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Debra S. Copit
MD, FACR

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* Dr. Copit has been in practice for over 20 years. She is a widely published, nationally recognized leader in the field of breast imaging and pioneer in digital breast tomosynthesis. Dr. Copit is also an Associate Professor of Radiology and recipient of numerous honors and awards.
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Don’t mess with Title X, vital for women’s health

Proposed changes to the regulations threaten the preventive health care benefits for women and families that the program was originally created to provide.

As practicing obstetrician-gynecologists in a safety-net hospital, we strongly support Title X and are dismayed by a proposed federal rule change threatening to severely compromise it. We are privileged to serve beneficiaries of Title X, the only federal grant program that guarantees contraceptive access for low-income women, and we see the positive impact the program has on their lives and health. In New Mexico, where we practice, a large percentage of women receive services through Title X. With one of the country’s highest adolescent pregnancy rates and a high rate of medically complex patients, Title X allows New Mexican women of all ages to make positive health choices.

Enacted in 1970 during the Nixon administration, Title X drew bipartisan support with no dissenting votes in the Senate and only 32 dissenting votes in the House, demonstrating the overwhelming support for family planning as an integral component of preventive health care. The broad base of support came from a shared understanding that greater access to birth control would lead to fewer abortions by reducing unintended pregnancies.

Since enactment, Title X has become a critical safety net providing comprehensive contraceptive services to underserved women. Providers are required to follow quality guidelines mandating evidence-based practices, including the provision of the full range of FDA-approved methods. Research confirms that Title X centers are more likely than others to provide a broad array of contraceptives, including highly effective long-acting reversible contraceptives (LARC) and to employ protocols that facilitate the initial and continued use of contraception by patients.

The proposed regulatory changes to Title X would severely undermine the program’s success. At risk is care that complies with the Institute of Medicine’s six dimensions of quality: care that is safe, timely, patient-centered, effective, efficient and equitable. The proposed binding rule restricts providers’ ability to offer the evidence-based contraceptive care and reproductive health counseling known to result in improved health outcomes. Although evidence is clear that abortion rates are lowest in regions that invest in family planning services, this ill-conceived rule change promotes less effective contraceptive methods and reduces access to abortion. We explain only a few of the many damaging components of the rule:

- The rule undermines access to comprehensive contraception through several mechanisms. One is the removal of the requirement for provision of “medically approved” family planning methods. In contrast to the current requirement, it would allow for exclusion of contraceptive methods based on grantee bias, limiting methods provided. Another is the provision of funds to faith-based entities that promote fertility awareness and abstinence. The rule change would open the door for ideologically-driven entities that oppose abortion and most forms of contraception—for example, so called “crisis pregnancy centers”—to become

How to minimize vaginal birth complications Dr Lockwood and other experts explain how they manage unexpected problems Read more on page 20.

A new normal A look at how fathers and children are impacted by maternal mortality Read more on page 30.
There are thousands of gene variations that cause a higher risk of cancer. With comprehensive, affordable genetic insights, she can make screening and prevention decisions that make a difference—today and for years to come.

This moment matters.
Title X grantees, offering medically inaccurate information and a single form of contraception, i.e., natural family planning. The rule elevates natural family planning and abstinence counseling to a program priority and excludes reference to evidence-based contraception guidelines.

- The rule creates burdensome requirements intended to block federal funds to Planned Parenthood. It requires Title X grantees to create additional financial and physical separation of contraception and abortion services. The rule targets centers that provide both Title X family planning services and non-federally funded abortion services, forcing clinics to stop providing abortion care or to shutter their Title X family planning component. In a similar change, when Texas excluded abortion providers from its family planning program in 2013, the number of contraceptive prescriptions, provision of LARC and number of women served by the program dropped dramatically.

- The rule restricts non-directive pregnancy options counseling and abortion referral: The most explicit anti-abortion components of the rule egregiously violate the patient-provider relationship and limit access to reproductive health care. Title X providers could not encourage, promote or “present” the option of abortion unless the patient had already chosen to terminate the pregnancy and explicitly requested a referral. In that case, a physician may, but is not required, to give her a list of providers, all of whom must offer prenatal care but only some of whom may also provide abortion. The physician may not tell the patient which providers on the list provide both abortion and prenatal care, even if she explicitly asks. If the patient has not made up her mind but requests information regarding abortion referral, the provider may only give her a list of providers who offer prenatal care. This “gag” component violates providers’ ethical duty to impart complete, unbiased, and accurate information and is counter to the quality-care principles of the Institute of Medicine.

- The rule undermines adolescents’ confidentiality: Under current rules, Title X providers must offer confidential services to adolescents. The proposed rule requires providers to certify that they encourage family participation in minors’ decisions to seek family-planning services, including required documentation of specific actions taken to encourage family involvement. Because this requirement would undoubtedly deter many minors from seeking care, it runs counter to our national goal of re-

### TABLE 1  Title X requirements

<table>
<thead>
<tr>
<th>Original requirement</th>
<th>Proposed change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title X agencies must provide a range of medically approved family planning methods or options to the patient.</td>
<td>Removes the requirement that Title X providers offer patients access to a full-range of medically approved contraceptive methods.</td>
</tr>
<tr>
<td>Title X agencies are encouraged to partner with community or faith-based agencies in the creation and implementation of programs.</td>
<td>Would prioritize awarding funding to faith-based or ideologically-driven agencies that oppose abortion and most forms of contraception, potentially presenting patients with medically inaccurate information and limited contraception options.</td>
</tr>
<tr>
<td>Title X federal funds support family planning and contraceptive care available through providers that also offer abortion in its range of services, such as Planned Parenthood. Abortion is not provided as part of the Title X program.</td>
<td>Would require Title X grantees to create additional financial and physical separation between contraception and abortion services, forcing clinics to stop providing abortion care or to shutter their Title X family planning component.</td>
</tr>
<tr>
<td>Title X requires referral for a range of non-directive options for prenatal care, delivery, abortion, adoption.</td>
<td>Would restrict non-directive pregnancy options, counseling, and abortion referral, effectively placing a “gag” order on Title X providers with regard to abortion. If a patient requests information on abortion she may be given a list of prenatal care providers, only some of whom may also provide abortion services, with no indication which providers on the list provide what services.</td>
</tr>
</tbody>
</table>

Title X providers encourage family participation in an adolescent’s care, including family-planning services, while preserving the confidentiality of the adolescent patient.

Title X providers must offer confidential services to adolescents. The proposed rule requires providers to certify that they encourage family participation in minors’ decisions to seek family-planning services, including required documentation of specific actions taken to encourage family involvement. Because this requirement would undoubtedly deter many minors from seeking care, it runs counter to our national goal of re-
ducing the high rate of teen pregnancy and sexually transmitted infections.

In addition, the dense 31-page document outlining the proposed rule contains vague and confusing language. Struggling to understand what is and is not permissible, providers are apt to err on the side of a more conservative interpretation, lest they inadvertently violate the rule. If authorized, this rule would make effective birth control far less accessible to low income women—including women of color—and would therefore exacerbate the socioeconomic and racial health inequities tarnishing American society.

Title X has had an enormous positive impact on women’s health. Twenty percent of women in the United States who receive contraceptive services obtain them from a Title X-supported clinic. Consequently, in the past two decades Title X has averted nearly 20 million unintended pregnancies and 9 million abortions. The program has saved three tax-payer dollars for every dollar invested. The Centers for Disease Control and Prevention heralded family planning as one of the top 10 public health achievements of the 20th century. Family planning has led to improved health outcomes for infants, children, and adult women and has provided new social and economic opportunities for women.

The comment period for the rule changes ended on July 31, 2018. The American College of Obstetricians and Gynecologists, along with 40 of its state Sections—including New Mexico ACOG—submitted formal comments to the Department of Health and Human Services detailing all these concerns on behalf of women’s health care providers. Many other leading medical organizations also lent their expertise to oppose the rule, and we’re hopeful the Administration will take heed. In the meantime, while we wait to hear the decision on final rule language, as ob/gyns, we must take our place in the vanguard, continuing to honor our human-rights charge of empowering women, families and societies through access to family planning.

Dr Espey is Professor and Chair, Department of Obstetrics and Gynecology, the University of New Mexico.

Dr Pickett is PGY-3, Department of Obstetrics and Gynecology, the University of New Mexico

DISCLAIMER This guest editorial does not necessarily reflect the views of all members of the editorial staff or the board of Contemporary OB/GYN.

FOR REFERENCES VISIT contemporaryobgyn.net/TitleX

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Can this low-cost blood test help prevent toxoplasmosis?

A point-of-care test can reliably detect toxoplasmosis with a finger-prick and return results fast and inexpensively.

Contemporaryobgyn.net/toxoplasmosis

Does ARRIVE set the stage for 39-week induction?

Release of results from the ARRIVE trial has provided answers to some concerns about 39-week induction while leading to some questions about the participants and the implication of the findings for clinical practice.

Contemporaryobgyn.net/arrive

CDC updates on Zika virus

The Centers for Disease Control and Prevention (CDC) has issued new guidance about Zika virus for couples planning a pregnancy. Also updated are the CDC’s statistics on the impact of the virus on babies in US territories.

Contemporaryobgyn.net/zikaupdates

FDA warns about tests for rupture of membranes

False-negative results are possible with rupture of membrane (ROM) tests and clinicians shouldn’t use them independently to diagnose the condition in a pregnant woman, according to the US Food and Drug Administration (FDA).

Contemporaryobgyn.net/ROM

Updated USPSTF screening recommendation for cervical cancer adds HPV testing

The USPSTF has updated its recommendations for HPV testing, but widespread adoption of primary screening is expected to be slow.

Contemporaryobgyn.net/screening
FOR THE TREATMENT OF WOMEN WITH MODERATE TO SEVERE DYSpareunia,
A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENOPAUSE

IMPORTANT SAFETY INFORMATION

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy
• There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
• Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
• The Women’s Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
• The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Estrogen Plus Progestin Therapy
• Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
• The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)
• The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

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**CONTRAINDICATIONS**
- IMVEXXY™ is contraindicated in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia; active DVT, PE, or history of these conditions; active arterial thromboembolic disease or a history of these conditions; known anaphylactic reaction or angioedema to IMVEXXY; known liver impairment or disease; known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders.

**WARNINGS AND PRECAUTIONS**
- IMVEXXY is intended only for vaginal administration. Systemic absorption may occur with the use of IMVEXXY.
- The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation.
- The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer. A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.
- Other warnings include: gallbladder disease; severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice.
- Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.
- Women on thyroid replacement therapy should have their thyroid function monitored.

**ADVERSE REACTIONS**
- The most common adverse reaction with IMVEXXY (incidence ≥ 3 percent) and greater than placebo was headache.

**INDICATION**
**IMVEXXY™** (estradiol vaginal inserts) is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

**IMPORTANT IMVEXXY FEATURES**
- Applicator-free, any time of day administration¹
- Mess-free administration with no applicator, dose preparation, or cleanup needed¹²
- Freedom to enjoy her everyday activities without interruption after insertion¹
- Improvement in moderate to severe dyspareunia seen at week 12 and beginning as early as week 2 (a secondary endpoint)¹²
- Both doses of IMVEXXY resulted in average systemic hormone levels that were within the normal postmenopausal range.¹,³

Please see Brief Summary of the Full Prescribing Information, including the Boxed Warning, on the following pages.


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IVXY-20116 08/2018
**Estrogen Alone Therapy**

**Endometrial Cancer**

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal vaginal bleeding (see Warnings and Precautions (5.3) in full prescribing information).

**Cardiovascular Disorders and Probable Dementia**

Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia (see Warnings and Precautions (5.2, 5.4), and Clinical Studies (14.2, 14.3) in full prescribing information).

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily oral conjugated estrogens (CE) (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women (see Warnings and Precautions (5.3), Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information).

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

**Estrogen Plus Progestin Therapy**

**Cardiovascular Disorders and Probable Dementia**

Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia (see Warnings and Precautions (5.2, 5.4), and Clinical Studies (14.2, 14.3) in full prescribing information).

The WHI estrogen plus progestin substudy reported increased risks of DVT, pulmonary embolism (PE), stroke, and myocardial infarction (MI) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral CE (0.625 mg) combined with medroxyprogesterone acetate (MPA) (2.5 mg) relative to placebo (see Warnings and Precautions (5.2), and Clinical Studies (14.2) in full prescribing information).

The WHIMS estrogen plus progestin ancillary study of the WHI, reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE (0.625 mg)- alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women (see Warnings and Precautions (5.3), Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information).

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens and progestogens.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

**INDICATIONS AND USAGE**

**IMVEXXY** (estradiol vaginal inserts) is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

**DOSAGE AND ADMINISTRATION**

Generally, estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer. A woman without a uterus does not need a progestin. In some cases, however, hysterectomized women with androgen recalcitrant women with a history of endometriosis may need a progestin (see Warnings and Precautions (5.3, 5.15) in full prescribing information).

Use of estrogen-alone, or in combination with a progestin, should be with the lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary.

**CONTRAINDICATIONS**

**IMVEXXY** is contraindicated in women with any of the following conditions:

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of breast cancer
- Known or suspected estrogen-dependent neoplasia
- Active DVT, PE, or history of these conditions
- Active arterial thromboembolic disease (for example, stroke and myocardial infarction (MI), or a history of these conditions)
- Known or suspected angioedema with IMVEXXY
- Known liver impairment or disease
- Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders

**WARNINGS AND PRECAUTIONS**

**Risks from Systemic Absorption**

IMVEXXY is intended only for vaginal administration. Systemic absorption may occur with the use of IMVEXXY (Pharmacokinetics [12.3] in full prescribing information). The warnings, precautions, and adverse reactions associated with the use of systemic estrogen-alone therapy should be taken into account.

**Cardiovascular Disorders**

An increased risk of stroke and DVT has been reported with estrogen-alone therapy. An increased risk of PE, DVT, stroke, and MI has been reported with estrogen plus progestin therapy. Should these occur or be suspected, estrogen with or without progestin therapy should be discontinued immediately.

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

This Brief Summary does not include all the information needed to use IMVEXXY safely and effectively. See package insert for full Prescribing Information.

**WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA**

Risk factors for arterial vascular disease (for example, hypertension, diabetes mellitus, tobacco use, hypercholesterolemia, and obesity) and/or venous thromboembolism (VTE) (for example, personal history or family history of VTE, obesity, and systemic lupus erythematosus) should be managed appropriately.

**Stroke**

In the WHI estrogen-alone substudy, a statistically significant increased risk of stroke was reported in women 50 to 79 years of age receiving daily CE (0.625 mg)-alone compared to women in the same age group receiving placebo (45 versus 33 per 10,000 women-years). The increase in risk was demonstrated in year 1 and persisted (see Clinical Studies (14.2) in full prescribing information). Should a stroke occur or be suspected, estrogen-alone therapy should be discontinued immediately.

**Coronary Heart Disease**

In the WHI estrogen-alone substudy, no overall effect on coronary heart disease (CHD) events (defined as nonfatal MI, silent MI, or CHD death) was reported in women receiving estrogen-alone compared to placebo (see Clinical Studies (14.2) in full prescribing information).

**Subgroup analyses of women 50 to 59 years of age suggests a statistically non-significant reduction in CHD events (CE 0.625 mg-alone compared to placebo) in women with less than 10 years since menopause (8 versus 10 per 10,000 women-years).**

In the WHI estrogen plus progestin substudy, there was a statistically non-significant increased risk of CHD events reported in women receiving daily CE (0.625 mg) plus MPA (2.5 mg) compared to women receiving placebo (41 versus 34 per 10,000 women-years). An increase in relative risk was demonstrated in year 1, and persisted toward decreasing relative risk was reported in years 2 through 5 (see Clinical Studies (14.2) in full prescribing information).

**Venous Thromboembolism**

In the WHI estrogen-alone substudy, the risk of VTE (DVT and PE) was increased for women receiving daily CE (0.625 mg)-alone compared to placebo (30 versus 22 per 10,000 women-years), although only the increased risk of DVT reached statistical significance (23 versus 15 per 10,000 women-years). The increase in VTE risk was demonstrated during the first 2 years (see Clinical Studies (14.2) in full prescribing information).

**Should a VTE occur or be suspected, estrogen plus progestin therapy should be discontinued immediately.**

**Malignant Neoplasms**

**Endometrial Cancer**

An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in a woman with a uterus. The reported endometrial cancer risk among unopposed estrogen users is about 2 to 12 times greater than in non-users, and appears dependent on duration of treatment and on estrogen dose. However, these show a significantly increased risk associated with use of estrogens for less than 1 year. The greatest risk appears associated with prolonged use, with an increased risk of 15- to 24-fold for 5 to 10 years or more and this risk has been shown to persist for at least 8 to 15 years after estrogen therapy is discontinued.

Clinical surveillance of all women using estrogen-alone or estrogen plus progestin therapy is important. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

There is no evidence that the use of natural estrogens results in a different endometrial risk profile than synthetic estrogens of equivalent estrogen dose. Adding a progestin to estrogen therapy in postmenopausal women has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer.

**Breast Cancer**

The most important randomized clinical trial providing information about breast cancer in estrogen-alone users is the WHI substudy of daily CE (0.625 mg)-alone. In the WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE alone was not associated with an increased risk of invasive breast cancer [relative risk (RR) 0.80] (see Clinical Studies (14.2) in full prescribing information).

**The most important randomized clinical trial providing information about breast cancer in estrogen plus progestin users is the WHI substudy of daily CE (0.625 mg) plus MPA (2.5 mg). After a mean follow-up of 5.6 years, the estrogen plus progestin substudy reported an increased risk of invasive breast cancer in women who took daily CE plus MPA. In this substudy, prior use of estrogen-alone or estrogen plus progestin therapy was reported by 26 percent of the women. The relative risk of invasive breast cancer was 1.24, and the absolute risk was 46 versus 41 per 100,000 women-years, for CE plus MPA compared with placebo. Among women who reported prior use of hormone therapy, the relative risk of invasive breast cancer was 1.36, and the absolute risk was 46 versus 25 per 10,000 women-years, for CE plus MPA compared with placebo. Among women who reported no prior use of hormone therapy, the relative risk of invasive breast cancer was 1.09, and the absolute risk was 40 versus 36 per 10,000 women-years for CE plus MPA compared with placebo. In the same substudy, invasive breast cancers were larger, were more likely (continued on next page)
to be node positive, and were diagnosed at a more advanced stage in the CE (0.625 mg) plus MPA (2.5 mg) group compared with the placebo group. Metastatic disease was rare, with no apparent difference between the two groups, although other prognostic factors, such as histologic subtype, grade and hormone receptor status did not differ between the groups [see Clinical Studies (14.2) in full prescribing information].

Consistent with the WHI clinical trial, observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen-alone therapy, after several years of use. The relative risk associated with use of CE plus MPA compared to estrogen-alone therapy was 1.49 (95 percent CI, 0.83-2.66). The absolute risk of probable dementia for CE-alone versus placebo was 1.58 (95 percent CI, 0.77 to 3.24). The absolute risk for CE plus MPA versus placebo was 4 versus 3 cases per 10,000 women-years.7

A meta-analysis of 17 prospective and 35 retrospective epidemiologic studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer. The primary analysis, using case-control comparisons, included 12,110 cancer cases from the 17 prospective studies. The relative risks associated with current use of hormonal therapy was 1.41 (95% confidence interval [CI] 1.32 to 1.50); there was no difference in the risk estimates by duration of the exposure (less than 5 years [median of 3 years] vs. greater than 5 years [median of 10 years] of use before the cancer diagnosis). The relative risk associated with combined current and recent use (discontinued use within 5 years before cancer diagnosis) was 1.37 (95% CI 1.27 to 1.48), and the elevated risk was significant for both estrogen-alone and estrogen plus progestin products. The exact duration of hormone therapy use associated with an increased risk of ovarian cancer, however, is unknown.

Probable Dementia

In the WHIMS estrogen-alone ancillary study of WHI, a population of 2,947 hysterectomized women 65 to 79 years of age was randomized to daily CE (0.625 mg) alone or placebo. After an average follow-up of 5.2 years, 28 women in the estrogen-alone group and 19 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE-alone versus placebo was 1.49 (95 percent CI, 0.83-2.65). The absolute risk of probable dementia for CE-alone versus placebo was 37 versus 25 cases per 10,000 women-years [see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].

In the WHIMS estrogen plus progestin ancillary study of WHI, a population of 4,532 postmenopausal women 65 to 79 years of age was randomized to daily CE (0.625 mg) plus MPA (2.5 mg) or placebo. After an average follow-up of 4 years, 40 women in the CE plus MPA group and 21 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE plus MPA versus placebo was 2.05 (95 percent CI, 1.21-3.48). The absolute risk of probable dementia for CE plus MPA versus placebo was 45 versus 22 cases per 10,000 women-years [see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].

When data from the two populations in the WHIMS estrogen-alone and estrogen plus progestin ancillary studies were pooled as planned in the WHIMS protocol, the reported overall relative risk for probable dementia was 1.76 (95 percent CI, 1.19-2.59). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether these findings apply to younger postmenopausal women [see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].

Gallbladder Disease

A 2- to 4-fold increase in the risk of gallbladder disease requiring surgery in postmenopausal women receiving estrogen has been reported.

Hypercalcemia

Estrogen administration may lead to severe hypercalcemia in women with breast cancer and bone metastases. If hypercalcemia occurs, use of the drug should be stopped and appropriate measures taken to reduce the serum calcium level.

Visual Abnormalities

Retinal vascular thrombosis has been reported in women receiving estrogens. Discontinue medication pending examination if there is a sudden partial or complete loss of vision, or a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, estrogen should be permanently discontinued.

Addition of a Progestin When a Woman Has Not Had a Hysterectomy

Studies of the addition of a progestin for 10 or more days of a cycle of estrogen administration, or daily with estrogen in a continuous regimen, have reported a low incidence of endometrial hyperplasia; thus would be induced by estrogen treatment alone. Endometrial hyperplasia may be a precursor to endometrial cancer. There are, however, possible risks that may be associated with the use of progestins with estrogens compared to estrogen-alone regimens. These include an increased risk of breast cancer.

Elevated Blood Lipids

Elevated blood lipids, such as total cholesterol, low-density lipoprotein (LDL) cholesterol concentrations, increased triglyceride levels.

In-vitro and in-vivo studies have shown that estrogens are metabolized partially by cytochrome P450 3A4 (CYP3A4). Therefore, inducers or inhibitors of CYP3A4 may affect estrogen drug metabolism. Inducers of CYP3A4, such as St. John’s wort (Hypericum perforatum) preparations, phenobarbital, carbamazepine, and rifampin, may reduce plasma concentrations of estrogens, possibly resulting in a decrease in therapeutic effectiveness and/or changes in the uterine bleeding profile. Inhibitors of CYP3A4 such as erythromycin, clarithromycin, ketoconazole, itraconazole, citalopram, viloxazine, cimetidine, inhibin, nortriptyline, and fluoxetine may increase plasma concentrations of estrogen and may result in side effects.

USE IN SPECIFIC POPULATIONS

IMVEXXY is not indicated for use in pregnancy, in females of reproductive potential, or in children.

Geriatric Use

There have been sufficient numbers of geriatric women involved in clinical studies utilizing IMVEXXY to determine whether those over 65 years of age differ from younger subjects in their response to IMVEXXY. The women’s Health Initiative Studies

In the WHIMS estrogen-alone substudy (daily CE [0.625 mg] alone versus placebo), there was a higher relative risk of stroke in women greater than 65 years of age [see Clinical Studies (14.2) in full prescribing information].

In the WHIMS estrogen plus progestin substudy (daily CE [0.625 mg] plus MPA [2.5 mg] versus placebo), there was a higher relative risk of nonfatal stroke and invasive breast cancer in women greater than 65 years of age [see Clinical Studies (14.2) in full prescribing information].

The Women’s Health Initiative Memory Study

In the WHIMS ancillary studies of postmenopausal women 65 to 79 years of age, there was an increased risk of developing probable dementia in women receiving estrogen-alone or estrogen plus progestin when compared to placebo [see Warnings and Precautions (5.5), and Clinical Studies (14.3) in full prescribing information].

OVERDOSAGE

Overdosage of estrogen may cause nausea, vomiting, breast tenderness, abdominal pain, drowsiness and fatigue, and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of IMVEXXY therapy with institution of appropriate symptomatic care.

PATIENT COUNSELING INFORMATION

Based on FDA-approved PATIENT COUNSELING INFORMATION.
Historical perspective on septic abortion

Dear Dr. Zelop:

The article “Sepsis and Septic Shock in Pregnancy” in the June 2018 issue was informative. I thought you would be interested, at least for historical perspective, in the experience at Los Angeles County-USC Medical Center in the 1950-1960 era. At that time septic abortion was by far the most common and severe form of pregnancy infection, especially with complications of generalized sepsis, septicemia, endotoxin shock, renal shutdown (acute cortical necrosis) and vascular collapse.

Until our protocols were developed, at least one fatality per month occurred at that facility. Most of the techniques were employed as described in the contemporary article, including diagnosis—usually very easy—then vascular support, very aggressive antibiotics, antitoxin and steroids, removal of infected tissue (early) and “peritoneal dialysis.”

Enclosed herein (link to the article is below) is a 1963 paper from the Green Journal from LA County-USC Medical Center by the late and great Gail Anderson, first full-time chief of OB/GYN at LA County-USC Medical Center and me, on a special subset caused by clostridium welchii organism. Early removal of infected tissue by hysterectomy, peritoneal dialysis, antitoxin along with antibiotics all were necessary to lower the incidence of morbidity and mortality.

Another paper referenced in this article described the more “usual” septic abortion (E. coli, etc). Of course, since Roe v Wade these medical problems are much reduced, although principles of diagnosis, treatment, etc. described in your article are very beneficial.

The clash between “right to choose” and “right to life” has powerful arguments on both sides. Perhaps more effective, cheaper and safer contraception will help solve the medical, economic, and moral dilemmas on both sides.

Sincerely yours,

Marshall Kadner, MD

DR. ZELOP RESPONSE:

Dear Dr. Kadner:

Thank you for sharing your historical perspective with our readership regarding septic abortion. I would like to take this opportunity to acknowledge the significant clinical contributions to women’s health care made by providers like you who work so diligently in the trenches.

Best regards,

Carolyn

On obstetrics and the Hippocratic Oath

HOWIE MANDEL, MD

Dr. Lance Lang, the Chief Medical Officer of Covered California (a California health care exchange), has said “time’s up” regarding cesarean delivery rates. By 2019, hospitals whose rates do not meet the ACA Exchange’s average cesarean rate will be kicked out of their network. But the ethical question for physicians and society alike is, is this even moral?

I have been an ob/gyn for most of four decades and my approach to obstetrics has not changed. Some years, my cesarean delivery rate was very low, and in others I was an “outlier” on the high side.

Women must be treated as individuals. Although the industrial revolution increased quality and decreased costs in manufacturing, I do not believe that we can or should apply those principles to our patients. Women are not widgets.

In the Oath of Maimonides, we are called upon to vow and say, “May the
Balcoltra™ offers a balance of high efficacy and low dose

- Low-dose levonorgestrel/ethinyl estradiol combination oral contraceptive (COC)
- Familiar 21/7 dosing
- Cycle control with 4% breakthrough bleeding and 1 unintended pregnancy per 100 woman-years

Visit balcoltra.com to learn more about how Balcoltra may help your patients.

*Most eligible patients will pay no more than $21 per co-pay. Patients should present this coupon with their prescription to their participating pharmacy. For each Balcoltra prescription, patients pay the first $21 of their out-of-pocket expense and Avion will cover up to $100 of their remaining expense. This offer is good for 21 uses. Cardholders with questions, please call 1-877-838-3846 (8:30 AM - 5:30 PM ET, Monday-Friday).
Balcoltra™ (levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets and ferrous bisglycinate 36.5 mg tablets) for oral administration

Brief Summary of Prescribing Information

For additional information, refer to the full Prescribing Information

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.
love for my art actuate me at all time; may neither avarice nor miserliness … engage my mind. " Yet government regulators, insurance companies, the Leap Frog organization, Dr. Ezekiel Emanuel and Dr. Lang appear to have lost their memory of this oath. In Ancient Greece, Hippocrates said, "Whatsoever house I may enter, my visit shall be for the convenience and advantage of the patient."

In 1964, Louis Lasagna, the Academic Dean of the School of Medicine at Tufts University, created the modern version of the Hippocratic Oath that most schools use today. In it, we swear to “apply, for the benefit of the sick, all measures which are required …” to the benefit of the sick, not to the benefit of government, the federal budget, an ACO or the Covered California ACA Exchange. Dr. Charles Lockwood’s discussion on the “industrialization of medicine”1 and Dr. Allan Jacobs’s "Is There a Happy Medium?"2 articulate how physicians have lost their ability and autonomy to individualize care in their patients’ best interests.

I will always defend best practices as well as the rights of women to have full and truly unbiased informed consent. I will not compromise either my primary responsibility to my individual patients nor my commitment to adhere to the oaths of Maimonides and Hippocrates, and I would advocate that every physician try to understand that perspective when analyzing data on physicians who appear to be outliers.

I recognize the goals of the government and insurance companies, but as someone who had zero NTSV (Nulliparous, Term, Singleton, Vertex) cesareans for many quarters, I would caution administrators about over-analyzing low-volume physicians like me or hospitals whose demographics differ from the “average.” The statistical swings caused by several patients in any one quarter are truly meaningless. For many years, my cesarean rate was one of the lowest at Cedars-Sinai Medical Center and as noted above, I have not changed my practice style or my patient demographics; other years I was an “outlier” on the high side.

Clearly the informed consent of a 42-year-old who had in vitro fertilization, has a floating vertex presentation with a low Bishop score, and an estimated fetal weight of 4000 g at 40 6/7 weeks must include the risks of primary cesarean but also the risks of a long labor that ends up in a cesarean, the occasional risk of shoulder dystocia or third- or fourth-degree extension. Not having had a shoulder dystocia or third/fourth degree in over a decade clearly justifies my rationale.

Approximately 20 years ago I was “politely” criticized by our then-department chairman for doing serial scalp testing (with good pHs) in the second stage of labor on a primipara. FHTs had deep severe variables with a stable baseline and moderate variability. Once safely deliverable, I placed low forceps and shortened the second stage—cord gases were normal: 7.21/7.23. His argument was that even though I was following the “book,” 1% of the time scalp testing will be falsely negative (saying normal pH when in fact there was acidosis) and that the institution would prefer to have us do a cesarean to avoid litigation. In today’s climate, hospital leadership would prefer the vaginal delivery, lowering their insurance company and government-monitored NTSV cesarean rate. Have women changed in 20 years? Why, then, has the practice of obstetrics?

Brilliant economists like Peter Orzag and Jonathan Gruber recognized that only with consolidation as well as salaried physicians and nurse practitioners does this make financial sense. Women have not changed: they still want a natural delivery if possible.

Let me emphasize the documentation. What happened, why you thought it was happening, when, what you did, who you brought in to work with you if need be (theatre team, haematologist, anaesthetist …) and what you discussed with the patient. It is with the greatest sigh of relief to be able to counter any complaint of miscommunication or poor management or failure to follow up, with a crystal clear medical history.

Patients forget what is said, or misunderstand things for all sorts of good reasons. Being critically ill is not conducive for anyone, or their family, to take everything on board.

Sometimes despite our knowledge, we are no different as patients.

Good documentation will defend you & show how you cared, AND may help a patient understand & make sense of what happened.

-@aml1384
Minimize vaginal birth complications

Dr. Lockwood and other experts explain how to manage unexpected problems that may occur with vaginal birth.

**by BOB KRONEMYER**

There are several concrete steps clinicians can take to lessen the likelihood of vaginal birth complications, whether stemming from shoulder dystocia, a second twin or vaginal breech.

Having a protocol in place and simulation rehearsing with the entire medical team are two techniques proven to reduce complications.

“Often these complications are unexpected,” said Contemporary OB/GYN Editor-in-Chief Charles J. Lockwood, MD, MHCM. “For example, with shoulder dystocia, it is extremely difficult to predict who is at risk. And even when you predict those at risk, the patient usually does not have shoulder dystocia.”

**Shoulder dystocia**

Because a shoulder dystocia is typically unanticipated, “it is critical that clinicians have in mind a set protocol of steps to take in order to optimize outcomes,” said Dr. Lockwood. “It is also really important to document what you did and why you did it, so you have a credible defense, should there be an adverse outcome and you end up being sued.”

Shoulder dystocia occurs when the fetal head delivers but the shoulders do not deliver with normal maneuvers. It is one of the few emergencies encountered during labor that an urgent cesarean delivery or surgery cannot correct.

Hence, shoulder dystocia needs to be remedied with the maneuvers that the obstetrician is already trained in, according to Amy Mackey, MD, ob/gyn Residency Program Director at Abington Hospital-Jefferson Health in the Philadelphia area. Simulation and team training can also lessen some of the anxiety surrounding the event.

Incidence of shoulder dystocia ranges between 0.2% and 3%. “This wide range is due to subjectivity at the time of delivery as to what constitutes a shoulder dystocia,” said Dr. Mackey. “The definition that most people follow is a difficult shoulder delivery that does not resolve with gentle downward traction and requires additional obstetric maneuvers.”

A previous shoulder dystocia during delivery is the strongest risk factor. Other risk factors include operative delivery, maternal obesity, maternal diabetes, fetal macrosomia, a prolonged second stage and a precipitous delivery.

When encountering a shoulder dystocia, the positioning of the mother is the first consideration. “The patient should be brought down on the bed, so that the bed does not obstruct your ability to perform gentle, downward traction,” Dr. Mackey told Contemporary OB/GYN. “Also, make sure you have a stool in the room and that you have someone ready to exert suprapubic pressure. That team effort is really important, so preparation is key.”

In addition, the axis of the force applied for downward traction is important to decrease the strain on the brachial plexus.

Dr. Mackey said it is important not to panic when a shoulder dystocia is encountered. “Force is measured in newtons, which has an exponential time component in the denominator,” she said. “The faster you apply pressure to..."
PARAGARD® (intrauterine copper contraceptive) —
the only highly effective, reversible birth control that is completely hormone free.

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

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

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

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


* Data are from the Contraceptive CHOICE Project. The study evaluated 3- and 6-month self-reported bleeding and cramping patterns in 5011 long-acting reversible contraceptive (LARC) users (n=826, PARAGARD), and the association of these symptoms with method satisfaction. Study participants rated satisfaction with their LARC method as “very satisfied,” “somewhat satisfied,” or “not satisfied.” For the data analyses, “satisfied” and “very satisfied” were grouped together as “satisfied.”
† PARAGARD must be removed by a healthcare professional.
‡ Based on a September 2017 web-based survey of US women aged 18-45 years (N=300), where participants were asked about their attitudes about birth control that contains hormones. Respondents were required to be currently using birth control or have plans to use birth control in the next year. Repeat respondents within the previous 6 months were not permitted.
BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR ParaGard® T 380A Intrauterine Copper Contraceptive

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 uterine obstruction and expulsion if a woman is lactating.
   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 1-800-311-3455. 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 perforation, 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.

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 when ParaGard® is placed at times unrelated to delivery. However, expulsion may occur, usually during the menses and usually in the first few months after second trimester abortion is associated with a higher risk of expulsion than 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 for 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
- Anemia
- Backache
- Dysmenorrhea
- Dyspareunia
- Expulsion, complete or partial
- Leukorrhea
- Menstrual flow, prolonged
- Menstrual spotting
- Pain and cramping
- Urticarial allergic skin reaction
- Vaginitis

CopperSurgical, Inc
95 Corporate Drive
Trumbull, CT 06611

This brief summary is based on the ParaGard full prescribing information dated September 2014.
PAR-41287 01/18
the baby’s neck, the greater the force will be on the brachial plexus. Therefore, slow and gradual increase in pressure will be better tolerated by the fetus.”

Some physicians advocate delivering the posterior arm after performing the McRoberts Maneuver and suprapubic pressure as better than rotational maneuvers to alleviate shoulder dystocia. “But this is controversial,” said Dr. Mackey. “It really depends on the clinical situation.”

Dr. Mackey said the order of the maneuvers is less important than having a standardized approach. “You want everyone in the room to be able to anticipate what will happen next,” she said. “For us, the provider repeats all the maneuvers. If the provider is still unsuccessful at achieving delivery, a second provider tries.”

Dr. Mackey said obstetricians should never exert fundal pressure. “There is a higher incidence of permanent brachial plexus injury if you use fundal pressure at the time of a vaginal delivery with shoulder dystocia,” she said.

The maneuvers performed for shoulder dystocia are intended to prevent hypoxic injury to the baby. “The time that you have from the time you encounter shoulder dystocia to the time that the baby needs to be delivered is variable, based on the status of the baby going into the delivery,” said Dr. Mackey. “For example, if you have a baby that is well-oxygenated, you are going to have more time than if you have a baby that is borderline to relieve the shoulder to prevent hypoxic injury.”

Once a shoulder dystocia is resolved, the obstetrician must stay alert to postpartum complications. “Postpartum hemorrhage and third- and fourth-degree lacerations are increased in women who experience a shoulder dystocia,” said Dr. Mackey.

Second twin
In contrast to shoulder dystocia, a second twin is more often than not an anticipated potential complication. “The problem often results from an unstable lie,” Dr. Lockwood said. “In other words, as the second twin is coming down, you might think it is coming down vertex and then it flips, or it might be coming down breech and then it becomes transverse. The challenge is understanding the fluidity of that situation.”

Shoulder Dystocia Delivery Notes

While the below checklist can be helpful for documentation, the obstetrician must be vigilant in monitoring the patient for any postpartum complications. Hemorrhage and lacerations are among the most common complications following the procedure.

**Fetal vertex delivered by**

- □ Maternal effort
- □ Ritgen Maneuver
- □ Vacuum (see procedure note)
- □ Forceps (see procedure note)

**Time interval from delivery of head to completion of fetal delivery:**

______________________ minutes

**Attending provider present:**

____________________________

**Procedures attempted:**

*(please mark order attempted)*

- □ McRoberts Maneuver
- □ Suprapubic pressure applied by (RN/MD) and proper positioning verified by supervising provider
- □ Internal maneuver to rotate shoulders
- □ Delivery of posterior shoulder (right/left)
- □ Hands-and-knees positioning
- □ Other

**Cord gases obtained — see newborn notes:**

______________________ minutes

**Decreased upper arm motion with Moro:**

- □ Yes□ No

**Which arm:**

____________________________

**Patient and family counseled regarding the events of delivery by:**

____________________________

**Which fetal shoulder was anterior at the diagnosis of dystocia:**

<table>
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<th>Right</th>
<th>Left</th>
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SEPTEMBER 2018
As with shoulder dystocia, having a plan in place for effectively delivering that second twin is critical, whether that be an internal podalic version, an external version or a normal vaginal delivery in the vertex position.

“You want to also ensure that there is an adequate medical team available, including enough staff to perform a stat C-section, if needed,” Dr. Lockwood said. “In addition, there needs to be someone to help guide the second twin into the pelvis and someone to monitor the heart rate and other vital signs.”

Delivering the second twin can be tricky, according to Dr. Lockwood. “You can have ruptured membranes, or the umbilical cord can prolapse or present before the baby,” he said. “Occasionally there is even vasa previa and other complications that necessitate rapid action.”

Again, documentation is also key. Prevalence of vaginal delivery of twins, both vertex and breech, has increased over the years at Brigham and Women’s Hospital in Boston, parallel- ing a decrease in incidence of cesarean birth, possibly due to a comprehensive program entailing patient counseling, staff simulation training and an available team for twin deliveries.

“Although the literature about the delivery of twins is understandably limited, we believe that vaginal delivery is generally a safe thing to do,” said Julian Robinson, MD, Chief of Obstetrics at Brigham and Women’s Hospital, in Boston. “However, there is no optimal technique that can be used for delivery of the second twin. Furthermore, the choice of technique may change as the case progresses.”

Dr. Robinson told Contemporary OB/GYN that traditionally, obstetricians tend to favor a single technique for all situations.

Dr. Robinson counsels families that if the first twin is breech, both twins are delivered via cesarean. But if the first twin is head down, a vaginal delivery is planned for both twins, unless there is a good reason not to do so, such as the second twin being much larger than the first.

“We also factor in maternal wishes,” said Dr. Robinson. “For example, if the mother is very keen on having a C-section delivery rather than a vaginal delivery, we honor that request.”

In the case of both twins being head down, one approach is to be fairly hands off. “You deliver the first baby and then stabilize the lie of the second baby, head down,” said Dr. Robinson. “You actually let the second baby labor down before rupturing the membranes, so the head is well engaged.”

This approach is much more suitable for mothers who have previously delivered. “But for the mother who has not had a baby before, we are more proactive with early rupture of the membranes,” said Dr. Robinson.

In this scenario, Dr. Robinson rarely uses a high vacuum to pull the baby down quickly (a technique that he used to use preferentially) because the vacuum tends to disengage, plus it avoids two different instruments for vaginal delivery, such as vacuum and forceps. A second method to consider is to deliver the first twin vaginally and the second twin breech, if the head of the second twin is high but surrounded by amniotic fluid. “You change the second baby to a breech presentation by an internal podalic version for an almost instantaneous delivery,” said Dr. Robinson.

Dr. Robinson said mothers do not want a vaginal delivery of the first baby and a cesarean for the second. “What increases the probability of a C-section is the length of time between the delivery of the first and second baby,” he said. “The longer the wait, the more likely something will go wrong, like bleeding or a nonreassuring fetal heart rate, which precipitates intervention with a C-section.”

Organization and planning ahead are key to increasing the odds of a vaginal delivery of twins. What are the roles of each member of the obstetric team? What does the mother want? Logistically, will the twins be delivered in a labor room or the operating room (OR)? “Personally, I tell all my patients we are going to deliver in the OR, not because we think there is going to be an increased chance of an operation, but because we want the space,” said Dr. Robinson. “It takes a lot of room, particularly when you bring in two separate pediatric teams.”

Vaginal breech

Independent of twins, with breech birth there is always the possibility of a woman presenting to labor and delivery fully dilated with the breech at the perineum, in which case there is a risk of shoulder dystocia if the second twin is breech.
Solosec™ (secnidazole) is the first and only bacterial vaginosis (BV) treatment designed to deliver a complete course of therapy in just one oral dose\textsuperscript{1,2}

**INDICATION**

SOLOSEC™ (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women.

**SELECT IMPORTANT SAFETY INFORMATION**

- SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.
- Vulvo-vaginal candidiasis may develop with SOLOSEC and require treatment with an antifungal agent.
- Potential risk of carcinogenicity in patients taking single-dose of SOLOSEC to treat bacterial vaginosis is unclear. Chronic use should be avoided.
- SOLOSEC is a single-dose therapy for oral use. The entire contents of SOLOSEC packet should be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules. SOLOSEC is not intended to be dissolved in any liquid.
- In clinical studies, the most common adverse events occurring in (≥2%) of patients receiving SOLOSEC 2g oral granules were vulvovaginal candidiasis (9.6%), headache (3.6%), nausea (3.6%), dysgeusia (3.4%), vomiting (2.5%), diarrhea (2.5%), abdominal pain (2.0%), and vulvovaginal pruritus (2.0%).

Please see Brief Summary of Prescribing Information on adjacent page.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.


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SOLOSEC (secnidazole) 2g oral granules
Single oral dose

INDICATIONS AND USAGE
SOLOSEC is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in adult women.

DOSEAGE AND ADMINISTRATION
Administer a single 2-gram packet of granules once orally, without regard to the timing of meals. Sprinkle entire contents of packet onto yogurt, applesauce, or puddling and consume all of the mixture within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration of SOLOSEC to aid in swallowing. SOLOSEC is not intended to be dissolved in any liquid.

CONTRAINDICATIONS
Hypersensitivity. SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.

WARNINGS AND PRECAUTIONS
Vulvovaginal Candidiasis. The use of SOLOSEC may result in vulvovaginal candidiasis and may require treatment with an antifungal agent.

Potential Risk for Carcinogenicity. Carcinogenicity has been seen in mice and rats treated chronically with nitroimidazole derivatives, which are structurally related to secnidazole. It is unclear if the positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of SOLOSEC to treat bacterial vaginosis. Avoid chronic use of SOLOSEC.

Drug Resistance. Prescribing SOLOSEC in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

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

The safety data described below reflect exposure to 589 patients, of whom 518 received a 2g dose of SOLOSEC. SOLOSEC was evaluated in 3 clinical trials of patients diagnosed with bacterial vaginosis: 2 placebo-controlled trials (Trial 1 n=215, Trial 2 n=189) and 1 uncontrolled safety trial (Trial 3 n=321).

All patients received a single oral dose of study medication or placebo. Trial 1 evaluated a 1g (this dose is not approved) dose (n=71) and a 2g dose (n=72) of SOLOSEC. Trial 2 evaluated a 2g dose (n=125). The population was female, aged 15 to 54 years. Patients in the placebo-controlled trials were primarily Black or African American (54%) or Caucasian (41%). There were no deaths in the trials. Two patients in Trial 3 discontinued due to vulvovaginal candidiasis in the SOLOSEC-treated arm.

Table 1: Adverse Reactions Occurring (≥2% SOLOSEC-Treated Patients) in the Pooled Placebo-Controlled Trials 1 and 2 in Adult Women with Bacterial Vaginosis

| Adverse Reaction               | SOLOSEC N=197 (n (%) | Placebo N=136 (n (%)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vulvovaginal candidiasis</td>
<td>19 (9.6)</td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Headache</td>
<td>7 (3.6)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Nausea</td>
<td>7 (3.6)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5 (2.5)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>4 (2.0)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Vulvovaginal pruritus</td>
<td>4 (2.0)</td>
<td>2 (1.5)</td>
</tr>
</tbody>
</table>

Among the 321 patients in an uncontrolled trial, Trial 3, adverse reactions were reported in 30% of patients. Vulvovaginal candidiasis (8.4%), nausea (5.3%), vomiting (2.5%) and dysgeusia (3.4%) were the most common adverse reactions reported in this trial.

Postmarketing Experience. The following adverse reactions have been reported during use of other formulations of secnidazole 2g outside of the United States. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Reported adverse reactions were: nausea, dysgeusia, abdominal pain, headache, and vomiting.

DRUG INTERACTIONS
Oral Contraceptives. There was no clinically significant drug interaction between secnidazole and the combination oral contraceptive, ethinyl estradiol plus norethindrone. SOLOSEC can be co-administered with combination oral contraceptives (eg, ethinyl estradiol plus norethindrone).

USE IN SPECIFIC POPULATIONS
Pregnancy. Limited available data with SOLOSEC use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. In animal reproduction studies, there were no adverse developmental outcomes when secnidazole was administered orally to pregnant rats and rabbits during organogenesis at doses up to 4 times the clinical dose.

Lactation. Breastfeeding is not recommended. Discontinue breastfeeding for 96 hours after administration of SOLOSEC.

Geriatric Use. Clinical studies with secnidazole did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Nitroimidazoles, which have similar chemical structures to secnidazole, have been associated with tumors affecting the liver, lungs, mammary, and lymphatic tissues in animals after lifetime exposures. It is unclear if these positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of secnidazole to treat bacterial vaginosis.

Secnidazole was positive in the bacterial reverse mutation assay, but was negative for the rat micronucleus test and mouse lymphoma test.

In a rat fertility study, females were dosed for 2 weeks prior to mating until Day 7 of gestation with males that were dosed for a minimum of 28 days before cohabitation. No parental toxicity or adverse effects on mating performance, estrous cycles, fertility or conception was observed at doses of up to the maximum tolerated dose (300 mg/kg/day, approximately 1.4 times the recommended dose based on AUC comparisons).

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

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Vaginal Breech Delivery Notes

For a vaginal breech delivery, preparation is key but documentation is just as important. This checklist can help the obstetrician prepare for the procedure, communicate with the patient, and document what steps were taken.

Instruction checklist for procedure (check each step done)

☐ Advanced labor with delivery imminent
☐ >36 wks EGA
☐ EFW between 2 and 4 kg
☐ Fetus complete or frank breech with well-flexed head
☐ Maternal pelvis adequate clinically
☐ No absolute maternal/fetal contraindications to vaginal delivery
☐ Normal progress of labor
☐ No known fetal anomalies
☐ Patient counseled
☐ Other: ______________

Patient counseled as to the:

(Use this statement, or create your own — 255 character limit.)

Risks of fetal head entrapment with neurologic injury and/or death, bone fractures or dislocation, maternal injury of the pelvic floor, lacerations into bowel/bladder with risk of incontinence. Patient consented verbally for attempted vaginal delivery.

In the delivery the following steps were performed: (check each step done)

☐ Delivery of the infant to the level of the umbilicus by maternal effort
☐ Opposite rotation and flexion of each knee to deliver each leg
☐ Wrapped the lower extremities and trunk with towel to support the fetus
☐ Awaited maternal expulsion to the level of the scapula
☐ Rotated the infant to allow sweep across chest to deliver one arm. Rotated infant in the opposite direction to sweep the other arm across the chest to deliver
☐ Rotated infant so occiput was anterior
☐ Rewrapped infant’s body in towel for support
☐ Performed cephalic flexion with 2 fingers on the fetal maxilla to flex the head
☐ Suprapubic pressure applied by assistant
☐ Piper forceps applied (see notes for details)
☐ Other: ______________

Time from delivery of fetal trunk to delivery of fetal head:

☐ <2 minutes
☐ 2-3 minutes
☐ >3 minutes
☐ Other

Additional comments:

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

is no time for a cesarean. “Therefore, it is important in that circumstance to know how to deliver the vaginal breech,” Dr. Lockwood said.

Similarly, in the case of a woman desiring a planned vaginal breech delivery, the clinician should aim for a good outcome that is safe.

“Sometimes you can have trouble delivering breeches at C-section, so having a good C-section technique available is also important,” Dr. Lockwood said.

Documenting every aspect of the delivery, whatever the means, is critical.

Learning several simple skills can make a breech birth safer for both mother and baby. “Upright vaginal breech is actually an easier way to deliver the babies breech,” said Annette Fineberg, MD, an ob/gyn at Sutter Medical Group in Davis, Calif. “Gravity, combined with 1 to 2 cm of extra space, results in rarely needing forceps or complicated maneuvers.”

Dr. Fineberg told Contemporary OB/GYN that when the baby is in the upright position, gravity helps the baby be born. “The baby is able to rotate and flex on its own,” she said. “By knowing what is supposed to happen, you then know when to intervene. A lot of times, the birth will happen on its own. In essence, hands off the breech, unless there is a danger sign.”

Many of the tips Dr. Fineberg shared originate from Frank Louwen, MD, an ob/gyn in Frankfurt, Germany, and his colleagues.

In the case of a surprise breech, when the mother is starting to deliver, “It is best for the mother to get on her hands and knees,” said Dr. Fineberg. “The baby will then perform specific
maneuvers to get itself out. If the baby does not rotate properly, you know there is a problem."

Likewise, if there is no crease in the baby’s chest, “you may need to do a Løvset maneuver to retrieve a nuchal arm,” said Dr. Fineberg.

“The baby has a limited time to get out. With a reassuring fetal heart rate and a vigorous infant, you have about five minutes,” said Dr. Fineberg.

Conversely, ob/gyns need to know when to abandon a breech birth and deliver by cesarean instead. “If the baby is not following the expected rotation and descent, you are probably better off pushing the baby up,” said Dr. Fineberg.

Dr. Fineberg has heard numerous stories of mothers being placed at risk, when in reality the baby was simply trying to come out on its own. “For example, a mother having her fifth baby at 36 weeks is put under general anesthesia after a full meal,” she said. “If the mother had been able to push instead, the baby probably would have been born in five minutes.”

Good candidates for vaginal breech delivery are mothers who are at least 36 to 37 weeks’ pregnant, frank or complete breech, spontaneous labor progressing, normal descent, adequate pelvis and an estimated fetal weight between 2,500 and 4,000 g.

“MRI pelvimetry is not absolutely needed, but it can decrease the odds of needing an intrapartum cesarean,” said Dr. Fineberg.

A growth-restricted or preterm baby is actually more dangerous for breech delivery than a large baby because the body can be small and the head bigger in proportion.

For an unplanned breech birth, the two signs of an adequate pelvis are rapidly progressing cervical dilatation and rapid decent of the baby. “You should also check the fetal head position with ultrasound,” said Dr. Fineberg.

One newer technique to increase safety during breech delivery is a shoulder press, “You apply pressure at the midclavicular line, which causes a reflexive tuck of the chin,” said Dr. Fineberg.

Most obstetricians learn to perform a routine episiotomy for breech, especially with a first-time birth. “But an intact perineum can often help the baby flex its own head,” said Dr. Fineberg.

Many studies published since 2000 have been encouraging about risk of a vaginal breech. “There is no question that vaginal breech babies have lower Apgar scores than C-section babies, but the incidence of serious long-term complications is not significantly different between the two techniques,” said Dr. Fineberg.

Based on more recent optimistic clinical studies, organizations in UK, Canada and the American College of Obstetricians and Gynecologists (ACOG) now have published more positive breech guidelines. In August, ACOG issued an interim update of its committee opinion on term singleton breech delivery (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Com-

"The main problem, though, is that most obstetricians have not learned how to deliver babies breech,” said Dr. Fineberg.

For an unplanned breach or an emergency situation, "I want the ob/gyn to feel more safe and comfortable performing a vaginal breech," said Dr. Fineberg. "I would also like to see referral centers, so mothers have an option."

For all vaginal birth complications, training the entire staff with simulation year-round is vital, “so when the actual emergency occurs, the staff is ready and knows exactly what to do,” Dr. Lockwood said. “The team is prepared to proceed in a very orderly and logical fashion, with a minimum of chaos. That will minimize errors.”

Likewise, for all scenarios, “you want to have a protocol in mind that is burned and seared into your memory,” Dr. Lockwood said. “You do not want to panic when confronted with any of these emergencies.”

---

Documenting every aspect of the delivery, whatever the means, is critical.
Sexual discomfort due to vaginal dryness can have a simple solution: **K-Y® ULTRAGEL®**.

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**ALSO AVAILABLE:**
**K-Y® LIQUIBEADS®**
**LESS-MESS MOISTURIZER**

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A new normal: How families and fathers are affected by maternal mortality

by BEN SCHWARTZ

The embarrassingly high rate of maternal mortality in the United States when compared to other industrialized nations has received a great deal of publicity over the past months. Many articles focus on the “why” and the “who” in their coverage of the issue, and while these are undoubtedly important questions, what often gets lost in the reporting is the “how” and the “what” — as in, How are the families of these mothers affected by their loss? and What happens to the surviving child, the father, and the rest of the family? Ob/gyns can play a role in helping the families of their lost patients by providing support.

From 2000 to 2014, the United States saw a 26.6% increase in maternal deaths.¹ During that same period, maternal mortality rates fell in similarly developed nations. As has been discussed in Contemporary OB/GYN’s previous coverage of maternal mortality, several contributing factors have been identified. Among these are obesity, cardiac disease, hemorrhage, hypertension, sepsis, thromboembolism, anesthesia complications, substance abuse and self-harm, mental health issues, disparity in care, and several other factors, with the Centers for Disease Control and Prevention (CDC) reporting in 2017 that cardiovascular disease accounted for the highest proportion of maternal mortality cases (26.5%).² Disparities in race and ethnicity also exist in maternal mortality rates.³

The high risk for complications resulting in maternal mortality that African-American mothers face can have significant impact on the surviving family due in large part to family structures. According to 2015 research from the Pew...
Research Center, the majority of white, Hispanic, and Asian children were living in two-parent households, while only 31% of African-American children were living with two married parents, with more than half (54%) living in single-parent households. In 2015, 71% of African-American women gave birth outside of marriage, compared to 29% of non-marital births among white women. Additionally, according to a 2014 report from the United States Department of Labor, among mothers with children younger than 18, African-American mothers are the most likely to be in the workforce (75.4%), with 74% of African-American mothers considered to be the primary breadwinners of their families. Not only are these mothers more at risk, but if tragedy does strike, their surviving immediate family members lose their primary breadwinner and often lack the support system within the family structure to adapt.

Following the loss of a mother, family members are often forced to take on different roles. While it is usually the father’s role that changes most dramatically, the roles of other siblings and second-degree relatives, such as grandparents, aunts and uncles, may also evolve. In families in which the mother was the primary breadwinner, the father and sometimes the older children may be forced to take on a larger role in providing for the family financially. This has several repercussions. Since the father must focus more time and energy on both providing for the family and caring for the newborn infant, second-degree relatives may decide to either temporarily or permanently move into the household to help raise the infant. When this situation isn’t available, the father may be forced to hire childcare, which can further stretch the available income and resources.

**One family’s story**

On April 12, 2016, Kira Johnson, who was healthy throughout her pregnancy, went in for a routine cesarean delivery with her husband, Charles, at Cedars-Sinai Medical Center in Los Angeles. Charles and Kira’s second son, Langston, was born perfectly healthy, and Kira was taken to the post-anesthesia recovery area. During an interview with Contemporary OB/GYN, Charles recalled, “As I’m sitting there by Kira’s bedside, just looking at my family and overwhelmed with pride and this full heart after welcoming this gift into our lives, I looked down and I noticed that the catheter coming from Kira’s bedside is beginning to turn pink with blood.” After bringing this to the attention of the nurses, a series of tests were ordered, including blood work and a computed tomography (CT) scan that was supposed to be performed stat. An ultrasound showed that there was fluid building up in Kira’s abdomen and as she continued to deteriorate, there were clear signs that she was hemorrhaging.

Just after midnight, she finally received the CT scan that had been ordered six hours earlier. Following the scan, she was scheduled to go into surgery. Charles recalled, “As we’re going down the hall, Kira is holding my hand and she goes, ‘Baby, I’m scared.’ As we approached the door to the OR, the doctor walking next to her bed says to me, ‘we’re going to go back in through the same incision I made earlier with the cesarean, we’ll find out what’s going wrong, and I’ll fix it. She’ll be back in 15 minutes.’” There were 3.5 L of blood in Kira’s abdomen. She coded soon thereafter.

When his first son was born, Kira made Charles promise her that he wouldn’t leave the hospital for any reason without the two of them. He made the same promise to her the second time around, but now he, his newborn son, Langston, and his 18-month-old son, also named Charles, left the hospital without her. “Kira and I were partners in every sense of the word,” Charles said, “but I found myself being thrust into this new reality of being a single dad of two VERY small children and trying to figure it out. I knew that I couldn’t replace her; I had to step into that gap as best I could, and I was going to change every single diaper, fill every bottle, and I was not going to let Langston out of my sight.”

Charles, who was living in Los Angeles, moved to Atlanta to be closer to family. He moved in with his mother and she helped him take care of his grandsons. But the challenges involved with raising two young sons alone were evident almost immediately. “I had a days-old newborn and an 18-month-old who was missing his mother terribly and didn’t want me out of his sight. My older son would wake up in the middle of the night because he missed his mommy and his cries would wake up the baby and the baby’s cries would wake my older son back up and it just went back and forth like that for a few nights. But I was hell-
bent on doing everything myself. It was a way to keep me busy and help with my grief,” said Charles. After a few nights like this, he reached out to MomsOnCall, a consulting organization for new parents, and was put in touch with the owner. “She met with me and showed me the steps I could take to raise my sons on my own,” continued Charles. “She showed me how to raise Langston so that he could sleep through the night on his own at three months old and that literally saved my life. I had been through [raising a newborn] recently but doing it by yourself is a whole different ballgame—particularly with two little ones.”

Not all families are able to move across the country to be closer to people who can help them raise their children, and family fragmentation is common following maternal mortality. When the family loses a breadwinner and resources become stretched, a family may decide the best course of action is to have the children live with other relatives. In addition to the older children, this can include the newborn being raised by grandparents or other second-degree relatives.

The family can also be affected by potential family or household economic costs associated with maternal illness and death. Among these are changes in labor allocation, productivity, consumption, and investment, as well as direct costs, such as medical or funeral expenditures.5

While 92 countries offer paternity leave, the United States does not, and only a few states and cities have passed family leave and paternity leave laws.6

While more companies are beginning to offer paternity leave, the only legal protection for fathers comes from the 1993 Family and Medical Leave Act (FMLA), which allows new parents to take up to 12 weeks of unpaid leave without the threat of job loss. But the FMLA covers only employees who have worked 1,240 hours over 12 months at a company that employs more than 50 people; small business employees and part-time workers are not covered. And even if a father qualifies for FMLA paternity leave, he may not be able to afford it, given all the additional expenses that come with raising a newborn plus the direct costs resulting from the mother’s death, such as medical and funeral expenses.

As his children have grown older and more inquisitive, Charles has had to answer questions about what their mother was like and what happened to her. He has taken the approach of trying to be open with his children and, while it can be difficult, his hope is that they’ll develop an image in their minds of who their mother was, rather than growing up with more questions than answers. Photographs of Kira hang on the walls throughout their home and he has tried to make sure that his sons feel comfortable to ask him questions about their mother. “Kira’s presence is very much in everything that we do. I never want the topic of Mommy to be off-limits with my sons.”

“Kira’s presence is very much in everything we do. I never want the topic of Mommy to be off-limit with my sons.”

For Charles, the biggest thing that needs to change is turning what are now policies into mandates. “Groups like the Alliance for Innovation on Maternal Health (AIM) have these wonderful toolkits and bundles on postpartum care and hemorrhage,” explained Charles. “But even in California, a state that has been a poster child for implementing these strategies and has seen a tremendous decrease in maternal mortality rates, no one paid any attention to those resources in Kira’s case because it was a suggestion and a tool rather than a mandate. If you have a tool, what good is it if no one is using it?” He also believes that developing consistent standards of care can help cut through some of the other troubling factors intertwined with raising a newborn plus the direct costs resulting from the mother’s death, such as medical and funeral expenses.

As his children have grown older and more inquisitive, Charles has had to answer questions about what their mother was like and what happened to her. He has taken the approach of trying to be open with his children and, while it can be difficult, his hope is that they’ll develop an image in their minds of who their mother was, rather than growing up with more questions than answers. Photographs of Kira hang on the walls throughout their home and he has tried to make sure that his sons feel comfortable to ask him questions about their mother. “Kira’s presence is very much in everything that we do. I never want the topic of Mommy to be off-limits or taboo with my sons,” he says.

Charles also started a foundation in honor of his late wife, 4Kira4Moms. The foundation has a strong focus on getting legislation passed to help reduce maternal mortality, specifically H.R. 1318 and S.B. 1112, two bills that call for maternal mortality review committees in all 50 states. The foundation also provides resources for families through financial support, counseling, parenting materials and also aids families that are facing high-risk pregnancies by assisting them with additional birthing services, such as doulas and financial assistance for seeing specialists.

While Charles and his foundation have done much work, expectant fathers can also take proactive steps on their own to help solve the maternal mortality crisis. This includes being present, being supportive and being an advocate. Charles urged, “Listen to your wife or your partner. A woman knows her body and if something isn’t right. A lot of these women simply aren’t being listened to and it’s our responsibility as a partner to advocate on her behalf.”
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I am proud to release the titles of the 28 Postgraduate Courses taking place at this year’s 47th AAGL Global Congress. When developing these courses, the Scientific Program Committee focused on the enhancement of surgical technique. We are offering a variety of learning environments, with courses that include in-depth hands-on instruction with a cadaver, courses that include simulation, and detailed didactic courses. All PG Courses feature world renowned expert faculty who love to teach and share their knowledge. We encourage you to register now as the PG Courses normally sell out. Looking forward to welcoming you to Vegas!

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Sunday, November 11, 2018

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- ROBO-601: Cadaveric/Simulation Lab: Robotics: Beyond Hysterectomy
- ANAT-602: Didactic: The Competent Surgeon - A Master of Retropelvic Anatomy AND Surgical Dissection
- ANAT-603: Cadaveric Lab: Deep Dive into the Underground Labyrinth of the Pelvic Anatomy
- URO-604: Didactic: The Pelvic Floor and So Much More
- URO-605: Cadaveric Lab: The Pelvic Floor and So Much More
- SUTR-606: Didactic/Simulation Lab: Fundamentals of Laparoscopic Suturing
- SUTR-607: Didactic/Simulation Lab: Advanced Suturing
- HYST-610: Didactic: Laparoscopic Hysterectomy: From A to Z
- PELV-611: Didactic: Unraveling Pelvic Pain: A Practical Approach to Everyday Practice
- HSC-612: Didactic: Hysteroscopy Master’s Symposium

Monday, November 12, 2018

- HSC-709: Didactic/Simulation Lab: Hysteroscopy: The Essential Do’s and Don’ts
- COMPLX-700: Didactic: 1st International School of Surgical Anatomy (ISSA) Course: Tips and Tricks in Laparoscopic Retropertoneal Surgical Anatomy to Perform Safe Gynecologic Surgery
- COMPLX-701: Cadaveric Lab: 1st International School of Surgical Anatomy (ISSA) Course: Tips and Tricks in Laparoscopic Retropertoneal Surgical Anatomy to Perform Safe Gynecologic Surgery
- HYST-702: Didactic: Laparoscopic Hysterectomy from Basic to Complex
- HYST-703: Cadaveric Lab: Laparoscopic Hysterectomy: Surgical Techniques to Make Complex Pathology Look Easy
- NEURO-704: Didactic: International School of Neuropelveology with an Emphasis on Neurogynecology
- LAPA-705: Didactic: Optimizing Tissue and Procedural Outcome During Laparoscopic Surgery
- SUTR-707: Didactic/Simulation Lab (Spanish): Practical Application for Tissue Reapproximation, Intracorporeal and Extracorporeal Knots, Barbed Suture, and Suturing Technologies
- PEARLS-708: Didactic: Gynecologic Oncology Pearls for the Generalists
- PUSH-710: Didactic: Push the Envelope
- FIBR-711: Didactic: Fibroids from A to Z: Medical, Procedural, and Surgical Management
- GENDR-712: Didactic: The Role of the Gynecologic Surgeon in Transgender Care
- REPRO-713: Didactic: Reproductive Surgery: Mastering Fertility-Enhancing Minimally Invasive Surgery
- GOLF-714: Didactic/Interactive: Play and Learn with the Masters: 18 Pearls of Surgical Excellence
Toxic environmental exposures in maternal, fetal, and reproductive health

Educating patients about toxins to avoid in daily life may seem daunting but the authors advise focusing on simple, concrete steps that women can take.

by NATHANIEL DENICOLA, MD, MSHP, MARYA G. ZLATNIK, MD, MMS, AND JEANNE CONRY, MD, PHD

Environmental health occupies a unique place in perinatal and reproductive health counseling. The “environment” can be as omnipresent as the air a woman breathes, and as specific as the cosmetic product she chooses. It can encompass the epigenetics induced by several generations of nutrition—you are what your grandmother ate—as well as the food preparation of tonight’s meal or the selection of tomorrow’s baby bottle. Given this wide range of exposures and the general inexperience with counseling patients on any of them, it is not surprising that most women’s health providers simply ignore the topic. However, this approach is ultimately unfair to patients who need trusted sources of data to protect them from unknown toxins. Failure of such counseling misses the public health opportunity to intervene in outcomes as diverse as preterm birth (PTB), low birthweight (LBW), and neurodevelopmental disorders like autism. And it fails to take advantage of resources that have emerged to provide guidance in this rapidly evolving space. Ob/gyns and all women’s health providers should become facile on environmental health risk assessment, exposure reduction, and feasible clinical counseling.

A critical window

Before delving into types of environmental exposures, it is important to consider the vital role of women’s health providers in protecting pregnancies from harm. Because pregnancy and

Six chemicals widely used in consumer products have been deemed to contribute to neurodevelopmental disorders including learning disabilities, attention deficit hyperactivity disorder, autism, and behavioral and intellectual impairment.

An estimated 3.32% of preterm births could be attributed to the air pollutant fine inhalable particulate matter < 2.5 μm (PM_{2.5}), creating $760 million in medical costs.

Educating patients about toxins to avoid in daily life may seem daunting but the authors advise focusing on simple, concrete steps that women can take.
the fetal period is perhaps the most critical time-window for human development, any toxic exposure during this time can cause lasting damage to brain development and interfere with a child’s ability to reach his or her full potential.1 Further, every women’s health provider will encounter opportunities for counseling. Toxic chemicals are so numerous that every pregnant woman is likely exposed at some point in gestation to over 60 of them.2,3

To approach the intersection between environmental health and women’s health, it can be helpful to organize the exposures and outcomes. These exposures can be thought of in two general categories—toxic chemicals and climate change-related and air pollution exposures—affecting three ob/gyn health outcomes: fertility and pregnancy, neurodevelopmental impairment, and cancer.

**Toxic chemicals**
The United States manufactures and imports chemicals at voluminous rates. The US Environmental Protection Agency (EPA) has a chemical inventory of tens of thousands of chemicals; nearly 3,000 of these are produced or imported at > 1 million lb per year and only a scant minority are evaluated for toxic effects on brain development.4-7 To focus efforts on reducing these toxic exposures, a group of expert toxicologists, health professionals, and patient advocates called Project TENDR (Targeting Environmental Neuro-Developmental Risk) developed consensus on highlighting six prime examples.1

These six toxic exposures (Table 1) include chemicals widely used in consumer products, those present in the home setting, and broad public space exposures. They are: organophosphate pesticides, polybrominated diphenyl ether (PBDE) flame retardants, combustion-related air pollutants, lead, mercury, and polychlorinated biphenyls (often used in carbonless copy paper). Each of these has been deemed contributory to neurodevelopmental disorders including learning disabilities, attention deficit hyperactivity disorder (ADHD), autism, and behavioral or intellectual impairment.1

In addition to these six examples, other groups of chemicals have been identified as chemicals of concern. Prime among them are phthalates.3 Phthalates are ubiquitous in consumer products as a binding or durability agent, appearing in everything from plastic children’s toys to personal care products and perfume. Like many of the chemicals listed above, phthalates can act as endocrine disruptors, mimicking estrogen, androgen, and other hormonal effects, thereby increasing risk of not only neurodevelopmental disorders but also infertility, breast cancer, and prostate cancer.8

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**TABLE 1**

| Prime examples of neurodevelopmentally toxic chemicals (Project TENDR) |
|-----------------|-----------------------------------------------------------------|
| **Organophosphate (OP) pesticides** | Found as residues in some foods, particularly conventionally grown produce; occupational exposures; exposure to pesticides used in the home |
| **Polybrominated diphenyl ether (PBDE) flame retardants** | Found in house dust, especially when old foam furniture is crumbling; also found in the plastics for electronics and in some fatty foods |
| **Combustion-related air pollutants**, which generally include PAHs, nitrogen dioxide and particulate matter, and other air pollutants for which nitrogen dioxide and particulate matter are markers | Air pollution in the home, outdoor environment, and in occupational settings |
| **Lead** | Found in house dust, especially in older homes with lead paint; also can be found in water and in contaminated soil, such as in gardens in urban or near-urban areas, and in some imported ethnic products such as herbal remedies, cosmetics, candies, and jewelry |
| **Mercury** | Found in fish, especially larger fish in the top of the food chain. Less common exposures are from broken thermometers, occupational and industrial sources |
| **Polychlorinated biphenyls (PCBs)** | Found in some foods, especially fish (bottom feeders), meat, dairy products and in the air near old (pre-1977) electric devices. |

Source: https://atsdr.cdc.gov/PHS/PHS.asp?id=139&tid=26
The American College of Obstetricians and Gynecologists (ACOG) and the International Federation of Gynecology and Obstetrics (FIGO) have issued guidance on the numerous ob/gyn health outcomes at risk due to these toxic environmental exposures as they concern fertility and pregnancy, neurodevelopmental impairment, and cancer (Table 2). In addition to outcomes discussed above, these include PTB, LBW, spontaneous miscarriage, and decreased semen quality.9,10

### Air pollution and climate change

Similar to the broad expanse of environmental health, a discussion of air pollution and climate change and human health has far-reaching implications across multiple generations. The American Academy of Pediatrics (AAP) lists numerous climate-related effects on children alone, including heat stress, increased allergy and asthma exacerbation, heightened infection risk due to altered vector-borne disease patterns, psychological sequelae of weather disasters, and food and water insecurity.11 The Medical Society Consortium on Climate and Health (MSCCH), a coalition of over 20 medical societies representing nearly half of US physicians, has published a "Medical Alert" describing other climate-related health impacts like exacerbations of chronic disease, increased hospitalizations for bronchitis, chest pain, and increased risk for lung cancer.12

The health effects of air pollution and extreme heat are of particular concern for pregnant women and the developing fetus. Numerous studies have linked air pollution with PTB and LBW babies. These have been conducted on large US populations as well as with international studies.13,14 Specific to the United States, an estimated 3.32% of PTB could be attributed to the air pollutant fine inhalable particulate matter < 2.5 μ (PM2.5), creating $760 million in medical costs.13 Proximity to fracking sites has also been associated with low birthweight.15 Extreme temperature during the third trimester—defined as cold below the 10th percentile or heat above the 90th percentile of average temperatures for a region—increases the risk of LBW by 30%.16-18

### TABLE 2

<table>
<thead>
<tr>
<th>Fertility and pregnancy</th>
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<tbody>
<tr>
<td>• Decreased semen quality with PCBs</td>
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<tr>
<td>• Spontaneous abortion and fetal loss with chemical solvents</td>
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<tr>
<td>• Impaired fetal growth with pesticides</td>
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<tr>
<td>• Fetal loss, low birth weight, and preterm delivery with air pollutants</td>
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<tr>
<td>• Decreased fetal and birthweight and congenital malformations with toluene</td>
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<tr>
<td>• Shortened gestational age with phthalates</td>
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<tr>
<td>• Low birth weight with PCBs</td>
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<tr>
<td>• Reduced birth weight and fetal growth with perfluorinated compounds</td>
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<tr>
<th>Neurodevelopment</th>
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<tbody>
<tr>
<td>• Impaired cognitive and neurodevelopment, increase in attention problems and attention deficit hyperactivity disorder behaviors at age 5 years, and reduction in working memory capabilities at age 7 years with pesticides</td>
</tr>
<tr>
<td>• Impaired neurodevelopment in girls and reduction in executive function at age 4–9 years with phthalates</td>
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<tr>
<td>• Intellectual impairment with lead</td>
</tr>
<tr>
<td>• Reduced cognitive performance, impaired neurodevelopment, and reduced psychomotor outcomes with methyl mercury</td>
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<tr>
<td>• Decreased placental expression of genes implicated in normal neurodevelopmental trajectories with increasing in utero exposure to fine particle air pollution</td>
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<tr>
<td>• Reduced intelligence quotient score and a wide range of attention and executive function deficits with PCBs</td>
</tr>
<tr>
<td>• Impaired neurodevelopment and reduction in sustained attention with polybrominated diphenol ethers</td>
</tr>
<tr>
<td>• Attention problems at age 6–7 years with polycyclic aromatic hydrocarbons</td>
</tr>
<tr>
<td>• Aggression and hyperactivity in girls, and reduction in executive functioning skills in girls aged 3 years with bisphenol A</td>
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<tr>
<th>Cancer</th>
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<tbody>
<tr>
<td>• Maternal breast cancer risk with PCBs</td>
</tr>
<tr>
<td>• Increased childhood cancers and susceptibility to testicular cancer with pesticides</td>
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Savings for Physicians’ Alliance of America (PAA) Members

Physicians’ Alliance of America is a nonprofit national healthcare Group Purchasing Organization (GPO) that uses the purchasing power of physicians in all 50 states (and D.C.) to negotiate discounts and preferred terms for the goods and services private practices use every day.

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Clinical counseling and patient advocacy

In the face of so many toxic environmental exposures, some of which seem ubiquitous and unavoidable, it can be daunting to approach solutions. Nonetheless, solutions are imperative. Future generations deserve protection from outcomes like PTB, LBW, and neurodevelopmental delay.

In clinical practice, the focus can be on simple, individual steps (Table 3). Avoiding heating foods in plastic containers can reduce exposure to plastic resins that have endocrine-disrupting effects. Avoiding any food that comes into substantial contact with plastic is even better. Patients can limit heavy metals with their seafood choices. Providers can take a minute to review counseling on personal care products; some brands contain hidden chemicals such as phthalates that are used to bind scents.20 Because personal care products with scents contain endocrine-disruptor phthalates, “fragrance-free” versions are probably preferable. Even those that are labeled “unscented” are less desirable, as these likely contain multiple scents that are still bound by phthalates that are mixed to cancel each other out. Fast food, in addition to its nutrition concerns, typically comes in phthalate-lined wrapping that can increase exposure to endocrine disruptors.20 A web-based tool from the Centers for Disease Control and Prevention’s ATS-DR will be released soon. The Prenatal Assessment of Environmental Risk website will allow women and their providers to focus on individual risks based on the latest science.

As stated in guidelines from ACOG, “Pregnant women should eat fish for their nutritional benefits, but take care to avoid fish that may contain high levels of mercury or other toxins.”21 The FDA provides clear advice to women (at: http://bit.ly/FDAConsumerResources); this link is also available through ACOG’s Guidelines for Perinatal Care at http://bit.ly/ACOGPerinatalCare.

Also, clinicians can play a crucial role as patient advocates. This can be done by participating in awareness campaigns (FIGO hosts an annual Earth Day Social Media Campaign with health messages @FIGOHQ) or interacting directly with representatives (former ACOG President’s blogs have challenged ob/gyns to be champions of environmental science.22

And finally, recall too, that all of the gains made toward more pristine environments—clean water standards, decreased lead in gasoline and paint, reduced pollution with improved recycling campaigns—all pass on to the patient as well. Generations of work have built the foundation for healthier, sustainable improvements.

Healthy mom, healthy baby starts with a healthy environment.

DISCLOSURE The authors report no potential conflicts of interest with regard to this article.

For references visit contemporaryobgyn.net/ToxicExposures

Numerous studies have linked air pollution with preterm birth and low birthweight babies.

TABLE 3 CLINICAL COUNSELING ON REDUCING EXPOSURE TO TOXIC ENVIRONMENTAL AGENTS

- Avoiding heating food in plastic. Glass containers are preferable.
- Minimize plastic contact with food; reduce use of plastic storage containers, plastic straws
- Wash hands frequently, especially prior to eating as hand gel only kills bacteria, it doesn’t remove toxins
- Decrease use of scented personal care products. “Fragrance-free” labels, if available, are preferable to scented or unscented products
- Avoid foods, especially seafood, high in heavy metals. See the FDA’s advice: https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm393070.htm
- Be mindful of air quality alerts when doing outdoor exercise
- Choose “organic” food where possible
- Limit the use of chemical solvents in home cleaning; alternatives with vinegar can be used
- Frequent damp-mopping of home can decrease exposure to heavy metals in dust
To the top of the ladder and beyond

Female presence in the ob/gyn profession has increased, but leadership roles are not representative of the rise.

by PAMELA TABAR

WOMEN REPRESENT NEARLY HALF OF ALL STUDENTS ENTERING MEDICAL SCHOOL.

In 2012, the percentage of faculty who were female in departments of obstetrics and gynecology was 52.7%, higher than any other medical or surgical department, including pediatrics. In 2016 the rate of women matching into ob/gyn residency rose to a whopping 82.3% and by 2017, the proportion of women in ob/gyn practice stood at 58.7%, higher than any other group of active surgeons. By 2022, it is expected that two-thirds of ob/gyns will be women. Despite these impressive numbers, representation ratios demonstrate that obstetrics and gynecology lags behind other specialties in progression of women to departmental and other leadership roles.

With a patient base that is 100% female, women are clearly needed as leaders in this field as in no other. Empowering and supporting women to move up the ladder and into leadership positions should be a concern of all practitioners.

“Wait... YOU’RE the doctor?”

Zarina Ali, MD, hears it from patients all the time even though she has been conducting brain and spinal surgery at Pennsylvania Hospital since 2016.

Patient reactions were even more polarized when she was doing surgical rounds while eight months pregnant with twins, she recalled. “I just take it as an opportunity to educate that person by saying, ‘No, I’m the neurosurgeon who’s going to be operating on your dad’s brain tomorrow, so let me explain the procedure.’”

Female applicants to medical school have increased by more than 50% in the past 15 years. In 2017, for the first time, more women entered US medical schools than men, notes the Association of American Medical Colleges (AAMC). While AAMC President and CEO Darrell G. Kirch, MD, called this a “notable milestone,” today’s numbers make other disparities even more glaring than in the past.

Female physicians still are disproportionately sparse among the upper echelons of academia and as leads on research teams and in medical departments. Even fewer women are represented in medical specialty societies—many specialty societies didn’t honor any female recipients with recognition awards until the 1990s, noted the 2017 study “Where Are The Women?”

The barriers to female leadership and career advancement are deep within the fabric of the US medical profession and within us as people, explained Valencia Walker, MD, MPH, immediate past-president of the Association of Black Women Physicians. The obstacles for female physicians of color are geometrically greater, including in the wallet: National medi-
Female physicians are still disproportionately sparse among the upper echelons of academia and as leaders on research teams and in medical departments.

A part of helping people foster their dreams and ambitions is showing them that it can be done. Whether or not another young woman ob-gyn aspires to be ACOG president, or chair of a university’s department of obstetrics and gynecology, one of my hopes is that by holding this position I am demonstrating that there is room and opportunity for women to lead in our field, and they should reach for their boldest goals in whatever direction that takes them.

— ACOG President Lisa Hollier, MD
others. Insist on inclusivity and encourage participation in staff meetings and on care teams. Practice openness in idea exchange while respecting that men and women can have different yet equally valid interpretations.

**Mentor as a mission**
Both women and men have crucial roles to play as mentors for female physicians but not enough realize the importance of mentoring beyond medical school.

For Ali, female mentors and role models were rare during schooling and in her early days as Penn Hospital’s first female neurosurgeon. But even after 10 years on the hospital staff, she said she still sees a dearth of female leadership and female mentors in the surgical field.

Female mentors provide a unique perspective, especially since one of the biggest conundrums for female physicians is weighing the choices of children and career. As a mother of four young children, Ali said the “family or field” decision is a life choice every woman must make for herself. “I’m a better mom because I get to practice medicine, and I’m a better physician because I care for four little kids. A lot of it comes with understanding who you are, understanding your own personality, and deciding what is going to make you happy.”

**TIP:** Valuable mentoring doesn’t always have to come from a structured program, and it doesn’t need to be a burden to physicians’ busy schedules. Encouraging a 15-minute coffee group, a job-shadowing period or an educational opportunity can help female physicians grow their potential—and the energy from idea exchange and learning can benefit the practice, too.

**Support the groundswell**
Times are changing, but not fast enough, Walker said. Inequality among physicians may not

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**Men and Women need to become more aware that there are a variety of effective leadership styles—some of which are more common among women—and to know that there is not just one way (or style) of good leadership. We all need to let go of the stereotypes about what or who makes a good leader and welcome a diversity of leadership styles as we welcome more women into positions of leadership.**

— Paula J. Adams Hillard, MD – COG board member

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**Sit at the table and speak up. Your voice matters. You are in the room for a reason; you have earned it and others depend upon you. Effective women leaders consider both sides and make the best decisions for the group. Support other women by inviting their participation, and respectfully call out behaviors that do not promote inclusion. As women in leadership, we stand on the shoulders of those who have paved the way for us, and we, in turn, must look to help nurture the leaders of tomorrow.**

— Ilana Cass, MD - COG Board Member

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**We need a sharper focus on removing barriers that prevent any young star with talent (experience, intellect, compassion, humility, strength of character, and a hunger for improvement) from rising into leadership positions. These barriers—some obvious and others latent—affect women and minorities more frequently, making this work even more imperative. Those in current positions of leadership now need to actively uncover those barriers and remove them, especially the latent, passive, and subconscious ones.**

— Christian Pettker, MD - COG Board Member

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CONTINUED ON PAGE 48
Navigating social nuances with patients and colleagues

A guide to social standards in the healthcare environment, from an expert on professionalism.

by SUE JACQUES

A gentleman I vaguely recognized approached me at the reception following a recent family funeral. He was the domestic partner of a relative, and though I knew we’d met before, I couldn’t remember much about him. When he asked if he could speak with me privately I said yes, thinking he had an expression of sympathy or a memory to share.

What came out his mouth next astonished me. “I think I may have touched you inappropriately when we said hello before the funeral, and I want to apologize so I don’t hear from your lawyer,” he uttered.

Whoa! I remembered that he’d given me a quick hug when he arrived at the funeral home. It was a caring and appropriate gesture, and I didn’t think anything of it.

But clearly he did. Red-faced, he went on to say that he thought his hand had slipped during the hug and he was afraid he’d touched my rear end. I’m sure he didn’t. Even if he did, it wouldn’t have occurred to me that it was intentional. We were, after all, in a crowded funeral home with lots of jostling going on.

This experience epitomized for me how our society has become increasingly en garde about physical and verbal displays of support. For years I’ve been hearing from clients who are wary of giving a compliment, offering advice, or sharing a touch at work for fear of retribution. And recent instances of on-the-job harassment have made things worse. The tension is palpable.

Medicine is a tactile profession. But can you give a coworker a hug anymore? Is it OK to place your hand on a patient other than during an examination? Do you take a risk by complimenting a colleague? And what do you do if you’re on the receiving end of an accolade or embrace?

Here are five guidelines to help you navigate the nuances of our ever-evolving social standards.

1. Talk before you touch.
Not everyone is comfortable with a pat, stroke, or hug, so let your words lead the way before you reach out and touch someone. If you feel compelled to lay a caring hand on someone, especially during a time of heightened emotion, ask for permission. A simple question like, “Is it OK if I give you a hug?” or, “Would it help if I hold your hand?” allows the potential recipient to guide the intimacy level of the exchange.

2. Shake on it.
A handshake is the most commonly accepted form of contact in North American culture, so make that your first point of connection. When doing so, ensure your handshake is solid and sincere. Whether you’re congratulating someone, sharing a moment of sorrow, or formalizing an agreement, you’ll enhance the meaning of the moment by also making eye contact and giving the other person your full attention.

MS. JACQUES is a professionalism expert, keynote speaker, consultant, and author who specializes in medical and corporate civility. A veteran forensic medicolegal death investigator, Jacques helps people and practices prosper through professionalism.

CONTINUED ON PAGE 44
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the global source for events and media in aesthetic medicine
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3. Focus on the work, not the wardrobe.
Most of us don’t think twice about being complimented on our style, in fact we’re flattered. But for many people, any comment along that line is out of bounds, especially from a colleague. That’s why it’s wise to limit your observations to someone’s work rather than their wardrobe. A statement like, “Your attention to detail is an asset,” is appropriate. “That outfit highlights your assets,” is not.

4. Understand the difference between “you” and “I.”
Not every piece of feedback we share is a compliment. Sometimes we need to extend an apology. Here’s a simple rule of thumb for both: When delivering a compliment, always begin with the word “you,” as in, “You did a great job,” or, “You performed that procedure with incredible finesse.” On the other hand, when an apology is in order, begin with the word “I,” such as: “I didn’t call when I said I would, and I’m sorry,” or, “I could have handled that situation with more tact. I apologize.”

5. Respond with grace.
Minimizing someone’s praise or apology dismisses the person who shared it. The most gracious response is to simply say thank you. If you feel the need to add more to that statement, keep it simple with an additional phrase like, “I appreciate your kindness,” or, “I value your feedback,” or, “I accept your apology.” If, on the other hand, you’re upset about what you’ve heard, it’s best to buy yourself some time before responding. You can do that by saying, “I need some time to think about your comment. Can we please discuss this later?”

There’s a time and a place for everything. While human contact is natural and banter is commonplace, we must be mindful of how our words and actions are received by those with different perceptions. You can reduce your chances of being misunderstood by approaching all you do with a foundation of respect.

In the end, I appreciated the apology that gentleman offered after the funeral. Well, except for the lawyer part, but I let that go.

On Obstetrics and the Hippocratic Oath

extenders working under strict centrally planned protocols could costs be contained. Yet these men are not at our patients’ bedtimes at 3:00 AM delivering babies. Another lead architect of the ACA, Dr. Ezekial Emanuel, also has advocated making societal trade-offs favoring budget savings over individual health, especially concerning people over the age of 75 or those with a small chance of success from costly therapy. Health economists like him accept more stillbirths, babies with hypoxic ischemic encephalopathy, cerebral palsy or Erb’s palsy as long as it lowers governmental expenditures. Do the parents of these children get a vote?

In my opinion, the overwhelming majority of practicing physicians, like me, feel more aligned with the oaths of Hippocrates and Maimonides. We believe that we have a moral, ethical and medical responsibility to the individual patient and not to an ACO or government bean counter.

■ I would suggest an overarching theme: Choice. Doesn’t our country, doesn’t our Constitution give us freedom to make our own intelligent decisions? Are we not given the right to make reasonable choices different from what others would? Are we not free to make reasonable decisions even if government or their surrogates prefer that we don’t?

■ Don’t doctors have the right to make different decisions based on reasonable data and their own interpretation of medical literature?

■ Does one size fit all? Imagine if there were only size 8 jeans in America. Some women couldn’t even fit in them and some would be swimming in them. So why does Washington or Covered California tell us there is only one way to practice obstetrics?

HOWIE MANDEL, MD is an obstetrician-gynecologist in Los Angeles, California and is affiliated with Cedars-Sinai Medical Center. He is also a volunteer at the Saban (Los Angeles) Free Clinic and he has advocated for equal access to health care for over three decades.

NOTE The editors reserve the right to shorten or edit letters and comments.

FOR REFERENCES VISIT contemporaryobgyn.net/ReaderReactSept18

CONTINUED FROM PAGE 19
Examining the clinical utility of new HPV testing modalities.

How should clinicians approach new cervical cancer screening methods that detect human papillomavirus (HPV) so that they can provide better quality of life and treatment planning for their patients?

In this online supplement, E. Marshall Austin, MD, PhD offers insight on the issues that surround HPV testing modalities, including:

- The role of HPV in cervical cancer
- Performance data on HPV DNA tests vs. mRNA tests
- The benefits of HPV mRNA testing

read more at contemporaryobgyn.net/hpvdna
CONTINUED FROM PAGE 32

with the maternal mortality crisis, such as implicit bias and racial and class discrimination.

Following Kira’s death, Charles has developed a mantra for himself and his sons: “Wake up and make Mommy proud. Repeat.” For him, that is just one way of keeping Kira’s memory alive and raising his sons the right way. But while the mantra is simple, life and young children are complex and not every day is easy or straightforward. “While the statistics associated with the maternal mortality crisis are devastating, there’s no statistic that can quantify what it’s like to tell an 18-month-old that his mommy is not coming home or quantify what it’s like to try and explain to a son that has never known his mom just how amazing she was. We still deal with that,” says Charles.

Charles hopes that his and Kira’s story will remind physicians to treat patients with respect and do everything in their power to ensure their patients’ safety because, while the physician’s time with the patient often ends at discharge, the family must live with the consequences of their physician’s actions. “If you’re an ob/gyn, remember that these women are not statistics. They are precious mothers who are trusting you with their precious gifts. The reality of the situation is that training, legislation, resources, is not ultimately what is going to turn this around. It is you.”

BEN SCHWARTZ is the Associate Editor of Contemporary OB/GYN.

FOR REFERENCES VISIT contemporaryobgyn.net/NewNormal

MATERNAL MORTALITY RESOURCES

ORGANIZATIONS

4kira4moms
Charles Johnson’s foundation honoring his wife includes information on legislation and financial support, counseling, parenting materials for families
http://4kira4moms.com/

MomsOnCall
A book and consulting service to help new parents
http://momsoncall.com/

National Widowers’ Organization
A virtual toolkit for men coping with loss of a loved one and an avenue for meeting others going through the same transition
https://nationalwidowers.org

RESOURCES

National Alliance for Grieving Children
A collection of wide-ranging resources to assist children with overcoming loss
http://childrengrieve.org/

The Dougy Center
Provides grief resources as well as information on support groups
https://www.dougy.org/

The AWHONN Postpartum Hemorrhage Project
A collection of resources from the Association of Women’s Health, Obstetric and Neonatal Nurses to improve care in postpartum hemorrhage cases
http://www.pphproject.org/resources.asp

Family and Medical Leave Act Overview
Forms, guidelines, and fact sheets covering eligibility and information on the Family and Medical Leave Act
https://www.dol.gov/whd/fmla/

Advice to Newly Widowed Fathers of Young Children
A blog entry discussing how fathers can talk about difficult topics with their children following the death of their mothers
https://www.dol.gov/whd/fmla/

IMPROVING CARE

Blueprint for Advancing High-Value Maternity Care Through Physiologic Childbearing
Improvement strategies to transform maternity care into care that reliably enables all women and newborns to experience healthy physiologic processes around the time of birth
http://www.nationalpartnership.org/issues/health/reports/maternity-blueprint.html

FOR REFERENCES VISIT contemporaryobgyn.net/NewNormal

NEW NORMAL

CONTINUED FROM PAGE 32

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FOR REFERENCES VISIT contemporaryobgyn.net/NewNormal
Seventy-five ob/gyn residents took part in the Sixth Annual Gottesfeld-Hohler (GOHO) Memorial Foundation Resident Ultrasound Boot Camp at Mount Sinai Health System in New York on August 4 and 5. The PGY 2s attended lectures on a variety of topics including basic ultrasound in the first and second trimesters, the placenta, the cervix, twins and gynecologic ultrasound.

Then, the group walked over to the Mount Sinai clinical offices, where they scanned pregnant women under the guidance of some of the most experienced professors in ultrasound.

The 2-day course is offered free of charge to PGY 2s as part of the GOHO Foundation’s mission of ultrasound education.

Drs. Aleha Aziz, Angela Bianco, Eran Bornstein, Joshua Copel, George Doulaveris, Keith Eddleman, Natie Fox, Ana Monteagudo, Andrei Rebarber, Pat Rekawek, Lynne Simpson, Joanne Stone, Ilan Timor-Tritsch, Lucy Vieira and Brian Wagner volunteered their time to teach the residents how to scan. They covered basic and advanced fetal biometry and information on identifying fetal anatomy. The residents practiced gynecologic ultrasound on simulation machines.

Mount Sinai sonographer Dalia Sapoznikow, RDMS, Assistant Supervisor of Ultrasound in the Maternal Fetal Medicine department, recruited the models, and administrator Tara Jefferson coordinated all the logistics for the event at Mount Sinai Hospital.

The boot camp was sponsored by Philips, GE, and Samsung. Trice Imaging sent ultrasound images to all the patients, and SonoSim and Medaphor provided simulators for vaginal scanning.

The Gottesfeld-Hohler Memorial Foundation (www.gohofoundation.org) is a 501(c)(3) charity was founded by Drs. Larry Platt and John Hobbins along with two of the founders of the former ADR Ultrasound, Jim Binns and Marty Wilcox, to honor two early pioneers of ob/gyn ultrasound, Ken Gottesfeld and Chuck Hohler. The Foundation organizes a fundraising ultrasound course in Florida every December, with all proceeds going toward the educational mission of the group. This year the Foundation will hold an additional free educational program for MFM fellows during that program.
To the top of the ladder and beyond

CONTINUED FROM PAGE 41

Talent is not bounded by sex any more than it is by race or other personal characteristics, and in diversity of backgrounds there is great strength. Why on earth would we NOT want to advance women as leaders, especially in our field? The creative part of actually implementing those positive thoughts is figuring out how to help young leaders harmonize their work and personal lives.

— Joshua A. Copel, MD - COG Board Member

One thing seems clear:

Offering token mentoring programs and the occasional college course have value but aren’t enough to propel female physicians forward. The “soft” obstacles to career advancement and leadership—getting time off, finding available opportunities that fit with family responsibilities, gaining support, and encouragement from superiors—still shackle many female physicians.

Yet as the number of women entering the medical field surges, the cost of not changing seems detrimental both to female physicians and to the future of medical practice, Ali observed. “The more we can support each other to aspire to and achieve those goals of leadership positions, the greater the dividends will be not just for that individual, but for many, many other women down the road.”

PAMELA TABAR is a healthcare writer based in Cleveland, Ohio.

REFERENCE:

impossibly high standard of perfection,” Silver said. “We are constantly in a double-bind situation where if we are too nice then we may not be viewed as serious contenders for promotion, and if we are appropriately assertive we risk being labeled as too aggressive to be effective leaders. Women can do a lot to help each other by giving each other grace—by being slow to criticize and quick to provide backup support.”

It’s important for practices to encourage female colleagues to grow their leadership potential and learn from other leaders, added Silver, whose three-day “Career Advancement and Leadership Skills for Women in Healthcare” conference at Harvard Medical School has sold out since it began two years ago.

TIP: Encourage colleagues to take their innovative care programs or research to the conference forum as session speakers and to join relevant medical societies. Support female physicians who wish to attend conferences and find a way to help with funding or time off, if needed. Most importantly, ask them to share their educational findings with others.

Be the culture change

While changing the inequity within the physician practice community many not happen overnight, everyone can choose to make progress one person at a time. “One of the most important things that women can do for other women is to recognize our value and to not hold each other to an otherwise completely impossibly high standard of perfection,” Silver said. “We are constantly in a double-bind situation where if we are too nice then we may not be viewed as serious contenders for promotion, and if we are appropriately assertive we risk being labeled as too aggressive to be effective leaders. Women can do a lot to help each other by giving each other grace—by being slow to criticize and quick to provide backup support.”

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To the top of the ladder and beyond

seem as blatant in large metropolitan health systems and teaching institutions, but the issues holding women back are cultural and national. Physician practices can and should encourage participation in advocacy efforts to change the status quo, whether it be embracing an innovative education assistance initiative or adding female mentoring programs, she adds.

TIP: Both male and female physicians can increase their own awareness and discover ways to adopt healthier business practices by tapping into the leadership community. Check out diversity events happening at local hospitals and medical organizations, seek out local speaker presentations, and encourage colleagues to take part in conferences as session speakers.

PAMELA TABAR is a healthcare writer based in Cleveland, Ohio.

REFERENCE:
the patient’s care could create a duty to act on the information. Even worse, metadata will document if the provider reviewed critical documentation found elsewhere in the record. Deviation from care guidelines and clinical-decision guidelines may bolster the plaintiff’s case. Academic environments add an additional risk, as attendings must attest to the assessment and treatment plans of trainees. It is incumbent on the attending to read the entire note and ensure that all facets of the documented exam were performed, assessments are complete, and treatment plans appropriate. Failing to adequately review the documentation can expose the attending to liability.

**Metadata and Liability**

What is metadata? In short, it is data about data. Both EHRs and EMRs automatically generate a time stamp that documents who accessed the document, what was accessed and when, where access occurred, and even how long someone was in the record.

Physicians facing a suit may be tempted to review the record and clarify some salient points. That is fraught with much risk, particularly in the era of EHRs, with their inherent metadata. Today, it is not enough to defend just the medical record. Now one must defend the metadata.

An audit trail is metadata that records who, when, where, how and sometimes why a person accessed a patient’s medical record. Typically, the identity of the user who accesses the patient’s record, the time of access, the terminal or device used for access, the action taken by the user (i.e., viewing the record, changing the record), and the substance of anything added to the record and any changes or corrections made by the user are recorded in the metadata, which can be reproduced in the form of an audit trail or log. To emphasize the level of detail available, one study by a surgery department assessed preoperative review of computed tomography scans. The researchers were able to determine which residents accessed the record, whether just the report was viewed, if the images were viewed, how many images were viewed, and for how long. The authors found that senior residents viewed more images than junior residents or family medicine residents.

Of note, an audit trail only records who is logged into the computer. Thus, if an attending reviews the images with a resident who is logged in, the audit trail will not reflect that the attending viewed any images. The authors recommended that the attending login separately to view imaging studies and laboratory results to provide electronic confirmation of his or her involvement in a patient’s care. Without such documentation in the metadata, a rebuttable presumption is that the surgeon never looked at the images.

**Adverse neonatal outcome**

In an obstetrical case with an adverse newborn outcome, the nurses’ records document that Dr. X was notified of late decelerations. Shortly thereafter, the nurses again documented that they notified Dr. X of late decelerations. Dr. X testified that he reviewed the fetal heart rate (FHR) monitor remotely and the decelerations were not ominous. Metadata demonstrated that Dr. X failed to review the FHR recordings, even remotely. Remember, metadata shows who accessed the EHR, when and where. Dr. X’s credibility was severely damaged. The case was settled for an undisclosed amount.

**Unnecessary hysterectomy with complications**

A patient underwent a laparoscopic hysterectomy and suffered a bowel injury. The liability action included a claim of performing unnecessary surgery. At deposition, the surgeon testified that he had fully reviewed all studies in anticipation of the surgery. Multiple experts were deposed supporting the indications for hysterectomy and the surgeon’s performance of the surgery.

A subsequent audit of the metadata, however, demonstrated that the surgeon did not access the studies until after the suit was filed. Further, it demonstrated that the surgeon had not reviewed pertinent lab results prior to surgery. Even worse, the surgeon altered the record to ensure that all facets of the documented exam were performed, assessments are complete, and treatment plans appropriate. Failing to adequately review the documentation can expose the attending to liability.
justify the surgery, with the timing of the alteration found in the metadata. The credibility of the surgeon’s testimony was destroyed, he committed perjury, and the case settled. Further, sanctions were filed against the surgeon because the expert depositions were based on fallacious information. The surgeon paid $90,000 in restoration of the plaintiff attorney’s expenses and is facing possible loss of his license by the state board of medicine.

How common is alteration of the medical record? One plaintiff’s attorney estimated that 25% of cases involve alteration of the medical record (Personal communication, anonymous plaintiff attorney, June 20, 2018). As such, an audit trail expert is hired for every case. This expert examines the digital footprint of record, determining if there have been deletions, alterations, or modifications to the record. This has resulted in settlement of a number of cases—particularly if the modifications occurred after litigation began—that perhaps otherwise would have been defensible. Experts in metadata also advise the attorney on questions to ask to establish this type of evidence.

Making changes to the medical record
An EHR has the ability to generate templates for specific diagnoses or symptoms, which can be convenient and efficient. But errors in data entry can be propagated by copying and pasting. When discovered, a “correction” should be made. Corrections are changes in a patient’s medical record during the normal course of treatment. A change made prior to the issue of a claim or lawsuit would be considered a correction. Corrections are acceptable provided they are made appropriately.

Institutions and practices should establish a policy for appropriate medical record corrections. Typically an addendum is made to the medical record, denoting the date, time, and author of the correction and the reason for it. Striking through the erroneous entry with a single line is preferable. If appropriate, attention should be directed from the erroneous entry to the corrected entry. Once the correction is made, the erroneous entry should not be removed or deleted because it may have been relied upon by other health care team members. Removing or deleting such data alters the integrity of the medical record. Authorized and transparent alterations are considered a testament to the medical record’s accuracy, freedom from unauthorized alterations, and completeness.

In contrast, an “alteration” is when a provider receives a notice of suit and then goes to the medical record to “clarify” certain points, particularly for the purpose of aiding defense of the claim. Such alterations are considered a deliberate misrepresentation of the facts. Discovering such alterations during litigation severely impacts the ability to defend a claim. Further, many liability policies exclude coverage for claims in which the medical record was altered. Providers must not alter the medical record after receiving notice of a claim. In addition, after receiving notice of claim, physicians should refrain from accessing the medical records without first speaking with their liability carrier or legal counsel. Such access infers the possibility of record alteration.

Summary
EHRs offer great benefits with some potential new areas of liability. However, proper and timely documentation enhances the defense in liability actions. Metadata will become the standard when integrity of an EHR is questioned. “Metadata is evidence, typically stored electronically, that describes the characteristics, origins, usage and validity of other electronic evidence.” According to one attorney, “Metadata is discoverable evidence that our clients are obliged to preserve and produce. Metadata sheds light on the origins, context, authenticity, reliability and distribution of electronic evidence, as well as providing clues to human behavior. It’s the electronic equivalent of DNA, ballistics and fingerprint evidence, with a comparable power to exonerate and incriminate.”

Acknowledgements: A special thanks to Kevin J. Kuhn, Esq., a defense attorney with Wheeler Trigg O’Donnell, LLP, Denver, Colorado, for his insight and defense perspective on electronic health records. Also, a special thanks to the anonymous plaintiff attorney for his perspective on metadata and the use of audit trails in litigation.

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Electronic records and metadata: Old and new liability risks

Metadata from an EHR form an audit trail of activity, which can make or break a malpractice case.

Electronic records are ubiquitous. Whether confined to one provider or group's record of a patient's care, the electronic medical record (EMR) or the comprehensive record of a patient's entire care, the electronic health record (EHR), are now the standard for documenting a patient's care. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 authorized grants and incentives totaling an estimated $28 billion to promote "meaningful use" of EHRs by providers. In recent years, EHRs have become somewhat more user-friendly, allowing customization to enhance efficiency and access to critical information in a patient's record. The benefits are tangible, but new risks with EHRs are becoming evident.

**EHR benefits**

EHRs offer opportunities. With them, there is no question that records are legible, a significant improvement over hand-written accounts. When EHRs are complete, they enhance the quality of patient care and potentially reduce errors. Access to a patient's complete history allows all treating providers to coordinate care and communicate about the patient's care. EHRs offer rapid access to imaging studies, laboratory findings, pathology, and outside records, improving efficiency and care coordination. Better documentation of clinical decisions and activity, through both user-entered data and metadata, may improve the ability to defend against malpractice claims when care was appropriate. Automatic alerts warn physicians about a patient's allergies, potential harmful drug interactions, and caution about use of medications that may be contraindicated based on a patient's medical conditions. Care pathways offer consistent, evidence-based guidelines to enhance care and minimize complications. Ultimately, universal access to care wherever a patient is seen would markedly enhance efficiency and quality.

**EHR risks**

EHRs also present new challenges and risks. Liability can be increased based on inherent designs. Templates bring in data and assessments that may not have been performed or reviewed. Copying and pasting potentially propagates errors in documentation. Many "assessments" in EHRs merely list the diagnoses associated with the visit. Failure to document one's thought process, assessment of the potential causes of the condition, and a thorough differential diagnosis reduces defensibility (Kevin J. Kuhn Esq., Wheeler Trigg O'Donnell LLP, Denver, Colorado, personal communication, June 22, 2018).

Most juries understand physician judgment. Unfortunately, documentation in EHRs may not reflect this judgment. The ability to access all facets of
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• six species test options and add-on testing of 4 additional Candida species in refractory or recurrent cases

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