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control.

1.4 Folate Supplementation

Beyaz is indicated in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product.

4 CONTRAINDICATIONS

Do not prescribe Beyaz to women who are known to have the following:

- Renal impairment
- Adrenal insufficiency
- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
  - Smoke, if over age 35 *[see Boxed Warning and Warnings and Precautions (5.1)]*
  - Have deep vein thrombosis or pulmonary embolism, now or in the past *[see Warnings and Precautions (5.1)]*
  - Have cerebrovascular disease *[see Warnings and Precautions (5.1)]*
  - Have coronary artery disease *[see Warnings and Precautions (5.1)]*
  - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) *[see Warnings and Precautions (5.1)]*
  - Have inherited or acquired hypercoagulopathies *[see Warnings and Precautions (5.1)]*
  - Have uncontrolled hypertension *[see Warnings and Precautions (5.5)]*
  - Have diabetes mellitus with vascular disease *[see Warnings and Precautions (5.7)]*
  - Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35 *[see Warnings and Precautions (5.8)]*
- Undiagnosed abnormal uterine bleeding *[see Warnings and Precautions (5.9)]*
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past *[see Warnings and Precautions (5.3)]*
- Liver tumors, benign or malignant, or liver disease *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.7)]*
- Pregnancy, because there is no reason to use COCs during pregnancy *[see Warnings and Precautions (5.10) and Use in Specific Populations (8.1)]*

5 WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Disorders and Other Vascular Problems

Stop Beyaz if an arterial or deep venous thrombotic (VTE) event occurs. Although the use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The risk is highest during the first year of use of a COC. 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. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

If feasible, stop Beyaz at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism.

Start Beyaz no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with other underlying risk factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop Beyaz if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately. *[See Adverse Reactions (6).]*

Epidemiologic studies including a DRSP-containing COC

Several studies have investigated the relative risks of thromboembolism in women using a different DRSP-containing COC (Yasmin, which contains 0.03 mg of EE and 3 mg of DRSP) compared to those in women using COCs containing other progestins. Two prospective cohort studies, both evaluating the risk of venous and arterial thromboembolism and death, were initiated at the time of Yasmin approval.[2,3] The first (EURAS) showed the risk of thromboembolism (particularly venous thromboembolism) and death in Yasmin users to be comparable to that of other oral contraceptive preparations, including those containing levonorgestrel (a so-called second generation COC). The second prospective cohort study (Ingenix) also showed a comparable risk of thromboembolism in Yasmin users compared to users of other COCs, including those containing levonorgestrel. In the second study, COC comparator groups were selected based on their having similar characteristics to those being prescribed Yasmin.

Two additional epidemiological studies, one case-control study (van Hylckama Vlieg et al. [4]) and one retrospective cohort study (Lidegaard et al. [5]) suggested that the risk of venous thromboembolism occurring in Yasmin users was higher than that for users of levonorgestrel-containing COCs and lower than that for users of desogestrel/gestodene-containing COCs (so-called third generation COCs). In the case-control study, however, the number of Yasmin cases was very small (1.2% of all cases) making the risk estimates unreliable. The relative risk for Yasmin users in the retrospective cohort study was greater than that for users of other COC products when considering women who used the products for less than one year. However, these one-year estimates may not be reliable because the analysis may include women of varying risk levels. Among women who used the product for 1 to 4 years, the relative risk was similar for users of Yasmin to that for users of other COC products.

5.2 Hyperkalemia

Beyaz contains 3 mg of the progestin DRSP which has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25 mg dose of spironolactone. Beyaz should not be used in patients with conditions that predispose to hyperkalemia (i.e., renal insufficiency, hepatic dysfunction and adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium level checked during the first treatment cycle. Medications that may increase serum potassium include ACE inhibitors, angiotensin-II receptor antagonists, potassium-sparing diuretics, potassium supplementation, heparin, aldosterone antagonists, and NSAIDS.

5.3 Carcinoma of the Breasts and Reproductive Organs

Women who currently have or have had breast cancer should not use Beyaz because breast cancer is a hormonally-sensitive tumor.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings may be due to differences in sexual behavior and other factors.

5.4 Liver Disease

Discontinue Beyaz if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. 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.

Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3 cases/100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (> 8 years) COC users. However, the attributable risk of liver cancers in COC users is less than one case per million users.

Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis. Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

5.5 High Blood Pressure

For women with well-controlled hypertension, monitor blood pressure and stop Beyaz if blood pressure rises significantly. Women with uncontrolled hypertension or hypertension with vascular disease should not use COCs.

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

5.6 Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

5.7 Carbohydrate and Lipid Metabolic Effects

Carefully monitor prediabetic and diabetic women who are taking Beyaz. COCs may decrease glucose tolerance in a dose-related fashion.

Consider alternative contraception for women with uncontrolled dyslipidemia. A small proportion of women will have adverse lipid changes while on COCs.

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

5.8 Headache

If a woman taking Beyaz develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue Beyaz if indicated.

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

5.9 Bleeding Irregularities

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 COC.

Data for Beyaz show the average number of episodes of bleeding per reference period (90 days) was 3.2 in Cycles 4-6. The average number of bleeding and/or spotting days with Beyaz was 15.1 days. The intensity of bleeding for Beyaz based on the ratio of spotting-only days versus total bleeding and/or spotting days was 5.2/15.1 days.

Based on patient diaries from two contraceptive clinical trials of YAZ, 8 to 25% of women experienced unscheduled bleeding per 28-day cycle. A total of 12 subjects out of 1,056 (1.1%) discontinued YAZ due to menstrual disorders including intermenstrual bleeding, menorrhagia, and metrorrhagia.

Women who use Beyaz may experience absence of withdrawal bleeding, even if they are not pregnant. Based on subject diaries from YAZ contraception trials for up to 13 cycles, 6 to 10% of women experienced cycles with no withdrawal bleeding. Some women may encounter post-pill amenorrhea or oligomenorrhea, especially when such a condition was pre-existent.

If 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.

5.10 COC Use Before or During Early Pregnancy

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb-reduction defects are concerned, when taken inadvertently during early pregnancy. Discontinue Beyaz if pregnancy is confirmed and initiate a prenatal vitamin containing folate supplementation.

The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy *[see Use in Specific Populations (8.1)]*.

5.11 Depression

Women with a history of depression should be carefully observed and Beyaz discontinued if depression recurs to a serious degree.

5.12 Interference with Laboratory Tests

The use of COCs may change the results of some laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentrations of thyroid-binding globulin increase with use of COCs. DRSP causes an increase in plasma renin activity and plasma aldosterone induced by its mild antimineralocorticoid activity.

Folates may mask vitamin B12 deficiency.

5.13 Monitoring

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

5.14 Other Conditions

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

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the labeling:

- Serious cardiovascular events and smoking *[see Boxed Warning and Warnings and Precautions (5.1)]*
- Vascular events *[see Warnings and Precautions (5.1)]*
- Liver disease *[see Warnings and Precautions (5.4)]*

Adverse reactions commonly reported by COC users are:

- Irregular uterine bleeding
- Breast tenderness
- Nausea
- Headache

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed cannot be directly compared to rates in other clinical trials and may not reflect the rates observed in clinical practice.

Contraception, Acne and Folate Supplementation Clinical Trials

The data provided reflect the experience with the use of YAZ (3 mg DRSP/0.02 mg EE), in the adequate and well-controlled studies for contraception (N=1,056), for moderate acne vulgaris (N=536) and folate supplementation (N=379).

The adverse reactions seen across the 3 indications overlapped, and are reported using the frequencies

from the pooled dataset. The most common treatment-emergent adverse reactions (≥ 2% of users) were: headache/migraine (5.9%), menstrual irregularities (including vaginal hemorrhage [primarily spotting], metrorrhagia and menorrhagia) (4.1%), nausea/vomiting (3.5%), and breast pain/tenderness (3.2%).

PMDD Clinical Trials

Safety data from trials for the indication of PMDD are reported separately due to differences in study design and setting in the OC, Acne and Folate Supplementation studies as compared to the PMDD clinical program.

Common treatment-emergent adverse reactions (≥ 2% of users) were: menstrual irregularities (including vaginal hemorrhage [primarily spotting] and metrorrhagia) (24.9%), nausea (15.8%), headache (13.0%), breast tenderness (10.5%), fatigue (4.2%), irritability (2.8%), decreased libido (2.8%), increased weight (2.5%), and affect lability (2.1%).

Adverse Reactions (≥1%) Leading to Study Discontinuation:

Contraception Clinical Trials

Of 1,056 women, 6.6% discontinued from the clinical trials due to an adverse reaction; the most frequent adverse reactions leading to discontinuation were headache/migraine (1.6%) and nausea/vomiting (1.0%).

Acne Clinical Trials

Of 536 women, 5.4% discontinued from the clinical trials due to an adverse reaction; the most frequent adverse reaction leading to discontinuation was menstrual irregularities (including menometrorrhagia, menorrhagia, metrorrhagia and vaginal hemorrhage) (2.2%) .

Folate Clinical Trial

Of 285 women, 4.6% who used Beyaz or YAZ discontinued from the clinical trials due to an adverse reaction; no reaction leading to discontinuation occurred in ≥ 1% of women.

PMDD Clinical Trials

Of 285 women, 11.6% discontinued from the clinical trials due to an adverse reaction; the most frequent adverse reactions leading to discontinuation were: nausea/vomiting (4.6%), menstrual irregularity (including vaginal hemorrhage, menorrhagia, menstrual disorder, menstruation irregular and metrorrhagia) (4.2%), fatigue (1.8%), breast tenderness (1.4%), depression (1.4%), headache (1.1%), and irritability (1.1%).

Serious Adverse Reactions (Definitely, Probably, or Possibly Related to Study Drug):

Contraception Clinical Trials: migraine and cervical dysplasia

Acne Clinical Trials: none reported in the clinical trials

Folate Supplementation Clinical Trial: cervix carcinoma stage 0

PMDD Clinical Trials: cervical dysplasia

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of YAZ. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions are grouped into System Organ Classes, and ordered by frequency.

Vascular disorders: Venous and arterial thromboembolic events (including pulmonary emboli, deep vein thrombosis, cerebral thrombosis, retinal thrombosis, myocardial infarction and stroke), hypertension (including hypertensive crisis)

Hepatobiliary disorders: Gallbladder disease, liver function disturbances, liver tumors

Immune system disorders: Hypersensitivity (including anaphylactic reaction)

Metabolism and nutrition disorders: Hyperkalemia, hypertriglyceridemia, changes in glucose tolerance or effect on peripheral insulin resistance (including diabetes mellitus)

Skin and subcutaneous tissue disorders: Chloasma, angioedema, erythema nodosum, erythema multiforme

Gastrointestinal disorders: Inflammatory bowel disease

Musculoskeletal and connective tissue disorders: Systemic lupus erythematosus

7 DRUG INTERACTIONS

Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

7.1 Effects of Other Drugs on Combined Hormonal Contraceptives

Substances diminishing the efficacy of COCs: Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of COCs or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, topiramate and products containing St. John's wort. Interactions between oral contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. 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.

Substances increasing the plasma levels of COCs: Co-administration of atorvastatin and certain COCs containing EE increase AUC values for EE by approximately 20%. Ascorbic acid and acetaminophen may increase plasma EE levels, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma hormone levels.

HIV Protease Inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma levels of estrogen and progestin have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

Antibiotics: There have been reports of pregnancy while taking hormonal contraceptives and antibiotics, but clinical pharmacokinetic studies have not shown consistent effects of antibiotics on plasma concentrations of synthetic steroids.

Effect on DRSP: The main metabolites of DRSP in human plasma are generated without involvement of the cytochrome P450 system. Inhibitors of this enzyme system are therefore unlikely to influence the metabolism of DRSP.

7.2 Effects of Combined Oral Contraceptives on Other Drugs

COCs containing EE may inhibit the metabolism of other compounds. COCs have been shown to significantly decrease plasma concentrations of lamotrigine, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary. Consult the labeling of the concurrently-used drug to obtain further information about interactions with COCs or the potential for enzyme alterations.

In vitro and clinical studies did not indicate an inhibitory potential of DRSP towards human CYP450 enzymes at clinically relevant concentrations *[see Clinical Pharmacology (12.3)*].

7.3 Interactions that Have the Potential to Increase Serum Potassium

There is a potential for an increase in serum potassium in women taking Beyaz with other drugs that may increase serum potassium [*see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].*

7.4 Effects of Folates on Other Drugs

Folates may modify the pharmacokinetics or pharmacodynamics of certain antifolate drugs, e.g., antiepileptics (such as phenytoin), methotrexate or pyrimethamine, and may result in a decreased pharmacological effect of the antifolate drug.

7.5 Effects of Other Drugs on Folates

Several drugs have been reported to reduce folate levels by inhibition of the dihydrofolate reductase enzyme (e.g., methotrexate and sulfasalazine) or by reducing folate absorption (e.g., cholestyramine), or via unknown mechanisms (e.g., antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone and valproic acid).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is little or no increased risk of birth defects in women who inadvertently use COCs during early pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following exposure to low dose COCs prior to conception or during early pregnancy.

The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.

Women who do not breastfeed may start COCs no earlier than four weeks postpartum.

8.3 Nursing Mothers

When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing OCs 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. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.

After oral administration of 3 mg DRSP/0.03 mg EE tablets (Yasmin), about 0.02% of the DRSP dose was excreted into the breast milk of postpartum women within 24 hours. This results in a maximal daily dose of about 0.003 mg DRSP in an infant.

Studies to date indicate there is no adverse effect of folate on nursing infants.

8.4 Pediatric Use

Safety and efficacy of Beyaz has been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 18 and for users 18 years and older. Use of this product before menarche is not indicated.

8.5 Geriatric Use

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

8.6 Patients with Renal Impairment

Beyaz is contraindicated in patients with renal impairment *[see Contraindications (4) and Warnings and Precautions (5.2)].*

Following administration of DRSP 3 mg daily for 14 days, serum DRSP levels in subjects with mild renal impairment (creatinine clearance CLcr, 50-80 mL/min) were comparable to those in subjects with normal renal function (CLcr, >80 mL/min). The serum DRSP levels were on average 37 % higher in subjects with moderate renal impairment (CLcr, 30 - 50 mL/min) compared to those with normal renal function. DRSP treatment did not show any clinically significant effect on serum potassium concentration. Although hyperkalemia was not observed in the study, in five of the seven subjects who continued use of potassium sparing drugs during the study, mean serum potassium levels increased by up to 0.33 mEq/L. Therefore, potential exists for hyperkalemia to occur in subjects with renal impairment whose serum potassium is in the upper reference range, and who are concomitantly using potassium sparing drugs *[see Clinical Pharmacology (12.3)]*.

8.7 Patients with Hepatic Impairment

Beyaz is contraindicated in patients with hepatic disease *[see Contraindications (4) and Warnings and Precautions (5.4)]*. The mean exposure to DRSP in women with moderate liver impairment is approximately three times higher than the exposure in women with normal liver function. Beyaz has not been studied in women with severe hepatic impairment.

10 OVERDOSAGE

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

DRSP however, is a spironolactone analogue which has antimineralocorticoid properties. Serum concentration of potassium and sodium, and evidence of metabolic acidosis, should be monitored in cases of overdose.

Levomefolate calcium doses of 17 mg/day (37-fold higher than the levomefolate calcium dose of Beyaz) were well tolerated after long-term treatment up to 12 weeks.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 24 month oral carcinogenicity study in mice dosed with 10 mg/kg/day DRSP alone or 1 + 0.01, 3 + 0.03 and 10 + 0.1 mg/kg/day of DRSP and EE, 0.1 to 2 times the exposure (AUC of DRSP) of women taking a contraceptive dose, there was an increase in carcinomas of the harderian gland in the group that received the high dose of DRSP alone. In a similar study in rats given 10 mg/kg/day DRSP alone or 0.3 + 0.003, 3 + 0.03 and 10 + 0.1 mg/kg/day DRSP and EE, 0.8 to 10 times the exposure of women taking a contraceptive dose, there was an increased incidence of benign and malignant adrenal gland pheochromocytomas in the group receiving the high dose of DRSP. Mutagenesis studies for DRSP were conducted *in vivo* and *in vitro* and no evidence of mutagenic activity was observed.

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of levomefolate. Mutagenesis studies for levomefolate were conducted *in vitro* and *in vivo* and no evidence of mutagenic activity was observed.

17 PATIENT COUNSELING INFORMATION

[See FDA-approved Patient Labeling.]

- Counsel patients that cigarette smoking increases the risk of serious cardiovascular events from COC use, and that women who are over 35 years old and smoke should not use COCs.
- Counsel patients that Beyaz does not protect against HIV-infection (AIDS) and other sexually transmitted diseases.
- Counsel patients on Warnings and Precautions associated with COCs.
- Counsel patients that Beyaz contains DRSP. Drospirenone may increase potassium. Patients should be advised to inform their healthcare provider if they have kidney, liver or adrenal disease because the use of Beyaz in the presence of these conditions could cause serious heart and health problems. They should also inform their healthcare provider if they are currently on daily, long-term treatment (NSAIDs, potassium-sparing diuretics, potassium supplementation, ACE inhibitors, angiotensin-II receptor antagonists, heparin or aldosterone antagonists) for a chronic condition.
- Beyaz is not indicated during pregnancy. If pregnancy is planned or occurs during treatment with Beyaz, further intake must be stopped. However, women should be advised on the continued need of sufficient folate intake.
- Counsel patients to take one tablet daily by mouth at the same time every day. Instruct patients what to do in the event pills are missed. *See "What to Do if You Miss Pills" section in* ***FDA-Approved Patient Labeling***.
- Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with COCs.
- Counsel patients who are breastfeeding or who desire to breastfeed that COCs may reduce breast milk production. This is less likely to occur if breastfeeding is well established.
- Counsel any patient who starts COCs postpartum and who have not yet had a period, to use an additional method of contraception until she has taken a pink tablet for 7 consecutive days.
- Counsel patients that amenorrhea may occur. Rule out pregnancy in the event of amenorrhea in two or more consecutive cycles.
- Counsel patients to report whether they are taking folate supplements. Beyaz contains the equivalent of 0.4 mg (400 mcg) of folic acid.
- Counsel patients to maintain folate supplementation if they discontinue Beyaz due to pregnancy.

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Beneath the Surface

FOR ADOLESCENTS STRUGGLING to establish self-esteem, make friends, do well in school and generally get a foothold in the world, fighting with their face every day can be emotionally exhausting. Adolescent acne is not a superficial health concern. As our cover article explains, acne can have profound effects on all aspects of a teen's life.

My oldest son struggled with cystic acne through late middle school and his first 2 years of high school. Clearasil, Proactiv, Oxy 10, prescription antibiotics and prescription topicals. We tried them all. Finally, we reached Accutane.

The dermatologist told us at the first visit that for many patients, Accutane was "a miracle drug." That sounded pretty outlandish to me, but the layers of regulation and preparation required by the FDA to start the regimen certainly alerted me to its powerful characteristics. (Isotretinoin is no longer marketed under the brand name Accutane, but it is available in several generic formulations.)

At the time my son started Accutane treatment, he was a good student who was a successful goaltender on his junior varsity ice hockey team. He was shy and not very talkative around adults or in new situations, but he had a strong core group of friends who seemed to live at our house every weekend. These close friendships warmed my maternal heart, but I also suspected that he wasn't socially comfortable in general. He was reluctant to transition to contact lenses, and I wondered if the glasses and long shaggy hairstyle constituted a clumsily assembled mask.

After just a couple of rounds of Accutane, my son's skin began clearing quickly and dramatically. Suddenly, he was smiling more often, and he became more comfortable in social situations. By the time he finished the regimen, he had agreed to transition to contact lenses, a much easier way to watch the puck from behind his goalie mask. A good haircut was a long way off, however.

Today, at age 21, Andrew sports a closely cropped hairstyle, has made the dean's list four times, and is headed toward a career in which public speaking will be required at least once a week. It's an interesting and exciting turn of events! Certainly not all of this is due to effective acne treatment, but I believe that ridding Andrew of this external concern during a crucial developmental period freed him to better develop and showcase his internal attributes.

Amy Gouley is a physician assistant who is passionate about reaching teens with acne. She started a nonprofit corporation, Project Happy Face, to provide free acne treatment services and products to disadvantaged high school students.

"Teenage acne is devastating and can debilitate a child's social growth," Gouley told me. "We need to spend additional time with our teen patients. We need to let them know we truly desire improvement in skin and that it's absolutely possible, but it may take some time, and they must comply with the prescribed regimen."

To learn more about Project Happy Face or to donate to this unique program, visit www.projecthappyface.org. ■

— Michelle Perron Pronsati

advance for NPs&PAs

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MADE IN THE USA

By Jennifer Ford and Michelle Perron Pronsati

AANP Sets Record With 2011 Conference

LAS VEGAS — With a registered attendance of 5,764, the American Academy of Nurse Practitioners 2011 conference was the largest gathering of nurse practitioners in history. From the kickoff keynote by U.S. Health and Human Services Secretary Kathleen Sebelius to the announcement that NP profession cofounder Loretta Ford will be inducted to the National Women's Hall of Fame and be honored with a new AANP award in her name, this 5-day event was a smashing success all around.

Our DNP Perspectives columnist Lisa Chism was one of 50 NPs inducted as a fellow of the AANP.
photo by ADVANCE staff

Some of the most well attended sessions focused on healthy policy and legislation. Jan Towers, PhD, NP-C, CRNP, FAANP, FAAN, AANP's director of health policy for federal government and professional affairs, urged attendees to "pester, pester, pester" congressional lawmakers about issues affecting NP practice. She urged direct and immediate action on behalf of inclusion of NPs and their patients in the new regulations for Accountable Care Organizations and for passage of the Home Health Care Planning Improvement Act of 2011 (S 227 and HR 2267), which would permit NPs and PAs to order home healthcare without physician involvement. At the same session, AANP director of health policy for state government affairs Taynin Kopanos, DNP, NP, turned attention to how NPs can make a difference at the state level. "To be effective at moving policy forward, you must know the decision makers, look for opportunities to engage them, and use language and messaging that connects our issues to the broader healthcare conversation," Kopanos said.

Prescribing issues proved to be another big draw, particularly the FDA's Risk Evaluation and Mitigation Strategies (REMS) set to take effect in early 2012. REMS is focused on improving the safety and efficacy of pain management practices, and it was the subject of a panel discussion during the conference. REMS is a mandatory risk management plan that goes beyond standard drug labeling. Drugs flagged for inclusion in REMS are subject to requirements such as medication guides, communication plans or other specific steps designed to assure safe use. The complete REMS regulations won't be finalized until the fall, but the panelists said the rules are likely to require NPs, PAs and physicians to earn certification as "REMS prescribers." The increased use of opioids for nonmedical purposes was the primary impetus behind REMS, according to the panel.

Attendees at the conference had many opportunities to celebrate their profession. Fifty NPs were inducted into the AANP's fellows program, and 52 more were recognized with state awards for excellence in practice, research, NP education or community affairs. More than 250 companies also joined in celebrating NPs, in the form of a well-trafficked exhibit hall.

AANP membership has grown to nearly 32,000 NPs and 158 organizations, according to the academy's 2010 annual report. Prior to the 2011 conference, the AANP's largest attendance had been 4,500 notched in Nashville in 2009; last year's conference in Phoenix drew 3,500. In 2012, AANP members will gather June 20–24 in Orlando. For information, visit www.aanp.org.

In New York, NPs Use Media to Prod Lawmakers Toward Independence

NURSE PRACTITIONERS in New York have renewed efforts to obtain removal of the requirement for MD collaboration. The bill, A 5308/S 3289, sponsored by Rep. Richard N. Gottfried and Sen. Catharine Young, is also called the NP Modernization Act. A similar bill was introduced in 2008 but died.

This year, the Nurse Practitioner Association of New York (NPA) public awareness campaign, funded by the Legacy Fund, has worked to more effectively publicize the bill by organizing interviews with the media. In April, NPA president and CEO Seth Gordon was interviewed on "The Capitol Pressroom," a daily 1-hour public radio news magazine broadcast from the heart of New York's political hub: the Legislative Correspondents

An Incomplete Drug Dispensing Victory

LEGISLATION INTRODUCED on behalf of convenient care clinic chain ZoomCare in Oregon and passed by the Legislature in April will expand the authority of NPs and PAs to dispense medications in that state. However, the language in SB 952 (http://www.leg.state.or.us/11reg/measures/sb0900.dir/sb0952.a.html) prohibits NPs and PAs from dispensing controlled substances.

"The clinics sought to expand the ability of the PAs who work there, so that they can dispense medications on site," said Tracy Klein, NP, PhD, advanced practice consultant for the Oregon State Board of Nursing. "These clinics are not located in pharmacies and are primarily in urban parts of Portland." The new law includes nurse practitioners in its language.

Klein said that the state's NPs, through their professional organization Nurse Practitioners of Oregon, supported the legislation as long as it also removed statutory restrictions that limit NP dispensing to patients who meet specific financial and/or geographic criteria. The amended bill did remove that restriction.

Association press room in the state capitol (starting at 39:30 at http://blogs.wcny.org/the-capitol-pressroom-for-april-26-2011/). Also in April, Gordon was featured in an article in the Albany *Times Union* (http://www.timesunion.com/local/article/Practitioners-seeking-autonomy-1352283.php). The NPA also organized an informal poll on local TV network New York NOW that asked the public if they supported the bill. Ninety-six percent of respondents said yes.

"We've made a great deal of progress this year," Gordon said. The NPA's goal is to gain bipartisan support for the bill, and at press time six senators and 18 members of the Assembly had signed on as cosponsors. To advance to the floor of either chamber, it must be recommended by one of the higher education committees. The NPA has met with each member of those committees to seek support.

"This is a bill that obviously is controversial in terms of organized medicine; it's met with strong opposition," Gordon said. But as a resuly of media coverage and public relations, Gordon believes the NPA has garnered much public support.

Although 19 states and the District of Columbia no longer require a collaborative agreement between NPs and MDs, "unfortunately none of those states are major peer states that can compare to New York." Gordon said he hopes the need for primary care and the recent Institute of Medicine report urging expansion of NP practice authority will also bolster the bill.

"There is a growing recognition that this bill could help expand, in particular, our primary care capacity."

Best Master's Degrees

Forbes rated the physician assistant and nursing master's degrees among the top 10 in the nation, with PA taking the No. 1 slot.

No. 1: Physician Assistant

Projected growth by 2018: **39%**

No. 7: Nursing

Projected growth by 2018: **22%**

Source: http://blogs.forbes.com/jacquelynsmith/2011/06/06/the-best-and-worst-masters-degrees-for-jobs/

NCCPA Launches Specialty Certificate Program for PAs

FOR THE FIRST TIME, physician assistants can earn formal recognition of their specialty expertise. The National Commission on Certification of Physician Assistants (NCCPA), the credentialing body for PAs, has created certificate of added qualifications (CAQ) programs for certified PAs practicing in cardiovascular and thoracic surgery, emergency medicine, nephrology, orthopedic surgery, and psychiatry.

"As the only nationally recognized certifying organization for PAs, NCCPA is committed to providing credentials that address our responsibility to the public, as well as the needs and concerns of the PA profession," said Janet J. Lathrop, MBA, president and CEO of NCCPA, in a statement.

By earning a CAQ, PAs will augment their NCCPA generalist certification, a basic prerequisite for the CAQ program. To obtain a CAQ, certified PAs must meet licensure, education, experience and exam requirements. The first CAQ exams will be administered in September.

Vermont PA Modernization Bill Signed Into Law

OUTDATED PHYSICIAN ASSISTANT regulations were eliminated in June when Vermont Gov. Peter Shumlin signed into law changes to the PA practice act. Key changes include transitions to licensure and to delegation agreements rather than protocols, a change in verbiage from "physician's assistant" to "physician assistant," and removal of a training track allowing informally trained PAs to continue to practice.

State PA practice law had been unchanged for 25 years, said John Bond, PA-C, president of the Physician Assistant Academy of Vermont (PAAV). He said PAAV worked closely with the American Academy of Physician Assistants, the Vermont Medical Society and the Vermont Board of Medical Practice. (William Hoser, PA-C, is vice chairman of the board.) The most important change for PAs was from certification to licensure. "We were one of the few states that didn't have licensing as a way of regulating our practice," Bond said. The change will help PAs, because some payers only reimburse licensed practitioners. It also will help in disaster situations. After Hurricane Katrina, Bond says, licensed practitioners from other states could respond, but Vermont PAs legally could not.

The change to a delegation agreement will also streamline practice. Instead of certification numbers for each practice situation, one license number will suffice for the 26% of Vermont PAs whom Bond says practice at more than one site.

NP Recognized for Immunization Efforts

PATRICIA STINCHFIELD, MS, RN, CPNP, was the first nurse appointed to a Centers for Disease Control and Prevention (CDC) advisory committee whose mission is to prevent national disease outbreaks. In honor of the achievement, the American Nurses Association recently gave her an Immunity Award.

Patricia Stinchfield, MS, RN, CPNP

Stinchfield, director of infectious disease services at Children's Hospitals and Clinics of Minnesota, served on the Advisory Committee on Immunization Practices (ACIP) from 2004 to 2008. She now serves as the National Association of Pediatric Nurse Practitioners liaison to ACIP.

In addition to her infectious disease role at Children's, Stinchfield treats children and adolescents with HIV and other immune deficiencies. She helped increase the influenza vaccination rate among employees at Children's from 64% in 2006–2007 to 80% in 2008–2009. This increase earned Stinchfield and Children's a Healthcare Personnel Campaign award from the National Influenza Vaccine Summit in 2009. ■

How do NPs and PAs get information and learn?

By Kenneth E. Korber, PA, MHSc

THE INTERNET HAS BECOME a vital tool for self-directed learning among NPs and PAs and for the dissemination of continuing education programs for professional development outside their formal training programs.[1] Understanding clinicians' information-seeking behavior is critical for curricular decisions,[2] and continuing education developers use these data to create successful platforms for advancing medical knowledge.[3,4]

Research Project

To understand how healthcare providers seek information, where they seek it and how they integrate new data into practice, I developed a 10-question survey and distributed it prospectively to a randomized sample of 7,653 PAs and NPs.

The 3-month follow-up response rate for returned and completed surveys was 48% (1,823 PAs and 1,909 NPs), and respondents were matched for clinical background, practice characteristics and clinical roles and responsibilities.

Key Results

Responses to select survey questions demonstrate similarities and differences. For example, one question asked, "What category of patient questions are you most frequently asked on a weekly basis?" Patients' questions to PAs were most often about treatment guidelines, while patients most frequently asked NPs "other questions," such as about holistic health, risk factors and quality of life (Table 1).

Another question asked respondents to rank Internet sources for learning new medical information (Table 2). Responses showed no great disparities between the two professions.

Respondents also were asked about the kinds of sources they turned to most for keeping up-to-date about clinical advances. Overall among PAs, continuing medical education courses ranked No. 1, followed by clinical practice guidelines and peer-reviewed journals. NPs, in contrast, rated clinical practice guidelines first overall, followed by peer-reviewed articles and continuing education courses.

One question asked about influential factors for adopting new clinical practices. Here the results were more parallel, with each group ranking clinical practice guidelines as most influential, followed in order by journal articles and CME/CE courses for PAs, and CME/CE courses and journal articles for NPs.

Peer-reviewed journals were preferred for self-directed learning in both professions. Barriers to assimilating information also were similar, with limited availability of free resources a common response.

Discussion

This snapshot of self-directed learning and acquisition of knowledge reflects similar preferences and learning formats within a matched cohort of NPs and PAs, despite their differences in training. In actual practice, some patient-centered issues might differ. More research is needed to understand these differences.

The complete results of this survey will be presented in a poster at the Society for Medical Decision Making's annual meeting Oct. 22–26 at the Hyatt Regency Chicago. ■

KENNETH E. KORBER is a clinical research associate at the University of Illinois College of Medicine in Chicago and is the architect of the first U.S. cardiovascular fellowship curriculum for postgraduate PAs.

Table 1

Most Frequent Patient Questions

What category of patient questions are you most frequently asked on a weekly basis? (Rank 1 to 7, with 1 being the "most frequent" and 7 being the "least frequent")

	PAs	NPs
Treatment guideline questions	1	5
Alternative/ complementary therapy questions	2	7
Diagnosis questions	4	4
Drug–drug interaction questions	3	2
Medication side-effect questions	5	6
Treatment choice questions (medical/ nonmedical)	7	3
Other questions (holistic health, risk factors, quality of life)	6	1

Table 2

Top Online Learning Sources

What are your top Internet sources for learning about new medical information? (Rank 1 to 7, with 1 being the "most frequent" and 7 being the "least frequent")

	PAs	NPs
CDC	7	4
eMedicine	4	7
Epocrates	3	6
Medscape	6	3
ReachMD	5	5
UpToDate	2	1
WebMD	1	2

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[1]The Lancet, Vol 357, January 27, 2001; [2] Arch Intern Med. Vol 162, Oct 14, 2002; [3] Arthritis Rheum. 2004: 50, 9 (suppl): 251; [4] Arthritis and Rheumatism 2005: 52, 9 (suppl): 1203 GUIDE;

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Presenting at conferences: Rewarding, start to finish

By Nanette Lavoie-Vaughan, MSN, NP

HAVE YOU EVER thought about presenting an educational session at a professional conference? I took that leap after graduation and never looked back. Here are lessons I have learned along the way.

Getting Started

Seek conferences looking for speakers with your expertise. If you belong to a professional organization, its conference may offer a more comfortable initiation into public speaking. Most conferences are offered in the summer and fall, so plan at least 9 months ahead. The conference website is the best place to start.

Submitting a Proposal

Presenting an educational session requires submission of an abstract describing the main points of your presentation, the intended audience, and your expert credentials. It also requires a teaching plan that includes learning objectives with corresponding topical outline, teaching methods, time allotted and form of evaluation. Your submission will be reviewed by the conference planning committee.

Preparing the Presentation

If your proposal is accepted, the conference coordinator will send forms and a list of required documents. He or she will set a deadline for submission of all materials, including W-2 forms, permission to record your presentation, a photo release, a speaker readiness form and a conflict-of-interest disclosure. You'll need to submit a PowerPoint presentation, audience handouts and any other requested documents.

Putting the Pieces Together

Review the materials sent to you, the organization's website and previous conference programs. Once you understand your audience, plan content to meet conference objectives. Develop a list of topics and subtopics to match your outline, and gather research from multiple sources.

Do not write your presentation in sentences, because this will tempt you to read your notes rather than engaging with the audience. Instead, use an outline or note cards with topics and key points.

Developing a PowerPoint

Your slides should be discussion points that you expand on during your presentation. Use key words and phrases rather than sentences. Check that each slide presents one idea with a clear title and is formatted consistently. Underlining, boldface and unnecessary graphics can be distracting; if you use graphics and sound effects, assure that they are relevant and work with the software to be used at the conference.

Avoid dark colors or busy backgrounds on slides, which are distracting and hard to see when printed. Use an easy-to-read font and a type size of around 24 points for good readability. You'll be sending a copy of your PowerPoint to the coordinator to preload onto to the computer in the room where you are presenting, but bring a backup on a flash drive or CD.

Delivering the Presentation

Arrive early to the presentation to make sure your PowerPoint is loaded and working, adjust the microphone and review your notes. A room monitor may introduce you, so early arrival also gives you time to review the introduction.

Grab the audience's attention by opening with your professional background, a humorous anecdote, a question to answer, or a photo or quote. During the presentation, repeat or emphasize key points and transition between topics smoothly.

Speak in a normal, conversational tone and use your notes only when necessary. Look at your audience, not the computer or the screen behind you. If you are interrupted by questions, answer succinctly and remind the audience that you will take questions at the end.

Wrapping Up

If questions run past the time allotted, offer to meet with attendees outside the room. Have business cards handy.

Public speaking can showcase your skills and knowledge and advance your recognition as an expert in your area of practice. For people who are comfortable in front of an audience, it can be personally and professionally rewarding … and a lot of fun. ■

Steps for Success

1. **Identify** a topic on which you have expertise, then determine whether it will interest a conference audience.
2. **Submit** a proposal for the presentation. Be detailed, and meet the deadline.
3. **Prepare** the presentation according to the organizer's requirements.
4. **When** you arrive at the conference, scout your location: the specific room, the equipment resources, etc.
5. **Expect** the unexpected. Bring a backup copy of your presentation on CD or flash drive.

TOM WHALEN

NANETTE LAVOIE-VAUGHAN is an adult nurse practitioner who is a lecturer and clinical coordinator for the adult and gerontologic NP programs at the University of North Carolina in Greensboro. She also provides consultant services to gerontologic healthcare professionals and caregivers. For more information, visit www.nanettelavoie-vaughan.com.

NPs, PAs and Malpractice Insurance Policies

By Michael Gerchufsky

FEW WOULD ARGUE that medical errors are among the biggest problems in healthcare today, if not the biggest problem. Not only do medical errors sicken, injure and even kill a great number of Americans every year — their primary tragedy — but also they have other insidious side effects. The overhead associated with defending against or litigating claims jacks up the cost of healthcare for everyone, and the ubiquity of medical errors has led to the filing of frivolous lawsuits along with justified ones, making it difficult to determine which claims are meritorious and truly stem from clinical mistakes, and which claims are based on an outcome that likely would have occurred regardless of the quality of care provided.

Should NPs and PAs have their own named liability insurance policies, or is it sufficient to be insured under an institution's policy or a physician's policy?

Medical errors can directly ruin the careers and lives of NPs and PAs and other healthcare providers who are sued for malpractice. And they can wreak havoc with NPs' and PAs' lives and careers indirectly by pricing them right out of practicing in certain specialties, settings or geographic locations. As you no doubt are painfully aware, professional liability insurance rates have been increasing consistently and, for many, steeply.

MICHAEL GERCHUFSKY is co-editor of *ADVANCE for NPs & PAs* and the former editor of its predecessor, *ADVANCE for Physician Assistants*.

Named Policies?

Which brings up the age-old question: Should NPs and PAs have their own named insurance policies, or is it sufficient or even better to be insured under an institution's policy or a supervising or collaborating physician's policy?

There are no easy answers to this question. A wide range of opinions exist, and an individual NP or PA must make the decision based on many factors, including whether your practice is class A, B or C; whether you're self-employed or are employed by a hospital, a small group or an individual physician; which state you practice in and more.

Other decisions to consider carefully are how much coverage you need or feel comfortable with; whether to purchase tail coverage; whether to purchase a secondary policy for extra protection; and which insurer to go with, since policies, prices and coverage vary.

Two Schools of Thought

Essentially, the two schools of thought on the question of malpractice coverage go like this: Those who believe NPs and PAs should *not* have their own policies argue that being insured under your employer or supervising or collaborating physician's policy essentially makes you invisible, especially if you practice in a large system, because attorneys and their clients are more likely to go after a relatively deep-pocketed hospital or health system for a large quick payoff rather than seek small potatoes from individual clinicians.

Another argument against named NP and PA policies is that, overall, NPs and PAs less frequently incur malpractice judgments — an observation borne out by the National Practitioner Data Bank. The argument against named NP and PA policies can be summed up as, to borrow a phrase, "If you buy it, they will come."

Those who advocate that NPs and PAs have their own policies cite a list of reasons for that recommendation. Among them are that each clinician in practice is responsible for his or her own clinical decisions, regardless of the supervisory or collaborative relationship with physicians, and that despite that NPs and PAs are relatively infrequent targets of malpractice lawsuits, that's cold comfort for those who *do* get served papers from attorneys whose clients are suing everyone from the employer's CEO down to the guy with the broom. An individual policy also might make it easier to moonlight or to switch employers more seamlessly.

Protect Yourself

Whichever route you choose, the two camps agree on a few suggestions.

- Make sure you are covered at all times, including between employers.
- Get written proof of your being insured at least annually from your employer.
- Never take a job without knowing all the details about malpractice insurance and getting them in writing, in a contract. (You *do* have a written employment contract, don't you?) For example, who pays, and how much? What amount of coverage? Is tail coverage included if you leave? Are legal costs included if you get sued?
- Avoiding medical errors is the best insurance policy, of course. But since this isn't a perfect world, protect yourself by paying exquisite attention to proper and exacting documentation, which will be critical in determining whether a given patient's outcome is the result of a medical error or not. ■

TOM WHALEN

Hormone Therapy for Menopause

A concise update of the benefits and risks

By Jennifer Ribowsky, MS, RPA-C

Learning Objectives

1. Review the findings of the landmark Women's Health Initiative.
2. Summarize current study data on hormone replacement for menopause symptoms.
3. Discuss the benefits of hormone replacement for menopause symptoms.
4. Discuss the cardiovascular, vascular and cancer risk factors of hormone replacement for menopause symptoms.
5. Summarize the practical therapeutic aspects of hormone replacement for menopause symptoms.

MENOPAUSE IS A NATURALLY occurring part of a woman's life cycle, and its symptoms can vary significantly from woman to woman. Hormone therapy (HT) has been used to treat menopause symptoms for more than 60 years. In 2002, results from the Women's Health Initiative (WHI) challenged our understanding of HT and changed the way it is used in menopause.

The WHI revealed increased risks of breast cancer, coronary artery disease, stroke and venous thromboembolism (VTE) in postmenopausal women who were using standard-dose oral conjugated estrogen therapy (ET) and estrogen plus progestin (EPT) therapy. Reanalysis of WHI findings, along with additional data, confirm these HT-associated risks in postmenopausal women. This article briefly reviews the current data and discusses the benefits, risks and practical therapeutic aspects of the use of HT in menopause.

Menopause is defined as 12 months of amenorrhea in a woman 45 or older. Ovarian follicles are depleted at menopause, and the ovaries cease production of estradiol. The average age of menopause in U.S. women is about 51 years, although

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TOM WHALEN

5% of women experience menopause between 40 and 45, and another 5% experience menopause after 55.[1]

Short-term health issues associated with menopause include vasomotor symptoms such as hot flashes and night sweats, sleep disturbances and vaginal, sexual and urinary symptoms. Among the long-term menopause-associated health issues are cardiovascular disease and osteoporosis and its subsequent increased fracture risk.

Benefits of HT

While considerable discussion has taken place about the risks of HT, there is little debate that ET and EPT are the most effective medications available for treating menopause symptoms. Vasomotor symptoms — hot flashes and night sweats — are a

common menopause symptom, estimated to occur in 35% to 50% of perimenopausal women and in 30% to 80% of postmenopausal women.[2]

The primary indication for HT is treatment of moderate to severe vasomotor symptoms associated with menopause. All commonly used systemic estrogens, including oral conjugated equine estrogens (CEE), transdermal 17β-estradiol and low doses of combination HT (EPT), significantly reduce hot flashes compared with placebo.[3]

HT prevents bone loss associated with estrogen deficiency and menopause, and it increases bone mineral density.[4] Significant evidence demonstrates that the use of HT reduces postmenopausal osteoporotic fractures, including hip and vertebral fractures, and many hormone therapy products have approval from the U.S. Food and Drug Administration (FDA) for prevention of postmenopausal osteoporosis.

The WHI, which was the largest randomized trial of HT, enrolled more than 160,000 women. It documented a reduction in hip fractures, vertebral fractures and osteoporotic fractures with ET use.[4] In both the ET and EPT arms of the WHI, researchers noted a statistically significant reduction in the risk of any fracture among women taking HT.[4] However, the Heart and Estrogen/Progestin Replacement Study (HERS), which enrolled 2,763 postmenopausal women with an average age of 67, found no statistically significant difference between combined continuous HT (CEE 0.625 mg plus medroxyprogesterone acetate 2.5 mg) and placebo for fracture reduction.[5]

Additional trials investigating HT and fractures have found a statistically significant decrease in fracture risk for women taking HT compared with women taking placebo, but only with long-term use (4 to 5 years).[6] While HT has an FDA-approved indication for the prevention of postmenopausal osteoporosis, other nonhormonal alternatives (such as bisphosphonates) also are effective for osteoporosis prevention and treatment.

HT also is approved for treatment for moderate to severe symptoms of menopause-related atrophic vulvovaginitis; however, if that is a woman's only complaint, local vaginal estrogen therapy generally is preferred.[7] ET is highly effective for the treatment of atrophic vaginitis symptoms, which include dryness, burning and dyspareunia.[7,8] Vaginal creams, rings and tablets are available for atrophic vaginitis treatment; dosage and duration of therapy should be tailored to a woman's individual needs.[7] While clinical trials have not followed patients for longer than 52 weeks, low-dose vaginal ET can be continued indefinitely.[7] A recent cohort analysis of one randomized trial and one open-label trial concluded that ultra-low-dose vaginal estrogen does not appear to increase the risk for endometrial hyperplasia in women treated for 52 weeks.[9]

Other benefits of HT include a potential reduction in the risk of colorectal cancer and an overall reduction in mortality for younger women.[6]

Cardiovascular Risk and HT

Since the WHI, data about the risks of HT in postmenopausal women have been emerging rapidly, specifically regarding cardiovascular, VTE and breast cancer risks. Initial data from the WHI suggested that women in the EPT arm had an increased risk of coronary heart disease (CHD).[4] Reanalysis of WHI data that factored in women's years since menopause revealed that younger women who were enrolled within 10 years of menopause onset had a reduced CHD risk compared with the increase in CHD risk seen among women who were more distant from menopause.[10] This observation suggests that the timing of HT initiation has an impact on a woman's risk for CHD.

A meta-analysis of 19 randomized controlled trials and prospective cohort studies enrolling more than 16,000 postmenopausal women focused on HT's relationship to overall mortality in younger women.[11] The analysis examined studies of women younger than 60 (average age, 55) that compared HT with placebo for a duration of least 6 months. It found a reduction in mortality in younger postmenopausal women taking HT compared with those taking no treatment.[11]

The HERS trial — a randomized, blinded, placebo-controlled trial of 4.1 years' duration in 2,763 women with an average age of 67 and with CHD — showed no statistically significant increase in CHD events in the HT group compared with the placebo group.[12] More CHD events occurred in the HT group than in the placebo group during the first year of treatment, while fewer CHD events occurred in years 3 through 5.[12]

HERS II, a subsequent unblinded follow-up study of 2.7 years' duration in 2,321 women from the original HERS trial, looked at HT and primary outcomes of nonfatal myocardial infarction and CHD deaths.[13] HERS II found no differences in primary outcomes between women assigned to HT and those assigned to placebo. After 6.8 years (HERS and HERS II combined), women randomized to HT did not have a lower risk of cardiovascular disease.[13]

A recent randomized controlled trial enrolled more than 10,000 women with prior hysterectomy who were randomly assigned to oral CEE (0.625 mg/day) or placebo and were followed for 10.7 years; primary outcomes were CHD and invasive breast cancer.[14] Patients were followed during active treatment for 6 years, and then for 5 years after stopping treatment. While there was neither an increase nor a decrease in CHD risk among women of all ages on HT compared with those on placebo, younger women (in their 50s) who took ET had more favorable outcomes for CHD compared with older women.[14] These findings further support the importance of the timing of initiation of HT, specifically estrogen-only therapy. While postmenopausal women considering HT must be thoroughly evaluated for CHD risk factors, younger women who begin HT closer to menopause onset may have a reduction in risk for CHD.

Vascular Risk and HT

VTE was another risk reported in the WHI, and it is a known risk factor for HT, including estrogen-containing contraceptives. Women in the WHI's EPT arm had

While hormone therapy for menopause symptoms has a number of clear benefits, it also can increase the risk of coronary heart disease, stroke, venous thromboembolism and breast cancer.

double the rate of VTEs compared with women in the ET-only arm.[4] The risk of VTE was lower in women younger than 60, in whom VTEs were classified in the rare category.[4,8] The risk of VTE was highest in the first year of HT use.[8]

A meta-analysis of studies examining the risk of VTE with HT in postmenopausal women found that oral estrogen increased the VTE risk, but that transdermal estrogen did not.[15] Further trials comparing oral and transdermal HT preparations may provide more information about the differences in risks. Assessment of baseline risk factors for VTE is essential before initiating hormone therapy.

Ischemic stroke is a risk associated with HT use in postmenopausal women. In the WHI's EPT arm, eight additional ischemic strokes occurred per 10,000 woman-years, and 11 additional strokes occurred per 10,000 women-years in the ET-only arm.[8] In reanalysis of the WHI data on younger women (50 to 59 years), no significant increase was noted in the risk of stroke with HT.[8]

The Nurses' Health Study — the largest prospective study assessing HT and stroke risk — found an overall increase in the risk of ischemic stroke, a finding nearly identical to the WHI's overall findings. But follow-up analysis of the Nurses' Health Study found that HT increases stroke risk, and this increase is not related to the timing of the initiation of HT. While it did find that women starting low-dose HT within 4 years of menopause did not have an increased stroke risk, the authors attribute this to younger women's lower stroke risk and not to any effect of HT.[16] Nevertheless, study data indicate that in relation to vascular risk, increasing age is an important consideration in whether to initiate HT after menopause.

Breast Cancer Risk and HT

Breast cancer is another major concern with HT use. The WHI data showed 8 additional cases of breast cancer per 10,000 women using EPT for 5 or more years.[4,8] Women using estrogen only, however, showed no increased risk of breast cancer after an average of 7.1 years.[4,8] Women who started EPT immediately after menopause without a gap had an increase in breast cancer risk, and those who had a gap in HT of more than 5 years postmenopause did not have an increase in breast cancer risk.[4,8]

A prospective cohort study examined the risk of breast cancer in more than 53,000 postmenopausal women in France who were followed for an average of 8 years.[17] A greater risk of breast cancer was noted in women who started HT within 3 years of menopause, compared with no increased risk in women who started HT more than 3 years after menopause.

A large prospective cohort study of more than 1 million 50- to 64-year-old women in the United Kingdom assessed the risk of breast cancer in relation to HT type over a 2- to 4-year follow-up period.[18] Women using of all types of HT had an increased risk of invasive breast cancer, but women on EPT had a substantially greater risk than did those on ET.

A recent post-interventional study of the WHI examined health outcomes in women after stopping CEE; a 23% reduction in invasive breast cancer incidence was noted in women using ET compared with placebo after 10.7 years.[14] The reduction in breast cancer risk was noted in the active treatment phase (6 years) and in the post-treatment phase (5 years).

Advancing age increases the risk of all types of cancers; still, a woman's breast cancer risk should be assessed before initiating HT. While EPT is associated with an increased risk of breast cancer, ET alone does not appear to increase the risk and in fact may decrease the risk of invasive breast cancer.

Therapeutic Aspects of HT

For relief of moderate to severe vasomotor symptoms, choose an HT preparation with the lowest effective estrogen dose. Lower daily doses of estrogen include 0.3 mg of oral CEE, 0.5 mg of oral 17β-estradiol, and 0.04 mg to 0.025 mg of 17β-estradiol via transdermal patch.[7] In women with a uterus, add a low-dose progestin either continuously (every day) or cyclically for 14 days per month to reduce the risk of endometrial hyperplasia. Less bleeding is associated with the continuous combined HT regimens. Transdermal preparations may be associated with fewer instances of elevation of clotting factors and triglycerides.[19]

No data from large-scale head-to-head randomized controlled trials support the use of one type of estrogen or progestin, nor does sufficient scientific evidence support the benefit of bioidentical hormones over standard HT.[20] Vaginal symptoms can be treated with low-dose local vaginal estrogen creams, vaginal tablets or a vaginal ring.[7]

Vasomotor symptoms tend to occur with greatest frequency and severity in the menopausal transition and early menopause.[2] HT may be considered in younger women who have moderate to severe vasomotor symptoms at or near menopause. A clinical decision model evaluated the effect of 2 years of EPT in a hypothetical 50-year-old woman.[21] It concluded that women with severe menopause symptoms would gain 7 to 8 months in quality-adjusted life expectancy.

Timing of HT initiation is important, and most data suggest that CHD and stroke risks are highest in women who are older than 60 and thus who are more distant from menopause onset. While data suggest that long-term use of HT is associated with significant risks for CHD, stroke and breast cancer, no clear recommendations exist for the opti-

Fully evaluate a postmenopausal woman's baseline cardiovascular, thromboembolic and breast cancer risk factors before initiating hormone therapy, and closely monitor her for these risks during therapy.

mal duration of HT use, nor do specific guidelines exist for how to discontinue HT. Vasomotor symptoms recur in about 50% of women who discontinue HT.[7] Recurrence rates of vasomotor symptoms are similar when HT is stopped abruptly or tapered.[7,8]

Post-intervention health outcomes after discontinuance of HT were assessed in more than 15,000 WHI participants at 3 years after stopping randomized treatment with EPT or placebo.[22] Primary endpoints were CHD and invasive breast cancer, and the study also measured a global index summarizing the risks and benefits of HT. No statistically significant increase in CHD or fractures was found. Women who received HT had increased rates of all malignancies, including breast cancer and especially lung cancer. The global index of risk was 12% higher in the HT group compared with placebo.

Bottom Line: Evaluate Risks

While HT for menopause symptoms has a number of clear benefits, it also can increase the risk of CHD, stroke, VTE and breast cancer. Short-term low-dose HT is effective and appropriate for managing moderate to severe vasomotor symptoms in younger women who are at or near menopause. Baseline cardiovascular, thromboembolic and breast cancer risk factors should be fully evaluated before HT initiation, and women should be monitored during therapy for these risks.

In women with a hysterectomy, estrogen-only therapy may be associated with a lower risk of CHD and invasive breast cancer. Well designed studies comparing types of estrogens and progestins, as well as trials to compare transdermal preparations with oral preparations, may provide additional information on comparative risks and benefits. ■

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Questions

1. The Women's Health Initiative (WHI) revealed increased risks of which of the following conditions in postmenopausal women using standard-dose oral conjugated estrogen therapy and estrogen plus progestin therapy?
a. Cancer
b. Coronary artery disease
c. Stroke and venous thromboembolism
d. All of the above

2. Which one of the following is the average age of menopause in U.S. women?
a. 40 years
b. 45 years
c. 51 years
d. 55 years

3. Health issues associated with menopause include all of the following except which one?
a. Vasomotor symptoms
b. Cardiovascular disease
c. Breast cancer
d. Osteoporosis and fractures

4. All commonly used systemic estrogens significantly reduce hot flashes compared with placebo.
a. True
b. False

5. The WHI showed a reduction in which of the following fractures with estrogen therapy use?
a. Hip fractures, ulnar fractures and osteoporotic fractures
b. Hip fractures, vertebral fractures and osteoporotic fractures
c. Hip fractures only
d. Osteoporotic fractures only

6. Initial data from the WHI suggested that women taking estrogen plus progestin therapy had an increased risk of coronary heart disease (CHD). Later reanalysis of WHI data showed which one of the following to be true?
a. Younger women within 10 years of menopause onset had a reduced CHD risk, while women more distant from menopause had an increased CHD risk.
b. Younger women within 10 years of menopause onset had an increased CHD risk, while women more distant from menopause had a reduced CHD risk.
c. All women, regardless of years since menopause, had an increased CHD risk.
d. All women, regardless of years since menopause, had a reduced CHD risk.

7. The Nurses' Health Study found an overall increase in the risk of ischemic stroke in women on hormone therapy, a finding that contradicts the WHI's overall findings.
a. True
b. False

8. All of the following statements about the relationship between hormone therapy for menopause and breast cancer risk are true, except which one?
a. Estrogen plus progestin therapy is associated with an increased risk of breast cancer.
b. Estrogen therapy alone does not appear to increase the risk of breast cancer.
c. Estrogen plus progestin therapy does not appear to increase the risk of breast cancer.
d. Estrogen therapy alone may decrease the risk of invasive breast cancer.

9. A clinical decision model evaluating the effect of 2 years of estrogen plus progestin therapy in a hypothetical 50-year-old woman concluded that women with severe menopause symptoms would gain how much quality-adjusted life expectancy?
a. 2 months
b. 7 to 8 months
c. 2 years
d. 7 to 8 years

10. Vasomotor symptoms recur in what percentage of women who discontinue hormone therapy, whether abruptly or tapered?
a. 5%
b. 50%
c. 75%
d. 100%

Evaluation

1. The content was appropriate for my needs.
a. strongly disagree
b. disagree
c. neutral
d. agree
e. strongly agree

2. The educational objectives were achieved.
a. strongly disagree
b. disagree
c. neutral
d. agree
e. strongly agree

3. The information provided was practical and can be applied to my professional needs.
a. strongly disagree
b. disagree
c. neutral
d. agree
e. strongly agree

4. The information in the article was fair, balanced, free of commercial bias and supported by scientific evidence.
a. strongly disagree
b. disagree
c. neutral
d. agree
e. strongly agree

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	A	B	C	D		A	B	C	D
1.	○	○	○	○	6.	○	○	○	○
2.	○	○	○	○	7.	○	○	○	○
3.	○	○	○	○	8.	○	○	○	○
4.	○	○	○	○	9.	○	○	○	○
5.	○	○	○	○	10.	○	○	○	○

Evaluation

	A	B	C	D	E
1.	○	○	○	○	○
2.	○	○	○	○	○
3.	○	○	○	○	○
4.	○	○	○	○	○

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Best Face Forward

A commonsense guide to acne treatment

By Theodore D. Scott, RN, MSN, FNP-C, DCNP

ADOLESCENT ACNE is an age-old problem with multiple causes and upsetting effects for patients. Its impact may equal that of chronic disease. Anxiety, depression and reduced social functioning are real consequences of this condition.[1]

Pathophysiology

Many myths exist about the causes of acne. Chief among these is that dietary choices, stress and dirt in the air are responsible for acne. The real reason is that puberty causes androgen production. This stimulates increased sebum production. Increased sebum production combined with abnormal keratinization and plugging of the hair follicle and attached oil gland (the pilosebaceous unit) produces an inflamed and overfull pilosebaceous unit, known as a microcomedo.

Human sebum is rich in triglycerides. *Propionibacterium acnes* bacteria can colonize the sebum, produce a lipase enzyme and use the resulting free fatty acids as a food source. This leads to further inflammation and rupture of the follicular wall. The body responds with proinflammatory cytokines. This reaction produces the classic raised acne papule with erythema.

If this papule supernates and does not come in contact with outside oxygen, it is called a closed comedo or whitehead. If it is open to the air, the surface products oxidize, and it becomes an open comedo or blackhead. Skin that experiences repeated cycles of follicular rupture and inflammation can produce deeper and often painful nodules of cystic acne.[2]

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KYLE KIELINSKI

Products labeled 'scrub' or 'exfoliant' may irritate already inflamed skin. Teens should avoid them.

Treatment

Numerous products are available to treat acne. Based on my clinical experience in dermatology, acne should be treated in a stepwise fashion. Keep it simple — the fewer steps and products the adolescent patient has to use each day, the more likely he or she is to adhere to the prescribed regimen.

The first step is good basic skin care. I advise using a cleanser with an alpha-hydroxy acid (such as glycolic or lactic acid) or beta-hydroxy acid (salicylic acid). These gentle chemical keratolytics help dissolve matter plugging the sebaceous ducts.

The most common over-the-counter products for this purpose use salicylic acid 2% as the active agent. Advise the patient to wash gently and no more than twice daily. I advise adolescents with acne to avoid products labeled "scrub," "exfoliant" or "microdermabrasion," because most of these can irritate already inflamed skin.

Antimicrobials

The most commonly used nonprescription antimicrobial is benzoyl peroxide. It is available

in creams and gels and varies from 2.5% to 10% strength. Benzoyl peroxide produces oxygen in the sebum, which inhibits *P acnes,* an anaerobe. Benzoyl peroxide causes skin dryness and bleaching of hair and clothing.

Prescription antimicrobials for acne include erythromycin, clindamycin (Cleocin) and sulfacetamide (Plexion, Klaron) with or without sulfur. These have a direct antimicrobial effect on *P acnes*. Prescription antimicrobials are useful products, but they are susceptible to increasing bacterial resistance.[3]

Combination topical products are available by prescription and offer the convenience of delivering everything in one tube. But the generic versions of the individual ingredients tend to be more affordable for patients. And, prescribing each agent individually provides the ability to adjust dosing.

For patients with deep cysts or nodules, add an oral antibiotic: tetracycline 500 mg twice daily, doxycycline 100 mg twice daily or minocycline 100 mg twice daily. For patients who don't tolerate tetracyclines, prescribe erythromycin 500 mg twice daily. Trimethoprim–sulfamethoxazole twice daily is also effective.

Like the topicals, these antibiotics kill *P acnes* and reduce inflammation. Tetracyclines are best taken on an empty stomach and should not be ingested with high-dairy meals. Calcium, bismuth, aluminum and magnesium chelate the tetracyclines in the stomach, meaning that none of the dose will be absorbed. Warn patients about photosensitivity with tetracycline use and to notify you if any skin changes occur while taking sulfa-based antibiotics.[4]

Retinoids

Topical retinoids have become the gold standard treatment for acne. They are thought to work by normalizing the epithelialization of the pilosebaceous unit. This results in less plugging, normal excretion of sebum and decreased inflammation of the oil gland. The available topical retinoid preparations, from mildest to strongest, are adapalene (Differin), tretinoin (Retin-A, Avita) and tazarotene (Tazorac). Each of these preparations is typically applied once daily at bedtime on a dry face. Topical adapalene and tretinoin are pregnancy category C, and tazarotene is pregnancy category X.

Adolescents with severe acne that has not responded to other treatments should be referred to a dermatology practice, where providers can consider prescribing isotretinoin (Sotret, Amnesteem, Claravis), an oral retinoid. Isotretinoin reduces the size of sebaceous glands and inhibits sebum production. Isotretinoin is pregnancy category X and has been linked with behavioral changes. Because its side effects can be severe, isotretinoin is strictly controlled by the Food and Drug Administration. Prescribers, patients and pharmacies that handle the medication are required to register with the iPledge program, a nationwide registry of patients, providers and pharmacies that dispense isotretinoin. Patients are required to confirm adherence with the plan rules each month. These rules include pregnancy testing and two forms of birth control for young women. During each month of treatment, providers must certify that they have counseled the patient, reviewed his or her lab studies, and found the patient qualified to receive the medication.

Education of parents also is important, because acne treatment has changed since they were teens.

Hormone Therapies

In adolescent girls and women, sebum production is fueled by testosterone. Reducing testosterone levels may reduce excess sebum and help clear up acne, especially acne linked to a woman's menstrual cycle. Oral contraceptives, spironolactone (Aldactone) and low-dose corticosteroids all work to suppress androgen levels.

Oral contraceptives suppress androgen production in the ovaries. Ortho Tri-Cyclen (0.18 mg, 0.215 mg, and 0.25 mg norgestimate/0.035 mg ethinyl estradiol), Estrostep (1 mg norethindrone acetate with 20 mcg, 30 mcg or 35 mcg ethinyl estradiol), Yaz (3 mg drospirenone/0.02 mg ethinyl estradiol) and Beyaz (3 mg drospirenone/0.02 mg ethinyl estradiol/0.451 mg levomefolate calcium) have indications for acne treatment. Similar contraceptive formulations are also effective, but may not have specific labeling for this use.

Spironolactone, typically used as a diuretic, is an androgen antagonist. It reduces sebum production by binding to androgen receptors, thereby blocking the effects of testosterone. Its use for acne treatment is off-label and therefore it should be reserved for dermatology specialists. This medication is also pregnancy category X. All oral contraceptives increase the risk of blood clots, especially in smokers.

Putting It Into Practice

Patient education is the key to successful acne treatment in adolescents. The education of parents is equally important because treatments have changed significantly since the parents were teens. I use a patient handout from the National Institute of Arthritis and Musculoskeletal and Skin Diseases: http://www.niams.nih.gov/Health_Info/Acne/acne_ff.pdf.

I emphasize the following points to all acne patients and their parents:

- Take your medications exactly as prescribed.
- Protect yourself from the sun. Antibiotics and retinoids make you sun sensitive.
- Don't spot treat! Treat your entire face every day. Treat the chest and shoulders if you have acne there as well.
- Stay away from hair conditioners or combination shampoo–conditioners. They aggravate acne near the hairline.
- Keep your hands off your face. Don't ever pop pimples! ■

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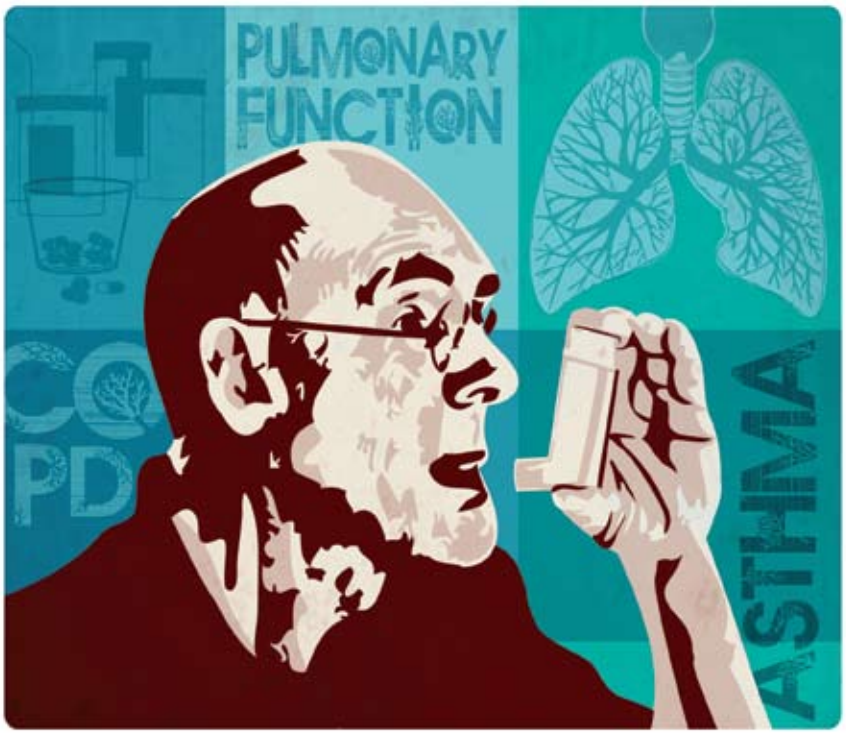
Toward Better COPD Management

Practical aspects of inhaler use

By Chris Garvey, FNP, MSN, MPA, FAACVPR, Gabriel Ortiz, MPAS, PA-C, DFAAPA, and Barbara P. Yawn, MD, MSc, MSPH, FAAFP

CHRONIC OBSTRUCTIVE pulmonary disease (COPD) is characterized by progressive airflow limitation leading to symptoms of dyspnea, cough and sputum production.[1] The disease is underdiagnosed, undertreated and associated with poor outcomes that burden patients and society.[2,3] U.S. deaths from COPD are projected to increase by more than 30% in the next 10 years.[3]



A Primary Care Concern

Many patients with COPD are diagnosed and treated exclusively in primary care settings. Primary care clinicians, however, may have limited time, limited experience in COPD treatment and limited awareness of available COPD treatments.

A recent survey of family practice physicians, nurse practitioners and physician assistants found that they did not always follow published guidelines for the treatment of COPD.[4] The survey also documented some shortcomings in knowledge about COPD epidemiology and treatment.[4]

Bronchodilators are the cornerstone of COPD management, and research shows they can produce improvement in symptoms and exercise capacity.[1]

Short-acting β_2 agonists are often used on an as-needed basis to control dyspnea and to provide acute management of symptoms, including exacerbations.

Maintenance pharmacotherapy, which includes long-acting β_2 agonists and anticholinergics, is used regularly to prevent or reduce symptoms and disease complications.

According to the Global Obstructive Lung Disease (GOLD) guidelines updated in December 2010,[1] acute and maintenance treatment of COPD with inhaled agents has the potential to maximize effectiveness and reduce side effects compared with oral agents. Combining bronchodilators with different mechanisms and durations of action may improve bronchodilation and reduce side effects.

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DAVE PERILLO

Many patients with COPD are diagnosed and treated exclusively in primary care settings. Primary care clinicians, however, may have limited time, experience in COPD treatment and awareness of available COPD treatments.

The addition of an inhaled corticosteroid (ICS) is recommended for patients with severe COPD and frequent exacerbations,[1] and this drug class may be used in combination with β_2 agonists. (ICSs are not approved for monotherapy in COPD.) However, poor inhaler technique is common and can considerably reduce the efficacy of the ICS or device, potentially resulting in poor outcomes.[5,6]

This article provides information on practical aspects of inhaler use, appropriate inhaler device selection and the role of NPs and PAs in ensuring patient understanding of the importance of proper inhaler use and adherence to prescribed therapy.

Device Selection

Four types of inhaler devices are available for COPD medications (Table 1). Metered-dose inhalers (MDIs) and dry powder inhalers (DPIs) are the most commonly prescribed.

Table 1

Available Inhaler Devices for COPD Therapy

Metered-dose inhalers (MDIs)
Short- and long-acting bronchodilators and combinations
Require a specific breathing technique involving coordination between breathing and actuation, slow and steady inspiration, and a breath hold
Can be used with a spacer or holding chamber (patients with poor coordination or improper inhaler technique)
Breath-actuated MDIs require less coordination than conventional MDIs
MDIs are a suitable option for most COPD patients, except for those who have difficulty performing the necessary breathing control

Dry powder inhalers (DPIs)
Long-acting bronchodilators and combinations
Breath-actuated delivery, reducing the need for breath-actuation coordination
Require an adequate peak inspiratory flow, which makes them unsuitable for COPD patients with very severe airflow limitation

Soft-mist inhalers (SMIs; available in Europe)
Low dexterity requirement compared with other portable inhalers
Need coordination between actuation and breathing (less coordination required than for an MDI)
Generate a relatively slow-moving, soft aerosol plume

Nebulizers
Short- and long-acting bronchodilators
Optimal for patients who have cognitive or physical barriers to effective use of inhalers
May be appropriate for treatment during exacerbation of COPD

Selection of an inhaler–drug combination should be individually tailored to each patient's needs.

For example, the patient's physical and cognitive ability to execute proper inhaler technique should be considered. COPD patients are often elderly and may have tremors, muscle weakness, poor hand–eye coordination, inadequate inspiratory flow rates, poor memory or learning difficulties.[1,5,7]

Inhaler properties should also be considered in device selection. Although DPIs have varying airflow resistance, virtually all stable COPD patients should be able to generate the amount of peak inspiratory flow (PIF) necessary to use these devices.[8]

Patients with very low PIFs may require further consultation with a healthcare professional who has expertise in lung diseases.

Similarly, coordinated breathing and actuation are necessary for MDI use. This skill can be improved with training. Any doubt about a patient's ability to effectively use an MDI should prompt selection of an alternative inhaler or the addition of a spacer or holding chamber. As a last resort, a nebulizer should be selected.

In addition to patient-related factors, prescribing clinicians should consider device and drug availability, clinical setting, the availability of combination medications in one device, out-of-pocket costs and administration time.[9]

An American Association for Respiratory Care review of inhaler device selection, properties and technique is available at www.aarc.org/education/aerosol_devices/aerosol_delivery_guide2.pdf.

Other useful patient resources include local pharmacists, pulmonary rehabilitation programs and Better Breathers clubs (American Lung Association, www.lungusa.org/lung-disease/copd/connect-with-others/better-breathers-clubs/).

Table 2
Common Errors in Inhaler Use[16]

Did not remove inhaler cap (all inhaler types)
Lack of coordination between inhalation and actuation (pMDIs)
Drug capsule not pierced properly (single-dose DPIs)
Failure to load dose before use (multidose DPIs)
Inhalation through nose during actuation (pMDIs)
Blowing into the inhaler instead of inhaling (single-dose and multidose DPIs)
Inhalation too weak or too slow (single-dose and multidose DPIs)

Abbreviations: DPIs, dry powder inhalers; pMDIs, pressurized metered dose inhalers with and without spacers.

Treatment Adherence

Adherence to prescribed treatment is paramount to successful COPD management.[7] Patient-specific factors such as health beliefs, cognitive ability, self-efficacy, comorbidities and psychosocial factors can contribute to nonadherence in patients with COPD.[10,11]

Treatment adherence may also be affected by dosing regimen, polypharmacy and side effects.[12] Other relevant factors are the patient's family, trust in the prescriber, access to medication, device training and follow-up.[7]

Clinicians' ability to effectively manage COPD can be affected by factors such as time limitations, workload, prioritizing of other health issues during a short office visit, insufficient training and lack of professional support.[13]

However, without thorough education and understanding on the part of both the prescriber and the patient, inhaler selection may be a counterproductive exercise, contributing to poor treatment adherence and shortcomings in therapeutic benefit.

In a Brazilian study of 60 patients with COPD and 60 patients with asthma, only 8% of COPD patients used their device correctly, and 69% said the prescribing healthcare professional had not watched them use their inhalers.[14]

Treatment adherence is also affected by errors in inhaler use (Table 2).[15] To maximize treatment adherence, healthcare professionals should not assume that a patient will read package inserts and follow written instructions. Face-to-face interactions that deliver simple and clear training can reduce inhaler errors and improve treatment adherence. ➤

Optimizing Inhaler Treatment

Optimal management of COPD is an ongoing endeavor, and it should include inhaler technique training.

Observations of real-world variations in general inhaler adherence rates (20% to 73%) and a concomitant increase in respiratory disease-related side effects underscore the need for individualized instruction.[16]

Proper inhaler technique can be easily demonstrated with a placebo device. If the patient cannot achieve coordinated breathing and actuation immediately in the clinical setting, this can be improved with individualized focused instruction. Inhaler technique should be regularly assessed at office visits.[17]

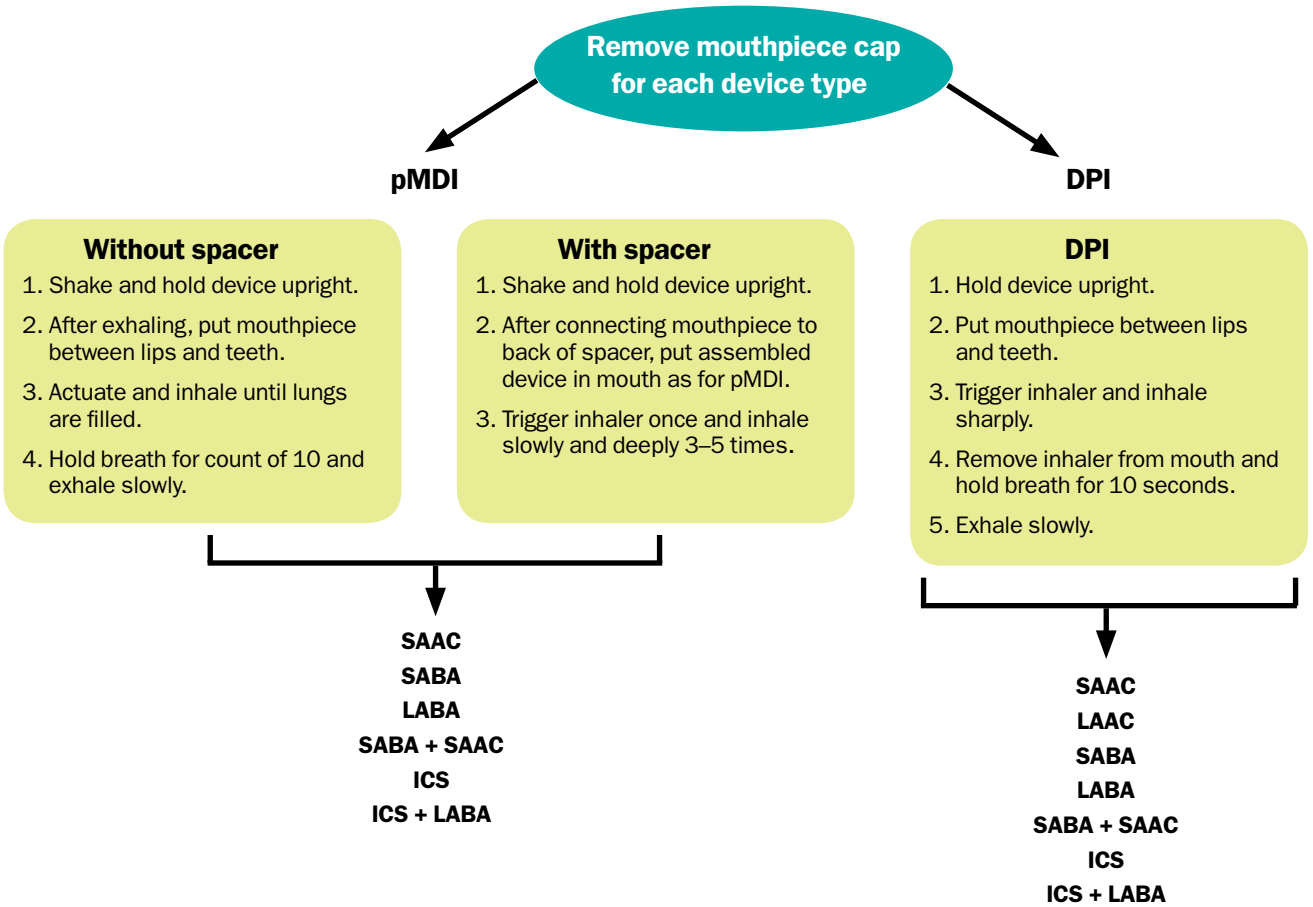
Research shows, however, that COPD patients generally receive little or no instruction in proper inhaler technique. When instruction is given, it is often insufficient or not reinforced with follow-up reviews and observation.[6,7] Inadequate instruction can lead to errors in inhaler use that can be as basic as not removing the cap. General guidance for using inhalers is shown in the figure.[6,18]

Healthcare providers as well as patients should be trained in inhaler use with a placebo device. Unfortunately, this convenient training tool is not available in many clinics and office settings. Alternatively, inhaler technique review can be performed using the patient's own inhaler.

The addition of a single dose of COPD medication for inhaler technique review is unlikely to cause any side effects. However, if a clinician is concerned about this issue, he or she should ask the patient to delay dosing until the visit where observation will take place. ➤

General Guidance for Using Inhalers

Drug classes and correct inhaler technique for metered dose inhalers and dry powder inhalers.



Abbreviations: DPI, dry powder inhaler; ICS, inhaled corticosteroid; LAAC, long-acting anticholinergic; LABA, long-acting β_2 agonist; pMDI, pressurized metered dose inhaler; SAAC, short-acting anticholinergic; SABA, short-acting β_2 agonist.

Most DPIs have built-in dose counters, but this is not the case with most MDIs. Patients need education that enables them to understand how to monitor their MDIs to determine when they require replacement.

For regularly scheduled inhalers, divide the number of puffs used daily by the total number of puffs in the inhaler to determine the number of days the inhaler will last. For inhalers used as needed, patients should track each use manually or with a commercial tracking device. Some inhalers are equipped with dose-counting capability.

A recent survey of family practice physicians, nurse practitioners and physician assistants found that they did not always follow published guidelines for the treatment of COPD.

The Role of NPs and PAs

Primary care providers play a key role in evaluating and building patient knowledge and skills during patients' office visits, and in promoting their adherence to prescribed therapy.[19]

In particular, NPs and PAs can effectively educate patients that COPD is a chronic disease with potential for acute episodes, emphasizing that ongoing treatment is vital for symptom management and well-being.

In addition, NPs and PAs can and should demonstrate and evaluate correct inhaler technique, identify improper inhaler use, and collaboratively work with each patient to improve technique.[17] Ongoing assessment and evaluation are important to help patients maintain effective inhaler technique.[20]

Patient-centered approaches recognize that patient motivation is necessary for acceptance and adherence to treatment. Potentially effective strategies include motivational interviewing, which focuses on promoting intrinsic motivation to follow recommendations and helps to resolve a patient's ambivalence toward behavior change.[21]

The use of inhaled medications should be related to the patient's values and goals (e.g., reduced dyspnea, improved quality of life), and it should be consistent with clinical goals.

A recent Spanish study of patients with COPD and/or asthma showed that involvement of a specialized nurse responsible for care coordination, patient education and monitoring of well-being produced marked improvements in patient self- management, including inhaler technique and adherence.[22]

Another published review concluded that an integrated approach to the care of patients with COPD can promote best practices and identify gaps in quality of care.[23]

These findings show that together with other members of the COPD care team, NPs and PAs can help improve patient understanding and acceptance of the disease process and can motivate patients to self-manage their disease effectively. ■

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Who Should Be Vaccinated Against HPV?

The list continues to grow.

By Lois McGuire, RN, MSN, WHNP

THE HUMAN PAPILLOMAVIRUS (HPV) vaccine is the first vaccine developed to prevent a specific cancer. It's an exciting step forward in healthcare, but it is one fraught with controversy.

Background and Scope

An estimated 6.2 million U.S. residents are infected with HPV each year.[1] Among all sexually active people, experts estimate a 75% lifetime chance of acquiring this infection.[1] More than 120 types of HPV have been identified, and about 40 types can infect the genital tract. Between 13 and 19 HPV types are considered at high risk for producing cancer.[1]

Evidence suggests a strong association between high-risk HPV genotypes and other cancers, including cancer of the penis, vagina, vulva, anus and oropharynx.[2] Therefore, vaccination against HPV may be important in preventing cancer in populations outside current indications.

The Food and Drug Administration has approved a quadrivalent HPV vaccine (Gardasil) and a bivalent HPV vaccine (Cervarix) for the prevention of cervical cancer in girls and young women. The FDA also has approved the quadrivalent vaccine for the prevention of genital warts in boys and young men ages 11 to 26. Gardasil also has a third FDA-approved indication, for the prevention of anal cancer in all people.

However, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) has not officially recommended HPV immunization for boys and men, nor has it recommended HPV vaccination against anal cancer. How should NPs and PAs respond in clinical practice to the discrepancy between these two important FDA indications and the ACIP's decision not to add these to its schedule?

HPV Immunization Options

The quadrivalent vaccine became available in 2006. It protects against HPV genotypes 6, 11, 16 and 18.[1] HPV 6 and 11 are responsible for 90% of genital warts in the United States.[3] These warts are usually benign but cause stress for most patients. HPV types 16 and 18 cause 70% of the cervical cancers in this country.[3] For cervical cancer prevention, the qua-

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JEFFREY LEESER

HPV Vaccination Overview

Agency	Vaccine Type	Indications	Recommendation or Policy
FDA	Quadrivalent	• Prevention of cervical cancer in girls and women ages 9 to 26 • Prevention of genital warts in boys and men ages 9 to 26 • Prevention of anal cancer in patients of all ages and both sexes	
ACIP	Quadrivalent		• Routine vaccination against cervical cancer for girls age 11 or 12; can be started at age 9. Catch-up vaccination at ages 13 through 26 • No recommendation for routine vaccination against genital warts in boys and men • No recommendation for routine vaccination of any population against anal cancer
VFC	Quadrivalent		• Available for girls ages 9 to 18 to prevent cervical cancer • Available for boys ages 9 to 18 to prevent genital warts
FDA	Bivalent	Prevention of cervical cancer caused by HPV 16 and HPV 18 (cause of 70% of cervical cancers) in girls and women ages 10 through 25	
ACIP	Bivalent		• Routine vaccination against cervical cancer for girls age 11 or 12; can be started at age 9. Catch-up vaccination at ages 13 through 26 • The quadrivalent and bivalent vaccines can be used interchangeably to complete the series, but selection of one is preferred

FDA = Food and Drug Administration
ACIP = Advisory Committee on Immunization Practices, a panel of the Centers for Disease Control and Prevention
VFC = Vaccines for Children, a program of the Centers for Disease Control and Prevention that provides free vaccines to certain economically disadvantaged children. See http://www.cdc.gov/features/vfcprogram/.

drivalent vaccine has an FDA indication for girls and women ages 9 to 26.

The bivalent vaccine was approved in 2010 and protects against two HPV types, 16 and 18. Cervarix protects against cervical cancer only; it does not prevent genital warts. The bivalent immunization is indicated for girls and women ages 10 to 25.

Both HPV vaccines are given intramuscularly as a series of three separate injections, but each has a specific dosing regimen. The quadrivalent form is given at 0, 2 and 6 months. The bivalent form is given at 0, 1 and 6 months.

Studies show that the efficacy rates for both vaccines are similar.[1] The vaccines are considered safe because they are composed of virus-like particles. The vaccines are made from benign biologic systems including yeast (Gardasil) or baculovirus (Cervarix). This means no oncogenic or disease-causing potential exists.[2]

The most common local adverse reactions associated with both vaccines are injection site pain, erythema and swelling.[1] The quadrivalent form also may cause pruritus. In premarket studies of Gardasil, systemic adverse events were similar between the placebo group and the vaccinated group. Cervarix was associated with low rates of systemic reactions. No one withdrew from premarket studies due to these reactions.[1]

The CDC tracks adverse vaccination events through three reporting systems. As of February 2011, more than 30 million doses of the quadrivalent vaccine had been distributed, and the CDC had received about 18,354 reports of adverse events.[4] Only 8% of the events were classified by the CDC as serious; most events were the same as those documented in premarket studies, but syncope and blood clots also have been reported since the vaccines have been in use. The events classified as serious included 32 deaths among girls and women who received the vaccine, but the CDC found "no unusual pattern or clustering to the deaths that would suggest that they were caused by the vaccine, and some reports indicated a cause of death unrelated to vaccination." This is important information, because many websites and antivaccination groups present misleading information about the risks of HPV vaccination.

When selecting a vaccine for a patient, ask specific questions to reduce the possibility of adverse events. For example, the tip cap and the rubber plunger of the needleless prefilled syringes in the bivalent preparation contain dry natural latex rubber that may cause allergic reactions in latex-sensitive patients.[1] If your patient has an allergy to latex, the quadrivalent vaccine would be the vaccine of choice. If your patient has an increased sensitivity to yeast, consider avoiding the yeast component in the quadrivalent vaccine and choose the bivalent preparation.

Protecting Girls and Women

Looking closer at the protection offered by vaccination of girls and women, Gardasil

carries an indication for use in female patients 9 to 26 years old for prevention of cervical cancer and genital warts (condyloma acuminata), along with the following precancerous or dysplastic lesions:

- cervical adenocarcinoma in situ
- cervical intraepithelial neoplasia grade 2 and grade 3
- vulvar intraepithelial neoplasia grade 2 and grade 3
- vaginal intraepithelial neoplasia grade 2 and grade 3
- cervical intraepithelial neoplasia grade 1.

Soon after the FDA approved these indications in 2006, the ACIP recommended the following:

- routine vaccination of 11- to 12-year-old girls with 3 doses of quadrivalent HPV vaccine (the vaccination series can be started as young as age 9)
- catch-up vaccination of girls and women 13 to 26 years old using the same vaccination series.

Cervical cancer used to be the No. 1 cancer killer of American women. Today, thanks to the Papanicolaou (Pap) test, cervical cancer does not have the impact it once did. Approximately 11,150 new cases of cervical cancer are diagnosed annually, with almost 3,700 deaths per year.[1] Because routine screening with a Pap test is not available for all women, cervical cancer remains on the global public health agenda. Worldwide statistics from 2008 estimate 530,000 new cases per year and 275,000 deaths.[5]

The population of girls and women ages 11 to 26 is important to target for HPV vaccination because 74% of new HPV infections occur between the ages of 15 and 24.[6] Adolescent girls are at high risk for sexually transmitted infections including HPV.[7]

The vagina is dark, warm and moist, creating the perfect environment for bacteria and viruses to grow. The transformation zone of the cervix is made up of immature and unstable cells, which also makes young women particularly vulnerable to sexually transmitted infections. The transformation zone of the cervix is where 99% of cervical cancers occur. For optimal HPV vaccine efficacy, it is important to vaccinate prior to initiation of sexual activity. National surveys show that approximately 24% of girls are sexually active by age 15.[2] By vaccinating at age 11 or 12, most adolescents will be protected prior to their sexual debut.

The reasons to focus our energy on immunizing girls and young women are clear. But many of these patients have not initiated the vaccine series.[8] Others have initiated the regime but have not completed it. In a study in Southern California, less than half of girls who started the series completed it.[9] Statistics show that minority adolescent girls and girls who live in poor neighborhoods are less likely to complete the vaccine series.[9]

Vaccination rates are likely to improve with increased patient reminders, administration of vaccines at every clinic or emergency department visit, and initiation of school-based vaccination programs. These are ambitious goals that will require years to accomplish. Targeting mothers is another important strategy for improving HPV immunization rates. But lack of recommendation by a healthcare provider is the single factor most associated with failure to receive any vaccine.[7] This means it is essential for NPs and PAs to talk with patients and parents about HPV vaccination.

We won't be able to see the full impact of the HPV vaccine on cervical cancer for many years, but research has given us great hope that we can reduce the number of women affected by cervical cancer in the future.

Protecting Boys and Men

Just as we know that immunizing girls and women against HPV reduces genital warts, research has found that immunizing boys and young men will also reduce risk.[10] Despite this evidence, the ACIP has not recommended routine HPV vaccination for boys and men. In 2010, the ACIP added boys and men to its list of populations who can benefit from quadrivalent vaccination, but it stopped short of recommending it as part of routine vaccination.

Initially, mathematical modeling suggested that if vaccination in women were widespread, vaccinating men would offer little benefit.[11] ACIP has cited these data, stating that the burden of HPV is heaviest on women. With widespread vaccine coverage in that population, the ACIP argues, it is not cost effective to push for equal coverage in boys.[11]

The result is that recommendations for exactly how the vaccine should be

The Price Factor

THE HEFTY PRICE TAG for HPV vaccination, around $130 per dose and $390 for the series, is a stumbling block to widespread immunization. Private health insurance plans have been slow to cover the cost, but the vaccines are available through some federal entitlement programs.

For children who qualify, the HPV vaccines are available at no charge through the federal Vaccines for Children (VFC) program in all 50 states. VFC provides vaccines for children ages 9 to 18 who are covered by Medicaid, or who are Alaska Native or Native American. The program also serves some underinsured or uninsured children.

Some states are working to force insurers to cover vaccination, the National Conference of State Legislatures reports. Lawmakers in at least 41 states and the District of Columbia have introduced legislation to require, fund or educate the public about HPV vaccination, and at least 20 states have enacted such legislation: Colorado, Indiana, Iowa, Louisiana, Maine, Maryland, Michigan, Minnesota, Missouri, Nevada, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Texas, Utah, Virginia and Washington. Few states have been successful in mandating that insurance companies pay for HPV vaccination, however.

TOM WHALEN

Immunizing girls and women against HPV reduces genital warts; research has found that immunizing boys and young men will also reduce risk. Still, ACIP has not recommended it for boys and men.

used in boys and men are vague. The FDA is now reviewing additional data on the vaccine's ability to prevent precancerous growths among men who have sex with men. More detailed advice on the use of HPV in specific higher-risk populations may be forthcoming.

Protection From Anal Cancer

Approximately 5,300 cases of anal cancer are diagnosed each year in the United States.[12] Women are diagnosed more often than men, especially women who have a history of infection with high-risk genotypes of HPV on the cervix, vagina or vulvar tissue. Men who have sex with men also have a high incidence of anal cancer.[13]

Between 1998 and 2003, the incidence rates of anal squamous cell carcinoma in this country increased 2.6% annually.[13] HPV 16 has been identified as a primary culprit in this disease.[13] Studies show that the quadrivalent HPV vaccine is 78% effective in preventing anal cancer.[14]

In late 2010, the FDA approved the quadrivalent HPV vaccine for the prevention of anal cancer. As of July 2011, the ACIP had not added this indication as part of routine immunization practices. Further guidelines about populations who should receive routine HPV immunization may be forthcoming as researchers continue to investigate HPV and anal cancer.

What's Ahead?

The FDA is responsible for protecting public health by assuring the safety, efficacy and security of human drugs. The ACIP has a different purpose. It provides advice and guidance about the effective control of vaccine-preventable diseases. The ACIP also develops written recommendations for routine administration of vaccines.

In the future, other populations and indications may be included in ACIP recommendations for HPV prevention. Because the FDA has approved the vaccine for the prevention of genital warts in boys and young men and for the prevention of anal cancer in all people, it is our responsibility as providers to collect a complete patient history and use our clinical judgment when counseling patients about HPV risk and their need for this protection. For now, the ACIP supports routine immunization only for girls and women ages 11 to 26. We must therefore work to achieve widespread immunization of these patients to prevent cervical cancer and genital warts. By doing so, we will have a great impact on the lives of women and on the HPV-associated cost burden on the healthcare system. ■

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When Heartburn Gets Serious

An update on Barrett's esophagus

By Kristy L. Oden, DNP, FNP-BC, MSN, RN

KYLE KIELINSKI

THE EXACT INCIDENCE of Barrett's esophagus in the United States is an elusive number, but experts agree that the condition is on the rise and warrants clinical attention due to its connection to esophageal cancer.[1,2]

Case Study

"Grace" is a 58-year-old white woman who presented to a gastroenterology practice after being treated for gastroesophageal reflux disease (GERD) with over-the-counter medication for the past year. She reported experiencing intermittent episodes of reflux despite the medication, and she said these symptoms were increasing in frequency and duration.

Grace has been diagnosed with hypertension and type 2 diabetes. At the time of this visit, she was taking metformin, atenolol and omeprazole 20 mg daily. Her body mass index was 31, classifying her as obese. Her surgical history included a cholecystectomy 4 years prior. Grace is retired. She stopped smoking 15 years ago, after a 20-year habit. She reported no alcohol or illegal drug use.

Based on an evaluation of symptoms and history, the gastroenterologist scheduled Grace for esophagogastroduodenoscopy (EGD). During this procedure, the physician noted an irregular z-line with patches of salmon-colored mucosa surrounded by normal tissue (see image, next page). The gastroenterologist obtained multiple biopsies for confirmation of Barrett's esophagus.

Pathophysiology

The esophagus is a hollow muscular tube approximately 23 cm to 25 cm long. It connects the oropharynx to the stomach and serves as a means of moving food and liquids to the stomach. Substances move through the esophagus by peristalsis, a rhythmic contraction and relaxation of the circular muscles of the esophagus.[3]

The esophagus can be divided into three areas: the upper portion consisting of striated muscles, the middle esophagus with smooth and striated muscles, and the lower esophagus containing smooth muscles.[4]

Barrett's esophagus is an alteration of the cells that line the esophagus. This alteration is called intestinal metaplasia.[3] When Barrett's esophagus is present, the cells appear salmon-colored when viewed during endoscopy. The esophageal cells mimic the cells lining the intestines and are not cancerous, but they can progress to adenocarcinoma of the esophagus. Each year, 1 in 200 patients with Barrett's esophagus develops esophageal cancer.[2] In this process, the cells progress from metaplasia to mild dysplasia to moderate dysplasia to carcinoma.[5] This occurs slowly and can be inhibited by control of symptoms. But because the condition does not produce symptoms, it is difficult to diagnose the disease and take preventive action.[5]

The esophagus has an upper and lower esophageal sphincter. Air cannot enter the esophagus during respirations by the upper esophageal sphincter (UES), and the lower esophageal sphincter (LES) prevents gastric content from regurgitat-

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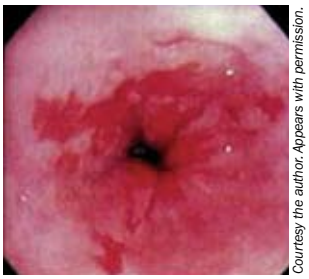
ing upward into the esophagus. A few hours after eating, the LES may relax, allowing acidic gastric content to come in contact with the esophagus. The acid is neutralized in the esophagus within 3 minutes, and peristalsis forces the content back into the stomach. As this occurs, tone resumes in the LES.[5] When this sequence occurs intermittently over a long period, it is classified as chronic GERD.



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Barrett's esophagus viewed during endoscopy.

Risk factors for Barrett's esophagus are chronic GERD, age 50 or older, obesity, hiatal hernia, intra-abdominal distribution of body fat, male gender and white race.[2,6-9] GERD is the risk factor most strongly associated with Barrett's esophagus. Case control studies suggest that patients with heartburn are 6 to 10 times more likely to have Barrett's esophagus than unaffected patients.[1] Patients with chronic GERD are more likely to develop the condition. Of note, the relationship between GERD severity and Barrett's esophagus is not particularly strong.[1]

Diagnosis

The diagnosis of Barrett's esophagus is a two-step process. The first is visualization of the salmon coloring of the esophageal lining by upper endoscopy (EGD). The second is histologic identification of intestinal metaplasia in the biopsy specimens.[10] The salmon-colored appearance of the mucosal lining of the esophagus contrasts its normal pale coloring.[11]

EGD is usually performed on an outpatient basis in freestanding surgery centers, ambulatory surgery centers, endoscopy units and GI specialty practices. Preprocedure precautions, such as nothing by mouth after midnight and sedation, are necessary.

Treatment

First and foremost, a diagnosis of Barrett's esophagus requires lifestyle changes to improve or prevent worsening of the condition. All patients should implement strategies to reduce GERD symptoms (Table 1). Other treatment options are described below. Earlier this year, the American Gastroenterological Association (AGA) published a technical review[1] and position statement[2] on the management of Barrett's esophagus. These documents are geared toward gastroenterology specialists, but their overall conclusions are necessary knowledge for all clinicians who treat adults (Table 2).

Medical management. Most patients have tried OTC acid reducers by the time Barrett's esophagus is diagnosed. Only 20% experience symptom improvement with this approach alone.[10] Proton pump inhibitors (PPIs) work to prevent disease progression by reducing GERD symptoms. Despite use of once- to twice-daily PPIs, however, some patients still have inadequate acid control.[8] In conjunction with PPIs, lifestyle modifications aimed at reducing GERD are necessary.[7]

Surgical management. Surgery may become necessary when reflux symptoms continue despite medical management. Previously, the gold standard for GERD treatment was a Nissen fundoplication to tighten the LES. It is minimally invasive and requires a short hospital stay. But Nissen fundoplication is a short-term solution to a long-term problem, because symptoms tend to return with time.[7,10]

Surgical treatment of Barrett's esophagus is based on the degree of damage in the esophagus as determined by a pathologist. A patient with Barrett's esophagus whose biopsy results are negative for dysplasia requires reevaluation every 3 to 5 years. Patients whose biopsies show mild dysplasia require re-evaluation every 6 to 12 months.[10] Treatment for moderate to severe dysplasia includes aggressive surveillance endoscopy with the use of large four-quadrant biopsies, ablation or esophagectomy. Patients who are medically unstable undergo aggressive surveillance endoscopy.[12]

Table 1

GERD Precautions

Avoid carbonated beverages
Avoid spicy foods
Avoid alcohol
Avoid chocolate
Avoid acidic fruits and fruit drinks
Stop smoking
Lose weight

Ablation therapy. Ablation therapy may be performed to resolve existing Barrett's esophagus because anti-reflux therapy (including PPIs) will not treat it. The ablation technique intentionally damages or ablates the mucosa in a controlled manner. After ablation, healing can take place with PPIs or reflux surgery. The three types of ablation therapy are chemical, thermal and mechanical.

Photodynamic therapy. Photodynamic therapy for Barrett's esophagus is performed by intravenously infusing a photosensitive agent, which is then absorbed by the dysplastic tissue. Forty-eight hours after administration of the photosensitive agent, an endoscopic light source is directed at the affected tissue, destroying it. Some advantages of photodynamic therapy for Barrett's esophagus are that it is cost effective, has a greater than 75% cure rate, and is associated with low morbidity and mortality, especially when compared to esophagectomy.[10,13] Complications of the procedure are esophageal stricture, chest pain, dysphagia and cardiac dysrhythmias.[10] Due to the photosensitivity these medications cause, patients must avoid sunlight for up to 2 months after treatment.[12]

Laser therapy. In laser therapy, laser beams are directed at the dysplastic tissue, causing the tissue to heat until it is destroyed. Complications include development of an esophageal stricture, dysphagia and chest discomfort.[10,12]

Multipolar electrocoagulation. This procedure uses an endoscope to insert a size-specific balloon into the esophagus to deliver thermal energy to the abnormal mucosa. The amount of energy that travels through the electrical circuit can be selected by the endoscopist. Treatment is achieved by application of the energy to half the esophagus followed by application to the remaining half. Successful eradication of the dysplastic cells occurs in 75% of cases, and the complications are similar to those of laser therapy.[10,12]

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Argon plasma coagulation. The most common ablative technique, argon plasma coagulation, uses a high-frequency monopolar current. The accessory channel of an endoscope is used to place a catheter in the esophagus, allowing ionized argon gas to flow to the affected tissue. This creates a current that burns the damaged tissue. The injury depth by argon plasma coagulation is less than that associated with laser or photodynamic therapy.[10,12] Complications can include esophageal stricture, dysphagia, bleeding, perforation and pulmonary alterations.[10] This treatment modality can be 98% effective, but maximum results may require up to 51 months of therapy.[10,12]

Radiofrequency ablation. In this technique, a balloon is placed in the esophagus and then inflated to come into contact with all sides of it.[14] Once the connection between the walls of the esophagus and the balloon is made, an electrical current is delivered to the metaplastic tissue.[10,12,14] If needed, the balloon is deflated, repositioned and reinflated to cover the entire area of damaged tissue. Studies show it can be more than 77% effective at treating Barrett's esophagus.[10,12,14] Complications include chest discomfort, risk of bleeding (especially in patients on anticoagulation therapy) and esophageal stricture.[14]

Cryoablation. During cryoablation, liquid nitrogen is sprayed at a low pressure onto the affected tissue, causing cell destruction. Complications are limited and results are promising.[10,12]

Mechanical ablation. With the technique of mechanical ablation, a cap or band is introduced into the esophagus by an endoscope. Using a solution commonly consisting of diluted epinephrine or normal saline, an area of affected tissue is injected to create a polyp-like appearance. This area of tissue is then snared in the band or cap, and with the use of electrocautery, it is removed. A series of biopsies is taken for complete eradication of the affected tissue. Initially, complications are related to bleeding. This is followed by the development of esophageal strictures. Due to the size of the biopsies, the affected tissue margins are easily identifiable.[7,10,12,15]

Multimodality therapy. Acid suppression is the mainstay of treatment for Barrett's esophagus. Greater effectiveness is achieved when it is combined with other therapies, such as ablation therapy and lifestyle modifications.[10,12]

Esophagectomy. Esophagectomy (surgical removal of the affected area) is the treatment standard for Barrett's esophagus patients with high-grade dysplasia or esophageal cancer as determined by biopsy. However, it is associated with high morbidity and mortality. Complications can occur in 50% of patients, and these include pneumonia, infections, leaks from the anastomosis site and cardiac complications. If persistent GERD is present after esophagectomy, Barrett's esophagus can redevelop in the remaining esophagus.[10]

Table 2

Key Points From the American Gastroenterological Association (AGA)[1,2]

Screening

In patients with multiple risk factors associated with esophageal cancer (age 50 or older, male gender, white race, chronic GERD, hiatal hernia, obesity and intra-abdominal distribution of body fat), AGA suggests screening for Barrett's esophagus. The AGA recommends *against* this screening in the general population with GERD.

Diagnosis of Dysplasia

The diagnosis of dysplasia in Barrett's esophagus should be confirmed by at least one additional pathologist, preferably one who is an expert in esophageal histopathology.

Acid Reducer Therapy

For patients with Barrett's esophagus, GERD therapy with medication effective for GERD symptoms is clearly indicated. However, evidence to support the use of acid-reducing agents (proton pump inhibitors) in patients with Barrett's esophagus solely to reduce the risk of dysplasia or cancer is indirect and is not supported by a long-term controlled trial.

Invasive Treatment

The AGA recommends endoscopic eradication therapy with radiofrequency ablation, photodynamic therapy or endoscopic mucosal resection, as follows:

Patients with confirmed high-grade dysplasia (advanced precancerous cells): Endoscopic eradication therapy is recommended.

Patients with confirmed low-grade dysplasia (beginning precancerous cells): Endoscopic eradication therapy is a treatment option and should be discussed with patients as such.

Patients with Barrett's esophagus without abnormal cells: Endoscopic eradication therapy is not recommended.

If eradication therapy is not indicated, is not available or is declined by a patient, the AGA recommends surveillance by endoscopy, as follows:

- every 3 months in patients with high-grade dysplasia
- every 6 to 12 months in patients with low-grade dysplasia
- every 3 to 5 years in patients with no dysplasia

Back to the Case

Treatment of Barrett's esophagus centers on acid suppression plus lifestyle and diet modification. Surgery is a viable treatment choice only when cancerous changes are documented. Grace was re-evaluated in the office 12 weeks after the endoscopy. By then she had lost 5 pounds by initiating dietary and lifestyle modifications, and she reported that a PPI dosed once daily was better controlling her reflux symptoms. Because her biopsy results indicated low-grade dysplasia, her healthcare providers will use surveillance endoscopy to follow her esophageal health.

Patients with persistent GERD should be referred for an initial endoscopic evaluation, and follow-up should be performed as recommended by the endoscopist. NPs and PAs must also be diligent in ensuring that patients diagnosed with Barrett's esophagus undergo surveillance endoscopies as recommended.

Continued on page 50

Sports physicals in convenient care

By Jennifer Ruel, NP

THE GOAL OF A PREPARTICIPATION physical exam (PPE) or sports physical is to promote the health and safety of student athletes. A recent survey found that 96% of U.S. residents believe it is important for young athletes to be evaluated by a qualified healthcare professional before they begin playing sports.[1] With the emergence of convenient care clinics, consumers have another option for this sought-after exam.

According to the American College of Sports Medicine, the primary objectives of PPEs are to detect conditions that may predispose to injury or may be life threatening or disabling, and to meet legal and insurance requirements. Secondary objectives are to determine general health, and to counsel on health-related issues and assess fitness.

PPE Coalition

The PPE Campaign and Coalition for Youth Sports Health and Safety was established to improve the quality and consistency of PPEs.[1,2] Because PPE requirements such as content, length and comprehensiveness vary from state to state, the coalition supports the widespread adoption and systematic use of the updated PPE tool that is available at www.ppesportsevaluation.org. This tool reflects the latest medical and scientific knowledge and includes information on ethical and legal considerations and on evaluating athletes with special needs.

Most legal challenges related to PPEs arise from adverse events after activity clearance.

The PPE doesn't substitute for regular health maintenance examinations, but it provides an opportunity to facilitate healthcare in patients with limited exposure and can set a foundation for an overall healthcare program.

Best Practice Tips

For the PPE to be an effective screening tool, a qualified healthcare professional must collect an appropriate medical history to identify diseases or processes that will affect the athlete. Classic history questions include, but are not limited to, the following issues:

- past history of asthma, seizures or other?
- unexplained syncope or near-syncope?
- head trauma or concussion?
- exertional chest pain or discomfort?
- exertional or unexplained dyspnea or fatigue with exercise?
- heart murmur?
- previous cardiac workup?
- elevated blood pressure?
- previous fractures, sprains or injuries?
- premature death (sudden, unexpected or other) or disability in a relative before age 50 due to heart disease?
- knowledge of cardiac conditions in self or family members?
- previous surgeries or hospitalizations?
- significant food, seasonal or drug allergies?
- full list of all prescription, over-the-counter and herbal medications.

During the physical examination, priority assessments include, but are not limited to, the following:

- height, weight, vital signs, visual acuity
- eyes and ears, including hearing, nose, throat
- skin
- lung sounds or wheezing
- heart murmur (check supine, standing and squatting or with Valsalva maneuver)
- abdominal exam
- inguinal hernia exam
- brachial and femoral artery checks
- joint flexibility and presence of any pain
- deep tendon reflex abnormalities
- curvature of the spine.

If concerns are identified during the PPE, the following principles should be kept in mind for determining clearance:[3]

- Does the concern place the athlete at increased risk for injury? Is another participant at risk for injury because of the problem?
- Can the athlete safely participate with treatment (e.g., medication, rehabilitation, bracing or padding)?
- Can limited participation be allowed while treatment is completed?
- If clearance is denied only for certain sports, which activities can the athlete safely participate in?

If clearance is denied, provide recommendations for correction prior to participation and specific instructions about follow-up evaluation.

Legal Concerns

Legal and ethical considerations are associated with PPE clearance. Most legal challenges arise from adverse events after activity clearance, but disqualification can lead to lawsuits as well. Studies report a disqualification rate of around 1% and a referral rate around 12%.[1,4] PPEs can help prevent injuries that can end a career or even a life. ■

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KYLE KIELINSKI

Self-Expression Through Body Art

Equipping adolescents to make smart decisions

By Catherine A. Ziegler, MSN, NP-C, FNP-BC

INCREASING NUMBERS of adolescents and young adults modify one or more body parts by piercing, tattooing, scarring or branding.[1] Some engage in these practices in an attempt to fit into a particular group or to express individuality. Others may seek body modification for aesthetic reasons. Whatever the motivation, NPs and PAs have an obligation to educate adolescents about the possible risks associated with some of these practices. This article focuses on the two most popular types of body alteration, tattooing and body piercing.

Tattooing

Tattooing requires puncturing of the skin to allow the insertion of indelible dye into the dermal layer. Tattoos are applied using machines equipped with rapidly moving needles that pierce the skin and inject a liquid dye into the upper layer of the dermis. The needles oscillate between 50 and 3,000 times per minute, depending on the amount of dye injected and the detail desired in the tattoo.[2]

The most common tattoo sites in men are the hand, arm, back, shoulder and leg.[1] Women prefer to get tattoos on the back, the leg, the abdomen or the hip and buttocks area.[1]

Approximately 10% of U.S. adolescents (ages 12 to 18) have at least one permanent tattoo.[1,3] A study of college students showed that about 13% of undergraduates had obtained their first tattoo between the ages of 12 and 18.[1,4] State laws regulating tattooing vary widely, but in general minors cannot obtain a tattoo without parental consent.

Piercing

Piercing requires the perforation of skin and underlying tissue to create a tunnel-like opening where jewelry can be inserted. Piercings are performed either by holding the skin taut with a forceps while a needle is inserted, or by using a spring-loaded piercing gun.[2] The most common sites for body piercing are the ears and belly button. Other piercing sites among both genders are the eyebrow, nose, lips, tongue, nipples and genital area.[1]

Approximately 51% of adolescents have obtained at least one body piercing by the time they enter college.[1] Research shows that most young men obtain their first piercing during their freshman or sophomore year in college, while the majority of women acquire their first piercings in high school (usually the ears).[5]

Motivation for Modification

Adolescents and young adults get tattoos and body piercings for a variety of reasons. Feelings of uniqueness, impulsiveness and peer pressure are the most common reasons adolescents cite for getting tattoos or piercings.[5]

Body embellishment is on display by numerous celebrities on TV and in the movies.[6,7] Many adolescents are eager to assume adult mannerisms and emulate their role models in an attempt to conform to a particular social clique or peer group.[8]

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The goal is to present information about body modification procedures, risks and aftercare in a way that will make sense to the adolescent. Once the patient has the information and understands it, he or she can make an informed decision about whether to pursue body modification.

One study examined the relationship between body modification and self-esteem in adolescent girls. The researchers found that patients with multiple body modifications reported the worst feelings about their bodies. This suggests that some adolescent girls may engage in body modification to gain a degree of control over their bodies and their changing appearance; they also may be inclined to copy people they admire.[9]

Some mental health experts have suggested that people with extensive body modifications engage in this behavior as a means of sensory stimulation. A study in Israel compared sensory processing in men and women with and without body alterations. It found that patients with body modifications reported underresponsiveness to sensory stimuli. These findings suggest that decreased sensation may lead certain people to sensory-seeking behaviors such as body piercing or tattooing.[9]

Whatever the motivation for body alteration, adolescents and young adults need to be aware of the health risks associated with tattooing and body piercing (see table).[10-18]

Risks of Body Modification

Most adolescents and young adults with body art report that they received their tattoos or body piercings from a recognized professional establishment, but they also acknowledge that they did not investigate whether the selected businesses were properly licensed or that they practiced under specific sterile conditions.[4] In one study, patients believed that if the establishment appeared clean, it was probably a safe place.[2] A few said they knew infection was a health risk associated with body modification, but none were aware of any other specific health risks associated with tattooing or body piercing.[2] This suggests that information about the health risks associated with body modification is not being effectively communicated to those who need it.

A Framework

Several health models can be used when providing health promotion services to adolescents. One of the most popular is the Health Belief Model, which attempts to change health behaviors by focusing on the patient's particular attitudes and beliefs. For example, if a patient knows a health condition exists and believes his or her actions will effect change in that condition, the motivation to make a change can develop.[19]

The Health Belief Model is used frequently in adolescent health promotion because it incorporates the exploration of health beliefs as well as understanding of how personal health practices related to those beliefs may affect overall health.[20] Although it is often used in association with disease or illness, the structure of this model makes it well suited to providing health information to teens. Many teenagers can use formal operational thinking and therefore are able to recognize positive versus negative outcomes of various health behaviors. This model enables teens to realize that they have the power to be in charge of their health.

Application to Practice

Use of the Health Belief Model requires clinicians to first assess adolescents' belief about their health in general. Some examples of possible questions to ask an adolescent include:

Risks Associated With Tattooing and Piercing

Increased risk for bloodborne infections such as hepatitis B and hepatitis C (when hygienic or sterile methods are not used)[12]
Localized infection as a result of poor aftercare (*Staphylococcus aureus*, group A streptococcus and *Pseudomonas* have been documented)[3,13]
Postprocedure pain and edema[14]
Prolonged bleeding[14]
Keloid formation at piercing sites[15]
Exudate, crusting or scar formation at tattoo sites[2]
Allergic reaction or sensitivity to the dye used in tattoos
Allergies or sensitivities to certain metals used for piercings[2]
Retained jewelry pieces at the piercing site[16]
Gingival recession causing tooth root exposure (piercing of tongue and lip)[17]
Chipping and cracking of teeth (lingual piercings)[18]
Mucosal abrasions, gingival trauma and alteration of salivary flow rates (oral piercings)[18]
Interference with infant attachment and latch-on for breastfeeding (nipple piercings)[19]
Injury to a newborn during vaginal delivery (genital piercings in women)[16]

• What do you think it means to be healthy?

• How do you try to stay healthy?

• What kinds of things do you associate with being unhealthy?

The next step is an assessment of the adolescent's beliefs or values about body modification. Possible questions to help gather this information might include:

• "Your earrings are very nice. Do you find piercings attractive?"

• "The pattern on your shirt looks like a tattoo. What do you think of tattoos?"

• "Have you ever thought about getting a piercing or tattoo?"

With this information and identification of the adolescent's preferred learning style, effective education can occur. Clinicians should present information about body modification, including information on particular procedures, their associated risks and appropriate aftercare. The goal is to present the information to an adolescent in a way that will make sense to him or her.

Helping Informed Decision-Making

Once the patient has the information and understands it, he or she can make an informed decision about whether to pursue body modification.

For example, if a teen still desires a tattoo or piercing after learning of the risks, the goal would be for the teen to perform appropriate aftercare to avoid complications. The teen should be aware of troublesome signs and symptoms and should receive detailed instructions about when to seek evaluation. This approach provides health promotion and guidance. It also helps adolescents realize what they perceive as important about their health, and how their behaviors can directly influence their health status.

NPs and PAs can provide this information during routine health screenings, at community health fairs or in a school setting such as during a health class. Other possible ways to reach adolescents with this information is where teens congregate, such as youth centers, malls and movie theaters. Effective dispersal of information about risks helps adolescents use formal operational thinking skills to recognize both desired and undesired possible outcomes.

Awareness Leads to Action

Healthcare providers cannot control their patients' actions. But they can make patients aware of the effects certain behaviors may have on health. Providing information about potential risks may not dissuade an adolescent from engaging in body modification, but knowledge of these dangers and their consequences can empower teens to select a body art provider more carefully and to be more meticulous about aftercare. ■

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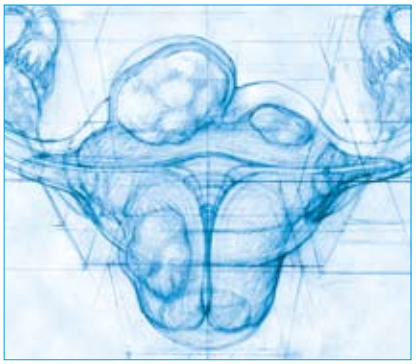
Uterine Fibroids

Clinical and surgical management

By Candy Wilson, NP



UTERINE LEIOMYOMAS (fibroids) are benign uterine tumors that develop in 20% to 30% of women older than 30.[1]

Clinical Presentation

Some women with leiomyomas do not experience symptoms. Those who are symptomatic usually complain of excessive uterine bleeding. Symptoms are typically related to the size, location and number of leiomyomas present.[2]

When collecting the medical history of a woman with excess bleeding, assess for complaints suggestive of iron deficiency anemia, dyspareunia, infertility, urinary infection, or bowel or pelvic problems. In some cases, a leiomyoma can be palpated in a bimanual pelvic examination. A negative exam result for enlarged or irregular uterine shape does not eliminate the need for a transvaginal ultrasound.

Even if transvaginal ultrasound confirms the presence of uterine fibroids, do not assume they are the sole cause of abnormal uterine bleeding. It may be necessary to conduct an endometrial biopsy to rule out other pathology. If the leiomyoma is the source of abnormal bleeding, interventions are warranted.

Medications

Pharmacotherapy is one option for symptom management. The typical first-line treatment is hormonal contraception, but combination therapy containing estrogen can increase the size of the leiomyoma. Therefore, the size of the tumor should be monitored during treatment.[2] Progestin-only methods reduce the risk for leiomyoma growth, but the incidence of breakthrough spotting is increased during the initiation of this treatment method.

Smokers older than 35 are limited to progestin-only hormonal methods of symptom management. The levonorgestrel intrauterine system (Mirena) has minimal systemic effects and provides localized endometrial control, which minimizes the amount of uterine bleeding.[2]

Gonadotropin-releasing hormone (GnRH) agonists induce amenorrhea. They can shrink the size of the leiomyoma by 35% to 65% within 3 months by producing a hypogonadotropic state. This treatment may be used prior to surgical intervention. Duration should be limited to 6 months. Provide hormonal add-back therapy to preserve bone health and reduce vasomotor symptoms produced by the pseudomenopause state.[2]

Aromatase inhibitors provide rapid control of bleeding and produce fewer side effects than GnRH agonists. Another choice is a progesterone modulator. Mifepristone is the most studied form. It acts at the level of the progesterone receptors, which are in high concentration in the affected uterus. The drug can reduce the size of the uterine tumor.[2]

Myomectomy

Myomectomy is ideal for uterine and fertility preservation and can be performed as an abdominal, laparoscopic or hysteroscopic myomectomy. Myomectomy typically results in near resolution of menorrhagia and pelvic pressure symptoms. However, it is associated with a risk of recurrence.[2]

Uterine Artery Embolization

Uterine artery embolization is typically performed by an interventional radiologist. The uterine arteries are embolized via a transcutaneous femoral artery approach that results in devascularization and involution of the leiomyoma. Recovery is quicker than with myomectomy, but reoperation rates are higher.[2]

Focused Ultrasound Surgery

MRI-guided ultrasound surgery directs high-intensity ultrasound waves at the leiomyoma. This intervention penetrates soft tissue to produce regions of protein denaturation and irreversible tumor cell damage, and it results in coagulative necrosis. This procedure requires long-term studies to determine outcomes and side effects.[2] ■

Classification of Heavy Uterine Bleeding

Classification	Regularity	Bleeding Amount	Days of Bleeding
Menorrhagia	Regular	More than 80 mL	More than 7 days
Metrorrhagia	Irregular, frequent	Variable	Variable
Menometrorrhagia	Irregular, frequent	Prolonged and excessive, more than 80 mL	Variable

CANDY WILSON is a women's health nurse practitioner who is a lieutenant colonel in the U.S. Air Force. She is stationed at Lackland Air Force Base, Texas. The views expressed in this article are those of the author and do not necessarily reflect the official policy or position of the U.S. Air Force, Department of Defense or the U.S. government.

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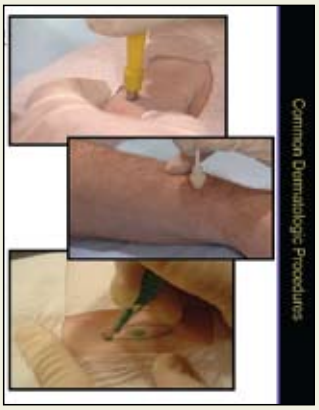

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When Heartburn Gets Serious

Continued from page 41

Early Diagnosis Essential

Early diagnosis and management of Barrett's esophagus are essential in the prevention of esophageal cancer. Multiple ablative treatment options are promising, but long-term data about effectiveness are lacking. The preferred treatment regimen is acid suppression in conjunction with lifestyle and dietary changes, sometimes followed by surgical intervention. ■

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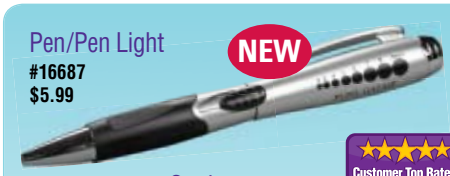

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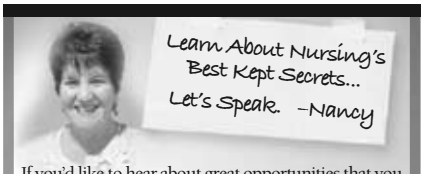

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Beverly Hills, FL 34464

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www.phpsc.com

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Advocate Medical Group, Illinois Heart & Lung is seeking two PA or APNs to join their practice. Work with 6 cardiologists and 1 PA and serve both OP and IP. Office hours are 8:30 - 5:00 and 8:00 - 5:30 when on hospital rotation. There is no call; however one Sat/Sun per month is required. Preferred candidates have cardiology experience; critical care/ICU experience is acceptable. A competitive salary and generous benefit package accompany this opportunity.

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Cathy Hall Nottoli, Advocate Medical Group, Physician Recruiter
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Contact: Jeff Curnes D.O. - jcurnes@hotmail.com
or Jeff Cater PA - jeffrey.cater@gmail.com
St. Lukes Emergency Department
1026 A Avenue NE, Cedar Rapids, IA 52402

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If you are interested in a great opportunity with an expanding organization please contact:

Jennie Brodhead, Recruiter at
jbrodhead@hardenhealthcare.com
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SOUTHWEST

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Cultural

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- **Pediatric Urology – Inpatient & possible OR (Req # 11270278)**
- **ENT Surgery – Inpatient & Clinic (Req # 11203459)**
- **Vascular Surgery – Inpatient & Clinic (Req # 11270252)**

Your credentials for all of the above openings must include an MSN or Graduate Degree from an accredited Physician Assistant Program coupled with 1 year experience in your field of specialization. CPR, ACLS or PALS, and Pediatric Nursing Certifications (as applicable) are essential. You must either be Licensed and Certified by the New Mexico Board of Medical Examiners Physician Assistant or by the New Mexico Board of Nursing.

Apply online at: **http://hospitals.unm.edu/jobs/**

and refer to the corresponding **REQ #'s** or email:

Tepadilla@salud.unm.edu

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EOE

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EOE

MOUNTAIN

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Physician Assistant • Boise, Idaho

St. Lukes Health System has several great opportunities for Physician Assistants or Nurse Practitioner to be responsible for providing quality health care in the outpatient setting under the supervision of a designated physician.

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• Competitive Salary • Comprehensive Benefit Package • Relocation Assistance

Minimum Requirements - Graduation from a school with current licensure from Idaho to practice as an advanced practice nurse/physician assistant with appropriate specialty.

To apply, please visit St. Luke's website at www.stlukesonline.org or contact Bill Swigart at swigartb@slhs.org.

St Luke's

Advanced Family Nurse Practitioner

The Winslow Indian Health Care Center (WIHCC) in northern Arizona is looking for an Advanced Family Nurse Practitioner to provide comprehensive ambulatory care to Navajo and other Native American patients. Our FNPs work with 16 physicians at our health center in Winslow and at two field clinics on the Navajo Reservation. WIHCC is approved for National Health Service Corps scholarship payback and loan repayment, and offers an awesome mix of professional, cultural, and recreational opportunities. Located just 7 miles from the breathtaking beauty of Navajoland and its people, and 50 miles from Flagstaff. Attractive salary and benefits; team-oriented, supportive work environment.

Send CV to Frank Armao, MD
Clinical Director at:
frank.armao@wihcc.org
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PeaceHealth Medical Group is seeking experienced, board certified **Nurse Practitioners** to join our group.

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Neurohospitalist NP and Family Medicine
Urgent Care NP

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PeaceHealth
Sacred Heart Medical Center
PeaceHealth Medical Group

Please visit our website at **www.peacehealth.org**. Contact Denise Etchison at **541-222-2529** or e-mail at **DEtchison@peacehealth.org** for more information or to apply.

Institute For Multicultural Counseling & Education Service (I.M.C.E.S.) has an immediate opening for **Registered Nurse** with psychiatric background and experience and/or a Nurse Practitioner. I.M.C.E.S. is an outpatient community clinic.
Qualifications: 1. Bachelor Degree (BSN) minimum; MSN, DNP, or PhD 2. Minimum 2 years experience 3. Positive attitude, flexible 4. Excellent writing and verbal communication skills 5. Fluency with Microsoft Office 6. Experience with Medi-Cal and Department of Mental Health documentation
Compensation: Excellent salary and benefits commensurate with experience
Contact: Nicole Shellcroft at: **nicoleshellcroft@imces.org**

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NATIONAL

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Students, you can earn an income and full benefits without having to work during your last year of school, plus have a guaranteed job upon graduation that will fully utilize your training and provide valuable experience! To learn more about a BOP sponsorship through the US Public Health Service Commissioned Corps Externship Program (SRCOSTEP), refer to **www.usphs.gov**.

Contact the BOP at
BOP-HSD/Recruitment@bop.gov
or **1-800-800-2676**

AA/EEOE/DFW
Age restrictions may apply

NPs & PAs Have Prescribing Power

Considering that about 3.9 billion prescriptions were written in the United States in 2009, NPs and PAs pull their prescribing weight. Given that there are an estimated 773,800 active physicians, NPs and PAs together write roughly 23% of all prescriptions while accounting for 21% of prescribers.

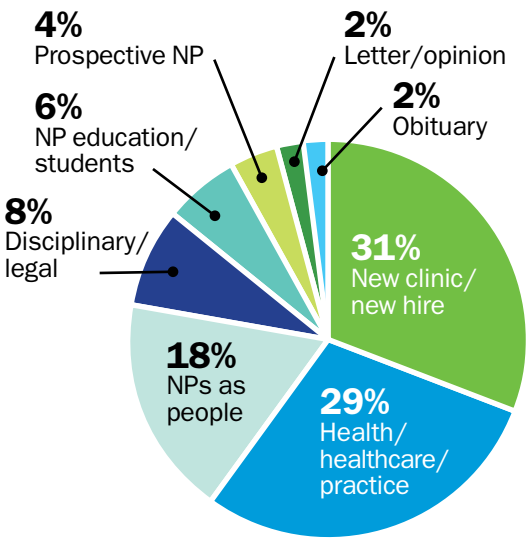
Bridging the NP and PA Knowledge Gap

'The two professions suffer from huge holes in understanding what, where, why and how they each exist. It's in the eye of the beholder how much the differences matter.'

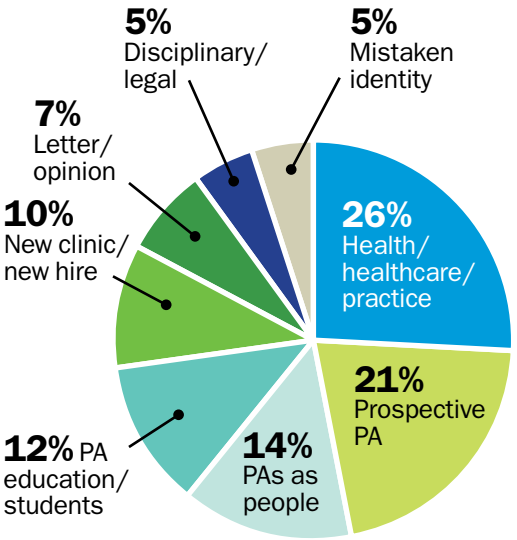
—Roderick S. Hooker, PhD, MBA, PA, in the September 2010 issue of ADVANCE.

NPs and PAs in the News

NP News Articles



PA News Articles



NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS alike are keenly interested in increasing awareness and recognition of their professions among lawmakers, patients and the public. NPs have a history of strong grassroots advocacy about the NP role, and the level of satisfaction among them about NP awareness seems to be high. PAs, on the other hand, have a generally less-developed self-advocacy history and by and large have looked to their professional organizations (particularly the AAPA) to develop a concerted PR campaign strategy. And a significant subset of PAs expresses dissatisfaction with the level of understanding of what a PA is. (In fact, AAPA interim CEO/EVP James Potter said at the 2011 IMPACT conference, "We have been at times our own worst enemy about self-promoting and promoting the profession.")

Nevertheless, across the United States (and beyond) each day, the news media cover individual NPs and PAs and each profession's role in healthcare. With few exceptions, this coverage is accurate and equitable. To get an idea of how (and how often) NPs and PAs are mentioned in the mainstream media, set up a Google Alert for "nurse practitioner" and another for "physician assistant." Each day, you'll get an email with links to the previous day's news stories mentioning either term. Go to google.com/alerts to get started.

We analyzed (albeit informally) the results of the Google Alerts updates sent to us for "nurse practitioner" and "physician assistant" for the 3-day period of Friday, June 10, through Sunday, June 12. The PA Google Alert returned 16 news results on Friday, 15 on Saturday and 11 on Sunday; the NP alert returned 20, 15 and 16 results on the same respective days. Sources ranged in reach from major (e.g., *USA Today,* the *San Francisco Chronicle, ADVANCE for NPs & PAs*) to miniscule (e.g., *The Telegram* of Herkimer, N.Y., *The Dodge City Daily Globe,* the Johnstown, Pa., *Tribune-Democrat*). Interestingly, in addition to domestic articles, the NP alert returned three news stories from Canadian media and one from England's *The Guardian*; the PA alert returned an article from Ghana and one from the *Tehran Times* in Iran.

The charts here show how many articles appeared over the 3 days and what those articles were about. For the sake of comparison, we grouped them into broad categories. For example, articles on health and illnesses, healthcare and/or clinical practice that quoted, reported on or otherwise included NPs or PAs were classified as "health/healthcare/practice." We grouped articles including PAs or NPs, but not in a professional capacity (e.g., "man on the street" interviews), as PAs or NPs "as people." And a word about the two articles in the "mistaken identity" category among PA news: One was about a high school student who worked summers as a "physician's assistant" — obviously not a PA — while the other was about a man who was "neither a licensed physician nor a physician's assistant" pleading guilty to impersonating a healthcare provider. ■

— Michael Gerchufsky

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