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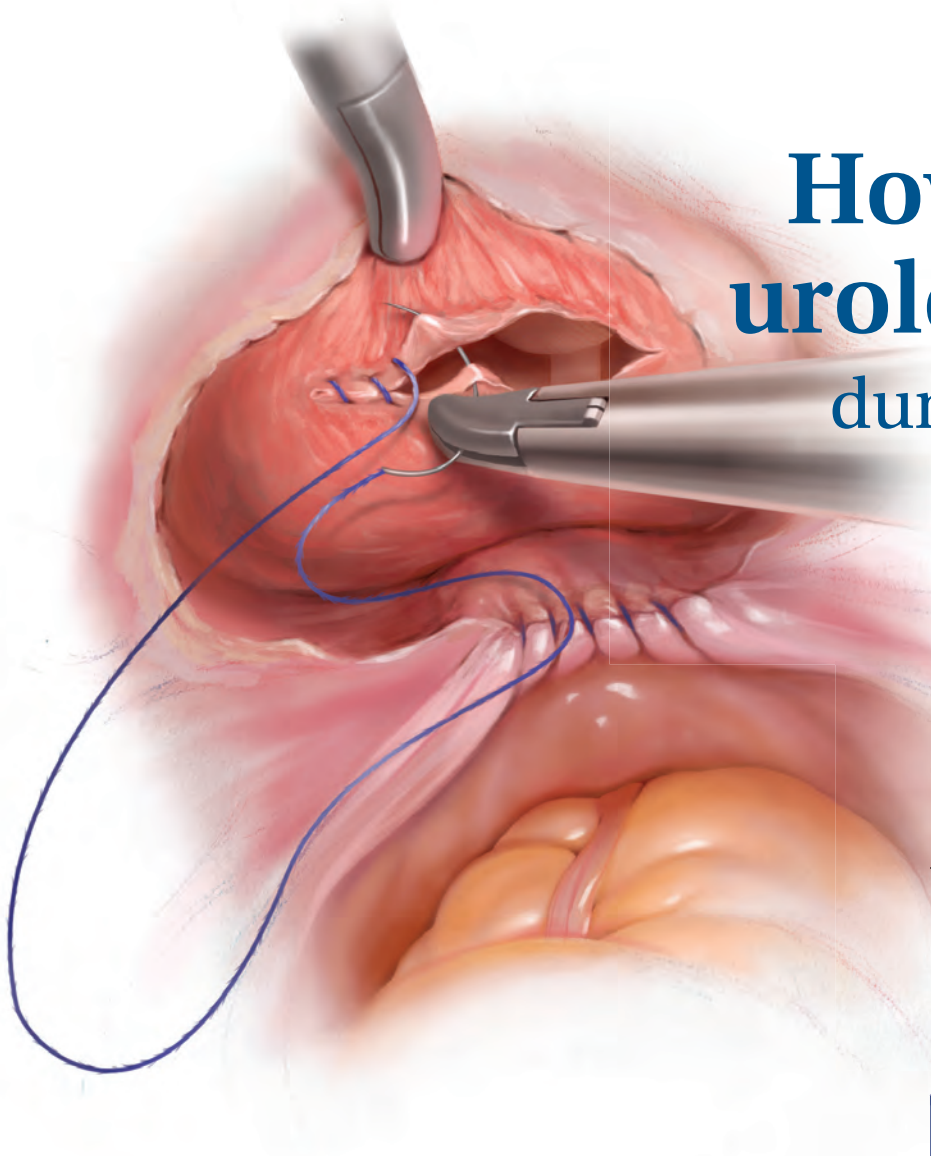
OBG MANAGEMENT

Start offering antenatal corticosteroids to women delivering between 34 0/7 and 36 6/7 weeks

Robert L. Barbieri, MD

Dr. Steven Chavoustie on bacterial vaginosis treatment, at obgmanagement.com

Will newly available data change your approach to periviable infants?



How to repair urologic injury during gyn surgery

Elizabeth R. Mueller, MD, MSME

Cervical disease updates

Mark H. Einstein, MD, MS

LARCs and adolescents: Management pearls

HIGHLIGHTS FROM THE 2017 SOCIETY OF GYNECOLOGIC SURGEONS SCIENTIFIC MEETING

See page SS1

References: 1. The North American Menopause Society. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause.* 2013;20(9):888-902. **2**. Wysocki S, Kingsberg S, Krychman M. Management of vaginal atrophy: implications from the REVIVE survey. *Clin Med Insights Reprod Health.* 2014;8:23-30. **3.** Mac Bride MB, Rhodes DJ, Shuster LT. Vulvovaginal atrophy. *Mayo Clin Proc.* 2010;85(1):87-94. **4**. Portman DJ, Gass ML; Vulvovaginal Atrophy Terminology Consensus Conference Panel. Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and the North American Menopause Society. *Menopause.* 2014;21(10):1063-1068. **5**. Kingsberg SA, Wysocki S, Magnus L, Krychman ML. Vulvar and vaginal atrophy in postmenopausal women: findings from the REVIVE (REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs) survey. *J Sex Med.* 2013;10(7):1790-1799.

WHEN SIMPLE THINGS BECOME VERY VERY AWFUL

It may be vulvar and vaginal atrophy (VVA), a chronic and progressive medical condition that affects many menopausal women.[1-3]

VVA, a component of genitourinary syndrome of menopause (GSM), is a common condition in menopausal women caused by a decrease in estrogen.[1-4] Approximately 1 in 2 menopausal women in the United States experience VVA symptoms.[2,3] The most common physical symptoms of VVA include dyspareunia (painful sex), vaginal dryness, burning, and irritation or soreness. Urinary symptoms such as dysuria (painful urination) and recurrent urinary tract infections are also associated with VVA.[1-4] These symptoms may negatively impact a woman's sense of self, relationships, and enjoyment of life.[2,5]

Unlike night sweats and hot flashes, VVA may not resolve without treatment,[1] putting many women in a prickly situation.

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*Source: Kantar Media, Medical Surgical Study December 2016, Obstetrics/Gynecology Combined Office & Hospital Readers. Accounting for statistical significance.

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1 Palacio et al.: Meta-analysis of studies on biochemical marker tests for the diagnosis of premature rupture of membranes: comparison of performance indexes. BMC Pregnancy and Childbirth 2014 14:183

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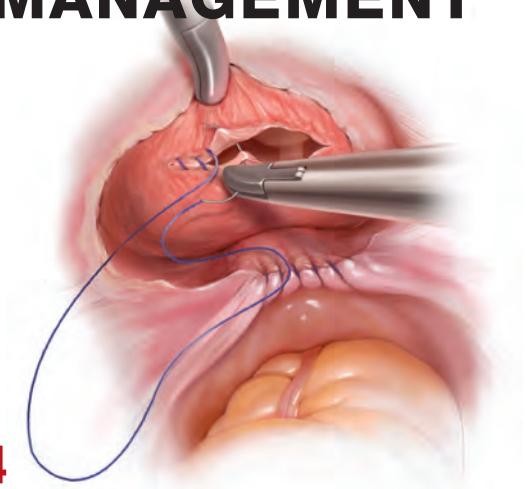

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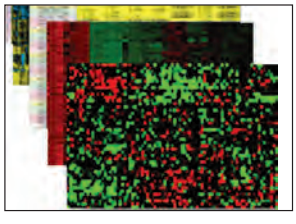
Mentoring
SS8



Cervical disease
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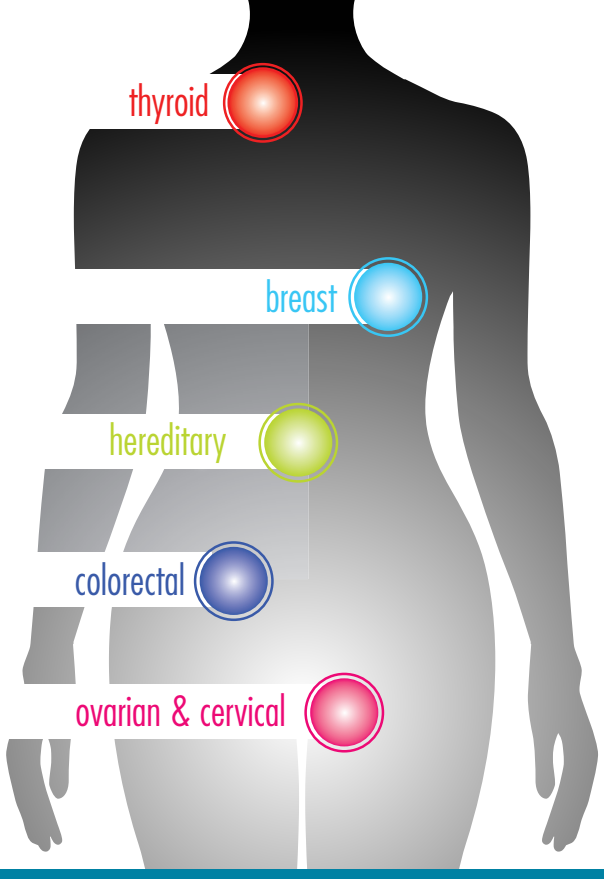

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WEB EXCLUSIVES

GYN Imaging Quiz: Multiple miscarriages in 29-year-old woman

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Medical Verdicts: Fistula developed after delivery—$50M award

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Approaches to isolating the uterine artery at its origin from the internal iliac artery

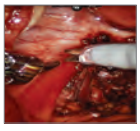
MICHELLE LOUIE, MD, AND ERIN CAREY, MD, MSCR

Brought to you by the Society of Gynecologic Surgeons

See page 20 for QR code

Webcast: Providing LARC methods of contraception to adolescents

RONALD T. BURKMAN, MD



Robotic-assisted laparoscopic excision of a rectovaginal endometriotic nodule

OBIANUJU SANDRA MADUEKE-LAVEAUX, MD, MPH; KHARA M. SIMPSON, MD; AND ARNOLD P. ADVINCULA, MD

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Bacterial vaginosis: Meeting patients' needs with effective diagnosis and treatment

STEVEN CHAVOUSTIE, MD

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Start offering antenatal corticosteroids to women delivering between 34 0/7 and 36 6/7 weeks of gestation to improve newborn outcomes

Consider 3 options for your practice. Offer antenatal corticosteroids to: 1) all women at high risk for late preterm delivery, or 2) women scheduled for a cesarean delivery for an obstetric indication between 34 0/7 and 36 6/7 weeks of gestation, or 3) women at high risk for late preterm delivery whose newborns are most likely to benefit from treatment, those women at 34 0/7 to 35 6/7 weeks of gestation.

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Antenatal corticosteroid treatment prior to preterm birth is the most important pharmacologic intervention available to obstetricians to improve newborn health. Antenatal corticosteroids reduce preterm newborn morbidity and mortality.[1] The American College of Obstetricians and Gynecologists (ACOG) recently has summarized updated recommendations for the use of antenatal steroid treatment.[2]

ACOG guidance includes:

- "A single course of corticosteroids is recommended for pregnant women between 24 0/7 weeks and 33 6/7 weeks of gestation, including for those with ruptured membranes and multiple gestations." This guidance is supported by many high-quality trials and meta-analyses.[1]
- A single course of corticosteroids "may be considered for pregnant women starting at 23 0/7 weeks of gestation who are at risk of preterm delivery within 7 days."
- "A single repeat course of antenatal corticosteroids should be considered in women who are less than 34 0/7 weeks of gestation who have an imminent risk of preterm delivery within the next 7 days and whose prior course of antenatal corticosteroids was administered more than 14 days previously." A repeat course of corticosteroids could be considered as early as 7 days from the prior dose.
- **No more than 2 courses of antenatal steroids should be administered.**

An important new ACOG recommendation is:

- **"A single course of betamethasone is recommended for pregnant women between 34 0/7 and 36 6/7 weeks of gestation at risk**

CONTINUED ON PAGE 12

Instant Poll

For mothers at 34 3/7 weeks of gestation who are at high risk for preterm delivery within 1 week, will you offer a single course of antenatal glucocorticoids in your practice?

Tell us at **rbarbieri@frontlinemedcom.com** Please include your name and city and state.

Have you considered NEXPLANON for all appropriate patients?

Laura, 19
College Student

Maria, 27
Young Professional

Jen, 34
Mom

Models

When getting pregnant isn't part of her 3-year plan, talk to her about NEXPLANON.

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

NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

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

Complications of insertion and removal

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

NEXPLANON and pregnancy

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

Educate her about the risk of serious vascular events

- The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events [stroke and myocardial infarction (MI)] or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis (DVT), retinal vein thrombosis, and pulmonary embolism). Women with risk factors known to increase the risk of these events should be carefully assessed. Postmarketing reports in women using the nonradiopaque etonogestrel implant have included pulmonary emboli (some fatal), DVT, MI, and stroke. NEXPLANON should be removed if thrombosis occurs.
- Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum.

NEXPLANON is a LARC* placed in the arm

*LARC=long-acting reversible contraceptive.

Nexplanon®
(etonogestrel implant) 68mg
Radiopaque

[a]Less than 1 pregnancy per 100 women who used NEXPLANON for 1 year

In a clinical trial, mean insertion time† was 27.9 ± 29.3 seconds

†From the removal of the protective cap of the applicator until retraction of the needle from the arm.

All health care providers performing insertions and/or removals of NEXPLANON should receive instructions and training prior to inserting or removing the implant.

SELECTED SAFETY INFORMATION (*continued*)

- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removing the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

Counsel her about changes in bleeding patterns

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

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

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

Before prescribing NEXPLANON, please read the adjacent Brief Summary of the Prescribing Information.

MERCK

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

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

INDICATION AND USAGE

NEXPLANON is indicated for use by women for the prevention of pregnancy.

DOSAGE AND ADMINISTRATION

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

CONTRAINDICATIONS

NEXPLANON should not be used in women who have

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

WARNINGS AND PRECAUTIONS

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

1. **Complications of Insertion and Removal**

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

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

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

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

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

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

2. **Changes in Menstrual Bleeding Patterns**

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

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

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

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

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

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

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

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

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

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

3. **Ectopic Pregnancies**

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

4. **Thrombotic and Other Vascular Events**

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

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

5. **Ovarian Cysts**

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

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

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

7. **Liver Disease**

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

8. **Weight Gain**

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

9. **Elevated Blood Pressure**

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

10. **Gallbladder Disease**

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

11. **Carbohydrate and Lipid Metabolic Effects**

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

12. **Depressed Mood**

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

13. **Return to Ovulation**

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

Nexplanon®
(etonogestrel implant) 68mg

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

Changes in Contraceptive Effectiveness Associated With Coadministration of Other Products

Drugs or herbal products that induce enzymes, including CYP3A4, that metabolize progestins may decrease the plasma concentrations of progestins, and may decrease the effectiveness of NEXPLANON. In women on long-term treatment with hepatic enzyme inducing drugs, it is recommended to remove the implant and to advise a contraceptive method that is unaffected by the interacting drug.

Some of these drugs or herbal products that induce enzymes, including CYP3A4, include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

HIV Antiretrovirals

Significant changes (increase or decrease) in the plasma levels of progestin have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors. Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

Increase in Plasma Concentrations of Etonogestrel Associated with Coadministered Drugs

CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma concentrations of etonogestrel.

Changes in Plasma Concentrations of Coadministered Drugs

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

USE IN SPECIFIC POPULATIONS

1. **Pregnancy**
NEXPLANON is not indicated for use during pregnancy *[see Contraindications]*.
Teratology studies have been performed in rats and rabbits using oral administration up to 390 and 790 times the human etonogestrel dose (based upon body surface), respectively, and revealed no evidence of fetal harm due to etonogestrel exposure. Studies have revealed no increased risk of birth defects in women who have used combination oral contraceptives before pregnancy or during early pregnancy. There is no evidence that the risk associated with etonogestrel is different from that of combination oral contraceptives. NEXPLANON should be removed if maintaining a pregnancy.
2. **Nursing Mothers**
Based on limited clinical data, NEXPLANON may be used during breastfeeding after the fourth postpartum week. Use of NEXPLANON before the fourth postpartum week has not been studied. Small amounts of etonogestrel are excreted in breast milk. During the first months after insertion of NEXPLANON, when maternal blood levels of etonogestrel are highest, about 100 ng of etonogestrel may be ingested by the child per day based on an average daily milk ingestion of 658 mL. Based on daily milk ingestion of 150 mL/kg, the mean daily infant etonogestrel dose one month after insertion of the non-radiopaque etonogestrel implant (IMPLANON) is about 2.2% of the weight-adjusted maternal daily dose, or about 0.2% of the estimated absolute maternal daily dose. The health of breastfed infants whose mothers began using the non-radiopaque etonogestrel implant during the fourth to eighth week postpartum (n=38) was evaluated in a comparative study with infants of mothers using a non-hormonal IUD (n=33). They were breastfed for a mean duration of 14 months and followed up to 36 months of age. No significant effects and no differences between the groups were observed on the physical and psychomotor development of these infants. No differences between groups in the production or quality of breast milk were detected. Healthcare providers should discuss both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients.
3. **Pediatric Use**
Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON are expected to be the same for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.
4. **Geriatric Use**
This product has not been studied in women over 65 years of age and is not indicated in this population.
5. **Hepatic Impairment**
No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated *[see Contraindications]*.
6. **Renal Impairment**
No studies were conducted to evaluate the effect of renal disease on the disposition of NEXPLANON.
7. **Overweight Women**
The effectiveness of the etonogestrel implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. It is therefore possible that NEXPLANON may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations such as concomitant use of hepatic enzyme inducers.

OVERDOSAGE

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

NONCLINICAL TOXICOLOGY

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

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

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

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Revised: 03/2016
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WOMN-1185102-0000 08/16

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TABLE Newborn and maternal outcomes in the Antenatal Late Preterm Steroids trial[3]

Outcome	Treatment		Relative risk (95% confidence interval)	*P* value
	Betamethasone, % (n = 1,429)	Placebo, % (n = 1,402)		
Need for resuscitation at birth	14.5	18.7	0.78 (0.66–0.92)	.003
Severe respiratory complications	8.1	12.1	0.67 (0.53–0.84)	<.001
Transient tachypnea of the newborn	5.5	6.4	0.68 (0.53–0.87)	.002
Surfactant use	1.8	3.1	0.59 (0.37–0.96)	.03
Bronchopulmonary dysplasia	0.1	0.6	0.22 (0.02–0.92)	.04
Neonatal hypoglycemia	24.0	15.0	1.60 (1.37–1.87)	<.001
Neonatal sepsis	0.6	0.8	0.80 (0.33–1.93)	.62
Chorioamnionitis	1.4	2.3	0.61 (0.35–1.07)	.08
Postpartum endometritis	1.1	1.1	0.98 (0.49–1.95)	.96

of preterm birth within 7 days, and who have not received a previous course of antenatal corticosteroids."

This recommendation is based, in part, on a high-quality, randomized trial including 2,831 women at high risk for preterm birth between 34 0/7 and 36 6/7 weeks of gestation who were randomly assigned to receive a course of betamethasone or placebo. The newborn and maternal outcomes observed in this study are summarized in the **TABLE**.[3]

A few points relevant to the Antenatal Late Preterm Steroids study bear emphasizing. The women enrolled in this trial were at high risk for preterm delivery based on preterm labor with a cervical dilation of ≥3 cm or 75% effacement, spontaneous rupture of the membranes, or a planned late preterm delivery by cesarean or induction. No tocolytics were administered to women in this study, and approximately 40% of the women delivered within 24 hours of entry into the trial and only received 1 dose of corticosteroid or placebo.

Women with multiple gestations, pregestational diabetes, or a prior course of corticosteroids were not included in the trial; therefore, this study cannot guide our clinical practice for these subgroups of women. Of note, betamethasone should not be administered to women in the late preterm who have chorioamnionitis.

The investigators calculated that 35 women would need to be treated to prevent one case of the primary outcome: a composite score of the use of respiratory support. Consequently, 34 fetuses who do not benefit from treatment are exposed *in utero* to betamethasone. Long-term follow-up of infants born to mothers participating in this study is currently underway.

A recent meta-analysis of 3 trials including 3,200 women at high risk for preterm delivery at 34 0/7 to 36 6/7 weeks of gestation reported that the corticosteroid administration reduced newborn risk for transient tachypnea of the newborn (relative risk [RR], 0.72; 95% confidence interval [CI], 0.56–0.92), severe respiratory distress syndrome (RR, 0.60; 95% CI, 0.33–0.94), and use of surfactant (RR, 0.61; 95% CI, 0.38–0.99).[4]

The recommendation to offer a single course of betamethasone for pregnant women between 34 0/7 and 36 6/7 weeks of gestation at risk for preterm birth has not been embraced enthusiastically by all obstetricians. Many experts have emphasized that the **known risks** of late preterm betamethasone, including neonatal hypoglycemia and the **unknown long-term risks** of treatment, including suboptimal neurodevelopmental, cardiovascular, and metabolic outcomes should dampen enthusiasm for embracing the new ACOG recommendation.[5] Experts also emphasize that late preterm newborns are less likely to benefit from antenatal corticosteroid treatment than babies born at less than 34 weeks. Hence, many late preterm newborns will be exposed to a potentially harmful intervention and have only a small chance of benefiting from the treatment.[6]

Many neonatologists believe that for the newborn, the benefits of maternal corticosteroid treatment outweigh the risks.[7–9] In a 30-year follow-up of 534 newborns participating in antenatal corticosteroid trials, treatment had no effect on body size, blood lipids, blood

pressure, plasma cortisol, prevalence of diabetes, lung function, history of cardiovascular disease, educational attainment, or socioeconomic status. Corticosteroid treatment was associated with increased insulin secretion in response to a glucose load.[10] In this study, the mothers received treatment at a median of 33 weeks of gestation and births occurred at a median of 35 weeks. Hence this study is relevant to the issue of late preterm corticosteroid treatment.

Balancing risks and benefits is complex. Balancing immediate benefits against long-term risks is most challenging. Regarding antenatal steroid use there are many unknowns, including optimal dose, drug formulation, and timing from treatment to delivery. In addition we need more high-quality data delineating the long-term effects of antenatal corticosteroids on childhood and adult health.

Consider these 3 options for your practice

As noted, the Antenatal Late Preterm Steroids trial investigators are pursuing long-term follow-up of the children born after maternal treatment with antenatal glucocorticoids. Both ACOG and the Society for Maternal-Fetal Medicine (SMFM)[11] recommend administration of antenatal glucocorticoids to women at high risk for late preterm delivery. However, since some experts are concerned that a great number of babies born late preterm will have been exposed to glucocorticoids, whose long-term risks are not well known, with only a few babies having a modest short-term benefit, 3 options could be considered for your clinical practice.

Option 1

Follow the ACOG and SMFM suggestion that all women with a high risk of late preterm birth be offered antenatal corticosteroids. Counsel the mother and family about the potential risks and benefits and involve them in the decision.

Two alternative options are to limit antenatal corticosteroid treatment to subgroups of late preterm babies most likely to benefit from treatment, those born by cesarean delivery and those born at the earliest gestational ages.

Option 2

Limit the use of antenatal corticosteroids in the late preterm to women who are scheduled for a cesarean delivery for an obstetric indication between 34 0/7 weeks and 36 6/7 weeks of gestation. This approach greatly reduces the number of babies born in the late preterm that will be exposed to antenatal corticosteroids and focuses the treatment on a subset of babies who are

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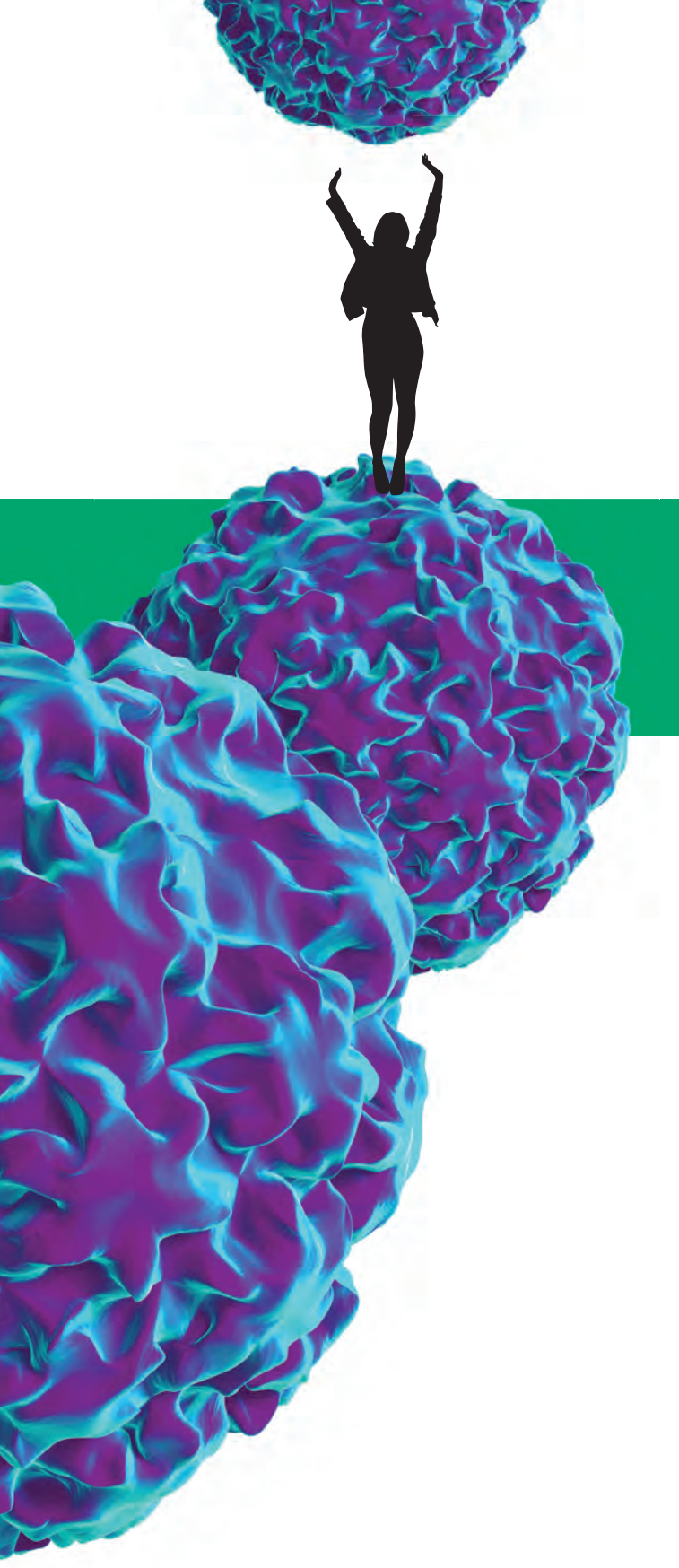

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References: 1. Leyden WA, Manos MM, Geiger AM, et al. Cervical cancer in women with comprehensive health care access: attributable factors in the screening process. *J Natl Cancer Inst.* 2005;97(9):675-683. **2.** Andrae B, Kemetli L, Sparén P, et al. Screening-preventable cervical cancer risks: evidence from a nationwide audit in Sweden. *J Natl Cancer Inst.* 2008;100(9):622-629. **3.** cobas® HPV Test Package Insert. **4.** ACOG Practice Bulletin 157; January 2016. **5.** Huh WK, Ault KA, Chelmow D, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. *Gynecol Oncol.* 2015;136(2):178-182. doi:10.1016/j.ygyno.2014.12.022.

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KNOW THE RISK

New guidelines redefine the role of HPV testing in cervical cancer prevention

Robert B. Gore, MD

In January 2016, the American College of Obstetricians and Gynecologists (ACOG) released a practice bulletin and provided guidance supporting the use of an FDA-approved human papillomavirus (HPV) test for first-line cervical cancer screening (primary HPV screening) in women age 25 and older as an alternative to current cytology-based screening methods.[1]

ACOG's guidance culminated more than 50 years of continuing progress led by the introduction of the Pap test and the attendant steady decline in the incidence of cervical cancer. More recently, increased understanding of the role of HPV in cervical cancer development has shed new light on how HPV testing can be integrated into cervical cancer screening, with the goal of identifying patients at risk earlier while reducing overtesting and unnecessary interventions.[2]

The Addressing the Need for Advanced HPV Diagnostics (ATHENA) trial, a three-year prospective study of more than 47,000 women, concluded that HPV primary screening in women 25 years and older is as effective as a hybrid screening strategy that uses cytology for the 25-to-29 age group and co-testing for women 30 years and older.[3] Based on ATHENA and corroborating studies from around the world, the FDA approved a high-risk HPV test (cobas HPV Test, Roche Diagnostics) for use in primary HPV screening in 2014. The following year, interim guidance was published by a panel of eight experts representing the Society of Gynecologic Oncology (SGO), the American Society for Colposcopy and Cervical Pathology (ASCCP) and five other professional associations. The guidance supports primary HPV screening, using an FDA-approved test, in women 25 years and older as an alternative to current U.S. cytology-based cervical cancer screening.[4]

HPV primary screening and patient care

Prompted by the joint interim guidance and my own clinical experience, our practice began using HPV primary screening for patients 25 years and older in 2015. For patients who test positive for genotypes 16 and 18, which account for 70% of cervical cancer,[2] we proceed directly to colposcopy. Patients who test positive for other high-risk genotypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) receive a Pap test. A positive Pap test is followed by colposcopy.

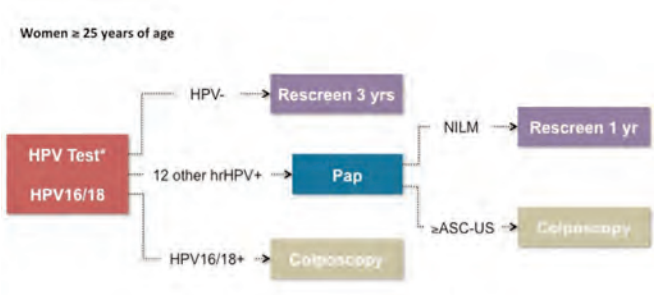

Figure 1: "The use of HPV 16/18 genotyping and reflex cytology for women positive for the 12 other hrHPV genotypes achieves a reasonable balance of disease detection with the number of screening tests and colposcopies required to achieve that detection."[4]

As a clinician, my goal is to identify patients at risk early enough to slow or halt disease progression. In the case of younger patients, early detection may also mean less invasive interventions that can spare the patient from future conception problems. The sharp rise in the incidence of invasive cervical cancer between the ages of 25 and 34, as shown by data from the National Cancer Institute's SEER Tumor Registry,[5] prompted me to reassess the previous co-testing algorithm—cytology only for 21- to 29-year-old women and co-testing in women over 30 years of age[2]—and to consider the added value of primary HPV screening, especially in the 25-to-29 age group.

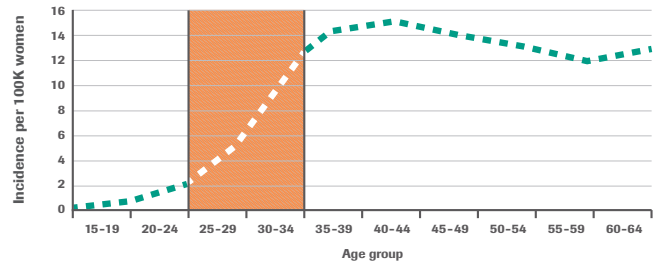

Figure 2: Age-specific incidence of cervical cancer in the U.S.[5]

Sensitivity is key to identifying more women at risk. The ATHENA trial demonstrated that over three years, primary HPV screening has the highest sensitivity for the detection of CIN3 in the 25-to-29 age group, compared to cytology alone.[3] For women concerned about conception in the future, early detection is especially important as it may help avoid more invasive interventions such as the loop electrosurgical excision procedure (LEEP). Topical trichloroacetic acid is another efficacious, simple and noninvasive option.[6]

HPV testing in everyday practice

Implementing primary HPV screening is something our practice had considered for several years, as I had personal knowledge of it from my European colleagues. The availability of an FDA-approved hrHPV test indicated for primary screening made it possible, and the support of professional societies reinforced our decision. It should be noted that both ACOG and the joint SGO/ASCCP interim guidance specify the use of a test that is FDA-approved for primary HPV screening , not just co-testing and ASC-US reflex.

Any discussion of cervical cancer screening and prevention should not leave unmentioned the fact that 50% of cervical cancer is found in women who have had either no screening or inadequate screening in the past 10 years. This is a public health issue that cannot be neglected and one that stands in the way of eradicating cervical cancer.

Robert B. Gore, MD, is a board-certified obstetrician and gynecologist who has practiced medicine in the Denver metro area for over three decades.

To view references and the full article text, please visit https://www.hpv16and18.com/hcp/HPV-primary-screening.html

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certain to be born preterm and most likely to benefit.

Option 3

Limit the use of antenatal corticosteroids to women at high risk for preterm birth whose newborns are most likely to benefit from treatment—women at 34 0/7 to 35 6/7 weeks of gestation. Neonates born in the 34th or 35th week of gestation are at higher risk for morbidity than those born in the 36th week of gestation and are likely to derive the greatest benefit from antenatal corticosteroid treatment.[3,12]

My advice

Yogi Berra advised, "It is tough to make predictions, especially about the future." Although ACOG and SMFM have recommended administration of glucocorticoids to women at high risk for late preterm birth, many experts caution that until the long-term effects of antenatal corticosteroids are better characterized we should limit the use of corticosteroids in the late preterm.[5,6,13] My prediction is that long-term follow-up studies will not document significant adverse effects of one course of late preterm antenatal glucocorticoid treatment on children. My advice is to start offering antenatal corticosteroids to some women at high risk for late preterm delivery.

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Dr. Barbieri reports no financial relationships relevant to this article.

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~94%

High patient satisfaction

~94% of women reported that they were satisfied with PARAGARD when considering their bleeding and cramping at 3 and 6 months postplacement[3*]

INDICATION

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

IMPORTANT SAFETY INFORMATION

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

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

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

†PARAGARD must be removed by a healthcare professional.[1]

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BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
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INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

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

WARNINGS

1. Intrauterine Pregnancy

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

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

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

2. Ectopic Pregnancy

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

3. Pelvic Infection

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

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

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

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

4. Immunocompromise

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

5. Embedment

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

6. Perforation

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

7. Expulsion

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

8. Wilson's Disease

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

PRECAUTIONS

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

1. Information for patients

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

2. Insertion precautions, continuing care, and removal.

3. Vaginal bleeding

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

4. Vasovagal reactions, including fainting

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

5. Expulsion following placement after a birth or abortion

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

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

6. Magnetic resonance imaging (MRI)

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

7. Medical diathermy

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

8. Pregnancy

ParaGard® is contraindicated during pregnancy.

9. Nursing mothers

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

10. Pediatric use

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

ADVERSE REACTIONS

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

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

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

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

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

PAR-41071 10/16

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"SHOULD THE LENGTH OF TREATMENT FOR TRICHOMONIASIS IN WOMEN BE RECONSIDERED?"
PATRICK DUFF, MD (MARCH 2017)

Longer metronidazole treatment is better than 1-day dose for women with trichomoniasis

From 37 years of experience as a Women's Healthcare Nurse Practitioner, I have found it is always better to prescribe metronidazole 500 mg bid for 7 days rather than 1-day treatment for women. I will prescribe 1-day treatment for men. I have been treating men and women using these regimens in a sexually transmitted diseases clinic for nearly 5 years. Colleagues have used the 1-time dose for women and it rarely works as well as the 7-day dose. However, I am always concerned about men taking the medication for 7 days, because often they are not symptomatic and they may stop taking their medication early if given the 1-week regimen, so I usually prescribe the 1-day dose for men. I wish more prescribers would offer treatment for the male partners, as they may not be symptomatic or may not want to spend the money to visit a provider. In my state, it is legal to prescribe for the partner without seeing him, and the Centers for Disease Control and Prevention suggests doing so. We encourage the men to come in but if the partner says he is unlikely to, we will treat without seeing him.

Carol Glascock, WHNP-BC
Columbia, Missouri

» Dr. Duff responds

I appreciate Ms. Glascock's thoughtful comments. I am pleased that her years of clinical experience support the main conclusion reached by Howe and Kissinger that, in general, patients do better when they receive multidose therapy for trichomonas infection.[1] I agree with Ms. Glascock's observation that single-dose therapy still has a role in situations in which patients may not be adherent with multidose therapy, such as the asymptomatic male partner of an infected woman. I also agree wholeheartedly that women will have less likelihood of recurrence when their partner receives adequate antibiotic treatment. I concur that, in states where this practice is legally permissible, we should be willing to offer antibiotic therapy to the partner of our female patient.

Reference

1. Howe K, Kissinger PJ. Single-dose compared with multidose metronidazole for the treatment of trichomoniasis in women: a meta-analysis. Sex Transm Dis. 2017;44(1):29–24.

"IT IS TIME FOR HPV VACCINATION TO BE CONSIDERED PART OF ROUTINE PREVENTIVE HEALTH CARE"
BARBARA S. LEVY, MD (MARCH 2017)

Nurse practitioner urges advocacy for HPV vaccination

I could not agree more with Dr. Levy's view on human papillomavirus (HPV) vaccination. I am a Doctor of Nursing Practice student and improving HPV vaccination rates in adolescents is the focus of my research project for the next year. Based on the current literature, the most significant factors for increasing vaccination rates are patient education and provider recommendation. As the article mentions, "special" attention should not be given to the HPV vaccine, because this raises questions with families presenting to the office for routine well-child care. There have been many missed opportunities for vaccination of our young people over the past 10 years. As a result, we will continue to see increases in HPV-related cancers. We have a vaccine that has the potential to significantly decrease these cases, but it is underutilized. The recent recommendation of a 2-dose series (before the age of 15) should make completing the series easier. I urge all providers to be better advocates for their patients and make appropriate changes to their current practice in order to reduce the significant burden this disease carries.

Tiffany Edwards, MSN, APRN, FNP-BC
Seaford, Delaware

"SHOULD YOU ADOPT THE PRACTICE OF VAGINAL CLEANSING WITH POVIDONE-IODINE PRIOR TO CESAREAN DELIVERY?"
ROBERT L. BARBIERI, MD
(EDITORIAL; JANUARY 2016)

"PREVENTING INFECTION AFTER CESAREAN DELIVERY: 5 MORE EVIDENCE-BASED MEASURES TO CONSIDER"
KATHRYN E. PATRICK, MD; SARA L. DEATSMAN, MD; AND PATRICK DUFF, MD (DECEMBER 2016)

Prepping the vagina before cesarean delivery

I enjoyed your review of the topic. I am interested in using vaginal preparation prior to cesarean in the settings of active-phase and second-stage arrest. This should be most valuable since we anticipate possible prolonged attempt at head delivery. There may be a need for head elevation as well. Of course, we have become enthusiastic about using reverse breech extraction in difficult cases since your article a few years ago. I have yet to do a Patwardhan maneuver. That seems to rely on rotating the spine anteriorly to get the second arm out. With the head impaction, there is limited range for neck rotation. With vaginal preparation, is there any concern about fetal exposure to iodine?

Kimberly Harney, MD
Stanford, California

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›› Dr. Barbieri responds

Dr. Harney raises the important issue of the potential adverse effects of povidone-iodine surgical preparation when used on a pregnant woman with ruptured membranes. There is very little direct evidence of a toxic effect of povidone-iodine on the fetus, but studies on women report that there is a transient increase in circulating iodine and iodine excretion following a vaginal povidone-iodine preparation.[1] The American College of Obstetricians and Gynecologists has suggested that chlorhexidine might be a superior vaginal disinfectant than povidone-iodine,[2] but chlorhexidine is not approved by the US Food and Drug Administration for use in the vagina, and many surgical nursing directors favor the use of povidone-iodine in the vagina.[3]

References

1. Velasco I, Naranjo S, Lopez-Pedrera C, Garriga MJ, Garcia-Fuentes E, Soriquer F. Use of povidine-iodine during the first trimester of pregnancy: a correct practice? BJOG. 2009;116(3):452–455.
2. Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists. Committee Opinion No. 571: solutions for surgical preparation of the vagina. Obstet Gynecol. 2013;122(3):718–720.
3. Guideline for preoperative patient skin antisepsis. In: Guidelines for perioperative practice. Denver, CO: Association of Perioperative Registered Nurses, Inc; 2014.

"PREVENTING INFECTION AFTER CESAREAN DELIVERY: 5 MORE EVIDENCE-BASED MEASURES TO CONSIDER"
KATHRYN E. PATRICK, MD; SARA L. DEATSMAN, MD; AND PATRICK DUFF, MD (DECEMBER 2016)

Another way to prevent post–cesarean delivery infections

After 40 years in ObGyn practice (I am now retired), I find it interesting that experts have ignored a major potential source of infection—the operation team. Back in the day of Phisohex (hexachlorophene) use, we scrubbed our hands, arms, and fingers for a finite time—10 minutes—systematically and religiously. Our infection rates increased only when house staff rather than surgical assistants "helped" us. When scrubbing, I was always amazed that the house staff appeared at the sink long after I did and left before I had completed my presurgical ritual. (This was not true of non-MD assistants.) And my private practice postoperative infection rate reflected the difference. So perhaps the evidence is skewed away from this source of infection, which I submit may well be the major one!

Steve Melkin, MD
Phoenix, Arizona

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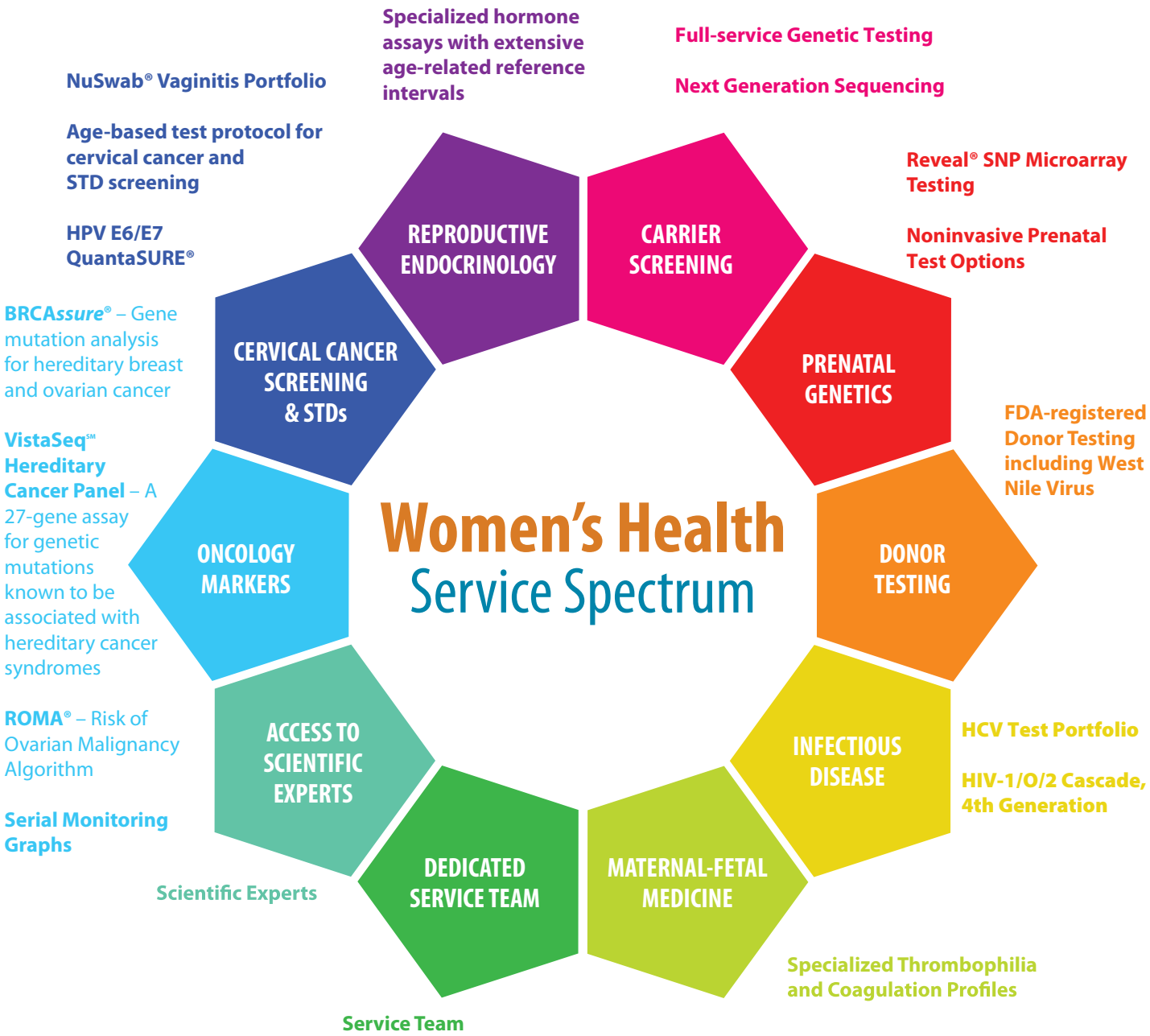

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Should recent evidence of improved outcomes for neonates born during the periviable period change our approach to these deliveries?

Need for continued focus on shared decision making with patients that incorporates individual and family values and preferences is the takeaway when examining changes in 1.5- to 2-year outcomes of periviable births from 2000 to 2011. Researchers observed small improvements in both overall survival and survival without neurodevelopmental impairment, but the absolute risk of death and neurologic impairment remained high.

FAST TRACK

For neonates born at less than 23 weeks' gestation, the risk of death or significant neurodevelopmental impairment is nearly universal

Younge N, Goldstein RF, Bann CF, et al; Eunice Kennedy Schriver National Institute of Child Health and Human Development Neonatal Research Unit. Survival and neurodevelopmental outcomes among periviable infants. N Engl J Med. 2017;376(7):617–628.

EXPERT COMMENTARY

›› **Jeffrey L. Ecker, MD,** is Joe Vincent Meigs Professor of Obstetrics and Gynecology, Massachusetts General Hospital, Harvard Medical School, Boston.

Pregnancy management when delivery appears to be imminent at 22 to 26 weeks' gestation—a window defined as the periviable period—is among the most challenging situations that obstetricians face. Expert guidance exists both at a national level in a shared guideline from the American College of Obstetricians and Gynecologists and the Society of Maternal Fetal Medicine and, ideally, at a local level where teams of obstetricians and neonatologists have considered in their facility what represents best care.[1] But whether national or local, such consensus is largely expert opinion based on a foundation limited by available evidence, which is almost always retrospective analysis of rare cases.

Among the most important yet often missing data points are outcomes of neonates born in the periviable period. Surveys suggest that obstetric care providers often underestimate the chance of survival following periviable delivery.[2] Understanding and weighing anticipated outcomes inform decision making regarding management and planned obstetric and neonatal interventions, including plans for neonatal resuscitation.

Not surprisingly, perhaps, survival of periviable neonates has been linked clearly to willingness to undertake resuscitation.[3] Yet decisions are not and should not be all about survival. Patients and providers want to know about short- and long-term morbidity, especially neurologic health, among

The author reports no financial relationships relevant to this article.

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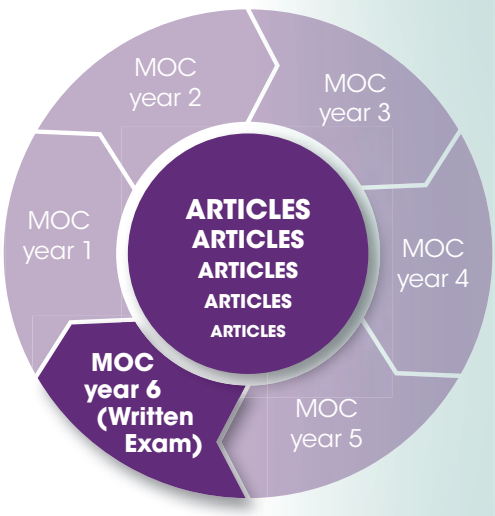

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WHAT THIS EVIDENCE MEANS FOR PRACTICE

Although there have been small improvements with time, the risk of death or significant neurodevelopmental impairment with delivery in the periviable period remains high and, at less than 23 weeks' gestation, is nearly universal. This finding emphasizes the importance of shared decision making, incorporating individual and family preferences and values. In addition to planned resuscitation, options to be discussed should include palliative care and, at appropriate gestational ages, the possibility of pregnancy termination.

›› JEFFREY L. ECKER, MD

survivors. Available collections of morbidity and mortality data, however, often are limited by whether all cases are captured or just those from specialized centers with particular management approaches, which outcomes are included and how they are defined, and the inevitable reality that the outcome of death "competes" with the outcome of neurologic development (that is, those neonates who die are not at risk for later abnormal neurologic outcome).

Given the need for more and better information, the data from a recent study by Younge and colleagues is especially welcome. The investigators reported on survival and neurologic outcome among more than 4,000 births between 22 and 24 weeks' gestation at 11 centers in the United States.

FAST TRACK

At 24 0/7 to 24 6/7 weeks' gestation in the 2008–2011 epoch, 55% of neonates survived, and 32% of infants survived without evidence of neurodevelopmental impairment at 18 to 22 months of age

Details of the study

The authors compared outcomes among three 3-year epochs between 2000 and 2011 and reported that the rate of survival without neurodevelopmental impairment increased over this period while the rate of survival with such impairment did not change. This argues that the observed overall increase in survival over these 12 years was not simply a tradeoff for life with significant impairment.

Within that overall message, however, the details of the data are important. Survival without neurodevelopmental impairment did improve from epoch 1 to epoch 3, but just from 16% to 20% (95% confidence interval [CI], 18–23; $P = .001$). Most neonates in the 2008–2011 epoch died (64%; 95% CI, 61–66; $P<.001$) or were severely impaired (16%; 95% CI, 14–18; $P = .29$). This led the authors to conclude that "despite improvements over time, the incidence of death, neurodevelopmental impairment, and other adverse outcomes remains high." Examined separately, outcomes for infants born at 22 0/7 to 22 6/7 weeks' gestation were very limited and unchanged over the 3 epochs studied, with death rates of 97% to 98% and survival without neurodevelopmental impairment of just 1%. In my own practice I do not encourage neonatal resuscitation, cesarean delivery, or many other interventions at less than 23 weeks' gestation.

By contrast, the study showed that at 24 0/7 to 24 6/7 weeks' gestation in the 2008–2011 epoch, 55% of neonates survived and, overall, 32% of infants survived without evidence of neurodevelopmental impairment at 18 to 22 months of age.

Study strengths and weaknesses

It is important to note that the definition of neurodevelopmental impairment used in the Younge study included only what many would classify as severe impairment, and survivors in this cohort "without" neurodevelopmental impairment may still have had important neurologic and other health concerns. In addition, the study did not track outcomes of the children at school age or beyond, when other developmental issues may become evident. As well, the study data may not be generalizable, for it included births from just 11 specialized centers, albeit a consortium accounting for 4% to 5% of periviable births in the United States.

Nevertheless, in supporting findings from other US and European analyses, these new data will help inform counseling conversations in the years to come. Such conversations should consider options for resuscitation, palliative care, and, at less than 24 weeks' gestation, pregnancy termination. In individual cases these and many other decisions will be informed by both specific clinical circumstances—estimated

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Can we increase LARC use among adolescents?

Data indicate that, yes, young women will use long-acting reversible contraception and unintended pregnancy rates will benefit. Here, a look at the proof and pearls for approaching your adolescent patients.

Ronald T. Burkman, MD

Unintended pregnancy in adolescents is a significant public health concern. In 2011, there were 45 unintended pregnancies for every 1,000 women aged 15 to 44 years.[1] Among women aged 19 years and younger, more than 4 out of 5 pregnancies are unintended.[2] When rates are recalculated to include only those who are sexually active, women aged 15 to 19 years have the highest unintended pregnancy rate of any age group.[1] Approximately 4.2 million women in the United States are not using a regular contraceptive method and are therefore at risk of pregnancy. A full 18% of these at-risk US women are aged 15 to 19.[3]

Three questions need to be addressed:

1. Can adolescents successfully use long-acting reversible contraceptives (LARCs)?
2. What is the public health impact of increased LARC use, especially intrauterine devices (IUDs), among adolescents?
3. What are barriers to providing increased LARC use for adolescents?

Dr. Burkman is Professor of Obstetrics and Gynecology at the University of Massachusetts Medical School-Baystate, and a practicing generalist obstetrician-gynecologist at Baystate Medical Center in Springfield, Massachusetts. He is an OBG MANAGEMENT Contributing Editor.

The author reports no financial relationships relevant to this article.

Successful LARC use in teens: Can it be achieved?

The answer is, yes. One example of successful LARC use in adolescents is the Contraceptive Choice Project—completed in St. Louis, Missouri, between 2007 and 2011.[4] The aim of the project was to reduce the unintended pregnancy rate in the St. Louis area by removing 2 major barriers to LARC use: financial obstacles and lack of patient awareness of LARC method safety and efficacy.

Through the Contraceptive Choice Project, each woman aged 14 to 45 years was provided a contraceptive method of her choice at no cost for 3 years. During standardized, preferential counseling, each participant was introduced to LARCs as a first-line contraceptive choice because they have a much higher efficacy rate: 52-mg levonorgestrel intrauterine device (LNG-IUD; Mirena, Bayer), copper IUD (Paragard, Teva), and subdermal implant (Implanon, Merck). Two-thirds of participants chose LARCs over other contraceptive methods. Counseling also included follow-up telephone interviews at 3 months and then at every 6 months thereafter.

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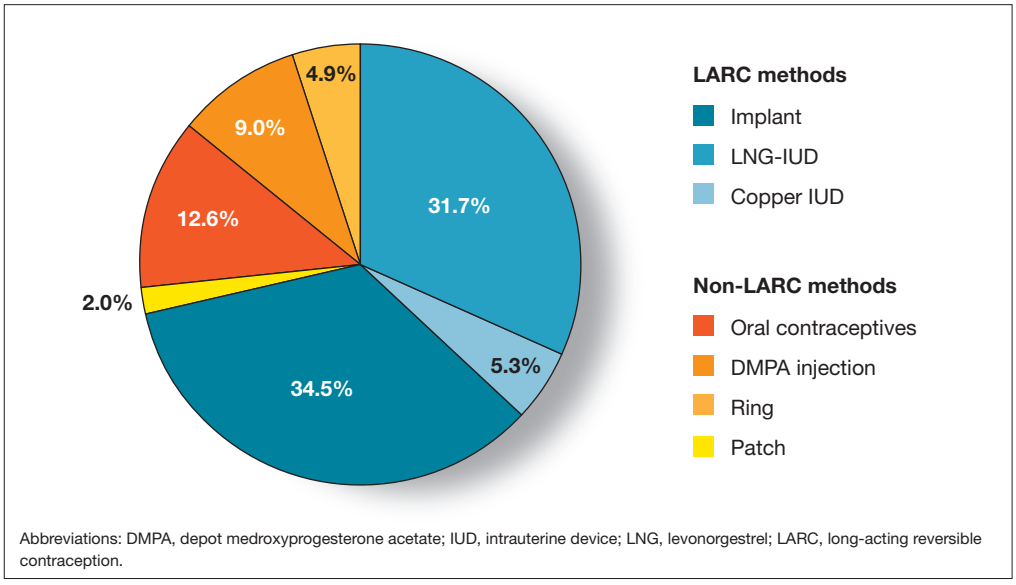
FIGURE Contraceptive methods used by adolescents aged 14-19 years in Contraceptive Choice Project[5]



Abbreviations: DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; LNG, levonorgestrel; LARC, long-acting reversible contraception.

FAST TRACK

CDC investigators found an increased risk of copper IUD expulsion, and possible increased risk of LNG-IUD expulsion, in women younger than age 25

Of the 9,256 Contraceptive Choice Project participants, 4,708 women were in the 3-year continuation study, including 644 adolescents aged 14 to 19 years. Because of the preferential type of counseling, about 63% (n = 405) of the adolescents chose LARCs, roughly evenly distributed between IUDs and implants, and about 37% (n = 239) chose other methods of contraception, with oral contraceptives the most prevalent (**FIGURE**).[5]

One year later, 82.1% of the adolescents who chose LARC methods continued to use them. This continuation rate dropped to 68% by 2 years and to about 52.6% by 3 years (**TABLE 1**, page 28).[4] However, when comparing this 52.6% to the 3-year rate of non-LARC continuation (21.2%), adolescents who chose a LARC method showed double the continuation rate of their non-LARC counterparts. This is a dramatic difference.

Safety considerations

Recently, investigators from the Centers for Disease Control and Prevention evaluated a number of studies that looked at the safety of IUDs among young women; they concluded that there is no association between IUD use and increased risk of adverse outcomes, such as pregnancy, perforation, infection, or heavy bleeding in women younger than age 25 compared with women older than 25.[6] However, they did find an increased risk of expulsion of copper IUDs and possibly an increased risk of LNG-IUD expulsion (**TABLE 2**, page 28).[6,7]

If you suspect possible expulsion, use alternative contraception until the diagnosis is made.

Insertion pearls for adolescents

In general, I have found it rarely is necessary to use smaller devices, such as the Skyla device, with most nulliparous adolescents. Further, such devices require replacement every 3 years, which can make them less attractive as a form of contraception for some adolescents. Exceptions to this approach could be young women who have had difficulty previously with an insertion, who have experienced an expulsion, or whose uterine cavity sounds to between 5.5 cm and 6.0 cm. I usually tell women to take about 600 mg of ibuprofen about one-half hour before the insertion. This practice seems to be helpful to reduce some of the discomfort during the insertion as well as uterine cramping afterward. However, it should be noted that a recent Cochrane review suggested nonsteroidal anti-inflammatory agents were

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TABLE 1 Contraceptive Choice Project contraception continuation rates, adolescents aged 14–19 years[3]

Method	Continuation rate		
	Year 1	Year 2	Year 3
All LARC (n = 405)	82.1%	68%	52.6%
LNG-IUD	–	–	54.6%
Copper IUD	–	–	49.5%
Implant	–	–	50.8%
Non-LARC (n = 257)	46.9%	32.9%	23.1%

not very effective in relieving insertion-related pain.[8] My insertion technique is not different for adolescents compared with other women.

What is the public health impact of increased LARC use among adolescents?

For the Contraceptive Choice Project, researchers compared the rates of pregnancy, birth, and abortion per 1,000 teens in: all US adolescents, sexually active US teens, and Choice Project participants. Dramatic reductions in the pregnancy and birth rates, as well as the abortion rates, were observed in the Choice Project participants (**TABLE 3,** page 30),[5] indicating a significant public health impact.

The Colorado Family Planning Initiative experience, which ran from 2009 to 2014, adds further support to the public health significance of increasing LARC use among adolescents.[9] In this particular project, grant support was provided to 68 clinics across Colorado that provide care primarily to low-income individuals. Because of the grant, 30,000 IUDs and implants were provided to women at low or no cost.[10] The use of these methods quadrupled. Further, the teenage birth rate fell from 37 to 22 births per 1,000, and it was estimated that this was due at least 75% of the time to the use of these methods. In addition, the teenage abortion

TABLE 2 Available LARC methods for adolescent use[6,7]

LARC method	Description	Use	Notes
IUD			
Kyleena	Levonorgestrel 19.5 mg	Up to 5 years	Possible increased risk of expulsion in age <25
Liletta	Levonorgestrel 52 mg	Up to 3 years	Possible increased risk of expulsion in age <25
Mirena	Levonorgestrel 52 mg	Up to 5 years for women who have had at least 1 child	Possible increased risk of expulsion in age <25
Skyla	Levonorgestrel 13.5 mg	Up to 3 years	Possible increased risk of expulsion in age <25
Paragard	Copper-bearing IUD	Up to 10 years	≥age 16; increased risk of expulsion in age <25
Implant			
Nexplanon	Etonogestrel 68 mg; barium sulfate 15 mg; radiopaque; implantable rod	Up to 3 years	May be less effective in overweight women

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TABLE 3 Pregnancy, birth, and abortion rates among US adolescents and Contraceptive Choice Project participants aged 15–19 years*,[4]

Outcome	All US teens, 2010	All sexually active US teens, 2008	Choice Project teens (mean, 2008–2013)
Pregnancy	57.4	158.5	34.0
Birth	34.4	94.0	19.4
Abortion	14.7	41.5	9.7

*No. per 1,000 teens.

rate in Colorado fell by about 35%.[11] It also was concluded that for each dollar spent on contraceptives the state saved $5.85 in Medicaid costs. Clearly this has public health significance. Finally, there are recent data that show a significant drop in unintended pregnancy rates for the first time in several decades in this country—from 50% to 45%;[1] included in these data are a decline in pregnancy rate and unintended pregnancy rate among teenagers. A likely significant contributor to this decrease is the increased use of LARC methods among women and adolescents.

FAST TRACK

Recent data indicate that if STD symptoms are not present at insertion, testing for STDs, and treatment if necessary, can occur after LARC placement

Overcoming barriers

Cost. The cost of contraception may be a barrier to LARC use for teens. Although the Liletta 52-mg LNG-IUD is available to certain clinics (340B) across the country at a very low cost, which may make it particularly available to some, the cost of the LARC devices can be significant for many. In several states Medicaid is now covering the cost of these contraceptive devices. Unfortunately, it is unclear whether proposed changes to the Affordable Care Act will adversely affect contraceptive care, particularly for teenagers.

Access. Many adolescents do not seek contraceptive care due to concern regarding the possible need for parental consent. Although the majority of states allow contraceptive care without parental consent, only 21 have essentially no restrictions and the others that do allow it do have some restrictions such that only if the patient is married, is a parent, or has had a prior pregnancy.[12]

Timing of insertion can be a third barrier to LARC use in teens. It has been felt that it is necessary to screen patients for sexually transmitted diseases (STDs), and have the results, before inserting an IUD. There are recent data, however, that indicate that as long as the woman or adolescent does not have symptoms of an STD, STD testing can occur postinsertion, and positive STD test results can be followed up with appropriate treatment after the insertion process. This management approach does not appear to substantially increase the risk of pelvic inflammatory disease.

Insertion immediately postpartum is an approach that should be encouraged, as 10% to 40% of women do not attend a postpartum visit. More than 50% in some instances have unprotected intercourse prior to the postpartum visit and, among adolescents, up to 50% of those having unprotected intercourse become pregnant again within the year after delivery. The implant of course can be placed readily after delivery, but with proper training, IUDs also can be placed immediately after vaginal delivery and certainly at the time of cesarean delivery. Keep in mind that there is a somewhat higher expulsion rate for IUDs placed in the immediate postpartum period.

Bottom line

Can adolescents successfully use LARC methods? Yes they can. What is the public health impact of increasing LARC use, especially IUDs, among adolescents? It is significant, by reducing unintended pregnancy rates as well as costs. Although barriers exist

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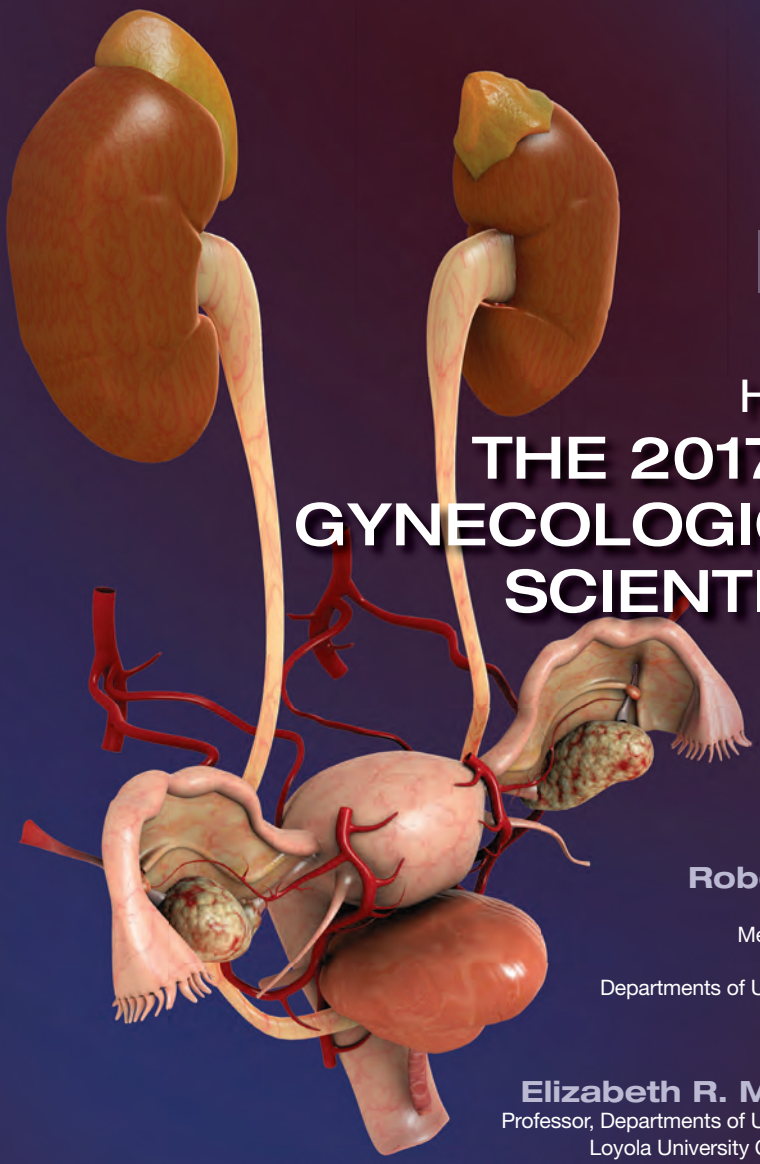
OBG MANAGEMENT

SPECIAL SECTION



HIGHLIGHTS FROM THE 2017 SOCIETY OF GYNECOLOGIC SURGEONS SCIENTIFIC MEETING

PART 1

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PHOTO: 3D4MEDICAL / SCIENCE SOURCE

Society of Gynecologic Surgeons meeting presenters offer the ObGyn community surgical, practical, and life lessons

SGS meeting faculty offer features on mentor-mentee relationships, urologic injury management during gynecologic surgery, and accomplishments from the FPRN

Robert E. Gutman, MD

Welcome to Part 1 of 2 special sections of OBG MANAGEMENT, which highlights recent events from the Society of Gynecologic Surgeons (SGS) 2017 annual scientific meeting in San Antonio, Texas. The meeting's theme, "Mentorship in Surgery, Education, and Research," is extremely important for all medical professionals. We all can recall several people who were instrumental in our own personal development and career pathway, and many of us currently serve as mentors.

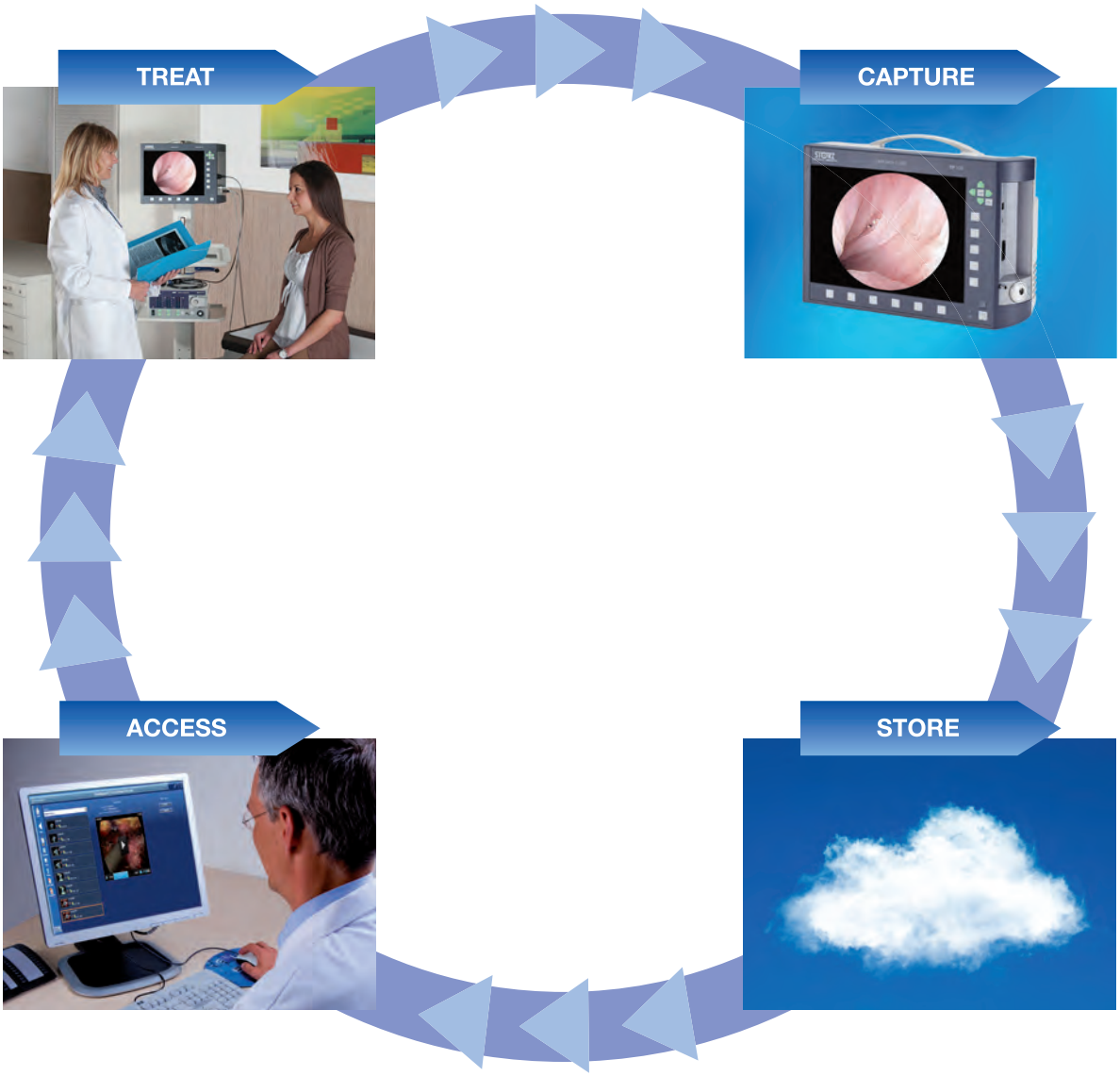
This month, SGS meeting keynote speaker Janet Bickel, MA, a leadership and career development coach and an expert on the topic of mentorship, shares insightful tips and recommendations for both mentors and mentees. Next month, part 2 of this special section will feature an article by Dr. Denise Elser on how to become actively involved in ObGyn mentorship. Dr. Elser's leadership role with the SGS and the American College of Obstetricians and Gynecologists mentorship programs helped make the SGS meeting's first-time "Mentorship Mingle" event a success. These authors offer valuable suggestions that reinforce current techniques, help you refine mentorship skills, and aid in overcoming obstacles to becoming a mentor.

The meeting began with 4 diverse postgraduate workshops: a cadaver course, 3D pelvic anatomy, iTeach for Gyn residents/fellows, and enhanced recovery after surgery. Drs. Elizabeth Mueller and Andrew Sokol ran the hands-on cadaver course, teaching laparoscopic suturing and management of bladder and ureteral injuries. In her article in this section, Dr. Mueller, the FPMRS division director at Loyola University, uses a case-based approach to summarize her expert opinion regarding minimally invasive techniques to detect and manage bladder and ureteral injuries at the time of gynecologic surgery.

Dr. Dee Fenner moderated an excellent debate about whether the specialty of obstetrics and gynecology should separate the "O" from the "G." The expertise and leadership of Drs. Kimberly Kenton and Geoffrey Cundiff in the field of ObGyn and female pelvic medicine and reconstructive surgery were evident as they provided compelling arguments for each side. Their thoughtful, balanced approach is relevant to all ObGyn providers and reinforces the potential benefit of increased tracking to achieve competency-based medical education in the specialty and subspecialty training of future ObGyns. They offer their perspectives in articles that will be featured next month.

Lastly, Drs. Kristin Jacobs and Lior Lowenstein highlight the 10-year anniversary of the Fellows Pelvic Research Network (FPRN). This network is the direct result of years of research mentorship by junior and senior advisory board members supported by SGS. ■

The author reports no financial relationships relevant to this article.



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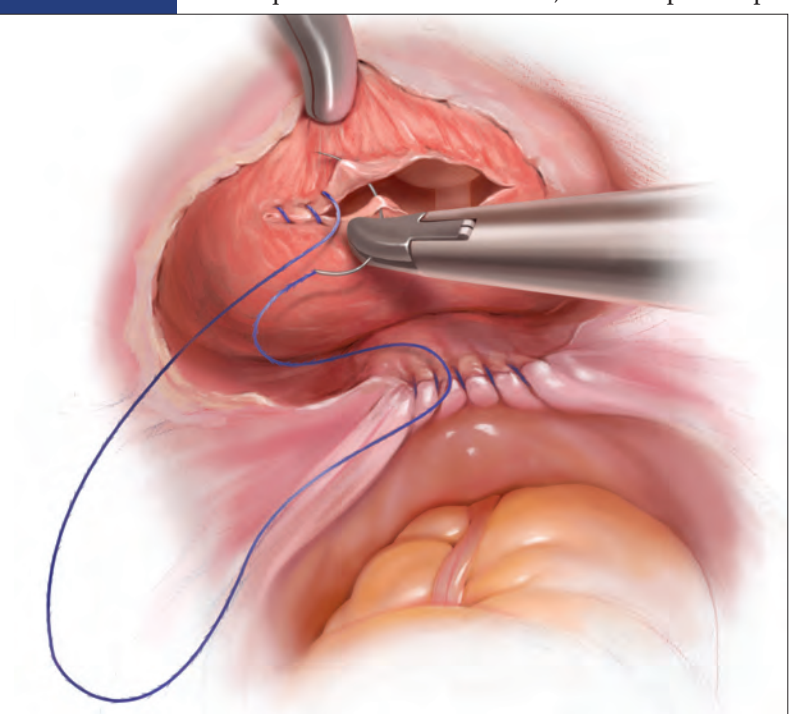
HOW TO REPAIR UROLOGIC INJURY AT THE TIME OF GYNECOLOGIC SURGERY

Urologic injury is a known complication of all gynecologic procedures. By identifying the injury intraoperatively, we can reduce postoperative complications and long-term sequelae.

Elizabeth R. Mueller, MD, MSME

Gynecologic surgeons have pioneered the use of minimally invasive surgical approaches to treat diseases in women. Since Dr. Harry Reich of Kingston, Pennsylvania, introduced laparoscopic hysterectomy in 1988, procedural refinements and technologic advancements have led to widespread use of this technique.[1] In the United States, use of laparoscopic approaches to hysterectomy increased from 0.3% in 1990 to 11.8% in 2003, with a resultant decline in both abdominal and vaginal approaches to hysterectomy.[2] Patients who undergo laparoscopic hysterectomy have shorter hospitalizations, fewer infections, less blood loss, and return to work more quickly than women who undergo an abdominal approach. Laparoscopic approaches are, however, associated with higher risks of bladder and ureteral injury.

In this article, I briefly review the literature, describe 2 cases involving lower urinary tract injury during laparoscopic surgery, and discuss treatment options when injury is detected.



Double-layered closure of a cystotomy using absorbable barbed suture, with care taken to incorporate the lateral edges of the incision.

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

The author reports that she is an investigator for and is on the advisory board of Astellas Medical and Scientific Affairs.

CASE 1 Cystotomy observed in the bladder wall after laparoscopic hysterectomy for prolapse

A 62-year-old woman with stage III pelvic organ prolapse consented to a laparoscopic hysterectomy, sacrocolpopexy, and a prophylactic midurethral sling. She had no history of abdominal surgery. The total laparoscopic hysterectomy proceeded without incident. The bladder flap was dissected down an additional 3 to 4 cm to accommodate the presence of the anterior mesh arm during sacrocolpopexy. The total vaginal hysterectomy was completed, the uterus was removed through the vaginal cuff, and the cuff was closed.

The surgeon performed a cystoscopy and observed that both ureters effluxed clear urine. However, he noted a 1.25-cm cystotomy in the midline posterior bladder wall about 2 cm behind the bladder trigone.

What approach would you take for repair? Consider these questions:

- When and how should the bladder cystotomy be closed?
- Should you complete the sacrocolpopexy?
- For how long should a Foley catheter be placed?
- Would you proceed with a midurethral sling?

Cystotomy: A known complication of gynecologic surgery

All these questions are legitimate and, of course, there are no randomized trials that can guide our clinical care. I will therefore discuss surgical principles, acknowledging that the following discussion is based on expert opinion. Ultimately, the treating surgeon's choices are based on his or her experience and clinical judgment at the time of the procedure.

Signs of a cystotomy during surgery may include an air-filled Foley drainage bag or blood-tinged urine in the Foley bag.

Cystotomies are a known complication of gynecologic procedures that involve mobilizing the bladder flap off the uterus, cervix, and vagina. Adelman performed a systematic review of English language studies over a 10-year period that enrolled more than 100 women.[3] The highest rates of injuries were to the bladder, ranging from 0.05% to 0.66%. Total laparoscopic hysterectomy had the highest injury rate, and supracervical hysterectomy the lowest. The majority of cystotomies (80.6%) were recognized intraoperatively, whereas 7.5% were recognized postoperatively. The conversion rate to laparotomy to repair bladder injuries was 11%.

Signs of a cystotomy during surgery may include an air-filled Foley catheter drainage bag that is usually identified by the anesthesia team as the result of the abdominal insufflation passing through the cystotomy to the bag, which is at atmospheric pressure. Other signs are blood-tinged urine in the Foley bag and difficulty visualizing the bladder walls when cystoscopy is performed. Blood clots in the bladder should be irrigated gently and removed. A clot at the base of the bladder may occlude the bladder defect and prevent fluid loss from the bladder.

Closing a bladder cystotomy

Once a cystotomy is identified by cystoscopy, the treating surgeon can visualize it intra-abdominally by elevating the posterior bladder wall and looking for the fluid leak, aided by the light from the cystoscope. Visualization of the bladder edge is facilitated when the bladder is full. For this reason, placing a 3-way Foley catheter (at least 22F) that is connected to a 5-L fluid source and clamping the output channel can aid in laparoscopic closure of the cystotomy.

Closure of the cystotomy can be performed using an absorbable barbed suture on both layers, eliminating knot tying. The first layer is closed with care taken to incorporate the lateral edges of the incision, where a small piece of bladder mucosa may be inadvertently puckered outside of the suture line. Angling the sutures at 45° at the lateral edges can prevent this complication. Take care to ensure that each bite is through bladder mucosa.

Typically, a larger bite of mucosa and a smaller bite of the bladder muscularis are sufficient for the first layer. Once the first layer is closed, the bladder should be sufficiently emptied to allow for placement of the second row of sutures tension-free. The purpose of the second layer is to imbricate the first layer completely. Therefore, the starting and ending edges of the second layer must be lateral to the first layer. The second suture line should include the bladder serosa and the bladder muscularis. The sutures do not penetrate the bladder lumen. Once 2 layers are closed, inspect the suture line with the bladder full. A repeat cystoscopy is not necessary unless there is a concern for a bladder clot. Gentle irrigation of a clot will dislodge it.

Completing the sacrocolpopexy

Whether or not to proceed with the sacrocolpopexy is a decision the operating surgeon makes. Our team usually proceeds with mesh placement. Because it is essential that the cystotomy suture line be tension-free, prior to starting the cystotomy repair we place a Lucite stent in the vagina to aid dissection and mobilize the bladder, making certain that the cystotomy is 2 to 3 cm proximal to the distal edge of the dissection. This is important because tensioning of the sacrocolpopexy mesh could inadvertently place tension on the cystotomy repair. A third layer of closure may be indicated if an omental or peritoneal flap cannot be placed

between the bladder closure and the anterior vaginal wall mesh.

How long to leave in the Foley catheter

A Foley catheter is typically left in place for 1 to 2 weeks. Keeping the bladder nondistended minimizes the likelihood that the posterior bladder wall will drape over the mesh. We typically do not perform a cystogram on removal of the Foley catheter, although other authors have advocated this.

Midurethral sling placement, or not

Surgeon preference dictates whether or not to proceed with a midurethral sling. In our case scenario, the sling is being placed to prevent potential stress incontinence. My practice is not to place a sling whenever there is a cystotomy at the posterior bladder wall or bladder dome. Once the catheter is removed, the bladder wall may be subjected to increased pressure due to increased urethral resistance if a sling has been placed. In some cases, higher than normal bladder pressures or frank obstruction may increase the risk that the cystotomy repair will break down. Given the low morbidity associated with performing the sling procedure at a later date, I would defer sling placement until 2 to 3 months following the cystotomy repair.

CASE 1 Resolved: Cystotomy repaired after laparoscopic hysterectomy

The patient did well after cystotomy repair. The Foley catheter was removed 10 days after surgery, and the patient passed her voiding trial. She had a midurethral sling placed 6 weeks after her original surgery for stress incontinence symptoms.

CASE 2 Ureter injured during laparoscopic hysterectomy for fibroids

A 61-year-old woman underwent a laparoscopic hysterectomy (850-g uterus) and bilateral salpingo-oophorectomy for symptomatic uterine fibroids. At the end of the procedure, a cystoscopy revealed that the left ureter was not effluxing urine. Pelvic inspection revealed that the ureter was dilated and incorporated in the pedicle that contains the ovarian artery.

Consider these questions when planning the repair:

- What should be your next steps?
- Should the ureter be reimplanted?
- What postoperative care will be required for a woman who presents with a ureterovaginal fistula?

Most ureteral injuries are found postoperatively

Ureteral injuries are described in the gynecologic literature but often without the level of detail that would allow for careful analysis. In a review of the English language world literature reporting ureteral injury during laparoscopic surgery, Ostrzenski and colleagues reported that only 8.6% of ureteral injuries were found intraoperatively, whereas 70% were found postoperatively.[4] More than 50% of the injuries were not described by location or instruments used at the time of the injury. Of the cases that were described, transection was most common, and the majority of the injuries occurred at the pelvic brim. Electrocautery was involved in 24% of cases, but this allows little perspective given that 48% of the time, the instrument used was not identified. A laparotomy was used to repair the ureteral injury in 61% of cases.

Steps in repairing the ureter

The first step in the surgical repair is to dissect out the ureter. If the pedicle was made from a thermal source, judicious use of small laparoscopic vascular clips helps to manage bleeding, and further thermal injuries are kept to a minimum until the anatomy is clearly identified. Dissection of the ureter below the pelvic brim on the left side is challenging because of the attachment of the descending and sigmoid colon to the left pelvic sidewall. Make a superficial incision in the posterior peritoneum medial to the ureter to protect the lateral blood supply.

> Of ureteral injury cases described in the literature, transection was the most common, and the majority occurred at the pelvic brim.

In a pure laparoscopic case, passing a retrograde ureteral catheter over a guidewire may help locate the site of obstruction. This typically is done without the use of fluoroscopic guidance due to limitations on the operative table. During robot-assisted surgery, newer da Vinci Surgical

Agents used to improve detection of the ureteral jets during cystoscopy

- Dextrose 10% solution as cystoscopy fluid. The fluid viscosity difference makes ureteral jets easier to detect.
- Indigotindisulfonate sodium (Indigo Carmine) 0.8% solution, 5 mL ampule given IV 10 minutes prior to cystoscopy. Has a half-life of 5 minutes and is currently unavailable in the United States.
- Indocyanine green (ICG; IC-Green) 25 mg/10 mL (off-label use) given IV 2–3 minutes prior to cystoscopy.[1]
- Phenazopyridine (Pyridium) 200 mg orally with a sip of water in preoperative holding area.

Reference

1. Doyle PJ, Lipetskaia L, Duecy E, Buchsbaum G, Wood RW. Sodium fluorescein use during intraoperative cystoscopy. Obstet Gynecol. 2015;125(3):548–550.

System robots have a near-infrared (NIR) fluorescence imaging system that can be turned on with a simple foot pedal. Indocyanine green, or ICG (25 mg sterile IC-Green [Akorn, Inc] in 10 mL of distilled water), is injected retrograde through the ureter using a cone-tipped catheter. The ICG binds reversibly to proteins on the urothelial lining.[5] With the NIR fluorescence imaging system, the ureter outline can be seen clearly as a bright green image; this helps identify the site of obstruction or ureteral transection.

If the ureter is partially transected, place a ureteral stent over a guidewire and place interrupted sutures through both ends of the defect and then cover with omentum. Take care to understand if the partial transection was made by cautery. If that is the case, transect the ureter completely and dissect free the 2 ends. Remove and then spatulate a portion of the ureter on each end, and take care to place the suture knots on the outside of the ureter.

Mucosa-to-mucosa coaptation of both ends of the ureter is critical to healing without a stenosis or fistula. Interrupted absorbable sutures should be placed on the lateral side of the ureter first, and then a stent over a wire is placed across the anastomosis. This is best done from the bladder with assistance from the laparoscopic surgeon. Once the first layer is completed, several interrupted sutures on the serosa of the ureteral ends will relieve some of the tension on the primary anastomosis.

A Foley catheter is left in place to ensure that any fluid entering the bladder from either kidney does not reflux up the stent on the affected side. While some experts advocate the use of a drain, it is not always necessary. If a drain is placed, it should be placed away from the anastomosis. The catheter is left in place for 2 weeks and removed in the office. The stent is removed in the operating room, and a retrograde pyelogram is taken to ensure that the ureter is patent and has healed without a stricture or anastomotic leak. A Lasix renal scan or ultrasound should be performed 6 weeks after stent removal to evaluate the kidneys and ureter.

Reimplanting the ureter into the bladder

The operating surgeon decides to proceed with a ureteral reimplant based on the degree of ureteral injury and the blood supply to the ureter. If the case is converted to a laparotomy, it is my practice to proceed with a ureteral reimplant, which typically has a higher success rate due to the excellent blood supply from the bladder.

Postoperative care for a woman with a ureterovaginal fistula

Patients with a delayed or unrecognized ureteral injury present with various symptoms, including vaginal drainage, fevers, flank pain, rising creatinine level, a fluid wave on physical examination, or peritonitis. The office examination includes a physical exam, laboratory testing, and a tampon dye test. Recommended imaging studies include renal ultrasound with radiography comment on ureteral jets and computed tomography urogram if creatinine levels are normal.

A trip to the operating room can aid in diagnosis and treatment. If a ureterovaginal fistula is found, we attempt to place a ureteral stent in retrograde fashion. If the stent cannot be placed due to technical difficulties, the radiology department often can place a stent antegrade through percutaneous nephrostomy access. If a stent can be internalized, a Foley catheter should be placed for 2 weeks to decrease the amount of urine that will pass across the fistula site by the refluxing ureteral stent.

Typically, if the patient presents with a ureterovaginal fistula, the vaginal drainage will

CONTINUED ON PAGE SS14

Hard work and talent are not enough: Mentoring and finding mentors across career stages

The recommendations presented here can boost your skills as both a mentor and a mentee

Janet Bickel, MA

Key takeaways

- Mentoring is the most tangible bridge to continuing excellence in the practice of obstetrics and gynecology, especially in academic settings.
- Rather than overrelying on their version of "reality," skilled mentors offer learner-centered mentoring, recognizing that there are many ways to build a career.
- Individuals having difficulty identifying good mentors or role models at their institution should cast a broader net and become more active in their professional societies.

The author reports no financial relationships relevant to this article.

Speed of change and complexities of competition mean both more opportunities to grow and more ways for careers to derail. Many skills not covered during medical school or postgraduate training have become crucial, such that hard work and talent are not enough to ensure career success or satisfaction.

Young professionals therefore largely rely on more experienced people in the specialty for help in acquiring and honing skills (including negotiation, project management, delegation, and interpretation of organizational politics) and in identifying a career direction that fits their strengths, values, and preferences. This knowledge traditionally is passed person to person through mentoring. The term has many connotations, but here *mentoring* might best be thought of as a scaffold for sharing expertise in the service of lifelong learning—expertise otherwise attainable only by direct experience. Mentoring is the most tangible bridge to continuing excellence in the practice of obstetrics and gynecology, especially in academic settings.

In this article, I present several recommendations for becoming a better mentor and identifying and mining the experience of mentors and learning partners. Health care providers and scientists committed to lifelong learning will find themselves in both camps for most of their professional lives.

Recommendations for mentors

These observations are intended to help mentors maximize their impact in the limited time they have for mentoring. What often distinguishes influential from less influential mentors is the ability to see beyond their experience. Rather than

ILLUSTRATION: PAUL ZWOLAK FOR OBG MANAGEMENT

overrelying on their version of "reality," skilled mentors offer learner-centered mentoring, recognizing there are many ways to build a career.

Other core practices include preparing for the first meeting, discussing expectations for the relationship, creating safety, and actively bridging differences.

Prepare for the first meeting

In advance, mentors should consider sending mentees a set of questions. Reflecting on the answers for just a few minutes helps mentors orient themselves to their mentees' unique needs. Example questions include:

- Which of your accomplishments are you proudest of?
- What are your greatest strengths and shortcomings in realizing your professional potential?
- Where do you see yourself in 5 to 10 years? What are the biggest questions you have about realizing your long-term goals?
- What skill and knowledge areas do you want to focus on during our time together?

Discuss expectations for the relationship

Mentors should invite mentees to articulate what they want out of their relationship. For mentees who struggle with the question, mentors can suggest these foci:

- career options assessment, including analysis of relevant trends
- competency building in project management, professional networking, management of tensions between personal life and work, and development of organizational savvy
- strategies for succeeding in new or upcoming roles and responsibilities
- participation in scholarly projects, such as identifying collaborators and determining author order on papers.

Create safety

At first, younger professionals may be unsure of themselves, or may avoid asking sensitive questions.[1] Mentors can help them open up by creating a safe exploratory space—by assuring and ensuring confidentiality and inviting any and all types of questions. Toward that end, it might be appropriate for mentors to disclose a difficulty or uncertainty they themselves experienced, so mentees could relate.

Actively bridge differences

Forming relationships is easiest for people who have much in common. Bridging differences such as gender and ethnicity requires more work, including demonstrating a sensitivity to often unconscious assumptions. Most cultures allow women and some minorities a narrower range of assertive behavior. For example, a man who engages in such behavior is often said to be confident, analytic, good at details, open, and passionate, whereas a woman doing the same thing is described as conceited, cold, picky, unsure, and controlling. Mentors constricted by any stereotype cannot accurately assess potential or effectively nurture superior performance.[2]

In order to foster mentees' work toward their personal goals and strengthen their sense of self-responsibility for development, mentors should try to discern what combination of support and challenge would be most beneficial. Does a mentee need more of a challenge, or less? Does he need more support, or less? The many questions that can be used to prompt dialogue along these lines include:

- What is your definition of success here?
- Tell me more about your understanding of this dilemma, and your options.
- How will you develop the necessary expertise?
- What is your plan for ensuring that you ____? And what is your plan B?
- How will you evaluate your progress?
- Let us agree on the desired outcome, and then we will discuss methods.
- Where are you being too hard, or too easy, on yourself?

At the end of an interaction, mentors should ask mentees to describe, in their own words, the takeaways of the discussion and any agreements reached. In addition, mentors and mentees should decide when to meet again. Two good closing questions are:

- What should I have asked you about, or encouraged you to do, that I did not?
- Is there another way our time together could have been more beneficial for you?

A productive relationship should be satisfying for both mentors and mentees. If after a few interactions the relationship seems a poor fit,

mentors should discuss their observations with mentees, invite the mentees' observations and, if appropriate, refer them to other mentors or advisors. Mentees who take the mentoring relationship for granted and underestimate the time and patience involved should be encouraged to become mentors themselves.

No matter their seniority level, dedicated professionals can improve their mentoring practices and outcomes. The ability to provide more learner-centered mentoring, which depends on an openness to differences, begins with an altruistic spirit of nurturing the next generation. Great mentors not only shape upcoming practitioners and leaders in their field but also expand their own legacy of positive influence in their own careers, likely becoming happier in the process. Vaillant's highly regarded longitudinal studies of adult development found a phase of career consolidation followed by a generativity phase, in which individuals guide the next generation unselfishly yet enjoy new levels of work- and nonwork-related meaning for themselves.[3] Mastering the tasks of the generative phase triples the likelihood that professionals will experience "vital elderhood"—joy and health in their 70s and beyond.

Recommendations for mentees

Even highly motivated young professionals sometimes fail to seek and secure mentoring. The work culture may be noncollegial or unwelcoming, good role models may be in short supply, and previous negative experience with authority figures may be self-limiting. Another barrier is the idea of needing the "perfect mentor." Setting too many specific requirements for a mentor can close off opportunities. For example, a woman who assumes she will feel comfortable talking only with another woman will eliminate many potentially helpful male mentors.

Explore available programs

Whereas some professionals are born with "mentor receptors"—they easily attract excellent mentors and put their help to good use—most must work at it. Fortunately, more residencies and medical centers now offer their trainees and faculty the assistance of mentoring programs. Individuals having difficulty identifying good

Recommended leadership resources

These resources can benefit professionals who augment the assistance of mentors.

Negotiating

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mentors or role models at their institution should cast a broader net and become more active in their professional societies.

Approach your selected mentors

Mentees approaching a prospective good career resource should think of the process as a joint exploration. They might open the conversation or request by saying, "You have [certain] qualities/skills, which I aspire/want to improve. May I buy you a cup of coffee and pick your brain about how you came to be so great at [lecturing]?" Similarly, in advance of a professional meeting, mentees might send a prospect an email reading, "I heard your talk last year, and it stuck with me, and I would appreciate a chance to meet briefly to learn of any progress you have made," or, "Your paper on [genetics] intersects with my interests. May I buy you a cup of coffee and…." If the meeting goes well, mentees can ask for another interaction. If the meeting goes really well, they can ask if the prospect will consider being a mentor or advisor. If the answer is no, mentees should not take it personally but should ask for a referral to another contact or possible advisor.

In a hiking analogy, as the best guides tend to be overbooked, savvy hikers should seek to connect with multiple experts and then seek to learn as much as possible from hikers they meet on the trail.[4] Likewise, by continuing to expand their circle of colleagues and learning partners throughout their career, mentees can avoid becoming overreliant on any one person. Until mentees commit to a specific path, they should expose themselves to a variety of styles and options—the better to discern what stimulates their own development.

Get the most out of being a mentee

After identifying a mentor, mentees should keep in mind the characteristics of a "highly effective mentee." For instance, one who:

- assumes and demonstrates responsibility for own career development
- collaborates with mentor to set goals for work together
- makes good use of mentor's areas of expertise
- prepares for meetings (includes acting on items agreed on during previous interaction)
- respects mentor's time
- expresses thanks
- understands what the mentee brings to the relationship—for example, appreciation, energy, or expertise in area of interest to mentor.

Stay competitive in your field

As attributed to the legendary poet Han-shan, "there is no path that goes all the way." So, too, professionals' developmental needs change over time, from early- to mid-career, and their constraints and possibilities are usually reevaluated at some point.[5] Midcareer professionals may need to look outside the traditional mentor relationship for people who can serve as sounding boards, helping them take a fresh look at what they think is important, such as, How can they remain competitive? What might "rejuvenation" consist of? Should they consider a new path? Some professionals seek out a coach, someone they consider an outsourced supplier of individualized attention and a co-creator of a framework for growth. Coaching can be specifically focused on exploring alternative career options, navigating a transition, maximizing success in a new role, or building a high-functioning team.

Just as hard work and talent are not enough to ensure career satisfaction, good intentions and wishful thinking are not enough to ensure the development of satisfying mentoring relationships. The recommendations presented here can boost professionals' skills as both mentors and mentees. ■

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The FPRN: Prioritizing the trainee in gynecologic surgery

The Fellows' Pelvic Research Network (FPRN)® has built a solid network of collaborative research and professional relationships over the last decade. Our sights forward remain entrenched in our founding commitment to education and research exposure.

Kristin M. Jacobs, MD, and Lior Lowenstein, MD, MS, MHA

Happy 10-year anniversary, Fellows' Pelvic Research Network (FPRN)®! It is hard to believe that a decade has passed already since this groundbreaking organization was initiated. Considering the productivity of past and current participants, however, it is also remarkable that it has been only 10 years since the beginning. In this article, we highlight the history of this great organization as well as where it is today. Importantly, we would like to recognize and thank the founders of the FPRN and the current junior and senior advisory board members for their ongoing support.

Groundbreaking idea born in 2007

In 2007, Lior Lowenstein, MD, a fellow in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at Loyola University, suggested starting a research group that would promote fellowship-initiated projects on a bigger stage. He recognized that research was a pivotal part of fellowship training yet was a highly variable experience among programs nationwide. Envisioning a fellow-led group similar in structure to the National Institutes of Health Pelvic Floor Disorders Network (PFDN), Dr. Lowenstein believed it was important for fellows to participate in their very own multicenter research network. This groundbreaking idea quickly gained support from the Society of Gynecologic Surgeons (SGS), as it founded the fellow-led research initiative to embody its mission statement to promote cutting-edge education and research in gynecologic surgery. Thus, the FPRN was born. At the helm stood some of the most influential members of the FPMRS community: Drs. Joe Schaffer, Steve Young, Linda Brubaker, Lior Lowenstein, Becky Rogers, Kim Kenton, Rajiv Gala, and Janet Hardy.

The first FPRN meeting was held at the April 2007 SGS annual meeting, with 18 fellows in attendance and 9 projects proposed, 2 of which were ultimately selected for implementation. The FPRN rapidly gained traction among FPMRS fellows, and within the first 5 years more than 10 articles had been published by FPRN members. By 2014, the FPRN became trademarked. In the same year, SGS joined forces with the American Urogynecologic Society (AUGS) and created the first specialty-specific group from the FPRN parent with focus on FPMRS fellows. And in 2015, the FPRN was happy to establish the Fellowship in Minimally Invasive Gynecologic Surgery (FMIGS) group. SGS provides funding to both groups, whereas the FPMRS group receives additional support from AUGS and the FMIGS group receives additional support from AAGL.

Network meeting attendance and published studies continue to grow

The FPRN groups meet twice annually: The FPMRS group meets at AUGS and SGS, and the FMIGS group meets at AAGL and SGS. The AUGS meeting in 2016 had 120 attendees, including fellows and junior and senior advisory board members. Our meetings review ongoing/current

The authors report no financial relationships relevant to this article.

projects, introduce new proposals for critique and vote, and feature discussions with prominent members of the FPMRS and FMIGS communities.

Through these meetings we are able to uphold the original aims of the FPRN as outlined by Dr. Lowenstein and the founders[1]:

- create an environment for fellows to participate in collaborative research and conduct multicenter studies as primary investigators
- enhance fellows' knowledge and skills in study design implementation of multicenter studies, data management, and statistical analysis
- provide an environment for fellows to develop professional relationships that will be sustained after graduation.

Fellows have made great use of the national FPRN network to examine numerous issues that significantly impact our practice. A retrospective study by Molden and colleagues, for example, identified risk factors for midurethral sling revision: pre-existing obstructive voiding symptoms, retropubic sling type, and concurrent surgery.[2] This work was awarded the 2010 SGS presidential prize for outstanding research in gynecologic surgery. Other studies have focused on resident training, such as the report by Jeppson and associates on robotic technology's impact on hysterectomy route and what it means for resident education.[3] Investigations even have looked into the use of social media by pelvic floor disorder patients. In a multicenter survey, Mazloomdoost and colleagues demonstrated that women presenting to a urogynecology clinic report high use of the Internet; such information can facilitate how we distribute information and communicate with our patients.[4]

To date, the FPRN has published more than 30 papers. In addition, 10 studies are currently ongoing, including our first double-blind, randomized, placebo-controlled trial, which is investigating nitrofurantoin prophylaxis in women undergoing catheterization for acute postoperative urinary retention after surgery for urinary incontinence and/or pelvic organ prolapse, with Dr. Erin Lavelle of Magee-Womens Hospital, Pittsburgh, serving as principal investigator.

Looking forward in gynecologic surgery

As the FPRN would not have been created without the founding members, it would not be thriving today without the continued support and dedication of our mentors. Currently, we have 28 senior advisory board members and 133 junior advisory board members. Our steering committee members include Dr. David "Ike" Rahn (FPMRS and FMIGS groups), Drs. Tom Gregory and Rob Gutman (FPMRS group), and Drs. Rosanne M. Kho and Allison Wyman (FMIGS group). Furthermore, the FPRN owes its continued success and growth to the deep commitment and persistent hard work of the SGS administration, Nancy Frankel, PhD, and Lennie Siegel. Last, but certainly not least, thank you to the AUGS, SGS, and AAGL staff who keep this growing organization on track.

It is an exciting time to be in gynecologic surgery. This field not only highly values evidence-based medicine but also is wholly dedicated to training and providing mentorship to young investigators by prioritizing the trainees' experience. Thank you to all who have made this possible. We are proud to be a part of the FPRN family and to work together to pioneer the discoveries that will enable us to provide better care to women for generations to come. ■

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stop within 24 to 48 hours of placement of a stent and a Foley catheter. Success rates for ureterovaginal fistula resolution with stent placement have been reported to be as high as 80%.[6]

Cystoscopy and agents that allow for easy discernment of ureteral efflux aid in identifying urinary tract injuries intraoperatively.

CASE 2 Resolved: Ureter repaired

The pedicle entrapping the ureter was located, and the ureter was dissected free from the pedicle. The ureteral wall was noted to have thermal marks. The decision was made to perform a laparoscopic ureteroureterostomy. The ureter was transected and 1 cm of ureter proximal and distal to the injury was removed. The ureter was spatulated on both ends and closed in an interrupted fashion. Once half of the sutures were in place, the stent was placed into the ureter through the transurethral cystoscope. In the recovery room, a plain film confirmed the proper location of the stent. The stent was removed 6 weeks after surgery in the clinic setting. A Lasix renal scan performed 12 weeks after surgery confirmed a well-healed ureter with no evidence of stricture or obstruction.

Look for injuries, and repair them, intraoperatively

Urinary tract injury is a known complication of all gynecologic procedures. Identifying the injury intraoperatively reduces postoperative complications and long-term sequelae. The use of cystoscopy and agents that allow for easy discernment of ureteral efflux aid in identifying urinary tract injuries intraoperatively. ■

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COMING IN PART 2

- **Should the Ob be separated from the Gyn?**
  Pro/con from Geoffrey W. Cundiff, MD, and Kimberly Kenton, MD
- **Mentorship in ObGyn and Gyn surgery**
  Denise Elser, MD

CERVICAL DISEASE

Findings from 2 studies answer key questions regarding cervical cancer screening. Plus, an explosion of new molecular technology applications has and continues to rapidly expand options for treatment and prevention of cervical cancer.

Mark H. Einstein, MD, MS
Dr. Einstein is Professor and Chair, Department of Obstetrics, Gynecology and Women's Health, and Assistant Dean, Clinical Research Unit, Rutgers New Jersey Medical School, Newark, New Jersey.

Dr. Einstein has advised, but does not receive an honorarium from any companies. In specific cases his employer has received payment for his consultation from Photocure, Papivax, Inovio, PDS Biotechnologies, Natera, and Immunovaccine. If travel is required for meetings with any industry, the company pays for Dr. Einstein's travel-related expenses. Also, his employers have received grant funding for research-related costs of clinical trials that Dr. Einstein has been the overall principal investigator or local principal investigator for the past 12 months from Baxalta, Photocure, Fujiboro, Eli Lilly, PDS Biotechnologies, and Becton-Dickinson.

Vaccination against human papillomavirus (HPV) infection and periodic cervical screening have significantly decreased the incidence of invasive cervical cancer. But cancers still exist despite the availability of these useful clinical tools, especially in women of reproductive age in developing regions of the world. In the 2016 update on cervical disease, I reviewed studies on 2 promising and novel immunotherapies for cervical cancer: HPV therapeutic vaccine and adoptive T-cell therapy. This year the focus is on remarkable advances in the field of genomics and related studies that are rapidly expanding our understanding of the molecular characteristics of cervical cancer. Rewards of this research already being explored include novel immunotherapeutic agents as well as the repurposed use of existing drugs.

But first, with regard to cervical screening and follow-up, 2 recent large studies have yielded findings that have important implications for patient management. One pertains to the monitoring of women who have persistent infection with high-risk HPV but cytology results that are negative. Its conclusion was unequivocal and very useful in the management of our patients. The other study tracked HPV screening performed every 3 years and reported on the diagnostic efficiency of this shorter interval screening strategy.

Persistent HPV infection has a higher risk than most clinicians might think

Elfgren K, Elfström KM, Naucler P, Arnheim-Dahlström L, Dillner J. Management of women with human papillomavirus persistence: long-term follow-up of a randomized clinical trial. Am J Obstet Gynecol. 2017;216(3):264.e1–e7.

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It is well known that most cases of cervical cancer arise from persistent HPV infection, with the highest percentage of cancers caused by high-risk types 16 or 18. What has been uncertain, however, is the actual degree of risk that persistent infection confers over time for the development of cervical intraepithelial neoplasia (CIN) or worse when a woman's repeated cytology reports are negative. In an analysis of a long-term double-blind, randomized, controlled screening study, Elfgren and colleagues showed that *all* women whose HPV infection persisted up to 7 years developed CIN grade 2 (CIN2+), while those whose infection cleared in that period, or changed genotype, had no precancerous lesions out to 13 years of follow-up.

Details of the study

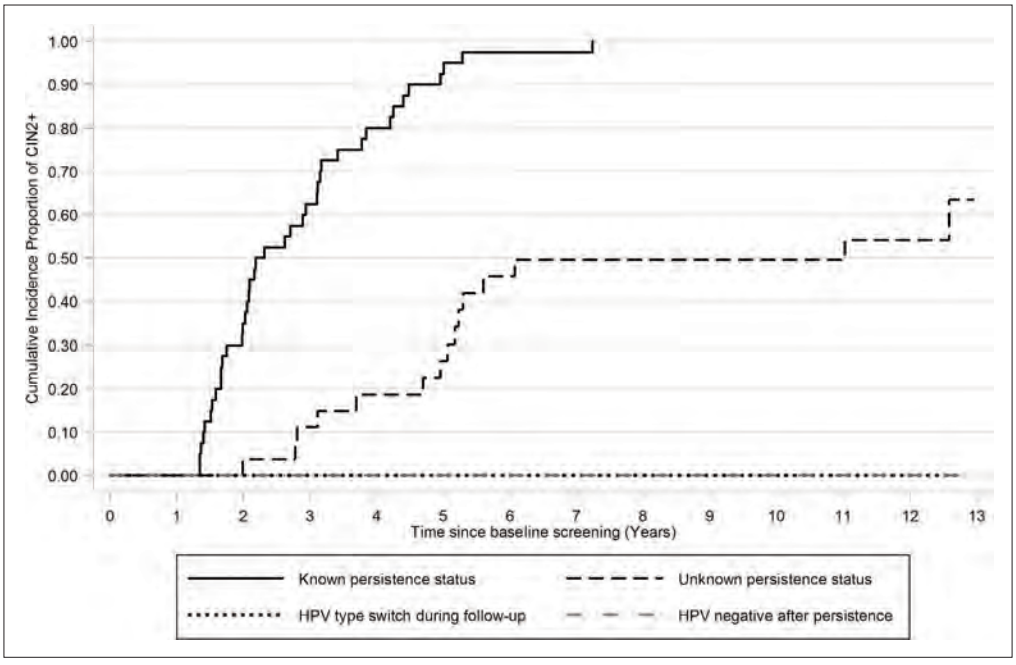
Between 1997 and 2000, 12,527 Swedish women between the ages of 32 and 38 years who were undergoing organized cervical cancer screening agreed to participate in a 1:1–randomized prospective trial to determine the benefit of screening with HPV and cytology (intervention group) compared with cytology screening alone (control group). However, brush sampling for HPV was performed even on women in the control group, with the samples frozen for later testing. All participants were identified in the Swedish National Cervical Screening Registry.

Women in the intervention group who initially tested positive for HPV but whose cytology test results were negative (n = 341) were invited to return a year later for repeat HPV testing; 270 women returned and 119 had type-specific HPV persistence. Of those with persistent infection, 100 agreed to undergo colposcopy; 111 women from the control group were randomly selected to undergo sham HPV testing and colposcopy, and 95 attended. Women with evident

FAST TRACK

In the trial by Elfgren and colleagues, 100% of women whose persistent HPV infection continued up to 7 years developed CIN2+ or worse

FIGURE 1 Implications of HPV infection persistence or clearance for CIN development



All 40 women whose type-specific HPV infection persisted continuously for 7 years (solid line) developed CIN2+. None of the 35 women whose HPV infection cleared or changed genotype developed CIN (dotted line overlapping dash-dot line). Twenty-seven women had unknown HPV persistence status (dashed line).

Abbreviation: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus.

Source: Am J Obstet Gynecol. 2017;216:264.e1–e7. Used with permission.

cytologic abnormalities received treatment per protocol. Those with negative cytology results were offered annual HPV testing thereafter, and each follow-up with documented type-specific HPV persistence led to repeat colposcopy. A comparable number of women from the control group had repeat colposcopies.

Although some women were lost to clinical follow-up throughout the trial, all 195 who attended the first colposcopy were followed for at least 5 years in the Swedish registry, and 191 were followed in the registry for 13 years. Of 102 women with known HPV persistence at baseline (100 in the treatment group; 2 in the randomly selected control group), 31 became HPV negative, 4 evidenced a switch in HPV type but cleared the initial infection, 27 had unknown persistence status due to missed HPV tests, and 40 had continuously type-specific persistence. Of note, persistent HPV16 infection seemed to impart a higher risk of CIN development than did persistent HPV18 infection.

All 40 participants with clinically verified continuously persistent HPV infection developed CIN2+ within 7 years of baseline documentation of persistence (**FIGURE 1**). Among the 27 women with unknown persistence status, risk of CIN2+ occurrence within 7 years was 50%. None of the 35 women who cleared their infection or switched HPV type developed CIN2+.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Cytology is a valuable tool, but it tells us only what is happening today. HPV testing is the crystal ball that tells us a patient's risk of having a precancerous CIN or cancer in the future. In this well-done randomized prospective trial by Elfgren and colleagues, 100% of women whose persistent HPV infection continued up to 7 years developed CIN2+ or worse. The unmistakable implication of this finding is the need for active follow-up for women with persistent HPV infection. Equally important is the finding that no women who cleared their initial infection developed CIN2+, a very reassuring outcome, and one we can share with patients whose HPV clears.

FAST TRACK

Current cervical cancer screening guidelines for 30- to 65-year-old women advise use of cytology every 3 years or combining HPV testing and cytology every 5 years

HPV–cytology cotesting every 3 years lowers population rates of cervical precancer and cancer

Silver MI, Schiffman M, Fetterman B, et al. The population impact of human papillomavirus/cytology cervical cotesting at 3-year intervals: reduced cervical cancer risk and decreased yield of precancer per screen. Cancer. 2016;122(23):3682–3686.

Current guidelines on screening for cervical cancer in women 30 to 65 years of age advise the preferred strategy of using cytology alone every 3 years or combining HPV testing and cytology every 5 years.[1] These guidelines, based on data available at the time they were written, were meant to offer a reasonable balance between timely detection of abnormalities and avoidance of potential harms from screening too frequently. However, many patients are reluctant to postpone repeat testing to the extent recommended. Several authorities have in fact asked that screening intervals be revisited, perhaps allowing for a range of strategies, contending that the level of protection once provided by annual screening should be the benchmark by which

TABLE Rates of cervical biopsy and precancerous lesion detection*

	Open cohort†		Closed cohort‡	
Years	Rate of biopsy	Rate of precancer§	Rate of biopsy	Rate of precancer§
2004–2006	1373.5	82.0	1535.5	80.5
2007–2009	2230.8	140.6	2347.5	118.6
2010–2012	2738.4	126.0	2793.9	84.9

*Rates are per 100,000 women screened.
†All women ≥30 years enrolled with Kaiser Permanente Northern California between 2003 and 2012.
‡Only those women ≥30 years old enrolled in 2003–2004 and followed longitudinally until 2012.
§CIN3+ or adenocarcinoma in situ.
Source: Cancer. 2016:122(23):3682–3686.

FAST TRACK

Analyzing data from >1 million women, Silver and colleagues found that 3-year HPV-cytology cotesting safely lowered population rates of cervical precancer and cancer

evolving strategies are judged.[2] Today, they point out, the risk of cancer doubles in the 3 years following an initial negative cytology result, and it also increases by lengthening the cotesting interval from 3 to 5 years. They additionally question the validity of using frequency of colposcopies as a surrogate to measure harms of screening, and suggest that many women would willingly accept the procedure's minimal discomfort and inconvenience to gain peace of mind.

The study by Silver and colleagues gives credence to considering a shorter cotesting interval. Since 2003, Kaiser Permanente Northern California (KPNC) has implemented 3-year cotesting. To determine actual clinical outcomes of cotesting at this interval, KPNC analyzed data on more than 1 million women in its care between 2003 and 2012. Although investigators expected that they might see decreasing efficiency in cotesting over time, they instead found an increased detection rate of precancerous lesions per woman screened in the larger of 2 study cohorts.

Details of the study

Included were all women 30 years of age or older enrolled in this study at KPNC between 2003 and 2012 who underwent HPV–cytology cotesting every 3 years. The population in its entirety (1,065,273 women) was deemed the "open cohort" and represented KPNC's total annual experience. A subset of this population, the "closed cohort," was designed to gauge the effect of repeated screening on a fixed population and comprised only those women enrolled and initially screened between 2003 and 2004 and then followed longitudinally until 2012.

For each cohort, investigators calculated the ratios of precancer and cancer diagnoses to the total number of cotests performed on the cohort's population. The 3-year testing periods were 2004–2006, 2007–2009, and 2010–2012. Also calculated in these periods were the ratios of colposcopic biopsies to cotests and the rates of precancer diagnoses (**TABLE**).

In the open cohort, the biopsy rate nearly doubled over the course of the study. Precancer diagnoses per number of cotests rose by 71.5% between the first and second testing periods ($P = .001$) and then eased off by 10% in the third period ($P<.001$). These corresponding increases throughout the study yielded a stable number of biopsies (16 to 22) needed to detect precancer.

In the closed long-term cohort, the biopsy rate rose, but not as much as in the

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Patients are dissatisfied with the 5-year screening interval for cotesting, and many of them wish to return to shorter interval testing. What this large-scale study shows is that 3-year cotesting safely lowers population rates of cervical precancer and cancer and does so at an interval that should help ease patients' minds.

open cohort. Precancer diagnoses per number of cotests rose by 47% between the first and second periods ($P \leq .001$), but in the third period fell back by 28% ($P < .001$) to a level just above the first period results. The number of biopsies needed to detect a precancerous lesion in the closed cohort rose from 19 to 33 over the course of the study, suggesting there may have been some loss of screening efficiency in the fixed group.

Molecular profiling of cervical cancer is revolutionizing treatment

The Cancer Genome Atlas Research Network. Integrated genomic and molecular characterization of cervical cancer. Nature. 2017;543(7645):378–384.

Effective treatments for cervical cancer could be close at hand, thanks to a recent explosion of knowledge at the molecular level about how specific cancers arise and what drives them other than HPV. The Cancer Genome Atlas Research Network (TCGA) recently published the results of its genomic and proteomic analyses, which yielded distinct profiles for 178 cervical cancers with important patterns common to other cancers, such as uterine and breast cancer. These recently published findings on cervical cancer highlight areas of gene and protein dysfunction it shares with these other cancers, which could open the doors for new targets for treatments already developed or in the pipeline.

How molecular profiling is paying off for cervical cancer

Cancers develop in any given tissue through the altered function of different genes and signaling pathways in the tissue's cells. The latest extensive investigation conducted by the TCGA network has identified significant mutations in 5 genes previously unrecognized in association with cervical cancer, bringing the total now to 14.

Several highlights are featured in the TCGA's recently published work. One discovery is the amplification of genes *CD274* and *PDCD1LG2*, which are involved with the expression of 2 cytolytic effector genes and are therefore likely targets for immunotherapeutic strategies. Another line of exploration, whole-genome sequencing, has detected an aberration in some cervical cancer tissue with the potential for immediate

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FIGURE 2 The Cancer Genome Atlas Research Network

Tumor characteristics:

DNA mutation

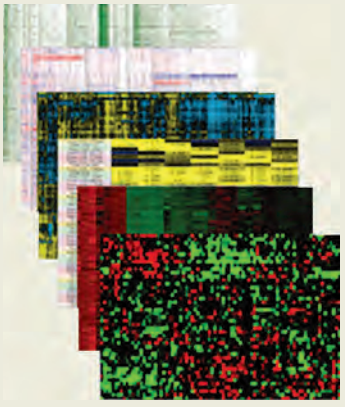
Copy-number variation

DNA methylation

MicroRNA expression

mRNA expression

Protein activity



The Cancer Genome Atlas Research Network (TCGA) is integrating data obtained from molecular-level tumor tissue analyses, such as DNA mutation and methylation, messenger- and micro-RNA expression, gene copy number variations, and reverse phase protein arrays to generate molecular profiles of clinical tumors and their subtypes. These profiles combined with clinical data are leading to novel molecular therapeutic strategies and prognostic indicators that increase the precision and effectiveness of cancer treatment. Using this multiplatform analytic approach, the TCGA has identified and profiled more than 200 types of cervical cancer.

Source: Liu Z, Zhang S. Toward a systematic understanding of cancers: a survey of the pan-cancer study. Front Genet. 2014;5:194.

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WHAT THIS EVIDENCE MEANS FOR PRACTICE

It is this kind of detailed molecular knowledge—which is far more clinically meaningful than information provided by standard histology—that will 1) define cancer typing at a more precise level, 2) guide the development of targeted individualized treatments, and 3) give new hope to patients with aggressive cancers. While much of the malignant transformation is HPV driven, other genetic patterns can be targeted. Therapeutic investigation is now moving forward, focusing on the recently revealed similarities between cancers in different parts of the body. The National Cancer Institute, in conjunction with clinical partners across the country, is enrolling patients with different tumor types in its NCI-MATCH (Molecular Analysis for Therapy Choice) trial. In brief, patients who have a tumor (regardless of origin or tissue type) containing specific molecular abnormalities already recognized in another cancer and targeted by an existing drug will receive that treatment to determine if it will prove effective.

For more information, visit the NCI-MATCH website: https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match.

application. Duplication and copy number gain of *BCAR4*, a noncoding RNA, facilitates cell proliferation through the HER2/HER3 pathway, a target of the tyrosine-kinase inhibitor, lapatinib, which is currently used to treat breast cancer.

The integration of data from multiple layers of analysis (**FIGURE 2,** page 35) is helping investigators identify variations in cancers. DNA methylation, for instance, is a means by which cells control gene expression. An analysis of this process in cervical tumor tissue has revealed additional cancer subgroups in which messenger RNA increases the transition of epithelial cells to invasive mesenchymal cells. Targeting that process in these subgroups would likely enhance the effectiveness of novel small-molecule inhibitors and some standard cytotoxic chemotherapy.

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to providing increased LARC use to adolescents, there are effective strategies that can address the increased cost of LARCs versus other contraceptive methods and insertion-timing barriers, specifically with regard to STD testing.

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Examining the **EVIDENCE**

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fetal weight, fetal sex, presence of infection, use of antenatal steroids—and, perhaps most important, individual and family values and preferences. Despite these new data, managing periviable gestations will remain a great and important challenge.

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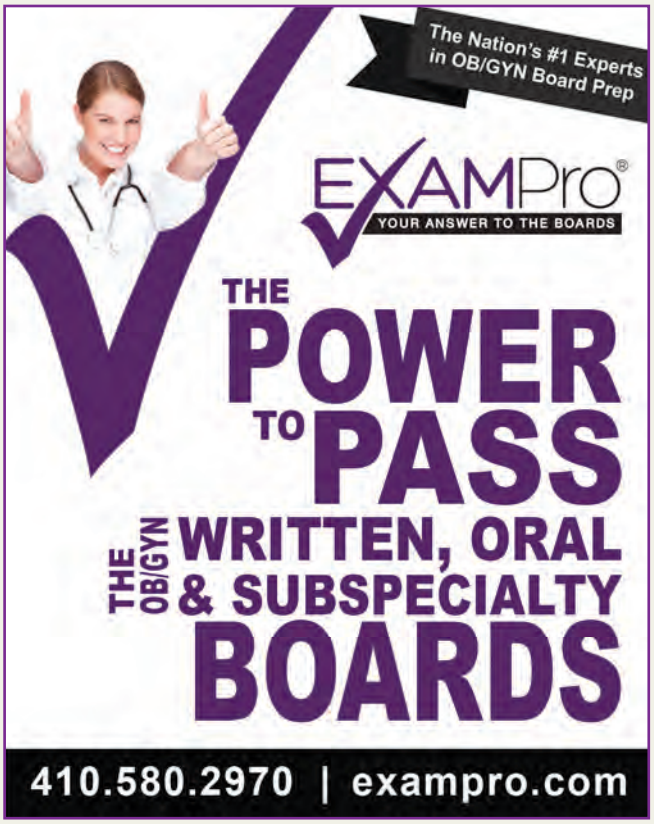

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UPDATE A distinguished Board of Editors

OBG MANAGEMENT

Every issue, the OBG MANAGEMENT masthead lists it most capable and valued Board of Editors. These top experts represent an always-expanding richness of awards for service and clinical accomplishments. Here are some highlights. The Editors salute these passionate consultants for their contributions to the success of the publication and honor them for their ongoing leadership and dedication to advancing women's health care.

ARNOLD P. ADVINCULA, MD, is past President of the American Association of Gynecologic Laparoscopists (AAGL), an 8,000-member organization promoting minimally invasive surgery worldwide. He also serves as the Medical Director of the Mary & Michael Jaharis Simulation Center at New York Presbyterian Hospital/ Columbia University Medical Center (NYP/CUMC). Dr. Advincula continues to develop innovative surgical devices and new robotic surgical platforms to facilitate minimally invasive surgery.

LINDA D. BRADLEY, MD, is Founder and serves as Chair of Cleveland Clinic Celebrate Sisterhood, a program dedicated to educating, energizing, and empowering women of color to take charge of their health, families, and community. Dr. Bradley is Associate Editor of the textbook, *Operative Techniques in Gynecologic Surgery: Gynecology* (Wolters Kluwer), published in April 2017.

STEVEN R. GOLDSTEIN, MD, NCMP, CCD, is past President of The American Institute of Ultrasound in Medicine (AIUM) and the North American Menopause Society (NAMS). He is currently the Treasurer of the International Menopause Society (IMS). This past year he received the Thomas B. Clarkson Outstanding Clinical and Basic Science Research Award from NAMS.

CHERYL B. IGLESIA, MD, is the Current Chair of the American College of Obstetricians and Gynecologists (ACOG) Patient Education Review Panel and remains Chair of the Pelvic Floor Disorders (PFD) Network Advisory Board of The Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health (NIH). She is also the current program chair of the American Urogynecologic Society (AUGS).

ANDREW M. KAUNITZ, MD, NCMP, serves as author of 11 chapters for *UpToDate*, an online, evidence-based, physician-authored, clinical support resource. He also serves as Editor in Chief for *NEJM Journal Watch Women's Health*. Dr. Kaunitz participates in clinical trials of new contraceptives, works with ACOG and the Centers for Disease Control and Prevention in preparing guidance regarding use of contraception in women with medical issues, and serves on a writing panel updating guidance regarding use of menopausal hormone therapy for NAMS.

DAVID G. MUTCH, MD, is Co-Chair of the National Cancer Institute Gynecologic Steering Committee. He is the Chair of the American Joint Committee on Cancer Staging for Gynecologic Cancers. He is also Chairman of the Board of Directors of the Foundation for Women's Cancer, formed by the Society of Gynecologic Oncologists. He has published more than 300 peer-reviewed papers and is the principal investigator of the Washington University U10 grant for translational genomics.

ERROL R. NORWITZ, MD, PHD, MBA, is Professor and Chair of ObGyn and a founding investigator of the Mother Infant Research Institute at Tufts Medical Center and Tufts University School of Medicine. He recently received his MBA from the Questrom School of Business at Boston University and was appointed Chief Scientific Officer at Tufts Medical Center. He is listed as one of Boston's "Top Doctors" and holds leadership positions in a number of national/international organizations, including the Society for Reproductive Investigation and the March of Dimes. His research interests include the genetics of adverse pregnancy events and the molecular regulation of parturition, both at term and preterm.

JOANN V. PINKERTON, MD, NCMP, received the University of Virginia Sharon L. Hostler Women in Medicine Leadership Award in 2013 and Best Doctor and Top Doctor since 2009. She is Executive Director of NAMS, chair of a panel of 23 experts writing the 2017 NAMS Hormone Therapy Position statement, and served as co-author on the Endocrine Society's menopause clinical practice guidelines and their bioidentical hormone therapy position statement. She is an Editor for *Menopause*, a Section Editor for *Journal of Women's Health*, and on the editorial board of *Climacteric*.

JOHN T. REPKE, MD, is past President of the North American Society for the Study of Hypertension in Pregnancy, a member of Alpha Omega Alpha, and a fellow of ACOG, the American Gynecological & Obstetrical Society, the Society for Maternal-Fetal Medicine, and the Society for Reproductive Investigation. Dr. Repke has chaired the Department of ObGyn at Penn State since 2002.

JOSEPH S. SANFILIPPO, MD, MBA, has been listed as Best/Top Doctor for 12 years. He completed 30 years as Editor-in-Chief of the *Journal of Pediatric and Adolescent Gynecology* and recently retired from his position as Executive Director of the North American Society for Pediatric and Adolescent Gynecology. He was a featured speaker at the Federation Internationale de Gynecologie Infantile et Juvenile (FIGIJ) meeting in Florence, Italy. He is chair of the Industry Committee of ACOG.

JAMES A. SIMON, MD, CCD, IF, NCMP, serves as an Associate Editor for *Sexual Medicine Reviews* and is President-Elect of the International Society for the Study of Women's Sexual Health (ISSWSH). He chairs the Ethics Committee of The International Society for Sexual Medicine (ISSM). He is a Certified Sexuality Counselor by The American Association of Sexuality Educators, Counselors and Therapists (AASECT).

ROBERT L. BARBIERI, MD, is Editor in Chief of OBG MANAGEMENT. He is also Editor in Chief of the Obstetrics, Gynecology, and Women's Health program for *UpToDate* and Co-Editor of Yen and Jaffe's *Reproductive Endocrinology*.

Board members' full titles and affiliations are listed on the Board of Editors Masthead, page 2.


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