

Contemporary OB/GYN

MARCH 2019
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DR. LOCKWOOD ON
Policing the
pregnant
woman



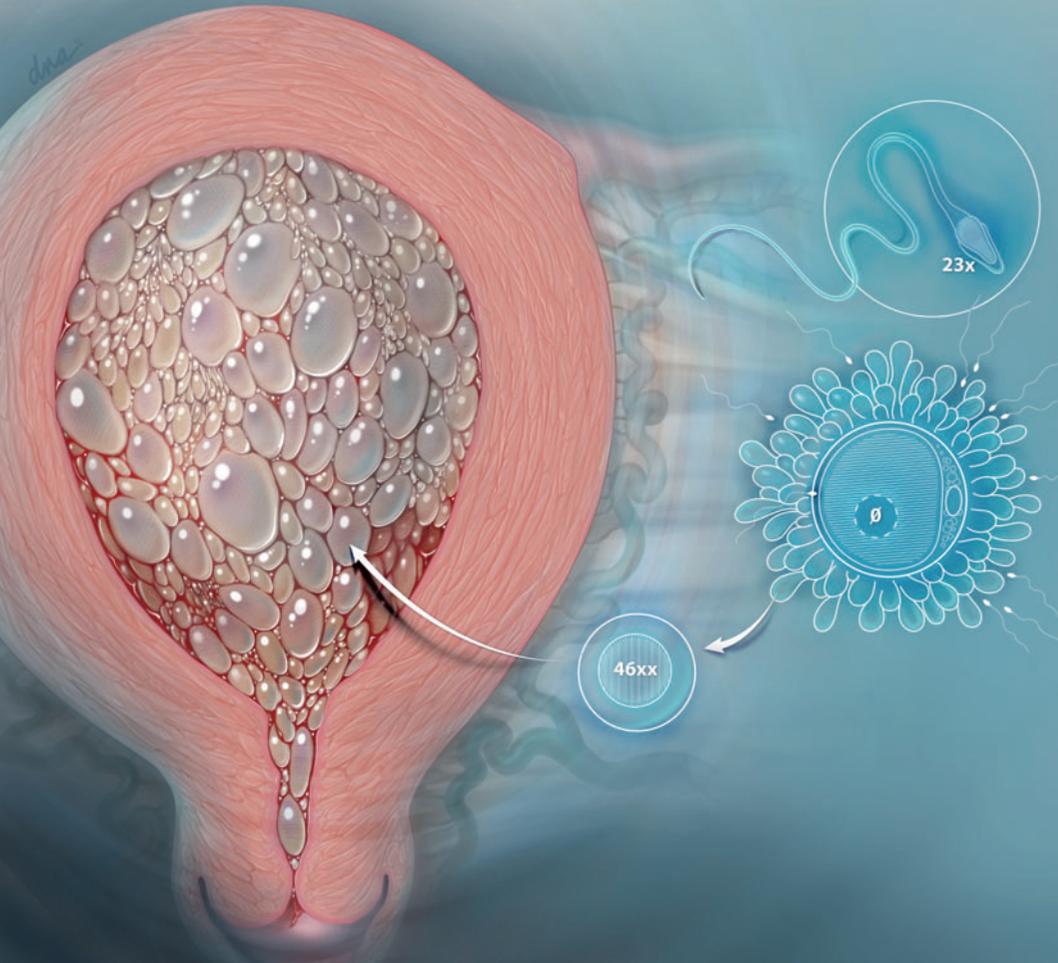
Expert Advice for Today's Ob/Gyn For Doctors by Doctors

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Molar pregnancy

Diagnosis and management

John R. Lurain, MD



Bladder cancer

Gender disparities in diagnosis, treatment

Lupus

Optimizing maternal, fetal outcomes

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Vulvar conditions

FLU UPDATE

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Cash flow tips for high-deductible plans

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A night on call

◀ Artistic interpretation of complete molar pregnancy. Overlay shows fertilization of egg containing no nuclear material resulting in trophoblastic proliferation (cytotrophoblast and syncytiotrophoblast).

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Indication

Paragard is intended for intrauterine contraception for up to 10 years.

Important Safety Information

- Paragard must not be used by women who have acute pelvic inflammatory disease (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.
- If a woman misses her period, she must be promptly evaluated for pregnancy.
- Possible serious complications that have been associated with intrauterine contraceptives are PID, embedment, perforation of the uterus, and expulsion.
- Paragard must not be used by women who are pregnant as this can be life threatening and may result in loss of pregnancy or infertility.
- The most common side effects of Paragard are bleeding and spotting; for most women, these typically subside after 2 to 3 months.
- **Paragard does not protect against HIV or other sexually transmitted infections (STI).**

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

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References: 1. Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use; 2017. 2. Kaneshiro B, Aeby T. Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device. *Int J Womens Health*. 2010;2:211-220. 3. Data on file, March 2018. CooperSurgical, Inc.

*According to the Centers for Disease Control and Prevention (CDC), Paragard is one of the least restrictive birth control options across all patient types compared to other IUDs.

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

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

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

WARNINGS

1. Intrauterine Pregnancy

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

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

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

2. Ectopic Pregnancy

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

3. Pelvic Infection

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

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID. Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomycetes-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 actinomycetes should be treated and have her IUD removed.

4. Immunocompromise

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

5. Embedment

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

6. Perforation

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

7. Expulsion

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

ParaGard® T 380A Intrauterine Copper Contraceptive

8. Wilson's Disease

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

PRECAUTIONS

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

1. Information for patients

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

2. Insertion precautions, continuing care, and removal.

3. Vaginal bleeding

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

4. Vasovagal reactions, including fainting

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

5. Expulsion following placement after a birth or abortion

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

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

6. Magnetic resonance imaging (MRI)

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

7. Medical diathermy

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

8. Pregnancy

ParaGard® is contraindicated during pregnancy.

9. Nursing mothers

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

10. Pediatric use

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

ADVERSE REACTIONS

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

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

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

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



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

PAR-41287 01/18

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CORRECTION In the February 2019 issue of *Contemporary OB/GYN* "Focus on fracture: Gateway to evaluating osteoporosis" author Kristi Tough DeSapri, MD, was reported having no disclosures. However, Dr. DeSapri is a speaker for Amgen and a consultant for Radius Health.

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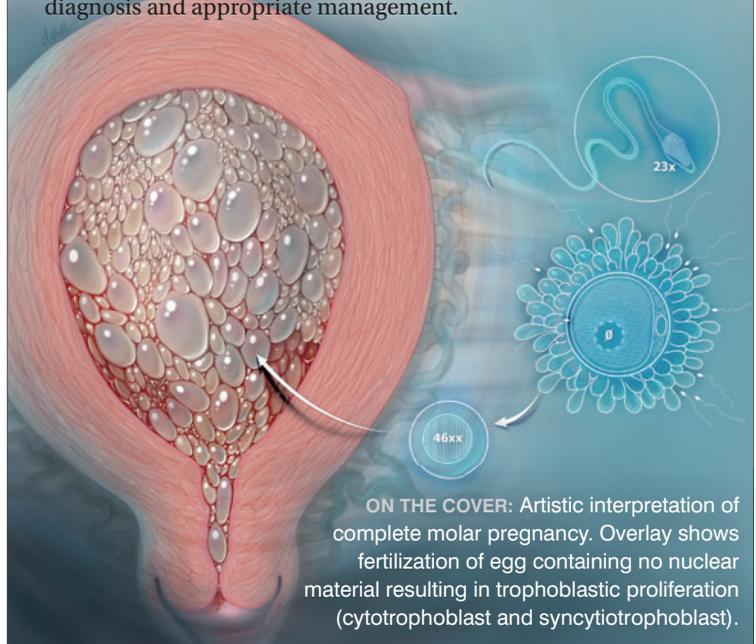
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by JAY WOLFSON, DRPH, JD, AND CHARLES J. LOCKWOOD, MD, MHCM

'Policing' pregnant women during the opioid epidemic

Getting to good medicine and good law

Should ob/gyns police their pregnant patients as part of the battle against the opioid epidemic?

Every 15 minutes a baby is born with neonatal abstinence syndrome (NAS), a condition whose incidence has increased 5-fold since 2004.¹ There are also increasing reports of opioid overdoses in breastfed babies whose mothers are ultrarapid metabolizers of codeine and tramadol.² The opioid epidemic clearly has hit obstetricians and pediatricians full bore. However, lost in discussions about how to mitigate the problem has been a growing state policy divide that pits protecting infant health against preserving maternal autonomy. There is now an increasingly bright line in state policies between states that have enacted punitive laws treating drug use during pregnancy as child abuse, and a possible crime, and states that have laws emphasizing supportive or preventive policies and practices.³

Advocates of criminalization note that failure to impose strict and clear expectations and consequences for illicit use of opioids has had the dual social impact of enabling bad behaviors and recklessly endangering the health of innocent newborns, thereby warranting a punitive policy re-



Hydatidiform moles While molar pregnancy is not very common, it is associated with serious morbidity and ob/gyns must understand the proper management [Read more on page 12.](#)

Test your knowledge A 77-year old patient presents with vulvar irritation. Can you make the diagnosis? [Read more on page 18.](#)

sponse. Moreover, they note, care for these infants consumes \$1.5 billion per year in health care costs that are frequently borne by state Medicaid coffers.⁴ In contrast, critics of punitive policies argue that criminalizing prenatal opioid use deters mothers from seeking appropriate care; brands women with a criminal stigma; and in some cases, destroys families by removing the newborn from the custody of the mother. They also argue that racial and economic profiling targets poorer women and that criminalizing a pregnant woman for opioid abuse is another step on the slippery slope of restricting or eliminating reproductive choice.^{5,6}

As is the case with many hot-button issues, our nation is sharply divided as to how the government, particularly states, should best protect the interests of pregnant mothers, their fetuses, and newborn children in the

face of the opioid crisis. We offer here what we hope is a balanced, reasoned perspective on this subject.

Consequences of opioid dependence.

Opioid use disorder (OUD) in pregnancy is associated with all the same risks to the mother as in non-pregnant women: overdose death, serious infections from intravenous injections and needle sharing, domestic violence, criminal behavior, and sexually transmitted diseases. Indeed, substance abuse is now a major risk factor for pregnancy-associated deaths.⁷ Obstetrical risks of untreated OUD include fetal growth restriction, abruption, stillbirth, and preterm labor.⁷ Depression is present during the antenatal period in 30% of affected women and 40% of such postpartum women.⁸ The major newborn risk is NAS, which is present in up to 80% of newborns

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has, in many jurisdictions, been translated into statute. “Reckless indifference,” a leap above simple negligence, is the general standard for criminalizing adult acts against children. Twenty-three states and the District of Columbia consider substance use during pregnancy to be child abuse under civil child-welfare statutes, and three states consider it grounds for civil commitment.¹⁶ Moreover, 24 states and the District of Columbia require health care professionals to report suspected prenatal drug use, and eight states require providers to test for prenatal drug exposure if they suspect drug use.

These jurisdictions ground their laws in a “compelling state interest” that places the health and welfare of the unborn and delivered child above the decisions and behaviors of the pregnant woman. Laws that criminalize opioid use during pregnancy presume the reckless endangerment of the child and posit that prevention of “bad acts” requires powerful, punitive deterrents. Protection of the child is a powerful and well-tested Constitutional basis for government policies; that of the fetus is more controversial and unsettled.

The policy alternative to criminalization has been more aggressive treatment and prevention programs, pursued by 21 states with 19 states having either created or funded drug treatment programs for pregnant women, and 17 states and the District of Columbia providing pregnant women with priority access to state-funded drug treatment programs.¹⁶ Ten states also prohibit publicly funded drug treatment programs from discriminating against pregnant women. The social and legal presumptions

driving this class of state initiatives are far more consistent with ACOG recommendations,⁷ including the premise that early and well-coordinated identification and treatment will result in “the best chance of helping infants and families.” Criminal sanctions are viewed as detrimental to the long-term solution to OUD because such laws might discourage affected women from seeking prenatal care altogether.⁴

Unanswered is whether either punitive or permissive state laws

Non-consensual diagnostic tests of mothers have been deemed unconstitutional but... newborn infants may be tested.

have made a difference. We suspect not because even though most states have enacted legislation to deter prenatal opioid abuse, with about half enacting principally punitive laws and the other half principally prevention/treatment laws, maternal opioid use and the prevalence of NAS continue to rise.¹⁷

Take-home message

We concur that there is a recognized, compelling state interest in protecting pregnant women and children, but what should be the pragmatic guiding policy principle(s) of government: Criminalization? Punitive sanctions? Stigma reduction? Prevention? Mitigation of adverse sequelae? We would contend that punitive laws will discourage some pregnant women from seeking any prenatal care, potentially exposing mothers, fetuses and newborns to greater harm than

isolated in utero opioid exposure.

Because obstetricians are on the front line of promoting maternal, fetal, and newborn health, what meaningful expanded role should we play, and will we be expected to participate in policing women to impose criminal penalties that can include removal of children from their patients? We posit that ob/gyns should follow current ACOG recommendations, which include: early universal screening, a brief counseling intervention, and referral for MAT. Obstetricians should never be placed in the position of directly policing their patients, a practice which violates our Hippocratic oath.

Breaching the current chasm in practice and policy concerning opioid use during pregnancy requires a combination of reasoned, informed discussion plus higher-quality evidence on optimal clinical management strategies and sound, tested public policies that decrease occurrence. Ultimately, good medicine and good law demand better data. ■

Dr. Wolfson, is Distinguished Service Professor of Public Health, Medicine and Pharmacy, Senior Associate Dean, Morsani College of Medicine, Associate Vice President USF Health, University of South Florida.

Dr. Lockwood, is Professor of Obstetrics & Gynecology, and Public Health, Dean, Morsani College of Medicine, Senior Vice President, USF Health, University of South Florida, and Editor-in-Chief of *Contemporary OB/GYN*

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READERS REACT

have a comment? SEND YOUR THOUGHTS TO COEDITORIAL@UBM.COM

Try to achieve ‘Happy Birth’

My answer to your question ‘How to minimize vaginal birth complications’ of some weeks ago is: Try to achieve ‘Happy Birth’ by performing as few as possible interventions. In other words, avoid the cascade of interventions.

Daily management:

1. Start early in pregnancy with offering women personal continuity of care (max. of 2 persons (doctor or midwife) per woman the whole process) for building up self-efficacy, motivation and locus of control.

2. Keep all women upright during birth (same as mentioned by the German doctor for breech birth). Upright women react better and more intuitively to signals from their bodies.
3. Strive for “no more than” 10% of births in beds (WHO and midwifery model of care recommendation)
4. Trust women’s abilities from day one as well as your own natural intuition.

Yours sincerely,

Tine Oudshoorn, senior midwife,
THE NETHERLANDS.



READ THE ARTICLE AND LET US KNOW WHAT YOU THINK.
CONTEMPORARYOBYGYN.NET/BIRTHCOMPLICATIONS



On Optimizing Breast Health

A typical Lockwood production: complete, accurate, readable.

I will encourage our trainees (and faculty) to read and retain.

Robert Wallach, MD
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Well-intentioned but misguided

Dear Dr. Lockwood,

Your editorial on saving America’s rural OB care is statistically accurate. Many of the conclusions are not. The picture statistics paint is more of a Picasso whereas rural physicians will paint a picture more like a Remington. Government and academia have created the problem (CMS, NRHA, USPSTF, etc) by encouraging different rules and regs for rural areas thinking they are helping (CAHs, Rural Health Clinics, FQHCs, itinerate doctors, paying mid-level providers more in rural areas than doctors, etc). Ask rural practitioners which laws, rules, or regulations they have to work under that do not apply to nearby metropolitan areas. How many rural hospitals have been closed by the 96-hour rule, the 30-mile rule, the introduction of a FQHC or Rural Health Clinic, and on down the line.

I wish you well in your endeavor to help rural OB, but it is likely to perpetuate the decline in the name of progress.

William Bart Pate, MD
DEPARTMENT OF FAMILY MEDICINE
FORT WORTH, TEXAS

TWITTER

**ContemporaryOBGYN**

@ContempOBGYN #Sepsis and septic shock in #pregnancy buff.ly/2DplKxJ

Dr. Vero Pimentel MD @DrVeroMe
Thanks. I read this last week. It is an excellent review.

**ContemporaryOBGYN**

@ContempOBGYN Would a minimum-volume standard improve #hysterectomy outcomes? buff.ly/2UtdCWb

Fibroids Network UK @fibroidssupport
Better Surgical training skills are needed for Hysterectomy (womb removal). There's issue of, some Drs not supporting the Apex ie pelvic organ support structures are not left in place, leading to Bladder/Vaginal Prolapse together with Incontinence Risk from it & Iatrogenic errors

**ContemporaryOBGYN**

@ContempOBGYN Does race influence #hysterectomy route and outcomes?

Adedotun @MustyLusi
You should read this @ShaqmanX @serikiomoba. Shocking

Shaq @ShaqmanX
I'm not shocked. I'll like to see the figures when they are corrected for quality of care viz a viz the surgeon's ability and complication rate. Black women have a much poorer access to quality care and I think the higher average BMI explains the rest.

Adedotun @MustyLusi
I think it was mentioned

Shaq @ShaqmanX
They mentioned it as a limitation of the study. Rightly so. They corrected for uterine size though. Which is impressive.

FACEBOOK



ContemporaryOBGYN We want to hear from you! Have you seen an increase in the number of your pregnant patients using #marijuana to treat symptoms associated with #pregnancy?

Cecille T Stgo I don't know if it's an actual increase or a more open attitude about admitting to the use

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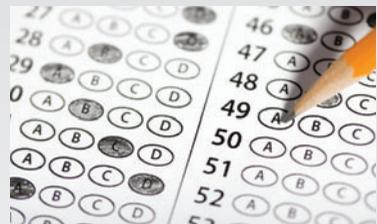
What do you say we all start a conversation with pregnant moms about cannabis?

Women's perspectives on cannabis use during pregnancy Bobby Lazara MD
Brought to you by Medical News Minute

OBSTETRICS Obesity and efficacy of combined OCs
Bob Kronemeyer

GYNECOLOGY Are endometriosis and birth weight linked?
Bob Kronemeyer

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Renée Bacher



QUIZ Adenomyosis and its impact on fertility
Nancy Monson

LEGAL Did unnecessary induction result in birth injury?
Andrew I Kaplan, Esq

UPDATES USPSTF makes recommendations on perinatal depression
Judith M. Orvos, ELS

Tweets and posts have been unedited

Hydatidiform mole

Recognition and management

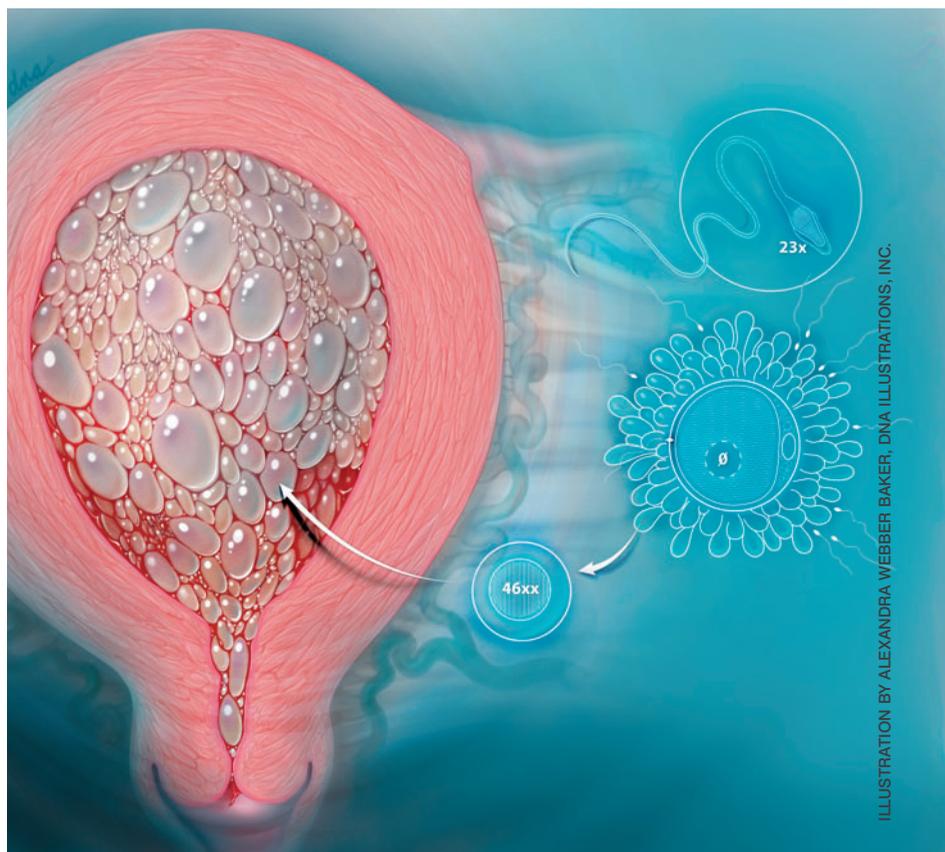
Molar pregnancies may be associated with serious morbidity so prompt diagnosis, appropriate management, and follow-up are essential.

by JOHN R. LURAIN, MD

Hydattidiform mole is an abnormal pregnancy characterized by varying degrees of trophoblastic proliferation (both cytotrophoblast and syncytiotrophoblast) and vesicular swelling of placental villi associated with an absent or abnormal fetus/embryo. Two types of hydatidiform mole, complete and partial, have been described based on both morphologic and cytogenetic criteria (Table 1).^{1,2}

Epidemiology

Epidemiologic studies have reported wide regional variations in the incidence of molar pregnancies. Estimates from studies in North America, Europe, Australia and New Zealand have shown incidence rates ranging from 0.57-1.1 per 1000 pregnancies, whereas studies in Southeast Asia and Japan have suggested an incidence rate as high as 2.0 per 1000 pregnancies. These reported differences may



DR. LURAIN is Marcia Stenn Professor of Gynecologic Oncology at the John I. Brewer Trophoblastic Disease Center within the Department of Obstetrics and Gynecology, Northwestern University Feinberg School of Medicine, Chicago.



be related to lack of standardization of data collection and reporting rather than true incidence differences. However, socioeconomic status and diet rather than genetic or cultural factors may also contribute to these reported differences in incidence rates. Declining incidence of molar pregnancies in Asia has been attributed to increasing western diet and improved standard of living. The overall incidence of molar pregnancies in the United States and Europe is about 1/1000 pregnancies for both complete and partial moles.^{1,2}

Several potential etiologic risk factors for development of molar pregnancy have been evaluated (Table 2).³ For complete hydatidiform moles, two well-established risk factors have emerged: (1) extremes of maternal age; and (2) prior molar pregnancy. Both advanced and very young maternal age have consistently correlated with higher rates of complete mole. Compared to risk in women aged 21 to 35 years, risk of complete mole is 1.9 times higher for women both < 21 years and > 35 years and 7.5 times higher for women > 40 years, including 1 in 3 pregnancies for women > 50 years. These observations suggest that ova of very young or older women are predisposed to abnormal fertilization events that lead to complete hydatidiform moles. Prior complete molar pregnancy increases risk of developing a subsequent complete molar pregnancy.

Risk of a repeat molar pregnancy after one mole is approximately 1%, about 10 to 20 times the risk for the general population, while after two moles, the risk of a third mole is 15% to 20%. History of prior spontaneous abortion also appears to increase risk of a molar pregnancy (both complete

TABLE 1 Clinicopathologic features of hydatidiform mole

Molar pregnancy type	Pathological features	Clinical factors
Complete mole	Diploid (45, XX; rarely 46, XY) Absent fetus/embryo Diffuse swelling of villi Diffuse trophoblastic hyperplasia	Vaginal bleeding Large for dates uterine size Bilateral theca lutein cysts Medical complications hCG often > 100,00 mIU/mL 15 to 20% postmolar GTN
Partial mole	Triploid (69, XXY; 69, XXY; 69, XXX) Abnormal fetus/embryo Focal swelling of villi Focal trophoblastic hyperplasia	Pre-D&C diagnosis usually incomplete or missed abortion Medical complications rare hCG rarely > 100,000 mIU/mL < 5% postmolar GTN

Abbreviations: GTN, gestational trophoblastic neoplasia; D&C, dilation and curettage

TABLE 2 Epidemiologic risk factors for hydatidiform mole

Risk factor	Complete mole	Partial mole
Maternal age < 20, > 40	++	-
Prior complete mole	++	-
History of spontaneous abortion	+	+
Dietary deficiency of β -carotene & animal fats	+	-
Ovulation induction	+	-
OCPs	+/-	+/-
History of menstrual irregularities	-	+
Ethnicity	+	-

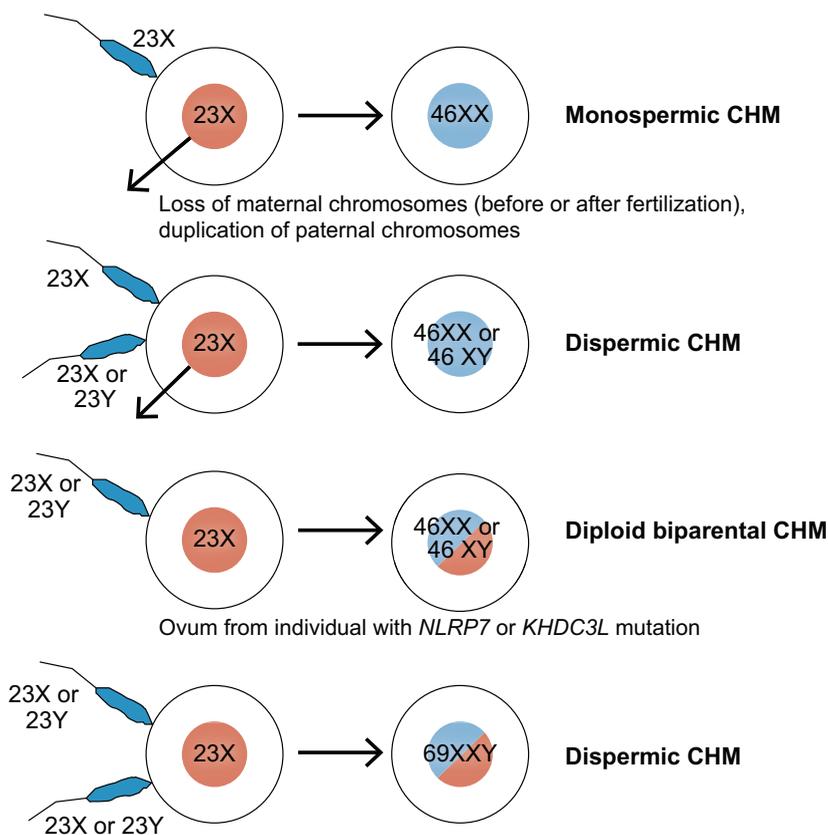
Abbreviations: OCPs, oral contraceptive pills

and partial) 2- to 3-fold compared to women without a history of prior miscarriage. Dietary deficiency of β -carotene and animal fat has been linked to an increase in complete moles. There appears to be a possible increased risk of molar pregnancy (partial and complete) with a history

of oral contraceptive use, while ovulation induction regimens may be associated with an increase in twin pregnancies consisting of a normal fetus(es) and a complete mole.

While several definite etiologic risk factors have been identified for complete moles, the epidemiologic char-

FIGURE 1. Genetics of hydatidiform mole



Abbreviations: CHM = complete hydatidiform mole

acteristics of partial moles differ and are less well defined. Importantly, the association between maternal age and complete molar pregnancies is not seen in women with partial molar pregnancies. Furthermore, partial molar pregnancies are more common in women with a history of irregular menses, miscarriage, and oral contraceptive use for > 4 years, but are not associated with ethnicity, ovulation induction, or dietary factors.

Genetics

Complete hydatidiform moles usually arise when an ovum without ma-

ternal chromosomes is fertilized by one sperm which then duplicates its DNA, resulting in a 46, XX androgenic karyotype in which all the chromosomes are paternally derived. About 10% of complete moles are 46, XY or 46, XX arising from fertilization of an “empty ovum” by two sperm. Biparental diploid complete moles are associated with a maternal autosomal-recessive missense gene mutation, most commonly *NLRP7* on chromosome 19q, which results in repetitive molar pregnancies. Partial hydatidiform moles have a triploid karyotype, usually 69, XXY, resulting from

dispermic fertilization of an apparently normal ovum (Figure 1).²

Pathology

Complete hydatidiform moles undergo early and uniform hydatid enlargement of villi in the absence of an ascertainable fetus or embryo, the trophoblast is consistently hyperplastic with varying degrees of atypia, and villous capillaries are absent. Partial hydatidiform moles demonstrate identifiable fetal or embryonic tissue, chorionic villi of varying size and shape with focal edema, scalloping and prominent stromal inclusions, a functioning villous circulation, as well as focal trophoblastic hyperplasia with only mild atypia. Immunohistochemical staining for p57 (a parentally imprinted, maternally expressed gene) may be useful for differentiating a positive partial mole from a negative complete mole, but cannot be used to distinguish a partial mole from a nonmolar abortus both of which are positive.⁴⁻⁶

Clinical presentation

Complete hydatidiform moles most commonly present with vaginal bleeding, usually occurring at 6 to 16 weeks of gestation in 90% of cases. The other classical clinical signs and symptoms, such as uterine enlargement greater than expected for gestational dates (28%), hyperemesis (8%), and toxemia, hyperthyroidism, and trophoblastic embolization (< 1%), occur less frequently in more recent years due to earlier diagnosis as a result of widespread use of ultrasonography and accurate tests for human chorionic gonadotrophin (hCG). Bilateral theca lutein cyst enlargement of the ovaries occurs in approximately 15% of cases, hCG levels are



often > 100,000 mIU/mL, and fetal heart sounds are absent.^{7,8}

Partial hydatidiform moles do not have the same presenting features as complete moles. Although the main presenting symptom is also vaginal bleeding, which occurs in about 75% of patients, excessive uterine enlargement, hyperemesis, pregnancy-induced hypertension, hyperthyroidism, and theca lutein cysts develop infrequently. Fewer than 10% have hCG levels > 100,000 mIU/mL. More than 90% of patients with partial moles have symptoms and ultrasound findings consistent with an incomplete or missed abortion, and the diagnosis is usually made only after histologic examination of uterine curettage specimens.⁹

Diagnosis

Ultrasonography plays a critical role in the diagnosis of both complete and partial molar pregnancy, and it has virtually replaced all other means of preoperative diagnosis. Because the chorionic villi of complete moles exhibit diffuse hydropic swelling, a characteristic vesicular ultrasonographic pattern can be observed consisting of multiple echoes (holes) within the placental mass and usually no fetus (Figure 2). Ultrasonography may also facilitate early diagnosis of a partial mole by demonstrating focal cystic spaces within the placenta and an increase in the transverse diameter of the gestational sac.¹²

hCG is a disease-specific tumor marker produced by the trophoblast of hydatidiform moles and gestational trophoblastic neoplasms as well as normal pregnancy. Hydatidiform moles are commonly associated

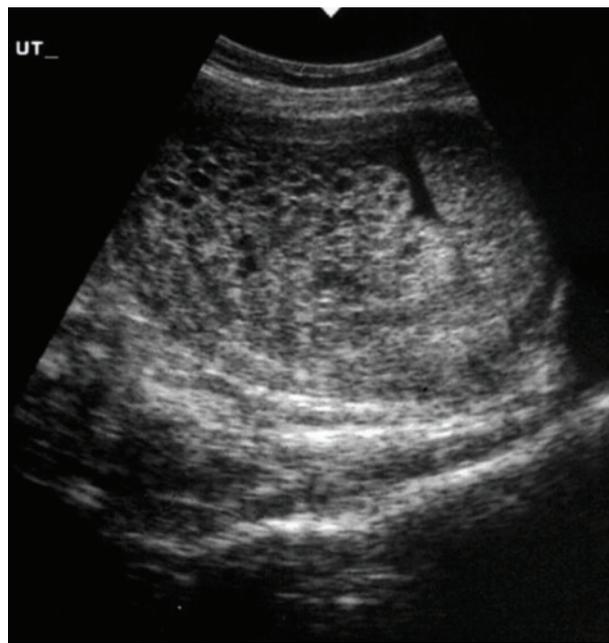


FIGURE 2. Ultrasound of complete hydatidiform mole. The characteristic vesicular “snowstorm” pattern of multiple echoes appearing as holes within the placenta and no fetus is present.

with markedly elevated hCG levels above those of normal pregnancy. Approximately 50% of complete moles have pre-evacuation hCG levels > 100,000 mIU/mL. However, a single hCG level is seldom helpful in differentiating a complete mole from another

Suction evacuation and curettage is the preferred method of evacuation of a hydatidiform mole.

type of pregnancy. Partial moles, on the other hand, are most often not associated with such elevated hCG levels, as noted previously.¹³

Despite earlier diagnosis of complete moles resulting in fewer complications, there has not been a simultaneous reduction in incidence of postmolar gestational trophoblastic neoplasia (GTN).

Management

Once the diagnosis of molar pregnancy is suspected based on history, physical examination, hCG level, and ultrasound findings, the patient should be evaluated for the presence of medical complications (anemia, preeclampsia, hyperthyroidism), which may need to be corrected. Basic laboratory tests should include complete blood count, comprehensive metabolic panel, thyroid function test, urinalysis, and chest x-ray, as well as blood type and screen with cross match if anemic or uterus ≥ 16-week gestational size. An electrocardiogram and coagulation profile may also be indicated. Once the patient is determined to be hemodynamically stable, the most appropriate method of molar evacuation should be decided upon.^{1,2,14}

Suction evacuation and curettage is the preferred method of evacuation of a hydatidiform mole, independent of uterine size, for patients who wish to



FIGURE 3A. Twin pregnancy consisting of a complete mole and a normal fetus.



FIGURE 3B. Normal placenta anterior and hydatidiform mole posterior.



FIGURE 3C. Fetus and molar placenta.

maintain their fertility. After anesthesia is achieved, the cervix is dilated to allow a 12- to 14-mm suction cannula to pass into the lower uterine segment and then rotated as the intrauterine

contents are removed, preferably under ultrasound guidance. Suction evacuation should be followed by gentle sharp curettage. Uterotonic drugs should be started after initiation of evacua-

tion of the uterus, although oxytocin receptors may be absent. Because risk of excessive bleeding increases with uterine size, 2 units of blood should be immediately available when the uterus is ≥ 16 -week gestational size. Attention to blood and crystalloid replacement decreases pulmonary complications. It is clear that with judicious use of appropriate equipment, access to blood products, careful intraoperative monitoring, and early anticipation of complications, patient outcomes improve. Patients who are Rh-negative should receive Rho(D) immune globulin at the time of evacuation, as Rh D factor is expressed on trophoblastic cells.

Hysterectomy is an alternative to suction curettage in patients who do not wish to preserve fertility or are older and at increased risk for development of postmolar GTN. The adnexa may be left intact even in the presence of theca lutein cysts. In addition to evacuating the molar pregnancy, hysterectomy provides permanent sterilization and eliminates risk of local myometrial invasion as a cause of persistent disease. Because of the potential for metastatic disease even after hysterectomy, risk of postmolar GTN still remains at 3% to 5%, thereby requiring continued hCG follow up.

Medical induction of labor and hysterotomy are not recommended for molar evacuation. These methods increase maternal morbidity, such as blood loss, incomplete evacuation requiring curettage, and the requirement for cesarean delivery in subsequent pregnancies. They also increase trophoblastic dissemination and the development of postmolar GTN requiring chemotherapy.

Prophylactic chemotherapy at the time or immediately after evacua-



tion of a molar pregnancy is associated with a reduction in incidence of postmolar GTN from approximately 15% to 20% down to 3% to 8%.¹⁵ Use of prophylactic chemotherapy should be limited, however, to special situations in which risk of postmolar GTN is much greater than normal (age > 40 years, hCG > 100,000 mIU/mL, excessive uterine enlargement, theca lutein cysts > 6 cm, medical complications) and/or when adequate hCG follow-up is unavailable or unreliable. Essentially all patients who are followed with serial hCG testing after molar evacuation and are found to have persistent GTN can be cured with appropriate chemotherapy.

Twin pregnancy consisting of a complete mole and a coexisting normal fetus is estimated to occur once in every 22,000 to 100,000 pregnancies (Figure 3). It must be distinguished from a partial mole (triploid pregnancy with fetus). The diagnosis can usually be established by ultrasound, but cytogenetics may be used to differentiate between chromosomally normal, potentially viable fetuses and triploid nonviable fetuses. Patients with a normal fetus/complete mole twin pregnancy should be cautioned that they may be at increased risk for hemorrhage, medical complications,

and development of persistent GTN. Suction evacuation and curettage in the operating room under ultrasound guidance is recommended for desired pregnancy termination, bleeding, or medical complications. However, up

Medical induction of labor and hysterectomy are **not recommended** for molar evacuation.

to 40% of these pregnancies will result in normal viable births if allowed to continue.^{16,17}

Follow-up

After evacuation of a hydatidiform mole, follow-up is essential to detect trophoblastic sequelae (invasive mole and choriocarcinoma), which develop in approximately 15% to 20% of patients with complete mole and 1% to 5% with partial mole.^{1,2,14,18} Clinical findings of prompt uterine involution, ovarian cyst regression, and cessation of bleeding are all reassuring signs, however, definitive follow-up requires serial serum hCG measurements every 1 to 2 weeks until three consecutive tests show normal hCG

levels, after which hCG levels should be determined at 3-month intervals for 6 months after the spontaneous return to normal. Contraception is recommended during the follow-up period for 6 months after the first normal hCG result. Oral contraceptives are preferred because they have the advantage of suppressing endogenous luteinizing hormone (LH), which may interfere with the measurement of hCG at low levels, and do not increase the risk of postmolar GTN. Indications for treatment of postmolar GTN are: plateauing hCG

levels x4 values over 3 weeks, rising hCG levels $\geq 10\%$ x three values over 2 weeks, persistently elevated hCG levels 6 months after evacuation, a histopathologic diagnosis of choriocarcinoma or intermediate trophoblastic tumor, or detection of metastases.¹⁹⁻²¹ In all future pregnancies, pathologic examination of the placenta or other products of conception as well as determination of a 6-week postpartum hCG level are recommended. ■

DISCLOSURE The author reports no potential conflicts of interest with regard to this article.

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TEST YOUR KNOWLEDGE

THIS IS THE FIRST IN A NEW MONTHLY SERIES OF PUZZLERS THAT WILL TEST YOUR KNOWLEDGE OF VULVAR DISEASES

Irregular vulvar mass in a postmenopausal woman

Do you know how to differentiate precancerous from cancerous vulvar lesions?

by MATT GROSSI, MD, ROSALYN ELIZABETH MABEN-FEASTER, MD, DIANA CURRAN, MD, JOHN O. DELANCEY, MD, AND HOPE K HAEFNER, MD



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Gynecology, Director, Pelvic Floor Research, and Group Director, Fellowship in Female Pelvic Medicine and Reconstructive Surgery, University of Michigan Medical School, Ann Arbor.



Dr. Haefner is professor, Department of Obstetrics and

Gynecology, Michigan Medicine, University of Michigan, Ann Arbor.



FIGURE 1. Appearance of the vulva in this case

HISTORY A 77-year-old woman presents for evaluation of an irritated area on her vulva (Figure 1). She has a history of vulvar lichen sclerosus since her teenage years and has been only partially compliant in using topical corticosteroids.

WHAT IS THE MOST LIKELY DIAGNOSIS?

- A. Differentiated vulvar intraepithelial neoplasia
- B. Squamous cell carcinoma
- C. Verrucous carcinoma
- D. Paget's disease
- E. Melanoma

THE NEXT STEP IN YOUR MANAGEMENT PLAN IS:

- A. Wide local excision of the lesion with at least 1-cm margins
- B. Refer to Gynecologic Oncology
- C. Magnetic resonance imaging of the pelvis
- D. Vulvar biopsy



FOR THE DIAGNOSIS, TREATMENT PLAN, AND DISCUSSION TURN TO **PAGE 32**

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Race and breastfeeding in the American South

Breastfeeding rates in the United States differ by race with rates lowest among African-American infants.

These trends are especially evident in the American South. A recent study appearing *Pediatrics* examined how effective a hospital- and community-based initiative could be in reducing racial disparities while at the same time helping participating hospitals achieve a *Baby-Friendly* designation.

Between 2014 and 2017, 33 hospitals enrolled in the CHAMPS (Communities and Hospitals Advancing Maternity Practices) program from Boston Medical Center's Center for Health Equity, Education and Research. The program was intended to decrease racial disparities in breastfeeding by using a community and hospital collaborative strategy to improve maternity care practices and implement the Ten Steps to Successful Breastfeeding Initiative.

Enrolled hospitals received intensive quality and technical assistance intervention to improve compliance. They were located in Mississippi (18), Louisiana (9), Texas (5), and Tennessee (2). All hospitals submitted monthly aggregate data stratified by race on breastfeeding initiation and exclusivity, skin-to-skin care, and rooming in practices.

The authors found that the average rate of breastfeeding initiation at CHAMPS-enrolled hospitals rose from 66% to 75% and the average rate



Among African-American infants, breastfeeding initiation and exclusivity increased from 46% to 63% and 19% to 31%, respectively.

of breastfeeding exclusivity rose from 34% to 39%. The disparity between African-American and white infants in regard to breastfeeding initiation disparity decreased by 9.6% over 31 months. Among African-American infants, breastfeeding initiation and exclusivity increased from 46% to 63% and 19% to 31%, respectively. Skin-to-skin care after vaginal birth increased from 33% to 88% and care after cesarean delivery increased from 11% to 67%. Rooming in increased from 11% to 75%.

The authors noted that skin-to-skin care after cesarean delivery was significantly associated with increased breastfeeding initiation and exclusivity overall, with the greatest impact seen among African-American infants.

Rooming in was also significantly associated with increased exclusive breastfeeding among African-American infants as they were 1.54 times more likely to breastfeed than infants who did not room in (95% CI: 1.14-2.07).

By 2017, 91% of all CHAMPS hospitals, including 100% of Mississippi CHAMPS hospitals, were on the Baby-Friendly pathway and 1 hospital had gained the designation. By November 2018, 14 CHAMPS hospitals were designated Baby-Friendly. Also, during enrollment, the number of hospitals that stopped distributing formula industry sample packs increased from 42% to 97%.

The authors believe their findings illustrate that breastfeeding rates in the American South can be improved

through implementing Baby-Friendly practices in hospitals. Their data show that increased compliance in the program was associated with a decrease in racial and/or ethnic disparities in breastfeeding initiation in hospitals and increased breastfeeding initiation, breastfeeding exclusivity, skin-to-skin care and rooming in across all races. The researchers also noted that during the implementation process, many outdated and non-evidence practices, such as breast binding, universal “trials of swallowing” with bottles of sterile water, and long periods of maternal/infant separation came to light. In addition, many evidence-based practices, such as delayed cord clamping and placing infants on their



EXPERT PERSPECTIVE *This report shows that racial disparity in breastfeeding initiation, exclusive breastfeeding, and continuation can be overcome through innovation, education, care coordination and follow up. Implementation of Baby-Friendly breastfeeding strategies requires leadership from administrators and staff and commitment to patient-centered care and shared decision-making. Improving breastfeeding racial disparity can also lead to generation disparity in childhood and adult obesity, diabetes and hypertension.*

Haywood L. Brown, MD Vice President for Diversity, Inclusion & Equal Opportunity
University of South Florida, Tampa, past President American College of Obstetricians & Gynecologists.

backs for safe sleep were often lacking. As hospitals worked towards improving care, these unsafe practices were eliminated and replaced with updated, evidence-based care. ■

SOURCE

Merewood AM, Bugg K, Burnham L, et al. Addressing racial inequalities in breastfeeding in the Southern United States. *Pediatrics*. Feb 2019, 143 (2) e20181897.

Can AI outperform humans in detecting cervical cancer?

by JUDITH M. ORVOS, ELS

Automated evaluation of digital images of the cervix may have potential in point-of-care cancer screening, according to results of a proof-of-concept study supported by the National Institutes of Health. Published in *The Journal of National Cancer Institute*, the research showed that a computer could be taught to distinguish cervical precancer/cancer from normal cells in images using a “deep learning” visual evaluation algorithm.

The images in the study were cervigrams, pairs of cervical photographs that are visually screened for cervical cancer and precursors. The method, called cervicography, has been discontinued but

was in use in Guanacaste, Costa Rica during the period of study—1993 to 2000. The population longitudinal cohort for this research was 9406 women aged 18 to 94 in that geographic area who were followed for 7 years.

The participants were screened with cervicography and other methods and their precancers were histologically confirmed. Tumor registry linkage identified cancers up to 18 years. Images from the patients’ cervigrams were used to train an automated visual evaluation algorithm. The authors designed the algorithm to detect the cervix within an image and predict the probability that the image represented cervical intraepithelial neoplasia (CIN) 2+. The resulting image predic-

tion score (0-1) could be categorized to balance sensitivity and specificity for detection of precancer/cancer.

Testing of automated evaluation of the cervigrams showed that the system was more accurate in identifying precancer/cancer cases than the original cervigram interpretations (AUC 0.91, 95% confidence interval [CI] 0.89 to 0.93 vs AUC 0.69, 95% CI 0.63 to 0.74; $P < .001$). The automated technique also was more accurate than conventional cytology (AUC 0.71; 95% CI 0.65 to 0.77; $P < .001$). A single visual screening round restricted to women aged 25 to 49 could identify 127 of 228 precancers (55.7%) diagnosed cumulatively in the adult population while referring 11% for management.

The authors said their results “support consideration of automated visual evaluation of cervical images from contemporary digital cancers,” to possibly expand point-of-care cervical screening. They believe it also has potential as a triage method for women who test human papillomavirus (HPV)-positive, if HPV is the primary screen and could reduce the need for speculum examinations. They noted, however, that this study had a small number of cases from a single cohort and that the algorithm ideally should be trained on more definitive precancer cases, such as CIN3 and adenocarcinoma in situ.

As an extension of this research, the authors are transferring automated visual evaluation to images from con-



EXPERT PERSPECTIVE *The use of deep learning for cervical cancer screening reveals the potential of this method. Deep Learning has networks that are capable of learning, unsupervised, from data that are largely unstructured and unlabeled. In combination with big data analytics, this technology will undoubtedly help us to get better information and improve our diagnostic capabilities in the near future.*

Jon I. Einarsson, MD, PhD, MPH Professor of obstetrics and gynecology, Harvard Medical School, Director, Division of Minimally Invasive Gynecologic Surgery, Brigham and Women’s Hospital, Boston, Mass.

temporary phone cameras and other digital image capture devices to create an accurate and affordable point-of-care screening method that would support a recently announced World Health Organization initiative to accelerate cervical cancer control. ■

SOURCE

Hu L, Bell D, Antani S, et al. An observational study of deep learning and automated evaluation of cervical images for cancer screening. *J Natl Cancer Inst.* 2019 Jan 10. doi: 10.1093/jnci/djy225. [Epub ahead of print].

Does endometrial scratching improve IVF live birth rates?

by **BEN SCHWARTZ**

Endometrial scratching—taking an endometrial-biopsy sample—has been proposed as a way to improve live birth rates with in vitro fertilization (IVF). Some studies have suggested a benefit for the procedure, but they have had limitations including small sample sizes and unclear methods of randomization. New data are now available on endometrial scratching from a large, multicenter, randomized trial.

The 1364 women in the study, published in *The New England Journal of Medicine*, were recruited from June 2014 through June 2017 at 13 sites in

five countries. All were undergoing IVF (both fresh- or frozen-embryo transfer) and had no recent exposure to disruptive intrauterine instrumentation, such as a hysterectomy. Participants were randomized 1:1 to either endometrial scratching by Pipelle biopsy or to no intervention.

The live birth rate for the endometrial scratching group was 26.1% versus 26.1% in the control group. There were also no significant differences between the two groups in rates of ongoing, clinical, biochemical, multiple or ectopic pregnancy or miscarriage. In women who had not failed implantation at least twice, no benefit was found for endometrial scratching (estimated interaction odds ratio, 0.63; 95% CI 0.35 to 1.15; $P = 0.14$). Furthermore, neither the number of



EXPERT PERSPECTIVE *This is an example of another test that initially showed clinical promise in some small observational studies which was ultimately proven to be unhelpful in a well-designed prospective clinical trial.*

Steven J. Ory, MD Professor of obstetrics and gynecology, Florida International University, Miami, Partner, IVF Florida, Margate.

days between endometrial scratching and embryo transfer nor reported pain during the procedure were associated with greater odds of live birth.

Because data on pain and bleeding were captured only in the endometrial scratch group, it was not possible to compare the frequency of these adverse events between groups. Identifi-

fied strengths of the research were large sample size and minimal attrition.

The authors said their results indicate that endometrial scratching is not beneficial for women trying to conceive through IVF. They suggest that clinicians not encourage their patients to pursue the procedure before IVF because it resulted in no improvement in

live birth rate, exposes women to the potential for pain, and is associated with a cost of approximately \$500 and inconvenience. ■

SOURCE

Lensen S, Oxavlyuk D, Armstrong S, et al. A randomized trial of endometrial scratching before in vitro fertilization, *N Engl J Med*. 2019 Jan;380:325-334.

Can sleeping habits predict late stillbirth?

by BEN SCHWARTZ

In high-income countries, 1.3 to 8.8 births per 1000 are late stillbirths. Because these fetal deaths at ≥ 28 weeks often occur in women with no established risk factors, research to identify potentially modifiable behaviors is needed. A new study looked at whether maternal sleep practices play a role.

Published in *Birth*, the results are from an analysis of data on an international cohort. Between September 2012 and August 2014, women were invited to participate in an anonymous online survey distributed across social media and through web-based advertising and word-of-mouth. All of them were at least 18 years old, fluent in reading and writing English, and had delivered a singleton stillborn baby at least 28 weeks' gestation within 1 month before completing the questionnaire. Controls were also at least 18 years old and either still pregnant (≥ 28 weeks) or had delivered a living baby within the month before responding.

Median duration of time since childbirth in the 480 controls was 13 days (range 1-29 days). Median gestation at

time of stillbirth in the 153 cases was 37 weeks (range 28-41 weeks) and 52% of stillbirths were male.

The authors found no differences in self-reported sleep practices before pregnancy in cases and controls. In the last month of pregnancy, however,

Having restful sleep was more likely in the stillbirth group in the last month.

nocturnal sleep duration was significantly longer in cases versus controls, as was 24-hour sleep duration.

Women with stillbirths were at significantly higher odds (aOR 1.75 [95% CI 1.10-2.79]) of sleeping ≥ 9 hours a night in the month before delivery. They were also more likely to report not waking up or waking up only once on the last night before delivery. Although no relationship was found between stillbirth and reported sleep position, the authors noted that the number of reported supine sleepers included in the study was universally low, which prevented full analysis.

Having restful sleep was more likely in the stillbirth group in the last month, even after accounting for other risk factors (aOR 1.73 [95% CI 1.03-2.99]). Odds of good/very good sleep quality in the last month were higher in the stillbirth group (OR 1.69 [95% CI 1.03-2.99]). A small number of women reported using sleep aids during the last month and on the last night before taking the survey, but no significant relationship was found with stillbirth. Women in the stillbirth group were also asked about their perception of when their baby died and 74% (n=83) believed it was during the night.

The authors believe their findings suggest that long periods of undisturbed sleep are associated with a late stillbirth. Reports of higher-quality sleep and lack of restless sleep were also more likely in the stillbirth group. ■

SOURCE

O'Brien L, Warland J, Stacey T, et al. Maternal sleep practices and stillbirth: Findings from an international case-controlled study. *Birth*. 2019 Jan 18. doi: 10.1111/birt.12415. [Epub ahead of print].

Gender disparities in bladder cancer

Diagnostic delays, therapeutic differences, and possibly biological factors may play a role in how physicians approach treatment.

by **MARCUS L. QUEK, MD, MICHAEL E. WOODS, MD, AND SPENCER T. HART, MD**

Persistent disparities in outcomes between men and women with bladder cancer highlight areas of needed improvement in delivery of oncologic care. There were 81,190 new cases of bladder cancer in the United States in 2018, the majority in men. While males are three to four times more likely to develop the disease, women tend to present at an advanced stage, experience differences in quality-of-life following treatment, and suffer higher cancer-specific mortality.¹ Based on Surveillance, Epidemiology, and End Results (SEER) data, women appear to have better cancer-specific mortality for most malignancies, but that does not appear to be the case for bladder cancer.² Epidemiologic and biologic explanations have been offered, but our incomplete

understanding of the issue suggests numerous contributing factors.

Disparities in evaluation and diagnosis

Perhaps the most evident disparity confronting women with bladder cancer is related to timely evaluation and diagnosis. The reasons for this are multifaceted and reflect differences in how women with hematuria progress through the health care system. Interpretation of hematuria in a woman can be challenging for primary care physicians. While it is certainly concerning for malignancy, it is also present in a number of benign conditions including urinary tract infections (UTIs), which are common in postmenopausal women. In a large population study performed by Cohn and colleagues, women presenting with hematuria who were ultimately

diagnosed with bladder cancer were far more likely to be treated for a suspected UTI during initial evaluation than men.³ Similarly, evaluation of practice patterns of primary care physicians by Buteau and colleagues demonstrated that women presenting with hematuria often underwent three or more pre-referral consultations with their primary care provider for the same complaint before referral for urologic evaluation (OR 2.31, 95% CI 1.98–2.69).⁴ It is possible that these barriers result from conflicting guidelines regarding evaluation of asymptomatic microscopic hematuria. While the American Urologic Association defines microscopic hematuria as greater than three red blood cells (RBCs) per high powered field as the trigger for further diagnostic evaluation, the recently released 2017 guidelines from the American Col-



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lege of Obstetricians and Gynecologists favors a cut-off of 25 RBCs per high powered field for non-smoking women under age 50. This may lead to confusion for primary care physicians as to when referral is appropriate. Similarly, women who present to their gynecologist for evaluation of microscopic hematuria may experience delays in urologic referral.

While individually, these factors likely play only a small role in the overall delay in evaluation, their net effect is notable. Cohn and colleagues demonstrated that women were more likely to experience a delay in time to diagnosis when compared to men (85.4 days vs 73.6 days; $P < 0.001$) and a higher rate of > 6-month delay in diagnosis (17.3% vs 14.1%; $P < 0.001$).³ It has been well documented that delays in diagnosis translate to poorer cancer-specific outcomes.⁵

Gender differences in cancer-specific outcomes

Even after diagnosis, women with bladder cancer continue to suffer worse outcomes than males following definitive treatment. While it has been proposed that advanced stage presentation in women may be to blame, this does not fully explain differences in overall survival. An analysis of 5-year survival between men and women with bladder cancer found that women fared worse across all stages.⁶ This would suggest that gender continues to play a role even after diagnosis.

One single-institution series suggests that women were less likely to receive intravesical therapy for non-muscle-invasive disease, but larger population cohorts have failed to demonstrate this.^{7,8} Several studies have examined use of various treatment

GENDER DIFFERENCES IN BLADDER CANCER

WOMEN

1 IN 89 The chance women will develop bladder cancer during their life.

85.4 DAYS Average time for women to be diagnosed after initial presentation with hematuria.³

44.6% The percentage of urinary retention rates among women who received orthotopic neobladder.¹⁶

17.3% The percentage of women who were diagnosed more than 6 months after initial presentation.³

5 YEAR SURVIVAL Women fared worse across all stages of bladder cancer.⁶

MEN

1 IN 27 The chance men will develop bladder cancer during their life.

73.6 DAYS Average time for men to be diagnosed after initial presentation with hematuria.³

65% The percentage of men who had an orthotopic neobladder and showed improved QoL.¹⁴

14.1% The percentage of men who were diagnosed more than 6 months after initial presentation.³

TWICE AS OFTEN The rate that continent urinary diversions are used in men compared to women.¹²

Lead stats are from cancer.org

modalities and associated outcomes in women with muscle-invasive bladder cancer. An analysis of SEER data which examined use of radical cystectomy or radiotherapy in patients with muscle-invasive bladder cancer revealed that while men were more likely to receive radiotherapy, there were no differences in use of radical cystectomy between men and women.⁹ Similarly, it has been demonstrated that, compared with men, women do not experience significant differences in surgical margin status and lymph node count at time of cystectomy.¹⁰ Outcomes regarding cancer-specific survival following cystectomy have unfortunately been conflicting. Although older series showed that female gender was an independent risk factor for worse cancer-specific

survival, newer series suggest that the gender gap may be closing.¹¹ While more studies are needed to confirm this new trend, it is encouraging. This may be due, in part, to heightened awareness of historical disparities in diagnosis and treatment of bladder cancer in women.

Urinary diversion and health-related QoL

Despite equivalent use of radical cystectomy between men and women, continent diversions are underutilized in women. A recent review of radical cystectomies performed in the United States revealed that use of continent urinary diversions has declined, but male patients still received this treatment at more than twice the rate of women.¹² It has been demonstrated



that women suffer worse health-related quality of life (QoL) outcomes following ileal conduit when compared to men.¹³ While patient perception of body image and the results of surgery impact a number of QoL measures in all patients, several studies have suggested this may be improved with use of continent diversion. In a meta-analysis performed by Cerruto et al, 65% of men who had an orthotopic neobladder following radical cystectomy showed improved QoL measures when compared to those who received an ileal conduit.¹⁴ (An orthotopic neobladder is a continent urinary reservoir to the urethra that allows for volitional voiding per urethra.) Few studies have compared health-related QoL measures in men and women following cystectomy. In one study of 73 women who underwent radical cystectomy, those who received an orthotopic neobladder were more likely to experience improvements in future perspective about their illness, perceptions of body image, and sexual function than those who received an ileal conduit.¹⁵

Factors driving underutilization of orthotopic neobladder use in females are unclear, but may be related to gender-specific complications and adverse outcomes following urinary diversion. A study of urinary functional outcomes in women receiving an orthotopic neobladder revealed that urinary retention rates may be as high as 44.6% in women.¹⁶ There is a paucity of data comparing men to women in terms of daytime incontinence, night time incontinence, urinary retention, and sexual function

following orthotopic diversion. Lack of standardization of questionnaires, varying definitions of continence, under-sampling of female patients, and variable assessments of sexual function are mostly to blame. Further assessment of gender differences in this area is needed.

Even after diagnosis, women with bladder cancer continue to suffer worse outcomes than males following definitive treatment.

Potential biologic differences

The role of sex steroids and the hormonal axis have been investigated as a potential biologic explanation for the gender divide in bladder cancer. Population analyses have demonstrated that bladder cancer is more common in postmenopausal than premenopausal women.¹⁷ This has led several investigators to assess the role of sex steroid receptors in bladder tumors. The primary points of interest have been expression of androgen receptor (AR) and estrogen receptor (ER) and their association with pathologic stage. In an analysis of 188 tumors, Miyamoto and colleagues showed that loss of AR and ER α and increases in ER β were associated with an increase in tumor grade and stage.¹⁸ It also appears that modulating ERs may inhibit growth of urothelial cell carcinoma. In a study conducted by Sonpavde and colleagues, raloxifene, a selective estrogen receptor modulator (SERM),

inhibited growth of urothelial cell carcinoma in an in vivo model.¹⁹ Implications of ARs and ERs as drivers of tumorigenesis are profound. The role of tamoxifen, another SERM, is currently under investigation for the treatment of low- and intermediate-risk bladder cancer (NCT02197897). Further study is needed to determine the role of androgens in treatment of bladder cancer.

Conclusion

Gender disparity in bladder cancer is a complex issue that likely stems from diagnostic delays, therapeutic differences, and possibly biological factors. Each of these areas provide oppor-

tunities for improvement and for the eventual elimination of the gender divide. Partnerships between primary care providers, gynecologists and urologists should remain a priority to improve education and understanding of the importance of timely evaluation of hematuria in women. It is hoped that continued understanding of the biologic drivers of urothelial carcinoma will provide novel therapeutic targets for both men and women with bladder cancer. ■

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Lupus in pregnancy

Maternal and fetal outcomes complicated by SLE require that patient, rheumatologist, and ob/gyn work as a team.

by MICHELLE PETRI, MD, MPH, AND ROMY KALLAS, MD

Systemic lupus erythematosus (SLE) is a multi-system autoimmune disease that affects women of childbearing age. Although most pregnancies are successful with reported live birth rates of 85%,¹ SLE pregnancies remain high-risk. The challenges posed by such pregnancies arise from increased maternal risk of flares,²⁻⁴ preeclampsia, and maternal mortality,⁵ as well as increased fetal risks of intrauterine growth restriction (IUGR), pregnancy loss⁶ and preterm birth (PTB).⁷ In this review, we consider what is known about the immunology of lupus in pregnancy as well as the maternal and fetal risks and outcomes.

SLE immunology

It is amazing how little is still known about the immunology of SLE in pregnancy. Gonadal and adrenal steroid hormones are dysregulated in SLE pregnancies.⁸ In normal pregnancies, estrogen and progesterone stimu-



- Preconception preparation should include assessing renal disease activity in a patient, knowing which treatments she is taking for SLE, and being aware of whether she is anti-Ro- and La-positive and has APS.
- Lupus-affected pregnancies are at risk for renal flares, preeclampsia, cesarean delivery and a twenty-fold increase in maternal mortality.

late Th2 and inhibit Th1 cytokines, while dehydroepiandrosterone sulfate (DHEA-S) plays an immunosuppressive role. Levels of these three hormones are significantly lower in SLE pregnancies, particularly during the second and third trimesters, possibly due to placental compromise.⁸ In pregnant SLE patients, prolactin levels are elevated in the second trimester and peak in the third trimester.¹ High prolactin level correlates with pregnancy disease activity^{1,9} and poor pregnancy outcomes.⁹

Cytokine imbalances have also been found in pregnancies complicated by SLE, regardless of whether the disease is clinically active or inactive. Increases in interleukin (IL)-6, a Th2 cytokine, are

lower than expected and IL-10, B-cell growth factor, is persistently elevated.¹⁰

In the PROMISSE Study, overactivation of the complement pathway, detected by increased Bb and SC5b-9 (products of this pathway), was present early in 487 SLE pregnancies when compared with 204 healthy pregnancies.¹¹ Increased Bb and SC5b-9 correlated with adverse pregnancy outcomes, which included fetal/neonatal death, preterm delivery or preeclampsia and/or IUGR.¹¹ In one SLE pregnancy, mutations in complement system regulatory proteins were found.¹² These proteins are highly expressed on trophoblast membranes and prevent excessive complement activation in uncomplicated pregnancies.¹³



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Angiogenic imbalance is present in SLE pregnancies complicated by preeclampsia. In a case-control study using stored serum samples, soluble fms-like tyrosine kinase-1 (sFlt1), an anti-angiogenic factor, was significantly higher in pregnant patients with SLE who had preeclampsia.¹⁴ Elevation of sFlt1, as early as 12 to 15 weeks, correlated strongly with adverse pregnancy outcomes.¹

Given the number and breadth of the immunologic, endocrine, and angiogenic changes in pregnancies complicated by SLE, it is no wonder that they are associated with multiple adverse outcomes. However, these changes have not been integrated in a way that would be useful clinically at the individual patient level.

Maternal outcomes

Lupus-affected pregnancies are at risk for renal flares,¹⁶ preeclampsia, cesarean delivery and a twenty-fold increase in maternal mortality.⁵

DISEASE ACTIVITY AND LUPUS NEPHRITIS

Multiple case-control studies have yielded conflicting results regarding the likelihood of flares during pregnancy. While some centers found no difference in flare rates,¹⁷⁻²⁰ others have found increased risk of flare (Table 1)²⁻⁴ in pregnant compared to non-pregnant women with SLE. The differences are likely due to patient selection rather than study design or definition of flare. In particular, studies that included African-Americans,

lupus nephritis and women with unplanned pregnancies have shown higher flare rates.¹

Patients with organ-specific lupus activity during the 6 months prior to conception were more likely to have persistence of, or an increase in, the same type of activity during pregnancy.²¹ Most of the flares were mild to moderate in intensity^{7,21-23} and manageable with small increases in prednisone. Severe flares constituted only 2% to 20% of flares.^{7,21-24} There has been no overall pattern of timing of flares, with some studies showing flares early²⁰ and some late in pregnancy.⁴

Patients with SLE who have lupus nephritis constitute a special population that has been studied separately. Case-control studies that evaluated

TABLE 1

Case-control studies of SLE flares

Study	Number of lupus pregnancies	Number of controls & type	Study design	Quantified measure of flare	Conclusions
Zulman, 1980 ²	24	24 Prepregnancy course	Case-control study	No	Increased flare rates in pregnancy
Lockshin, 1984 ¹⁷	33	28 Matched nonpregnant	Case-control study	No	No difference in flare rates
Meehan, 1987 ¹⁸	22	22 Matched nonpregnant	Case-control study	No	No difference in flare rates
Petri, 1991 ³	39	29 185 Postpregnancy course Nonpregnant SLE patients	Case-control study	Yes	Increased flare rates in pregnancy
Urtowitz, 1993 ¹⁹	61	59 219 Matched nonpregnant Nonpregnant	Case-control study	Yes	No difference in flare rates
Ruiz-Irastorza, 1996 ⁴	78	50 68 Matched nonpregnant Postpregnancy course	Case-control study	Yes	Increased flare rates in pregnancy
Georgiou, 2000 ²⁰	59	59 Matched nonpregnant	Case-control study	Yes	No difference in flare rates

risk of flares in lupus nephritis concluded that pregnancy does not increase risk for renal flares. However, the study population included mostly white women in complete or partial remission at time of conception (Table 2).^{25,26} Compared to patients without lupus nephritis, pregnant women who have nephritis are at increased risk of renal flare.¹⁶

Lupus activity (manifested as mild, moderate or severe disease flares) in the months prior to conception is a major predictor of pregnancy activity. Studies with more than one-third of their patients with active disease at conception reported flare rates ranging from 45% to 70%,^{3,23} while those with predominantly inactive or stable disease at conception reported flare rates lower than 20%.²²

In patients with lupus nephritis, renal disease activity prior to or at the time of conception, and shorter renal disease remission duration were predictors of pregnancy flare.^{16,25} Renal flares occurred in 5% of pregnancies in women who were in complete remission prior to conception compared to 40% of pregnancies in those who had active renal disease.²⁵ Renal activity within 4 months prior to conception was the strongest predictor.¹⁶ Kidney biopsy early in pregnancy is safe and informative in patients with suspected renal flares. In a case series of 11 patients with SLE who underwent kidney biopsy during pregnancy, all but one underwent a change in management as a result of findings on renal biopsy and none had biopsy-related complications.²⁷

PREECLAMPSIA

Women who have SLE-affected pregnancies are three times more likely to

suffer from preeclampsia.⁵ Reported rates of preeclampsia range from 13% to 35% in lupus-affected pregnancies.^{5,21,23}

Presence of hypertension is the main predictor of preeclampsia.²⁴ Hypertensive patients are 40 times more likely to have pregnancies complicated by preeclampsia.²⁴ Lupus nephritis is also a predictor, especially when combined with prolonged disease duration (14% per month), previous renal flares (with a relative risk of 10), and active nephritis.²⁴

Women who have SLE-affected pregnancies are **three times more likely** to suffer from preeclampsia.

Fetal outcomes

Major fetal complications of pregnancy affected by SLE include pregnancy loss, preterm birth, IUGR, and neonatal lupus.

PREGNANCY LOSS

Fetal loss rates for pregnancy complicated by lupus have decreased over the past 40 years, from a mean of 40% to 17%.⁶ In patients with SLE, pregnancy loss occurs mostly during the first trimester. Attribution of early losses to SLE is often not possible, as early pregnancy losses are also common in the general population. Second-trimester losses are mostly associated with secondary antiphospholipid syndrome (APS).¹

We have found that proteinuria (> 500 mg in a 24-hour urine collection or a urine protein-to-creatinine ratio > 0.5 g; OR = 2.1), secondary APS (APS in the setting of another auto-

immune disorder; OR = 3.4), hypertension (blood pressure > 140/90 mm Hg; OR = 4.4) and thrombocytopenia (platelet count < 150,000; OR = 3.0) at the first prenatal visit in patients with SLE is predictive of pregnancy loss. We coined the acronym PATH (proteinuria, antiphospholipid syndrome, thrombocytopenia and hypertension) to remember these risk factors.²⁸ Increased lupus disease activity in the first and second trimester,^{29,30} particularly when combined with low complement levels^{29,30} or second-trimester positive anti-dsDNA antibodies,²⁹ is associated with higher risk of pregnancy loss.

In our center, only presence of lupus anticoagulant at the first pregnancy visit (not a past history of positivity) predicted loss of that pregnancy.³⁰ Thus, if lupus anticoagulant is positive, we recommend low-dose aspirin and low-molecular-weight heparin.³¹ In patients with thrombosis due to secondary APS, full anticoagulation is indicated and should be done with unfractionated or low-molecular-weight heparin.

A history of pregnancy loss in the first pregnancy is not a predictor of poor outcomes in future pregnancies.^{28,32} In an Australian cohort, 90% of women with SLE and a history of first pregnancy loss had a live-born infant, with no recurrence of perinatal death.³²

PRETERM BIRTH

PTB is the most frequent adverse pregnancy outcome in SLE,³³ with a reported incidence of approximately 50%.^{7,34-37} PTB can be spontaneous, such as preterm labor or premature rupture of membranes (PROM), or indicated for maternal or fetal complications such as preeclampsia, IUGR or fetal distress.


TABLE 2 Case-control studies of renal flares

Study	Number of lupus pregnancies	Number of controls & type	Study design	Quantified measure of flare	Conclusions
Moroni, 2002 ²⁴	70	70 Prepregnancy course	Case-control study	Yes	No difference in flare rates
Tandon, 2004 ²⁵	78	78 Matched nonpregnant with lupus nephritis	Case-control study	Yes	No difference in flare rates

Maternal hypertension is an important predictor of PTB.⁷ In the Hopkins study, mean diastolic blood pressure correlated with preterm delivery.⁷ Use of low-dose aspirin therapy was not predictive of better outcome, but instead was predictive of increased PTB,⁷ likely due to a clinician sensing that the patient was already at high risk.

Disease activity, particularly in the second trimester and when combined with hypocomplementemia or anti-dsDNA antibodies, is a risk factor for PTB.²⁹ In the Hopkins cohort, 45% of patients who delivered preterm had a high physician global assessment of disease activity and 70% were on 20 mg or more of prednisone.⁷ Active, but not quiescent lupus nephritis during pregnancy (defined as achievement of 50% reduction in urine protein/creatinine ratio 4 months prior to conception) is associated with a higher incidence of PTB (46.3% compared to 25.9%, respectively).¹⁶

Low estradiol, elevated ferritin and elevated uric acid³⁸ levels at mid-gestation and maternal serum alpha-fetoprotein (AFP) levels³⁹ have been found to be potential markers of subsequent PTB.

In the Hopkins cohort, PROM occurred in 40% of preterm SLE pregnancies and was also common in term SLE pregnancies.³⁴ Occurrence of PROM

did not correlate with disease activity, prednisone use, or serologic tests. In the same cohort, preeclampsia or pregnancy-induced hypertension was the reason for PTB in 32%, while spontaneous premature labor occurred in only 11%.³⁴

IUGR affects 20% to 30% of pregnancies complicated by SLE.^{1,40} Mean birth weight was significantly less for infants born to mothers with SLE than mothers without SLE⁴¹. This effect became more marked the longer the gestational period, suggesting that IUGR simply becomes worse as the pregnancy progresses.¹

Despite the fact that infants of mothers with SLE are more likely to be premature and to have IUGR, they tend to do well.¹ Fewer than 2% had an Apgar score below 7.⁴² Risk of neonatal intensive care unit admission, however, was three times higher in infants born to mothers with SLE.⁴¹

NEONATAL LUPUS

Neonatal lupus consists of neonatal lupus rash or congenital heart block due to transplacental transfer of anti-Ro and anti-La antibodies. The rash usually resolves by about 6 months. Cardiac manifestations, including heart block and cardiomyopathy, are associated with 20% mortality and

60% rate of permanent cardiac pacing.⁴³ Anti-Ro-positive women without previously affected pregnancies have a 2% estimated risk of congenital heart block.⁴⁴ The rate of congenital heart block when a previous pregnancy resulted in cutaneous or cardiac neonatal lupus is 20%.^{45,46} Weekly fetal cardiac monitoring (by echocardiography assessing PR intervals, valvulopathy, and myocardial function) between weeks 16 and 24 is recommended. Fluorinated steroids are given—to prevent cardiomyopathy—when a fetal echocardiograph detects heart block.⁴⁷ To date, hydroxychloroquine is the only drug that has shown to be beneficial in decreasing incidence of neonatal lupus.^{48,49}

Management of SLE during pregnancy

Preconception preparation is key. Prior to pregnancy, it is essential to assess disease activity (especially renal) in a patient, know which treatments she is taking for SLE (to switch to medications allowed in pregnancy), and be aware of whether she is anti-Ro- and La-positive and has APS.

Hydroxychloroquine should be maintained or initiated in all pregnancies complicated by SLE. We tell patients that it is desirable in preg-



nancy—for both mother and fetus. The safety of hydroxychloroquine in pregnancy was first demonstrated by Parke et al.⁵⁰ Other studies have confirmed the drug's lack of fetal toxicity and congenital abnormalities.^{16,51,52} Maintaining hydroxychloroquine during pregnancy offers maternal benefits. It decreases disease activity and flares,^{16,24,52} particularly joint and constitutional flares.⁵² In the Hopkins cohort, among patients with low disease activity who discontinued hydroxychloroquine, 30% developed high disease activity during pregnancy compared to only 3% of those taking hydroxychloroquine.⁵² Hydroxychloroquine has an anti-thrombotic effect⁵³ and should be used in pregnancies complicated by SLE in view of the 10-fold increase in thrombosis risk.⁵ Hydroxychloroquine also reduces neonatal morbidity. Rates of prematurity and IUGR were lower in 41 pregnancies complicated by SLE exposed to hydroxychloroquine compared to 77 pregnancies not exposed to hydroxychloroquine.⁴⁰ Neonates born to mothers who continued hydroxychloroquine had higher gestational age, birth weight, and Apgar scores.⁵¹

Nonsteroidal anti-inflammatory drugs (NSAIDs) should be avoided in the second and third trimesters. They have been shown to increase risk of premature closure of ductus arteriosus and impair fetal renal function.^{54,55}

Increases in prednisone to doses equal or greater than 10 mg should be avoided. Exposure to glucocorticoids did not increase risk of major anomalies, but did increase risk of cleft palate in pregnancies to women who did not have SLE.⁵⁶ Exposure to prednisone during the first trimester, in the gen-

eral population, was associated with increased rates of miscarriage, PTB and low birth weight.⁵⁷ It was not possible to separate out the effects of the underlying conditions from the effects of prednisone. Moreover, prednisone use in pregnancy was shown to be associated with increased risk of gestational diabetes when used in patients with idiopathic thrombocytopenia⁵⁸

Despite the fact that infants of mothers with SLE are more likely to be premature and have IUGR, they tend to do well.

and inflammatory bowel disease.⁵⁹

A limited number of steroid-sparing agents are available for treatment and maintenance of disease control during pregnancy. Methotrexate, mycophenolate, and cyclophosphamide must be stopped prior to conception. In particular, we recommend that mycophenolate be stopped 3 months prior to conception and azathioprine substituted (after first ensuring safety by thiopurine methyltransferase testing). During that period, monitoring can be done for occurrence of renal flares on azathioprine.⁶⁰ A low risk of flares was observed in patients with lupus nephritis who were switched from mycophenolate to azathioprine, compared to those who were initially on azathioprine and maintained on it.⁶¹ If renal flare occurs, activity can be controlled by returning to mycophenolate prior to pregnancy. Once a patient's flares are controlled, she can be switched to azathioprine plus tacrolimus (again waiting to make sure the combination does control the renal lupus, prior to conception).

Azathioprine has not been associated with major congenital anomalies or poor pregnancy outcomes at daily doses not exceeding 2 mg/kg.⁶⁰ Azathioprine safety is explained by absence of the enzyme inosinate pyrophosphorylase in the immature fetal liver. This enzyme is essential to convert azathioprine to its active metabolite mercaptopurine.

Tacrolimus has been used successfully for maintenance and control of flares during pregnancy in nine patients with lupus nephritis, with no congenital abnormalities reported.⁶² In a retrospective review of 15 pregnancies complicated by SLE, tacrolimus use was not associated with adverse fetal and maternal outcomes.⁶³

Most pregnancies exposed to rituximab (monoclonal antibody against CD20 present on B cells) resulted in uncomplicated live births with no pattern of congenital anomalies.⁶⁴ Transient B-cell depletion in infants has been reported in three pregnancies exposed to rituximab less than 12 weeks before delivery. The recommendation remains to stop rituximab 12 months prior to conception.⁶⁴

Seventy-seven pregnancies exposed to belimumab (monoclonal antibody against B-cell activating factor) resulted in 38 live births and four congenital anomalies. The latter were chromosomal, urogenital, neural tube, and cardiovascular anomalies.⁶⁵ One was a mild Ebstein's anomaly.⁶⁶

Approach to SLE in pregnancy

Three issues regarding SLE in pregnancies were highlighted in recent studies. First, during pregnancy, patients with SLE do not visit their rheumatologists

CONTINUED ON PAGE 43



Squamous cell carcinoma

CONTINUED FROM PAGE 18



FIGURE 2. Vulvar HSIL

Vulvar squamous cell carcinoma

Any patient in whom cancer is diagnosed needs to be referred to a gynecologic oncologist. But the initial biopsy of a lesion can be done by an ob/gyn to expedite a patient's care. Over 90% of vulvar malignancies are histologically squamous cell carcinomas (SCC). There are two known causal pathways for development of vulvar SCC: human papillomavirus (HPV)-dependent and HPV-independent. Approximately 20% of vulvar SCC is HPV-dependent and accounts for the majority of vulvar SCC in younger women; 80% of vulvar SCC is HPV-independent and more often found in older women. Patients with HPV-independent disease often have a concurrent vulvar inflammatory disorder, such as lichen sclerosus. Other

risk factors for vulvar SCC include increasing age, cigarette smoking, multiple sexual partners, cervical dysplasia, and immunodeficiency. Biopsy is essential in diagnosis and work-up of a suspected vulvar SCC. Once the diagnosis is made by vulvar biopsy, treatment includes referral to a specialist in gynecologic oncology for primary surgery (radical vulvectomy), possible inguinofemoral lymph node dissection dependent on the depth of invasion, as well as adjuvant radiation and/or chemotherapy when indicated.¹

Precancerous lesions of the vulva

Terminology for precancerous vulvar lesions has changed several times over the past few decades. The most recent and most widely used is the International Society for the Study of

DIAGNOSIS:

B. Squamous cell carcinoma

TREATMENT PLAN:

D. Vulvar biopsy

Vulvovaginal Disease (ISSVD) terminology of 2015.

This classification system uses:

1. Low-grade squamous intraepithelial neoplasia (LSIL)
2. High-grade squamous intraepithelial neoplasia (HSIL) (Figure 2)
3. Differentiated vulvar intraepithelial neoplasia (dVIN)

LSIL of the vulva refers to flat condyloma or HPV-effect, which does not usually require treatment unless it is bothersome to the patient. HSIL of the vulva (previously usual-type VIN) is associated with HPV in over 80% of cases. Left untreated, a significant number of cases will progress to vulvar SCC, therefore, treatment is recommended for vulvar HSIL.^{2,3} Treatment of HSIL is with simple excision or carbon dioxide laser, dependent on whether the disease is in the hair-bearing or non-hair-bearing area and whether the clitoris is involved. Topical treatment with 5% imiquimod (off-label) has been found to be efficacious. Wide local excision is preferable if occult invasive disease cannot be excluded.⁴

Much less common than HSIL of the vulva, dVIN is associated with approximately a 35% chance of progression to SCC. Most cases of dVIN are independent of HPV but are associated with older age and presence of an inflammatory dermatosis, most commonly



lichen sclerosus. Treatment with life-long topical corticosteroids has been shown to decrease the chance of a patient with lichen sclerosus developing precancerous and cancerous lesions of the vulva. Wide local excision of dVIN is suggested to exclude areas of occult invasion.⁵ Laser therapy and topical treatments are not recommended, outside of exceptional circumstances.

Other less common vulvar diseases

Vulvar Paget's disease (Figure 3) is a multifocal disease process that accounts for approximately 1% of all vulvar malignancies, most often in postmenopausal white women. The disease is often multifocal, and delay in diagnosis can be several years,



FIGURE 3.
Paget's disease

so any non-resolving hyperkeratotic plaque on the vulva requires biopsy. Primary treatment of Paget's disease is generally wide local excision to ob-

tain clear margins. Treatment of invasive Paget's disease is typically radical vulvectomy and consideration of inguinofemoral lymph node sampling.⁵



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FIGURE 4. Verrucous carcinoma of the vulva



FIGURE 5. Vulvar melanoma

Invasive disease occurs in 10% to 25% of all extramammary Paget's disease. Perianal tissue is more likely to be associated with invasion than disease on other areas of the vulva.

Verrucous carcinoma

Verrucous carcinoma of the vulva (Figure 4), often grossly mistaken for condylomata, is a rare vulvar malignancy (fewer than 1% of vulvar cancers). It can present as an exophytic, ulcerated or bleeding mass.⁶ In general, this variant can be slow growing and is locally invasive.^{6,7} Distant metastases have not been reported with this histologic subtype of vulvar cancer. On histopathology, verrucous carcinoma is characterized by a verruciform growth pattern, a blunt interface between the neoplastic epithelium and the underlying submucosal stroma, and minimal nuclear atypia.^{6,8} Treatment is typically in the form of surgical

excision. Topical medications, ablation therapies, and radiotherapy have not been shown to be effective.^{6,9,10}

Melanoma

Vulvar melanoma (Figure 5) accounts for approximately 10% of all pigmented vulvar lesions.⁵ Incidence is highest

There are two known causal pathways for development of vulvar SCC: HPV-dependent and HPV-independent.

after the sixth decade in white women. Early diagnosis through biopsy has been shown to decrease mortality, so biopsy is warranted of any new or atypical-appearing nevus. Vulvar melanoma should be treated with surgery by a clinician experienced in management of cutaneous malignan-

cies. Five-year survival rates are often less than 50%.

Disease metastatic to the vulva

Metastases to the vulva from primary tumors located elsewhere in the body are uncommon and account for approximately 3% to 5% of all vulvar malignancies. Most common sites of metastases include the cervix and less commonly the uterus, however, reports of vulvar metastases exist from primary tumors arising in the breast, bladder, anus, appendix (and other parts of the gastrointestinal tract), kidney, lung, thyroid, and as a primary presentation of lymphoma. ■

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

FOR REFERENCES VISIT
contemporaryobgyn.net/IrregularVulvarMass

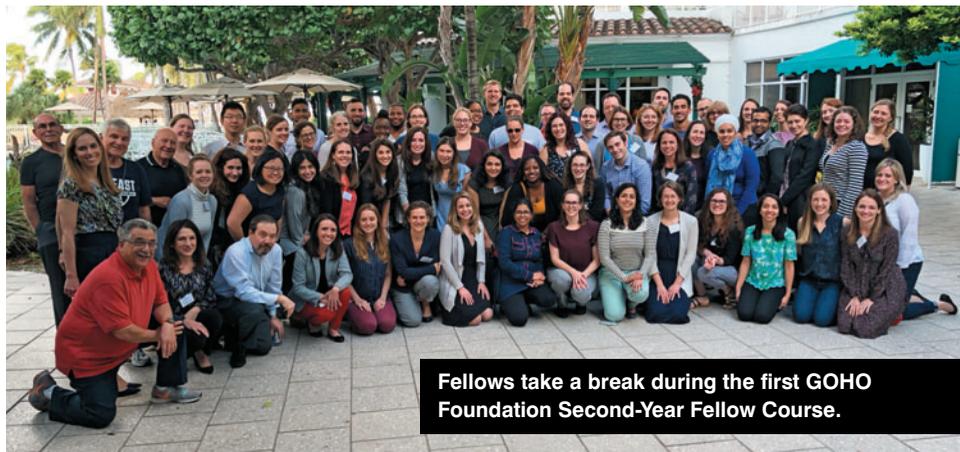
To read more about puzzling vulvar conditions visit our website CONTEMPORARYOBYGYN.NET

GOHO ultrasound program expands

The Gottesfeld-Hohler Memorial Foundation's (GOHO) ultrasound education program, previously just for residents, has been expanded. Late last year, the organization welcomed 65 students to its inaugural Second-Year Fellow Course.

During a 3-day retreat held at Lago Mar Resort & Club in Fort Lauderdale, Florida, the fellows received instruction from leaders in the field. Topics for the lectures included screening for fetal anomalies, first-trimester anatomy, chorionic villus sampling and amniocentesis, genetics, the role of magnetic resonance imaging in fetal brain imaging, and four-chamber view of the heart.

The fellows represented programs from across the United States. Faculty who volunteered to teach were Drs. Alfred Abuhamad, Beryl Benacerraf, Joshua Copel, Lorraine Dugoff, Helen Feltoich, Steven Goldstein, Christina Han, John Hobbins, Ana Monteagudo, Lawrence Platt, Magdalena Sanz Cortes, Lynne Simpson, Joanne Stone, and Ilan Timor-Tritsch.



Fellows take a break during the first GOHO Foundation Second-Year Fellow Course.

Like GOHO's course for residents, which is held annually during the summer at Mount Sinai in New York, the program for second-year fellows was offered free of charge as part of the Foundation's mission of ultrasound education.

The Gottesfeld-Hohler Memorial Foundation (www.gohofoundation.org) is a 501(c)(3) charity founded by Drs. Larry Platt and John Hobbins together 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 GOHO Foundation organizes a fundraising CME ultrasound course in Florida every December, with all proceeds going towards the educational mission of the group. ■

➕ *For more information on upcoming events, go to* [HTTP://GOHOFUNDATION.ORG](http://gohofoundation.org)

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Digital transformation of the women's health market is rapidly occurring through FemTech (female technology).

contemporaryobgyn.net/FemTech

How flu shots help protect the public

Here's what ob/gyns need to know when treating their at-risk patients.

from the pages of DRUG TOPICS

The 2018-2019 flu season got off to a slow start, but that doesn't mean patients should skip getting a flu shot or that ob/gyns can skimp on recommending them. "Flu activity has been low so far this year, but we expect activity will pick up soon," said Alicia Budd, MPH, an epidemiologist in the Influenza Division of the CDC's National Center for Immunization and Respiratory Diseases.

According to Budd, Influenza A (H1N1) is the predominant flu virus circulating so far this season. "Last season the flu vaccine reduced H1N1 risk by 65%."

The success of any season's flu vaccine depends on how well it matches the three or four viruses most likely to strike. As viruses evolve, vaccines are updated to counter new strains.

The roster of approved vaccines for the 2018-2019 season includes inactivated injectable vaccines (IIV), recombinant flu vaccines (RIV), and live attenuated vaccine (LAIV), which was

omitted last year. The CDC expresses no preference, as long as vaccines are licensed and age-appropriate.

Trivalent or Quadrivalent?

Although trivalent and quadrivalent vaccines are both available this season, manufacturers estimate that up to three-quarters of the flu vaccines administered this seasons will be quadrivalent because the vaccine's extra component protects patients from another strain of influenza.

Trivalent flu vaccines are designed to protect against three virus strains, two A viruses (H1N1 and H3N2) and one B virus, but there's often more than one B virus circulating during any flu season. Quadrivalent vaccines offer more protection by adding a second strain of B virus.

Although quadrivalent flu vaccines offer broader protection, the CDC does not recommend waiting in the event there's a shortage. Getting a trivalent flu shot when you can is considered more effective than waiting for a quadrivalent vaccine.

What's Changed This Season?

Both trivalent and quadrivalent vaccines contain the same H1N1 virus as last season. Updates were made to the H3N2 virus, and the B virus is a different strain from last year.

Components in this year's trivalent vaccine are:

- Type A H1N1: A/Michigan/45/2015 (H1N1)pdm09-like virus, same as last year.
- Type A H3N2: A/Singapore IN-FIMH-16-0019/2016 A(H3N2)-like virus, updated.
- The B virus this season is different, B/Colorado/06/2017-like (Victoria lineage) virus updated.

Quadrivalent vaccines feature an additional B virus:

- B/Phuket/3073/2013-like (B/Yamagata lineage) virus, which is the same as in the 2017-2018 flu vaccine.



TABLE 2018-2019 Vaccine options and suitability

Trade name [Manufacturer]	Presentation	Age indication	HA, μ G/dose (Each virus)	Egg-grown virus, cell culture- grown virus, or recombinant HA
QUADRIVALENT IIVS (IIV4S)				
Afluria Quadrivalent [Seqirus]	0.5 mL prefilled syringe	\geq 3 yrs	15	Egg
	5.0 mL multidose vial	\geq 6 mos (needle/syringe) 18 through 64 yrs Get injector)	7.5/0.25 mL 15/0.5 mL	Egg
Fluarix Quadrivalent [GlaxoSmithKline]	0.5 mL prefilled syringe	\geq 6 months	15	Egg
Flulaval Quadrivalent [ID Biomedical Corp. of Quebec]	0.5 mL prefilled syringe	\geq 6 months	15	Egg
	5.0 mL multidose vial	\geq 6 months	15	Egg
Flucelvax Quadrivalent [Seqirus] (cclIV4)	0.5 mL prefilled syringe	\geq 4 yrs	15	Cell
	5.0 ml multidose vial	\geq 4 yrs	15	Cell
Fluzone Quadrivalent [Sanofi Pasteur]	0.25 mL prefilled syringe	6 through 35 months	7.5/0.25 mL	Egg
	0.5 ml prefilled syringe	\geq 3 yrs	15/0.5 mL	Egg
TRIVALENT IIV (IIV3S)				
Afluria [Seqirus]	0.5 mL prefilled syringe	\geq 3 yrs	15	Egg
	5.0 mL multidose vial	\geq 6 mos (needle/syringe) 18 through 64 yrs Get injector)	7.5/0.25 mL 15/0.5 mL	Egg
Fluad [Seqirus] (allV3)	0.5 mL prefilled syringe	\geq 65 yrs	15	Egg (adjuvanted with MF59)
Fluzone High-Dose [Sanofi Pasteur] (HD-IIV3)	0.5 mL prefilled syringe	\geq 65 yrs	60	Egg
QUADRIVALENT RIV (RIV4)				
Flublok Quadrivalent [Sanofi Pasteur]	0.5 mL prefilled syringe	\geq 18 yrs	45	Recombinant

Source: CDC

This year's trivalent vaccines come in a standard dose for ages 18 through 64 and a stronger dose for people over 65 because a higher dose of flu vaccine is more effective in older adults.

A cell-based flu vaccine offers options for patients with egg allergies

since this type is grown in mammalian cells rather than in chicken eggs. The virus may contain traces of albumin, so people with a history of severe egg allergy should be vaccinated in a doctor's office, where any allergic reaction can be monitored and treated.

Patients who don't like needles can get the trivalent flu vaccine via an intradermal shot, which inserts medicine under the skin, or a jet injector, which uses a high-pressure stream of fluid.

CONTINUED ON PAGE 41

THE DIGITAL OB/GYN

Six healthcare technologies coming in the next 5 years

Technology can improve and streamline patient care, but a culture change is necessary before the benefits can be realized.

by DONNA MARBURY

Experts agree that forecasting the future of healthcare technology isn't difficult: machine learning, artificial intelligence (AI), and cloud technologies that apply to clinical, workplace, and financial processes will have better and richer incorporation into the industry.

But to get there, healthcare executives need to be laying the cultural foundation today for the technology changes coming in the next decade.

For example, investing in AI over the next 5 years could cost, on average, more than \$30 million per organization, according to a survey of 500 healthcare executives by OptimIQ that was published in November 2018. However, 38% of employers and 20% of health plans believe they would see a return on that investment in 4 years or less. Ultimately, 94% of respondents see investments in technologies, such as AI, as the clearest route to affordable, accessible and equitable healthcare in the future.

But in order to realize those future possibilities, a culture shift needs to

happen in healthcare today, says Tom Lawry, director of worldwide health for Microsoft. The future of healthcare technology relies more on the culture and framework being created by clinical and business leaders today, he tells *Drug Topics*.

Investing in AI over the next 5 years could cost, on average, more than \$30 million per organization.

"What really is going to be needed in the future is not just the breakthroughs in technology, but breakthroughs in creative thinking and the ability of leaders to think differently when redeveloping their processes to leverage the power of the technologies rather than trying to insert these new technologies into a framework," Lawry says.

Anil Jain, MD, vice president and chief information officer for Watson Health at IBM, says that healthcare organizations will need to shake the stigma of being bureaucratic and slow

to adapt so they can be agile enough to adopt future technologies.

"Healthcare organizations need to start to push the agenda that says innovation is important to healthcare. People outside of healthcare view the industry as very conservative, very slow to adapt," Jain tells *Drug Topics*. But when you talk to people inside the industry, we all think we're moving very, very quickly. The key is for these healthcare organizations to get involved in the national debate, at the advocacy level and advising others on what the industry needs, so that movement is made collectively."

These experts have given their insights on where healthcare technology will be the most impactful in the next decade.

1 Better cloud integration

Although devices collecting digital data are important to healthcare, how those data are shared is the most essential part of the equation, Lawry says.

More than 90% of healthcare organizations are widely using the cloud to host applications, accord-

ing to a 2017 Healthcare Information and Management Systems Society (HIMSS) survey on cloud use. However, the industry is still using the cloud for separate functions, such as clinical apps, data hosting, and backup, and not in a holistic fashion. The survey found that though there is a high level of cloud usage at healthcare organizations, the functionality is still limited.

Use of cloud integration has allowed for data from different healthcare silos to be shared, and as more organizations continue to connect those dots, and Lawry says that it will transform the industry.

“Everyone’s digitizing their data, whether that’s electronic medical records or X-rays. But digitizing data doesn’t do anything other than that. It changes data from one form to another instance,” Lawry says. “The transformation that’s brought about by the cloud and bringing that data together allows for all kinds of interesting things. That to us is the number one transformational aspect going forward for the next few years.”

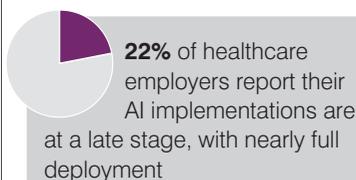
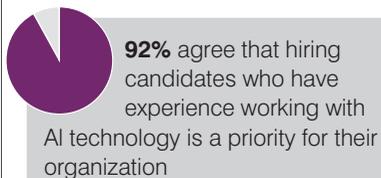
2 Deeper AI infusion

Artificial intelligence has been a part of the healthcare for years, but experts believe in the next decade it will be a regular part of the industry.

A survey of 200 healthcare professionals by Intel Corporation, released in July 2018, found that 37% of respondents were using AI in limited ways, and 54% believe that there will be widespread AI adoption in the next 5 years.

John Doyle, director of business strategy for Worldwide Health Industry at Microsoft, says moving forward,

INVESTING IN AI TODAY FOR FUTURE ROI



Source: November 2018 OptimIQ survey of 500 healthcare executives (<https://bit.ly/2K9jjj8>)

we should expect to see AI infused into all aspects of clinical and operational workflow.

“We are early in the journey for cloud and AI adoption today, but we are already starting see some amazing progress being made, and we expect this continue and with a broader adoption of applied AI in

areas such as the clinical interpretation of complex datasets, intelligent medical images, voice integration, and real-time insight of streaming medical devices and sensors data,” Doyle says.

As a new generation of consumer-focused services aim to merge patients and consumer journeys, applied AI will disrupt how patients engage with healthcare providers today, Doyle says. “Applied AI has the potential to reduce the complexity of how healthcare data is captured and analyzed, examples of this include how intelligent voice integration and bot technologies are being used during virtual consultations to reduce the time spent entering data by both patients and clinicians, and how pretrained clinical knowledge can be applied at the point of care.”

3 Infrastructure upgrades

The ability for clinicians to meet with patients via web and mobile portals is essential for chronic care management, says Rhonda Collins, DNP, RN, chief nursing officer at Vocera, and founder of the American Nurse Project.

“A majority of this country is still rural. So, we need to rely on technology to fill gaps in human connections in healthcare—telehealth will be more important going forward, as infrastructure and technology continue to improve. Hospitals and clinics will need to prepare for a world that technology is making smaller,” Collins says.

A 2017 report issued by the Federal Communications Commission found that 50% of U.S. counties house people who both have high occurrences of chronic diseases and a greater need for broadband connectivity.



“The idea is that we have to go beyond the pill. As a physician there has to be a better way to virtually have eyes on the patient even when they’re not in the exam room.”

The commission called this “double burden,” and incidents can be as high as 60% in rural counties.

“That makes a remote consultation with a doctor or video chat very difficult, but the situation is improving, and over time, I think at-home remote care will be most valuable in rural areas, where technology use is far more practical than a long drive to see a doctor,” Collins says.

As telehealth expansion continues through Medicare reimbursements, patients are still unclear about its availability and use. A survey released by Healthline in August 2018 found that 46% of Medicare Advantage members were unsure if telehealth was an option, and 37% stated telehealth was not offered even though it is.

Collins adds that hospitals are still lacking full-scale wi-fi and consistent cellular service, which impedes integration of telehealth and other mobile health offerings.

“These basic issues make it very difficult to bring technology in to provide extraordinary care and connectivity to all patients everywhere. Infrastructure upgrades are a must, and that should be the focus of many hospitals, so they can leverage great technologies that improve the lives of patients and clinicians alike,” Collins says.

4 Smarter therapies

Though smart phones, smart watches and other smart devices are being used by consumers, a focus on “smart” hasn’t translated to

healthcare solutions, says Kai Patel, MD, MBA, senior vice president of digital health at Flex, a solutions provider that builds intelligent products.

“By and large, many healthcare solutions lack meaning. They are not smart,” Patel says. “The data from them is either not collected at all or it is collected, and it stays in some type of local environment which inherently limits the value you can derive from that.”

Patel says in the next decade, drug delivery devices such as insulin pens, biologic auto injectors, inhalers, and smart packaging for pills will become commonplace and enhance both clinical and business operations in healthcare. The goal of tracking these data is to add to the landscape of behavioral insights that can help enhance patient care. Patel says the ability to observe how patients use chronic therapies both inside clinical settings and at home or inpatient care settings is enhanced by integrated cloud and artificial intelligence use.

“Most of that technology is already there, so in the next 5 to 10 years it’s about unlocking that data. Once you can unlock that data, we will really be able to see progress using artificial intelligence and machine learning within those data sets,” Patel says.

Jain says IBM Watson is currently studying concepts around prescribing digital therapies that can be powered by blockchain and artificial intelligence and can be tailored to patients’ behavior.

“Wouldn’t it be really interesting if I prescribed an antidiabetes tablet, and I’m also prescribing an app on the patient’s smart phone that makes sure that they stay somewhat adhering to the medication? If they have any side effects, they’re educated about when they should see the doctor or when they could just simply ignore them,” Jain says.

Smarter therapies could also prescribe diets that work in conjunction with medications and give patients more feedback on their progress, he says. “The idea is that we have to go beyond the pill. As a physician, there has to be a better way to virtually have eyes on the patient even when they’re not in my exam room four times a year for 15 minutes.”

5 Enhanced personal medical care

In the next decade, clinicians will have the ability to use blockchain, machine learning, and artificial intelligence seamlessly to provide specialized care to patients, says Jain.

“The biggest thing is going to be our ability to use these advanced technology enablers to get much better at doing personalized medicine and personalized healthcare with our patients,” Jain says. “Because the back-end healthcare technology is crunching all of their clinical data and administrative data, looking at their genomic profile, looking at their social determinates of health much faster than any human physician or

clinician could, and combining that information in a trusted way.”

Jain says that fitness trackers are currently collecting siloed data, but are an important part of the equation when the data can be integrated along with other health determinants. Ultimately, he says more personalized treatments, especially for chronic conditions, would increase adherence to care plans.

“Essentially a clinician will have the ability to say, instead of just practicing in an evidence-based way, we’re going to combine evidence and personalized choices to give patients a much higher likelihood of being successful at the first set of treatments that are offered, instead of going back and forth a few times trying to figure things out,” Jain says.

6 Mimicking consumer tech

Collins says she is hopeful that the workflow technology the

healthcare field adopts over the next 10 years will match and adapt to technology that people are used to in other areas of their lives.

“Before a hospital shift, someone can sit in their cars and buy movie tickets, make dinner reservations, and chat with friends—all from their smart phones. They then enter the hospital for a day’s work, and many times, the technology landscape is entirely different,” Collins says. She fears that antiquated processes and devices in healthcare workplaces will be a deterrent to tech-savvy millennials.

“When millennials go to work at a hospital, we are asking doctors, nurses and care teams to step back 20 years and use landline phones, fax machines, pagers, and overhead calls—all of which downgrade and add complexity to our millennial workforce. They carry a heavy burden every day working with patients in stressful hospital environments,

and the very basic technology they’re using only adds to the stress,” Collins says. “Furthermore, we are adding to cognitive loads by forcing them to remember procedures and how to use outdated technologies they are not naturally accustomed to using. So, over time, antiquated technology that doesn’t mirror what is used in our personal life and is not secure will be eliminated. As younger people continue to enter the workforce, many hospitals will be forced to modernize.” ■

Ms. Marbury is a journalist and communications specialist who has written for several publications including *Medical Economics*.

DISCLOSURES The author reports no potential conflicts of interest with regard to this article.

FROM THE PAGES OF
Managed Healthcare
The C-Suite Advisor EXECUTIVE

Flu shots CONTINUED FROM PAGE 37

Nasal spray

Nasal sprays are also back on the approved vaccine list due to an improvement in formula. A quadrivalent nasal-spray vaccine is now recommended for non-pregnant individuals who are 2 years through 49 years of age.

There are some important exclusions with the nasal-spray vaccine. Children aged 2 through 17 who take aspirin- or salicylate-containing medications; as well as children aged 2 to 4

who have asthma; and anyone with a weakened immune system, should not be administered the nasal vaccine.

Immunization is still recommended for everyone over 6 months of age. Flu shots are especially important for young children, adults 65 years of age and older, pregnant women, and people with asthma, diabetes and heart disease. ■

FROM THE PAGES OF
Drug Topics
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RESIDENTS CORNER

OB/GYNS IN THE MAKING REFLECT ON LESSONS LEARNED

Night call siren song

Responsibility, anxiety, and expectations converge for an on-duty resident.

by LUKE BURNS, MD

Nothing can compare to the old days of medicine when residents were literally “residents” of the hospital, but demands on US medical trainees are still unique in the Western world.

Last month I worked 3 weeks in a row without a break and by the end of it I was bone tired and mentally drained. My Sunday night was going just as I had planned and I was relishing my last few hours of freedom when I received a group-text from one of the senior residents asking if anyone could fill in for the night call resident, who was sick.

When it became clear that I was the only one available, I somewhat reluctantly donned my scrubs, went hunting for my stethoscope, and headed to the hospital.

And so began “signout,” the transfer of responsibility from the day team to me. Information on medical and surgical histories, issues and complaints, and likelihood of patients spontaneously dying overnight all were relayed to me as the resident “coming on.” Like two friends fighting to pay the check, the “day” resident

and I each volleyed responsibility for last-minute tasks:

“I’ll just finish this discharge summary, then I’ll be done.”

“No, you’ve been working all day, I’ll do it, go home!”

“It’s okay, I should have done this earlier—“

“I got it, go home! Go home!”

With all these unfamiliar patients...the idea wasn't to heal. *It was simply to keep them alive overnight.*

With signout completed, I was now responsible, during the night, for every patient in the hospital with a gynecological concern. Consults in the emergency room and phone calls from patients at home with gynecologic issues would also fall to me. With all these unfamiliar patients, many of whom were very sick with cancer or recovering from major surgery, the idea wasn't to heal. It was simply to keep them alive overnight.

Of course, I was never completely alone. There is a chain of authority

that night residents can climb with questions, starting with the senior resident working on labor and delivery, moving up to a junior attending “on call” from home, all the way up to the senior attendings. But sometimes calling for backup isn't an option. There is a certain compulsion not to phone the sleeping attending at home, especially for small problems we're expected to know how to fix on our own.

And then, it's 3 am and I'm being “hammer-paged,” as nurses, emergency room staff and patients calling the telephone consult service all vie for my attention:

“Patient in bed 22 says she has 9/10 pain, have already given oxycodone and Tylenol, she cannot get Motrin due to kidney disease, what do you want to do?”

“Patient calling from home has had heavy bleeding since 6 am; call back immediately.”

“Hi, consult in the ED. 79-year-old with chemo-resistant ovarian cancer, now with likely small bowel obstruction, please come see her asap, thanks”



Luke Burns, MD is a resident in obstetrics and gynecology at the University of Michigan.

Residents are expected to be experts in their field, but I often find myself scouring medical websites on my phone looking for answers on the way to a patient awaiting my keen critical input.

Each page is triaged for severity, corralled into a “to-do list of importance.” Then I do a quick mental calculation of the best path to take through the hospital to tick off as many tasks as efficiently as I can. All the while, there is paperwork to complete and an escalating mountain of notes to write. I do my best to document as I go, because in a few short hours, I’ll be signing out to the day team.

It feels like any mistake I make has dramatic consequences. Forget to ask a patient what medications they take? I won’t know she needs insulin and might send her into diabetic ketoacidosis. Overlook an obvious lab order? The morning attending will lay the blame on the day resident for the life-threatening electrolyte imbalance that I missed.

Night call is a game of constantly spinning plates, managing multiple sources of anxiety, scribbling notes as I clutch a phone in the crook of my neck and mouth apologies to the emergency medicine resident, who

has been waiting 2 hours for my treatment recommendations. Residents are expected to be experts in their field, but I often find myself scouring medical websites on my phone looking for answers on the way to a patient awaiting my keen clinical input.

And then finally, slowly, the morning approaches. My phone rings and I meet the day resident for another signout. This time, I’m the one recounting the events of the past shift—everything that happened overnight, everything I did for every patient who came in, everything still waiting to be done. Usually I will sign out to a more senior resident, whose gentle probing about each patient reveals the important details I forgot to gather. Kindly the resident will reassure me, promise it gets easier with time, and then repeat the “signout” pantomime:

“I still have a consult sitting in the ED I need to get to...”

“No, no, you go home, I’ll do it.”

“I can’t make you do that! It was my fault.”

“You need to sleep! Go home!”

“Well...are you sure?”

Leaving the hospital at this time of day carries a unique warmth. Against the flow of foot traffic headed toward the hospital elevators, I lope toward the parking lot, nodding knowingly at other who recognize the semi-delirious smile of a night resident going home.

After my first few night shifts, I was anxious about turning off my pager, nervous that someone might get sick or die if I didn’t immediately answer, or that I’d miss a call from an angry attending who couldn’t comprehend my treatment plan from the night before. But now I understand the meaning of signout, that informal but very real transfer of power and responsibility at the beginning and end of each day. I relish the moment I can turn off my pager, when I can cut the cord tying me to the hospital, to the impossible responsibility of caring for several dozen very sick strangers, and instead crawl into a familiar bed to pretend I am a lazy teenager again, sleeping deep into the late afternoon. ■

Lupus in pregnancy CONTINUED FROM PAGE 31

as often as they should. This is of concern and could indicate that patients are ignoring their disease while focusing on pregnancy.⁶⁷

Second, immunosuppressant use decreased in women with SLE during pregnancy. This is possibly due to inappropriate concern about fetal safety

of these drugs,⁶⁷ since azathioprine and tacrolimus therapy are permissible in pregnancy. Controlling lupus activity remains key to a successful pregnancy outcome.

Third, inadequate counselling and use of contraceptives in patients with SLE who are at risk of pregnancies

contributes to an increased number of unplanned pregnancies.⁶⁸ ■

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

FOR REFERENCES VISIT
contemporaryobgyn.net/LupusPregnancy

How to survive high-deductible health plans

Implementing a few simple financial policies can help ob/gyns improve cash flow.

by JORDAN ROSENFELD

More Americans are choosing high-deductible health plans for their lower monthly premiums, though this results in steeper out-of-pocket costs for care. According to the Centers for Disease Control and Prevention (CDC), in 2017 42.3% of insured patients were enrolled in high-deductible health plans, up from 39.4% in 2016. This leaves some physicians scrambling to collect payments and manage shrinking cash flow.

What can physicians do to improve their cash flow in this new landscape? Experts suggest that successful practices will review and establish new financial policies, do a better job of educating patients, and consider cash-pay services.

Put policies into place

Many physician practices erroneously assume their patients understand their financial obligations and insurance details, according to David Zetter, CHBC, a healthcare business consultant in Mechanicsburg, Pa.

“Most practices don’t have patients sign a financial policy, so most patients have no clue what the practice expects,” Zetter says.

Physicians need to set policies on getting money up front, he says. He usually recommends a practice rewrite their financial policies to include steps such as: charging a late or no-show fee; requiring

Most physicians erroneously assume that their patients understand their financial obligations and insurance details.

all patients to have a credit or debit card on file; or always taking a flat deposit upon booking an appointment, that can later be credited back to the copay once the patient’s percentage is determined.

“If the business isn’t taken care of first, you’re not going to be able to take care of patients, because you won’t be able to afford it,” Zetter says. He also recommends that every patient be required to have a phone meeting with a patient financial counselor, which can be an office staff person, who reviews the

practice’s financial policies and gets the patient to sign the practice’s agreement to the financial policies.

“I’ve got clients that won’t even accept patients if they don’t have a debit or credit card. They don’t have an accounts receivable problem,” Zetter explains. Other practices he’s consulted with have strict policies where patients can’t be seen until they catch up on outstanding payments.

Educate your patients

Tisha Rowe, MD, a primary care physician in private practice in Houston, Texas, says that it’s up to the practice to help patients understand their financial responsibility.

“Whether that’s highlighting that portion of their [explanation of benefits] in writing or maybe creating a short video that spells it out, you want to make sure patients know their deductible and what a visit costs them,” Rowe says.

She’s had many incidents where patients were upset with her for being charged around \$100 for something as simple as a medication refill where they had to come in office. However, the cost

of the visit is related to what percentage of the deductible the patient has to pay. "I can't change the price because [the patient] hasn't met their deductible," she says. "So we have to educate our patients."

Rowe creates simple videos she uploads to a YouTube channel on topics such as telemedicine and wellness tips, each no longer than a couple of minutes. "You're going to repeat that same information 20 times per day. Just put it out there, and make it accessible, and you can have partners share it," she says, adding that even if a physician is not tech savvy or doesn't have the time, it's not complicated to get help creating them.

Consider an insurance/concierge hybrid

With deductibles increasing to all-time highs, Rowe says people who are not managing a significant illness or expecting surgery are unlikely to ever meet their health plan's deductibles. Her practice has a hybrid concierge plan for these patients.

If she sees a patient for a physical and labs, they may end up paying \$1,000, she says. However, she says, if a patient signs up for her concierge plan for \$100 per month, the patient knows exactly what services they're getting, and get better access, as well.

She says that physicians shy away unnecessarily from concierge or self-pay plans because they believe that only wealthy people can afford them. In her practice, she says, most of her concierge patients are working-class people.

Rowe contends that people who use a high-deductible health plan can afford a concierge doctor because they're unlikely to ever meet their deductible anyway. "I guarantee you're not going

to see that much in medical care most years," she says.

Paula Muto, MD, FACS, a vascular surgeon in Lawrence, Mass., and the founder of UberDoc, which helps patients find specialists, agrees that doctors should have some form of self-pay offering because it works in both the physician's and the patient's favor. "It is usually cheaper for a patient with a high-deductible to pay cash for a procedure. You're never going to reach your deductible anyway."

Physicians get paid immediately without going through the hassles of billing, coding, or denials, she points

Another way to increase the likelihood of getting paid is to request a flat-rate deposit on all appointments.

out. Muto suggests cash pay also creates greater transparency. She says that bringing it back to cash leads the physician talk to the patient honestly not just about their care itself but about the cost of their care. "If deductibles are here to stay, we must be transparent," she says.

Take a deposit and/or get a credit card on file

Another way to increase the likelihood of getting paid is to request a flat-rate deposit on all appointments. Destiny Biggs, RN, practice manager for MedNow Urgent Care in Augusta, Ga, says that her practice requires a \$75 deposit and a credit card on file for all patients with a high-deductible plan.

Additionally, if a patient comes in and has an outstanding balance, the balance is due at the time of service.

"They don't get to say, 'I'll pay it next week,'" Biggs says.

Just having a credit card on file has made a tremendous difference in their collections. Whatever the patient owes beyond the \$75 deposit is charged at the time of service, and the patient is alerted at the same time. "With credit cards on file, we collected [an additional] 15% of our patient balances last year or this current year," Biggs says.

This puts a greater responsibility on front desk staff to be assertive in obtaining patient credit card information every time, so she says practices should be thoughtful when hiring for these positions or consider training them in this approach. At MedNow, the front desk staff sells the idea by reminding patients that putting a credit card on file means they won't have to receive bills in the mail and/or make payments later.

Think twice before you diagnose

For James Wilk, MD, an internist who works for the University of Colorado in Denver, high-deductible plans have changed the way he orders diagnostic tests.

He admits that he didn't know the cost of some of the tests he orders until patients complained about financial hardship, or worse, refused to get the tests, leading to worsening or untreated conditions. "So this person is walking around with probable but undiagnosed asthma because the cost of the test is so high that they couldn't get it," Wilk explains.

"I think twice about how necessary some diagnostic workups are. Instead of doing a bunch of tests, sometimes I'll just plan a three- or four-step kind

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When owner relationships fall apart

Though starting a new practice is exciting, smart owners should prepare for the worst.

by ERICKA L. ADLER, JD

Physicians often enter into practice ownership arrangements on the best of terms with colleagues. Unfortunately, there are many times when such rosy relationships turn sour. For this reason, regardless of how “friendly” an arrangement may begin, it is essential the parties sign a proper document in advance that sets forth how they will address disputes and how the arrangement can be terminated and/or dismantled, if necessary.

Because emotions often run high when relationships fall apart, having a written document can help resolve a situation more quickly and hopefully with minimal legal fees.

Here are four issues to consider when drafting an agreement among owners:

1 How to walk away

Can a physician owner simply elect to walk away from the relationship? Many documents do not allow somebody to simply leave or dissociate from the relationship, which can cause the

parties to be stuck without a viable resolution.

I always recommend that exit strategies outline:

- The length of notice an owner must provide before leaving. I typically suggest at least 6 months to allow for proper transition. This provision should also outline whether an owner can be voted out by other owners, how that process would work, and what vote count is required.
- The document should specify whether the entity or remaining owners must buy out the departing physician. If there are related entities (real estate or other companies), they should all be tied to the same outcome, unless the parties intentionally decide otherwise.
- If the departing physician is to be paid, calculation of payment should be detailed. An agreement between the owners can provide for a purchase price that varies based on the reason for departure, the amount of notice provided by the departing physician, and

even how long a physician worked in a practice before departure. These are all items to consider. Additionally, if the practice will be financially harmed by a physician's departure, language requiring a departing physician to remain personally responsible for certain expenses (e.g., leases or loans) for a certain time period is not unusual.

- A physician's departure can greatly impact cash flow in a practice, as well as many other operational aspects of the business. Severance formulas in the parties' document should always account for such concerns by allowing for payment over an extended period of time. The formula should be subject to adjustment if more than one physician is being paid out by the practice at the same time.

2 What the parties can and can't do

The document between owners of a practice should clearly outline what appropriate restrictions will be placed on a departed physician. Can the physician use a similar trade name? Can he or she solicit practice patients, staff, vendors, or others? What can either party say about the reason for the split?

3 Founder's provision

If one physician is the senior member of a relationship, the parties may also consider a founder's provision. This provision requires the parties try good faith efforts and/or mediation to resolve their differences, but then allows the practice's founder to declare irreconcilable differences. The founder retains the practice while the other party must depart.

In these circumstances, I also like to clarify the amount of notice, whether the covenant will apply, and the purchase price, among other considerations. This approach is not intended to unfairly treat the non-founding party. Instead, it sets a road map in advance for how the situation will be fairly handled.

4 Dispute resolution

Having a specific process to resolve disputes can also be helpful to the parties. For example, requiring a certain number of meetings to discuss an issue, specifically identifying

a trusted adviser to mediate disagreements, and other similar guidelines can sometimes lead to a surprisingly positive outcome.

Many physicians who are angry with their partners do not do a great job of expressing themselves and will turn to legal counsel before really trying to work things out. As with marriage, communication is key, and any partnership requires effort.

Physicians may enter into practice relationships with the best of intentions, but sometimes things do not go as planned. Having a document where the parties discuss various scenarios in

advance and plan for the worst possible outcome protects everyone involved. ■

Ericka L. Adler, JD, has practiced in the area of regulatory and transactional healthcare law for more than 20 years. She represents physicians and other healthcare providers across the country in their day-to-day legal needs, including contract negotiations, sale transactions, and complex joint ventures. She also works with providers on a wide variety of compliance issues such as Stark law, Anti-Kickback Statute, and HIPAA.

DISCLOSURE The author reports no potential conflicts of interest with regard to this article.

High-deductible health plans CONTINUED FROM PAGE 45

of thing. That way, if we make the diagnosis, we don't have to test for twelve things, which would cost a fortune."

He makes sure to inform his patients that he is ordering tests in the most cost-effective way possible. "They usually thank me for being conscientious of that," Wilk says.

While this is not his ideal way of practicing medicine, he understands that patients are facing increasing financial pressure and encourages patients to work with financial counselors so that they don't put off necessary treatment or tests.

Use big data and AI to determine propensity to pay

High deductibles may not be the only reason that patients are struggling to pay their doctor bills, according to Florian Otto, MD, co-founder of Cedar, a healthcare technology consulting business based in New York City.

He says that simply ranking patients by their propensity to pay may not be very effective because there may be multiple reasons ranging from:

- They don't have enough money
- They don't check their mail often
- They don't speak English
- The bill is incorrect/ not what they expected and patients don't know how to get a corrected bill

He recommends that practices use artificial intelligence-based programs that draw from basic demographic information and user data to assess more accurately why patients aren't paying. For example, he says, if a patient received their bill digitally and clicked on it three times but never paid, it might warrant sending a text asking if they are having trouble understanding the bill, and then connects them to a live chat function.

Additionally, he says, physicians should automate the billing process to make it easier for patients to pay. "We strongly believe that it shouldn't take longer than 20 to 30 seconds to pay your bill, similar to the Amazon Prime experience," Otto says.

Patients just want an easy, convenient and quick way to pay, he says, and it's up to physicians to offer these.

"Reducing friction makes happier patients, and also increases cash flow," Otto says. ■

Jordan Rosenfeld is the author of eight books and is a contributor for *Medical Economics*.

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Medical Economics
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Vesicovaginal fistula after hysterectomy

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- H/H 12.8 g/dL/40.2%
- UA 3+ protein; red blood cell (RBC) count 25-50 per high-power field (HPF); WBC: 50-100 per HPF

The patient was treated with rehydration and an oral gastric tube. A Foley catheter was placed with the recorded urine output: 0009 = 800 cc; 0809 = 800 cc; 24 hours = 1600 cc. The next day her BUN was 22 mg/dL and Cr 1.41 mg/dL. The patient's primary care physician (PCP) was consulted on Hospital Day 1. He documented that the patient began eating and was tolerating a normal diet and voiding normally. He confirmed that dehydration led to the increased BUN and Cr. A discrepancy was found in two notes: the PCP documented, "She has not had dysuria, hesitancy, or frequency." A nurse documented, "Loss of bladder control. Started October 17 [2 days post-operatively]." On Hospital Day 2 of the readmission there was leaking around the Foley catheter. It was replaced with clear urine returned. An intravenous pyelogram (IVP) had been ordered on admission but was cancelled with a note about the elevated Cr. The patient improved clinically with normalization of her BUN and Cr. She was discharged on Hospital Day 4.

Follow-up

Eleven days postoperatively (6 days after rehospitalization) the patient was seen with complaints of urinary urgency and some difficulty controlling her urine. UA revealed 2+ leukocytes and was positive for nitrites. The patient was diagnosed with a urinary

tract infection (UTI) and urgency and treated with sulfamethoxazole/trimethoprim and tolterodine.

On evaluation 1 week later, she was unable to control her urine. Entertaining the possibility of a vesicovaginal fistula (VVF), the gynecologist referred the patient to a urologist. She patient was seen 12 days later (18 days after surgery). The urologist documented, "Urinary incontinence since her surgery." Exam revealed a cystocele and a rectocele, with no obvious fistula. UA revealed 2+ leukocytes. An IVP revealed delayed extrusion of contrast into the vagina. On cystoscopy approximately 5 weeks after the initial surgery, the urologist found a dime-sized eschar, with fluid entering the vagina. A large eschar was found in the vagina, near the cuff. The patient was referred to a university hospital for management of VVF.

VVF repair

The patient was seen 3 months later (4 months after the original surgery) by the university urologist, who confirmed presence of a 10-mm VVF. Approximately 4 weeks later, the patient underwent laparotomy, cystotomy, and excision of VVF, approximately 1.5 cm from the right ureter. Pathology revealed fibrosis and chronic inflammation. Areas of marked chronic inflammation with extensive granulomatous inflammation with foreign body type giant cells were identified. The patient had an uncomplicated postoperative course and, after passing a voiding trial, had her indwelling catheter removed.

The trial

A suit was filed claiming:

- Failure to communicate treatment options to patient
- Failure to perform diagnostic tests
- Failure to perform surgery within the standard of care (SOC)
- Failure to detect bladder injury at surgery
- Failure to provide adequate postoperative care
- Premature discharge from hospital

The plaintiff's expert was critical of the preoperative work-up, specifically lack of an endometrial biopsy or hysteroscopy for abnormal uterine bleeding (AUB), particularly noting the patient's increased risk of endometrial hyperplasia or cancer due to morbid obesity. The expert also stated that magnetic resonance imaging should have been performed to diagnose adenomyosis, which he felt was the primary cause of the patient's AUB. He testified that a hysterectomy should not have been the recommended option. Rather, less invasive approaches, such as endometrial ablation or UAE, should have been performed, eliminating risk of VVF. Further, the patient should have had better glucose control, as her preoperative glucose (random = 170 mg/dL) placed her at greater risk of poor wound healing. He expressed no concerns about the surgical technique or a breach of the SOC from the time of original postsurgical discharge until she was readmitted. He stated the ileus was a result of urine leakage into the peritoneal cavity. He

admitted that bladder spasms are a known transient phenomenon after a hysterectomy. He testified that there was a thermal injury to the bladder, worsened by poor glucose control. However, he could not state that a fistula would not have developed if the patient's elevated blood sugar had been aggressively treated.

The plaintiff testified that she had not requested a hysterectomy. However, the defense attorney countered with the patient-completed intake form that stated her reason for the original gynecologic visit was, "Annual exam and talk about hyst." The patient also testified that she leaked all over herself beginning the day after surgery, not substantiated by chart documents.

The defendant testified the patient desired hysterectomy and removal of both ovaries. He discussed treatment options on two separate office visits prior to surgery, further discussing hormone replacement following hysterectomy and BSO. The defendant admitted he did not have cystoscopy privileges.

The defense expert testified that although it was appropriate to discuss endometrial ablation and UAD with patients, it is not necessary to encourage their use. Hysterectomy is within the SOC for definitive therapy for menorrhagia. The expert stated that the patient was not a suitable candidate for endometrial ablation, due to her adenomyosis and relatively young age, which both predisposed to treatment failure. Further, the woman's morbid obesity placed her at risk for endometrial hyperplasia and cancer. Although endometrial sampling is recommended prior to surgery for AUB, this oversight had no impact on the ultimate outcome.

LEARNING POINTS

1 Preoperative consent should include a discussion of the alternative treatments, with the risks and benefits of each.

2 Current evidence supports the use of a levonorgestrel intrauterine system for treatment of abnormal uterine bleeding and prevention or treatment of endometrial hyperplasia.

3 Electrosurgery increases the risk of thermal injury. Careful mobilization of surrounding tissues and use of appropriate uterine manipulators, although not wholly preventative, help reduce the risk of bladder injury.

4 Cystoscopy is becoming more commonplace following hysterectomy, as many bladder or ureteral injuries are not suspected or diagnosed at the original surgery. Gynecologists should consider obtaining the training to perform cystoscopy and, if available, obtain privileges to perform this procedure.

5 Early recognition and prompt referral to the appropriate specialist minimizes the adverse outcomes associated with surgical complications.

6 Having a knowledgeable and engaging expert is critical to trial success. Interviews with jurors following the case highlighted the trust that they felt in the defense expert, based on his demeanor, appearance, and affability, in addition to his knowledge of the procedures and related literature.

The defense expert testified that the procedure described in the operating notes comported with the SOC. Although cystoscopy was not performed, it is acknowledged that some hospitals, as in this case, do not grant general gynecologists cystoscopy privileges. The expert stated that the postoperative care rendered was appropriate, as was discharge timing. This expert testified that there was no substantiated evidence that a random glucose < 200 mg/dL leads to poor surgical healing.

The defense expert stated that the care rendered during the patient's initial rehospitalization was appropriate, with timely diagnostic procedures and consultations. With an elevated Cr, it was appropriate to cancel the ordered IVP. With rehydration, rapid resolution of the elevated BUN and Cr did not support a ureteral injury or peritoneal accumulation of urine. Outflow of clear urine from the Foley catheter did not support presence of a VVF. Further, even if a fistula had been diagnosed at that time, treatment would have been postponed.

At her initial postoperative office visit, the defendant reasonably diagnosed bladder control issues due to bladder spasms and a UTI, with appropriate treatment rendered. At the subsequent visit he appropriately considered a VVF and referred the patient appropriately to urology for further evaluation and treatment, with appropriate care rendered.

The verdict

With less than an hour's deliberation, the jury rendered a defense verdict. ■

SEMINARS

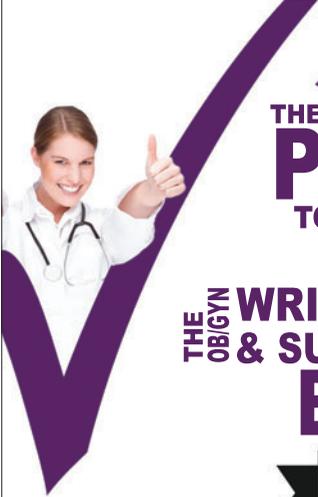


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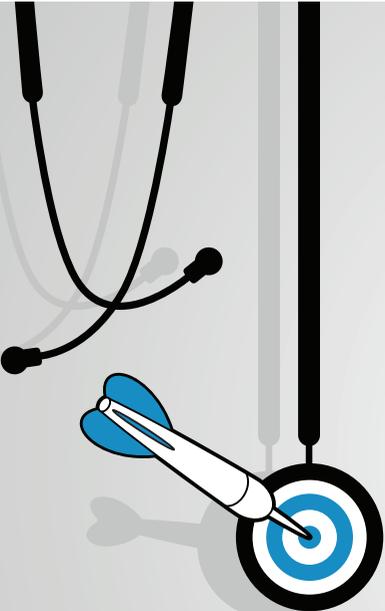


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by ANDREW I. KAPLAN, ESQ

CASE DISSECTION

Vesicovaginal fistula after laparoscopic hysterectomy

Patient communication and preoperative consent are the main issues in this case.

Preoperative events

A 40-year-old G3P3003 in for her annual exam complained of heavy, painful periods, which had previously failed to respond to treatment with cyclical progestins. She requested a hysterectomy. Her exam revealed a moderately enlarged uterus. Her weight was 250 lb, with a body mass index of 42.9 kg/m². Ultrasound revealed a 12.3 x 5.0 x 7.03-cm uterus, 1.9 x 1.6 x 1.9-cm fibroid, and 18-mm endometrium. The woman's left ovary had an exophytic area, thought to be a paraovarian cyst.

Five weeks later, the patient returned for a consultation about treatment. In addition to hysterectomy, the physician discussed uterine artery embolization (UAE), leuprolide acetate, and myomectomy. The patient chose a hysterectomy. The preoperative consent had the "standard" risks of surgery, including damage to surrounding tissues, and listed the discussed alternatives to surgery. Pertinent preoperative labs revealed hemoglobin and hematocrit (H/H) 12.4 g/dL and 41.2%, respectively, and random blood

glucose 173 mg/dL. Blood urea nitrogen (BUN) and creatinine (Cr) levels were normal. Urinalysis (UA) showed trace bacteria.

Hospitalization

Six days after the preoperative appointment, the patient underwent laparoscopic hysterectomy with bilateral salpingo-oophorectomy (BSO). A uterine manipulator with a paracervical ring was used for uterine manipulation. A bipolar sealing device was used for salpingo-oophorectomy and management of the uterine arteries. A circumferential vaginal incision was made with an L-shaped electro-surgical hook. The cuff was closed vaginally, as the laparoscopic needle drivers were broken. No evidence of bleeding or bladder injury or leakage was found on laparoscopy after cuff closure. A vaginal pack was placed postoperatively. Cystoscopy was not performed. The operating time was 96 minutes, with 75 cc of blood loss.

While in the postoperative area, the patient was noted to have blood-tinged urine that cleared within 30 minutes. On postoperative Day 1, she

was doing well, with 2000 mL of urine output after surgery and a stable blood count. The vaginal pack was removed, and she was discharged. Pathology revealed a 231-g uterus, with mild chronic endocervicitis, proliferative endometrium, and adenomyosis. Both ovaries were normal with a hydatid cyst of Morgagni.

Readmission

Three days later the patient was readmitted with an ileus, dehydration, and acute renal failure. She had tachycardia (119-131 bpm), a distended abdomen, and rare bowel sounds. An abdominal x-ray revealed an ileus.

Admission labs revealed the following:

- BUN 37.0 mg/dL (7-18 mg/dL);
- Cr 3.39 mg/dL (0.8-1.30 mg/dL)
- BUN/Cr ratio 11 (12-18)
- Glucose 330 mg/dL (70-99 mg/dL)
- White blood cell (WBC) count 16,600 cells/mcL (4000 -11,900)

FOR MORE LEGALLY SPEAKING
TURN TO PAGE 48



Andrew I Kaplan, Esq is a partner at Aaronson, Rappaport, Feinstein & Deutsch, LLP in New York City, specializing in medical malpractice defense and healthcare litigation. This case was handled by one of his partners.

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