SAFETY IN A SURGICAL PLUME

Managing threat of aerosolized COVID-19 viral particles

Sara Rahman, MD, Jordan Klebanoff, MD, and Gaby Moawad, MD.

OBSTETRICS
A1c and risk of maternal complications

GYNECOLOGY
Port site local anesthetic injection for laparoendoscopic surgery

WELL WOMAN
Discussing patients’ sexual concerns

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Pessary dislodgement risk factors

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PD-L1 as a biomarker in metastatic breast cancer

CONTRACEPTION
Pandemic perspective: Need for OTC Contraception
**Indications for Use:** Dilapan-S is for use by healthcare professionals trained in OB-GYN and is for use whenever cervical softening and dilation is desired, such as cervical ripening during term labor induction or gynecological procedures that require cervical preparation.

**IMPORTANT SAFETY INFORMATION**

**Contraindication:** Dilapan-S is contraindicated in the presence of clinically apparent genital tract infection.

**Warnings & Precautions:** Dilapan-S is intended for single use only. **Do not** re-use, re-sterilize, reprocess, or use if primary packaging has been opened or damaged. Discard after use.

**Please see Instructions for Use.**

**References:**

1. DILAPAN-S® Instructions for Use. DSPlenus-Rev018/2020-04.

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Website overhaul, podcast & more

The COVID-19 pandemic has been at the top of everyone’s mind for the past several months. More recently, social justice has taken the spotlight. According to the Centers for Disease Control and Prevention (CDC), racial and ethnic minority communities have been disproportionately affected by the virus.

In health care, it is impossible to treat patients without acknowledging these disparities. In this issue, Editor-in-Chief Catherine Y. Spong, MD, addresses implicit bias and makes the connection with COVID-19 in “A Collision of Crises.”

As we prepare for a potential second wave of illness in the fall, our new website will continue to reflect the ever-evolving landscape. It launched on June 12, and streamlines our industry-leading content for a more concise, reader-friendly user experience. We are eager to hear your feedback.

As we continue to evolve with each generation, we hope to continue to provide practicing ob/gyns with the exceptional clinical, peer-reviewed content they look for.

We would also like to announce the launch of our new podcast, Pap Talk, a weekly medical podcast that features in-depth interviews, treatment advice, commentary from industry experts and more.

Visit ContemporaryOBGYN.net/podcasts to learn more, and don’t forget to subscribe on Apple Podcasts, Spotify, or wherever you listen.

And, as always, let us know your thoughts by contacting Senior Editor Angie DeRosa at aderosa@mjhlifesciences.com.

Mike Hennessy, Sr.
Chairman and Founder, MJH Life Sciences
THE EDITORS ARE PLEASED TO ANNOUNCE the availability of our parent company’s continuing education activities. We’ve picked this one especially for our readers - bit.ly/BreastCancerCME
FOR THE TREATMENT OF WOMEN WITH MODERATE TO SEVERE DYSPAREUNIA, A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENOPAUSE

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INDICATION

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

IMPORTANT SAFETY INFORMATION

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

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy

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

Estrogen Plus Progestin Therapy

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

The most common adverse reaction with IMVEXXY (23%) was headache.


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In the absence of comparable data, these risks should be assumed to be similar for other doses of [see Warnings and Precautions (5.3), and Clinical Studies (14.2) in full prescribing information].

Cardiovascular Disorders and Probable Dementia

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

The WHI estrogen plus progestin substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo [see Warnings and Precautions (5.2), and Clinical Studies (14.2) in full prescribing information].

The WHI Memory Study (WMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women [see Warnings and Precautions (5.4), Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].

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

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

Ovarian Cancer

The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer [see Clinical Studies (14.2) in full prescribing information].

The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer [relative risk (RR) 0.80] [5 see Clinical Studies (14.2) in full prescribing information].

The WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE-alone was not associated with an increased risk of invasive breast cancer [relative risk (RR) 0.80] [see Clinical Studies (14.2) in full prescribing information].

Use in Specific Populations

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

INSTRUCTIONS AND USAGE

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

The WHI estrogen plus progestin substudy also demonstrated an increased risk of invasive breast cancer [see Warnings and Precautions (5.3), and Clinical Studies (14.2) in full prescribing information].

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

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

Other Warnings and Precautions include:

- Gallbladder disease; severe hypercalcemia; visual abnormalities; elevated blood pressure; hypertriglyceridemia; hepatic impairment and/or past history of cholelithiasis jaundice; hypothyroidism (women on thyroid replacement therapy may require higher doses of thyroid hormone); fluid retention; hypercalcemia; exacerbation of endometriosis; hereditary angioedema; exacerbation of other conditions (asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas).

- ADVERSE REACTIONS

  - Uses and Administration

  - Generally, when estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer.

  - A woman without a uterus does not need a progestin. In some cases, however, hysterectomized women with a history of endometriosis may need a progestin [see Warnings and Precautions (5.3, 5.15) in full prescribing information].

  - Use of estrogen-alone, or in combination with a progestin, should be with the lowest effective dose and for the shortest duration consistent with treatment goals and risks for the individual woman.

  - Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary.

  - CONTRAINDICATIONS

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

  - WARNINGS AND PRECAUTIONS

  - Risks from Systemic Absorption

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

  - Cardiovascular Disorders

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

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

  - Malignant Neoplasms

  - Endometrial Cancer

  - An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in a woman with a uterus. The reported endometrial cancer risk among unopposed estrogen users is about 2 to 12 times greater than in non-users, and appears dependent on duration of treatment and on estrogen dose. Most studies show no significant increased risk associated with use of estrogens for less than 1 year. The greatest risk appears associated with prolonged use, with an increased risk of 15- to 24-fold for 5 to 10 years and more and this risk has been shown to persist for at least 8 to 15 years after estrogen therapy is discontinued.

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

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

  - Breast Cancer

  - In the WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE-alone was not associated with an increased risk of invasive breast cancer [relative risk (RR) 0.80] [see Clinical Studies (14.2) in full prescribing information].

  - The WHI estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer. Consistent with the WHI clinical trial, observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen-alone therapy, after several years of use. The use of estrogen-alone and estrogen plus progestin therapy has been reported to result in an increase in abnormal mammograms requiring further evaluation. All women should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations.

  - Ovarian Cancer

  - The WHI estrogen plus progestin substudy reported a statistically non-significant increased risk of ovarian cancer.

  - A meta-analysis of 17 prospective and 35 retrospective epidemiology studies found that women who used hormonal therapy for menopausal symptoms had an increased risk for ovarian cancer.

  - Probable Dementia

  - In the WHIMS estrogen-alone ancillary study of WHI, a population of 2,947 hysterectomized women 65 to 79 years of age was randomized to daily CE (0.625 mg)-alone or placebo. After an average follow-up of 5.2 years, 28 women in the estrogen-alone group and 19 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE-alone versus placebo was 1.49 (95 percent CI, 0.83-2.60). The absolute risk of probable dementia for CE-alone versus placebo was 37 versus 25 cases per 10,000 women-years [see Use in Specific Populations (8.3), and Clinical Studies (14.3) in full prescribing information].

  - In the WHIMS estrogen plus progestin ancillary study of WHI, a population of 4,532 postmenopausal women 65 to 79 years of age was randomized to daily CE (0.625 mg) plus MPA (2.5 mg) or placebo. After an average follow-up of 4 years, 40 women in the CE plus MPA group and 21 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE plus MPA versus placebo was 2.05 (95 percent CI, 1.21-3.48). The absolute risk of probable dementia for CE plus MPA versus placebo was 45 versus 22 cases per 10,000 women-years [see Use in Specific Populations (8.3), and Clinical Studies (14.3) in full prescribing information].

  - When data from the two populations in the WHIMS estrogen-alone and estrogen plus progestin ancillary studies were pooled as planned in the WHIMS protocol, the reported overall relative risk for probable dementia was 1.76 (95 percent CI, 1.19-2.60). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether those findings apply to younger postmenopausal women [see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].

  - Other Warnings and Precautions include:

  - Gallbladder disease; severe hypercalcemia; visual abnormalities; elevated blood pressure; hypertriglyceridemia; hepatic impairment and/or past history of cholelithiasis jaundice; hypothyroidism (women on thyroid replacement therapy may require higher doses of thyroid hormone); fluid retention; hypercalcemia; exacerbation of endometriosis; hereditary angioedema; exacerbation of other conditions (asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas).

  - ADVERSE REACTIONS

  - Clinical Trials Experience: In a single, prospective, randomized, placebo-controlled, double-blind trial, the most common adverse reaction with IMVEXXY (incidence ≥ 3 percent) and greater than placebo was headache.

  - Post Marketing Experience: The following adverse reactions have been identified during post-approval use of IMVEXXY 4 and 10 mcg: Germinitary System: vaginal discharge.

  - DRUG INTERACTIONS

  - Inducers and inhibitors of CYP4A may affect estrogen drug metabolism and decrease or increase the estrogen plasma concentration.

  - USE IN SPECIFIC POPULATIONS

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

  - Geriatric Use

  - An increased risk of probable dementia in women over 65 years of age was reported in the Women's Health Initiative Memory ancillary studies of the Women's Health Initiative.
In the throes of COVID-19, with cases continuing to increase daily at my hospital, we are now further stressed with the brutal death of George Floyd, an African American whose death at the hands of law enforcement, while pleading that he could not breathe, is immortalized in a visceral video. His death and those of others has spurred nationwide protests against systemic racism that are colliding with attempts to mitigate the COVID-19 pandemic. With these crises on multiple fronts, we face increased tensions, anxiety, and stress.

COVID-19 has resulted in myriad changes and heightened anxieties, especially for patients of mine who are among the hardest hit. With schools no longer open, their children are home – as often are their spouses, as their jobs are lost and wages scarce. To add to this burden, we as a society are recognizing that we do not treat people equally, and just as the slogan “Black Lives Matter” says, we need to recognize that systemic racism and implicit bias are an issue and need to be addressed directly. Furthermore, COVID-19 disproportionately impacts people of color, another blow we must mitigate.

Nearly every professional society I belong to has launched campaigns and sent emails highlighting a zero tolerance policy of racism, for example:

- “The American College of Obstetricians and Gynecologists (ACOG) is committed to eliminating disparities in women’s health and to confronting implicit and explicit bias and racism. This means recognizing and examining our own prejudice and bias and addressing the way in which health care systems perpetuate inequality.”

- “The Society for Maternal-Fetal Medicine (SMFM) recognizes the impact of racism and is committed to working towards the elimination of the racism and health inequities that impact our members and the patients they serve.”

- “The American Board of Obstetrics and Gynecology (ABOG) stands in solidarity with our health care community in opposition to the institutional racism, discrimination, and violence that has plagued the country for so long.”
As healers, Alpha Omega Alpha (AΩA) condemns racism and bias in all forms, including police brutality. Racism, discrimination, and social injustice are barriers in the care of patients and public health. AΩA stands with and cares for people of all races, ethnicities, and gender identities. In these times of crisis for our country and world, we must guide medicine to be unbiased, open, accepting, inclusive, and culturally aware in order to be worthy to serve the suffering.

In addition to stating their support and the importance of these issues, these professional societies are committing to action. SMFM is educating their members and collaborating with other groups to promote policies to improve access to care and advocating for research. AΩA, a medical honor society, has a new award for excellence in inclusion, diversity, and equity in medical education and patient care. Both COVID-19 and racism have far-reaching impacts politically and medically. It is imperative that we as providers highlight these impacts, recognizing the serious consequences that may follow. A household survey by the Centers for Disease Control and Prevention that was intended to monitor anxiety and depression in the setting of COVID-19 – an important metric given the social distancing and isolation – takes on new meaning now.

Anxiety and depression have tripled in the last year, with US rates for anxiety around 8% in 2019 and over 30% in 2020 (Figure 1). Importantly, the rates of anxiety vary notably across racial groups, and those of mixed race have the highest rates with the ongoing demonstrations and protests. During the pandemic, women are reporting more anxiety than are men. In addition, people of reproductive age have the highest rates of anxiety (Figure 2). As the initial collision of crises passes, it will be vitally important to understand the impact going forward.

Critically, as the movement to raise awareness of social injustice and racism escalates, the rates of cases of COVID-19 continue to increase – the directionality of the interrelationship is unclear. Unfortunately, they are not mutually exclusive, and the critical need to raise awareness clashes with the social isolation needed to quell the spread of COVID-19. Neither is more important, neither is less.

As I round on my antepartum patients, I have a new routine speech. It is hard to live in the world today, much less to be pregnant. Being hospitalized without visitors, juggling the media and messages of racism with the need for social distancing, does not easily allow for a healthy mental or physical state. I listen, try to understand, and offer the services of psychiatry and psychology to provide some attempt at mental balance, although far from normalcy. We discuss that this is situational, not specific to my patients, and they may benefit from external support. In truth, we all may.

*Indicators of anxiety in the United States as reported by the Household Pulse Survey in 2020 and by the National Health Interview Survey in 2019; questions are a modified version of the two-item Patient Health Questionnaire (PHQ-2) and the two-item Generalized Anxiety Disorder (GAD-2) scale on the Household Pulse Survey, collecting information on symptoms over the last 7 days www.cdc.gov/nchs/covid19/pulse/mental-health.htm.

**FIGURE 2** People of reproductive age (18-49 years) report higher anxiety in last 7 days.*

*For references visit contemporaryobgyn.net/COGeditorial
Managing mesh problems

The scientific approach to categorizing mesh complications, as well as optimal methods to address them, have been complicated by the rapid proliferation and evolution of materials and techniques that have been used over the past 20 years in surgical treatment of pelvic floor disorders. In addition, terminology used to diagnose and categorize mesh complications, as well as the descriptions of surgical procedures to manage them, have been adopted inconsistently, further hampering development of a collective experience with a standardized lexicon. Finally, much of the high-quality data on management of mesh complications is based on materials that are rarely used or not commercially available today.

Women experiencing mesh complications need to be heard, and should have access to resources and providers who are most able to help. Many women require multiple procedures to address their mesh complications, and for some of these patients, relief is incomplete. We should strive to optimize the treatment at the initial diagnosis of a mesh-related complication.

This Position Statement has four goals:
1. Using the best and most relevant evidence available, provide guidance for the FPMRS subspecialist caring for patients who may be experiencing mesh complications.
2. Provide an algorithm outlining treatment choices for patients with mesh-related complications that can be used as a platform for shared decision-making in the treatment of these complications.
3. Identify and prioritize gaps in evidence concerning specific mesh complications and their treatments.
4. Identify provider and health facility characteristics that may optimize the outcomes of treatments for these complications.

The treatment algorithm requires consistent and accurate terminology for treatment procedures, as follows:
- **Mesh Revision:** either no mesh is removed (e.g., dissecting and primarily closing vaginal epithelium), or a small edge of mesh is removed such that the structural integrity of the implant is left intact.
- **Partial Vaginal Mesh Excision:** a segment/component of the mesh is removed or transected, such that the structural integrity of the implant is altered.
- **Complete Vaginal Mesh Excision:** the entirety of the mesh that is in contact with the vagina is excised.
- **Extra-vaginal Mesh Excision:** removal of segments or components of mesh beyond, or not in contact with, the vagina.
- **Total Mesh Excision:** the surgical goal is the removal of 100% of the implant; extirpation.

The treatment algorithm is presented, along with the level of evidence supporting each decision node. Recognizing that some patients will require more than one procedure, the recommendation is made that treatments are not repeated; if a given treatment is unsuccessful, consideration should be given to advancing to the next item on the algorithm.

Full text of “Management of Mesh-Related Complications for the FPMRS Specialist” can be found at www.augs.org/assets/16/joint_position_statement_on_the_management_of_1.pdf
Smoke evacuation in age of COVID-19

Though theoretical, the threat of aerosolized viral particles places health care providers at risk. Certain safety measures can be taken.

by SARA RAHMAN, MD, JORDAN KLEBANOFF, MD, AND GABY MOAWAD, MD, F.A.C.O.G.

The coronavirus pandemic presents many challenges to gynecologists, particularly in surgery. Although efforts have been made to either limit or appropriately triage non-emergent surgery during the COVID-19 pandemic, emergent procedures, such as ruptured ectopic pregnancy, must still be performed. Contemporary data on COVID-19 transmission risk during surgery are limited and many have questioned the safety of laparoscopic surgery for fear of aerosolized viral particles in surgical plume putting healthcare providers at risk. The worry is that use of pneumoperitoneum and electrosurgery, both of which are integral parts of laparoscopy, may enhance this risk. We aim to discuss this theoretical risk and what safety measures can be taken to provide a safer work environment for vital healthcare workers.

Aerosolization of viruses

The virus that causes the infection commonly referred to as COVID-19 is a novel respiratory pathogen (SARS-CoV-2), which spreads via droplets. The approximate size of COVID-19 virions range from 50 to 200 nm; N-95 masks filters, with 95% efficiency, against 300 nm particles. However, viral particles can also spread with aerosolization procedures such as intubation. SARS-CoV-2 has also been detected in blood and stool specimens, but the infectivity of these extrapulmonary specimens is unknown.

Since the viral RNA has been found in stool, it is suggested that the virus could also then be found within the gastrointestinal mucosa. Some have theorized that pneumoperitoneum in laparoscopy can create a stagnant heated volume of gas in the abdominal cavity, which could allow for concentrated aerosolization of the virus. Release of pneumoperitoneum from trocar valves during instrument exchange, venting, or removal could allow for virus transmission. Another concern stems from electrosurgical plume; when activated in laparoscopy, electrosurgical devices could release aerosolized debris into the abdomen. Both of these post a potential risk of viral transmission.

Most of our understanding of viral aerosolization comes from the study of other
viral diseases, mainly hepatitis B (HBV) and human papillomavirus (HPV), although admittedly, this issue is not well-studied in laparoscopy. One study demonstrated that HBV was detected from the surgical plume of infected patients.7 However, no subsequent studies were performed to determine if those HBV particles had viral infectivity or were capable of transmitting the disease. Several studies found that although aerosolized HPV DNA could be detected in surgical plume, there was no evidence that these particles could develop into an active infection or be transmitted to the surgical team.8-11 Furthermore, one of these studies demonstrated that with use of smoke evacuation systems and proper personal protective equipment (PPE), there was no evidence of dispersion of viral DNA onto the skin of the surgeon.9 Although the route of transmission for HBV and HPV is different than for SARS-CoV-2, there are no data to support viral transmission by laparoscopy. To mitigate the theorized risk of viral transmission during laparoscopy, many believe that using a closed-circuit surgical system for smoke evacuation prevents room contamination with aerosolized particles and minimizes the potential risk for transmission. Several different insufflation systems exist, some of which also include smoke evacuation components. Independent laparoscopic smoke evacuation systems also exist.

One system that has been suggested for use during the COVID-19 pandemic is the AirSeal (Conmed, Utica, NY). This device has valveless access ports, which minimizes any loss of pneumoperitoneum during instrument exchanges. The trilumen flow tube filters particles while simultaneously allowing carbon dioxide inflow and outflow. AirSeal also has a special mode that allows for smoke evacuation and more liberal circulation of pneumoperitoneum, decreasing possible concentration of aerosolized virus. The PneumoClear (Stryker, Kalamazoo, MI) is another integrated insufflator but uses traditional trocars with valves. The PneumoClear also has an added feature of de-sufflating the abdomen at the end of the case, which removes the need for release of any pneumoperitoneum. For both of these systems, ultra-low particle (ULPA) filters can be used, if available, to help filter viral particles that have been aerosolized during surgery. In conjunction with tightly fitting laparoscopic ports, a smoke evacuation and filtration system can be used to minimize release of potential virus in the operating room.

When smoke evacuation systems are not available, direct wall suction can be used to evacuate plume through a laparoscopic trocar. Wall suction devices can also be attached to the same ULPA filters used for endotracheal tubes, although this method does not guarantee the high filtration efficiency of manufactured smoke evacuation devices.12 In addition, minimizing use of energy devices during procedures whenever possible may decrease aerosolization of particles. Final risk reduction methods may include reducing the abdominal pressure of pneumoperitoneum required for the operation. Regardless, it is extremely important that all individuals in the operating room wear proper personal protective equipment (PPE), including N95 respirators.

**Recognition of Risk**

The aforementioned risks and possible solutions have been recognized by surgical societies worldwide. A joint statement issued by the American Association of Gynecologic Laparoscopists (AAGL) with multiple other gynecology professional societies acknowledged that steps must be taken for the safety our patients and our healthcare providers. Minimally invasive techniques are the preferred method if urgent surgery is required. Data about the risk of transmission of COVID-19 via surgical plume is limited. Proper PPE is always recommended.13

**Conclusion**

There is only a theoretical risk of transmission of viral particles from the abdomen of a COVID-19-infected individual. However, until definitive data are available, it seems prudent to use simple strategies to help mitigate these risks. These strategies include closed-circulation smoke evacuation, PPE, minimizing use of energy devices, low pneumoperitoneum pressures, and de-sufflating the abdomen using a smoke evacuation device or suction substitute with ULPA filters, if available. With the paucity of data, more research needs to be conducted around COVID-19 and laparoscopy.

**FOR REFERENCES VISIT**

contemporaryobgyn.net/smoke-evacuation
Australian researchers believe that PD-L1 may have potential as an indicator of potential response to chemotherapy in women with metastatic breast cancer. That was based on results of a randomized trial, presented at the European Society for Medical Oncology in Lugano, Switzerland.1

In SAFI-2 BREAST IMMUNO, 199 patients with metastatic breast cancer without actionable genetic alterations were randomized to 6 months of standard chemotherapy with durvalumab or maintenance chemotherapy. Of the patients, 83 had triple-negative disease.

For patients to respond to immunotherapy agents that target PD-1 or PD-L1, the tumors must express PD-L1. The aim of the study was to determine the predictive value of copy number alteration (DNA) for the PDL1 gene, which indicates whether the gene number has remained the same, decreased, or increased.

Using metastatic tumor samples from the participants, PDL1 CAN was characterized from array CGH analysis. The authors estimated treatment effect in each subgroup using a cox proportional hazard model.

Results showed that 23.8% of patients had copy gain or amplification of the PDL1 gene. Improvement in overall survival (OS) with durvalumab was limited to this group, with median OS of 9 months (95% confidence interval [CI] 4 to 18) in the chemotherapy arm and not reached in the durvalumab arm (hazard ratio 0.17, 95% CI 0.05 to 0.55).

“This exploratory subgroups analysis of the first randomized trial comparing a PDL1 inhibitor to chemotherapy in the maintenance setting,” the authors said, “shows that PDL1 CNA can be an important predictive marker for PD(L)1 inhibitor efficacy. If their findings are confirmed in a larger trial, they believe it may have important implications for development of immunotherapy in patients with metastatic breast cancer, particularly those with low immunogenicity.

Bob Kronemyer is a freelance writer for Contemporary OB/GYN.

SOURCE

Survival benefit in advanced or metastatic breast cancer with visceral metastases

Findings from a new study show significant overall survival benefit of Novartis’ ribociclib in hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer with visceral metastases. The findings from a subgroup analysis of the phase 3 MONALEESA-3 and MONALESSA-7 trials were presented during the ASCO20 Virtual Scientific Program. Visit contemporaryobgyn.net/metastatic and link through to sister site DrugTopics.com for the full article. The MONALEESA trials evaluated ribociclib in premenopausal women with non-steroidal aromatase inhibitor (NSAI) plus goserlin (MONALEESA-7) and in postmenopausal women in combination with fulvestrant (MONALEESA-3).
When screening for tuberculosis, which patients should clinicians assign the highest priority? What methods are currently available?

In this Contemporary OB/GYN® podcast, Amita Gupta, MD, MHS, discusses the efficacy and limitations of screening options, including the protein purified derivative (PPD) test, and interferon gamma release assays using either a chemiluminescence automated platform or an enzyme-linked immunospot assay.

Go to: contemporaryobgyn.net/tb-screening
Introduction
Forty-three percent of American women aged 18 to 85 report experiencing some form of sexual complaint; however, the actual incidence of self-reported significant distress from these issues is closer to 12%. Defined as distress due to lack of desire, impaired arousal, inability to achieve orgasm, pain with sex, or a combination of the above, sexual dysfunction is a commonly ignored topic given the societal stigma surrounding open discussion of female sexuality.

Unfortunately, this bias toward under-reporting by health care providers, who also report being less comfortable bringing up female sexuality, extends to health care providers, who also report being less comfortable bringing up female sexuality. While in part, this is due to the perception that there is inadequate time in clinic to address sexuality issues, some providers do not feel proficient in sexual dysfunction knowledge or management. Although over the last 10 years there has been a cultural shift toward acknowledging the spectrum of sexual relationships and conditions, several recent studies on training received in sexual medicine have not found increased attention on education in this area. Discomfort among practitioners who are managing sexual dysfunction remains high. In addition, while the Internet has made it easier for patients to find information about their symptoms, they remain less likely to bring up intimate issues with their healthcare providers unless directly asked.

Despite this hesitancy from patients and practitioners to delve into sexual health, many studies support the idea that regular sexual expression is associated with improved psychological well-being and reduction in physical problems. Intimacy has been found to be vital to overall well-being.

Details, please!
As health care practitioners, we effectively diagnose and treat disorders within our specialty. The challenge of sexual dysfunction is that the etiology may be complex, which can make starting the conversation about sexual function daunting. However, the American College of Obstetricians and Gynecologists (ACOG) recommends that all obstetrician and gynecologists should be initiating “clinical discussion of sexual function during routine care visits to identify issues that may require further exploration and to help
Although medical education regarding sexual medicine remains lacking, an advanced understanding is not needed to help patients feel comfortable. Start by normalizing the topic, ensuring patients that sexual problems are common and that the first step in improvement is being willing to talk about it. It can be effective to start the conversation with a simple open-ended question, for example: “Many women have concerns about sex. I wanted to check in and see how you’re doing.” Allowing the patient to speak freely, followed by empathetic listening and asking pointed, detailed clarifying questions gives the patient space to express herself.

If short appointment times are the primary barrier to discussing sexual health, there are validated sexual function checklists, such as the Patient-Reported Outcomes Measurement System or Female Sexual Function Index (FSFI), that can be incorporated into the intake process; however, the onus is then on the provider to acknowledge aberrant answers and schedule follow-up appointments.

If a patient raises specific issues, begin by validating her concerns. If you are under time constraints, it’s acceptable to schedule a future focused sexual health follow-up appointment. During that visit, take a detailed sexual and emotional history that includes: the patient’s sexual/gender identities, nature/duration/chronology and onset of symptoms, severity of distress caused by symptoms, patients’ personal attempts to alleviate symptoms, relationship quality, past/current abuse history (sexual, verbal, emotional or physical), and Internet/social media usage. Assess hygiene, sleep quality, and body changes/image concerns. In addition, as part of obtaining a history, discussing the female sexual response cycle can be helpful to evaluate where in the cycle the breakdown is occurring: desire, arousal, orgasm, or resolution. It is useful to review that in women, the sexual response is not always linear and that a satisfying sexual encounter (SSE) does not always require moving through all phases, nor is an orgasm always necessary for a SSE. A discussion focused on one area of concern of the cycle may shed light on underlying causes related to another problem. For example, a patient with pain with sex may think that her decreased ability to become aroused is due to other factors (relationship issues, age, lack of foreplay, etc.), when in actuality it is underlying vulvar vestibulitis and vulvar pathology that needs to be addressed. As part of this appointment, screen all patients for intimate partner violence because sexual dysfunction may be the primary and only manifestation. It is important to acknowledge that even after an initial intake appointment, the patient may not reveal the extent of her sexuality concern and that multiple appointments may be necessary for full disclosure.

Finally, assumptions in sexual medicine can be detrimental. Do not assume that all patients are heterosexual and engaging in monogamous relationships. Multiple relationship paradigms exist, and clinicians should be familiar with these sexual variations. Most importantly, try to create a welcoming, non-judgmental environment. Ensure that medical intake forms use inclusive language and pay attention to the descriptors a patient uses during her visit (for example, partner versus husband). You may never get a second chance to make a first impression. Comprehensive diagnosis, patience, and empathetic listening are the cornerstones for building a therapeutic alliance with your patient and facilitating a joint partnership in development of a treatment paradigm.

If a patient raises specific issues, begin by validating her concerns.

Stay focused

Although the etiology of female sexual dysfunction is often multifactorial, do not forget that the problem may actually be due to an underlying preexisting medical condition.

For example, changes in levels of thyroid hormone lead to alterations in circulating sex hormones. This can lead to autonomic dysregulation, causing sexual dysfunction. In women, both hypothyroidism and hyperthyroidism have been associated with altered desire, arousal, orgasm, and satisfaction with intercourse. If the patient has a male partner, thyroid disease can be associated with erectile and ejaculatory dysfunction.

Other chronic conditions may also impact sexual functioning. The role of diabetes in male sexual dysfunction is well established because erectile function can be severely diminished due to vascular complications of diabetes. The impact of diabetes on female sexual functioning is less clear; however, some studies confirm that it can diminish genital sensation. Similarly, neurologic diseases, such as Parkinson’s, multiple sclerosis, or sequelae of a cerebrovascular accident, can impact sexual function as mobility and sensation is often compromised.
Transient changes in health status should not be ignored. With all the focus on the arrival of a new baby, it can be easy for providers to forget to address sexual functioning with pregnant and postpartum women. Research has shown that hypoactive sexual desire disorder and painful intercourse/dyspareunia are common in postpartum women due to the interplay of low estrogen levels, mood changes, and fatigue. 

Remember to ask about sexual function at postpartum appointments, even if it is not a patient’s chief concern. Medication use may also be the cause of sexual problems. It is not uncommon for changes in sexual functioning to be associated with the start of a new medication. For example, some psychiatric medications have a reputation for causing sexual dysfunction; however, the true incidence is difficult to assess as sexual dysfunction can also be independently associated with psychiatric disorders such as depression, anxiety, and psychosis. 

Most commonly, selective serotonin receptor inhibitors (SSRIs), benzodiazepines, and first-generation antipsychotics impact the sexual response cycle.

Maintaining a patient’s mental health is the main priority and if she feels that her medication is to blame for a decreased libido, consider recommending that she discuss a medication switch with her psychiatrist. Aside from psychiatric medications, antiepileptics may be associated with sexual dysfunction as have hormonal contraceptives, although the data are conflicting and many confounding factors may be present.

Above all, optimization of general medical health conditions and well-being will allow you to provide the best care, treating the whole person rather than just her sexual considerations. Treatment of female sexual complaints should start by stabilizing any preexisting medical conditions and monitoring polypharmacy/excessive medication use. Medications can directly and indirectly impact sexual function and care should be taken to assess and evaluate the impact of prescriptions, herbs, supplements, and over-the-counter (OTC) formulations on sexual responsivity.

Sexual dysfunction rarely exists in a vacuum. Ensure that you take a thorough medical history prior to assuming intercourse is the real problem.

**Start with simple solutions**

Aside from addressing underlying medical issues, providing patients with simple behavioral modifications or interventions has been shown to improve or enhance sexual well-being. When men and women are satisfied with their sex lives, their overall health improves. Therefore, talking with patients about prioritizing time for intimacy and sex, as well as planning intimate activities with their partners, such as regular date nights, can help reset relationships. In a world where distractions and technology overload are commonplace, effort needs to be made to shift the focus back toward enhancing connections and fortifying bonds.

Aside from encouraging couples time, you may also want to suggest novel sexual adventures. Many patients may never have explored sex toys/aids, accessories, or the use of supplemental lubricating products. Patient education and support can be therapeutic as well. Patients may not be aware that multiple medical conditions and medications can impact arousal and sexual lubrication. For example, during menopause, vaginal tissue becomes pale, frail, and inelastic due to a hypoestrogenic state. As a result, the vagina produces less physiologic lubrication. Given that genitourinary syndrome of menopause (GSM) and vaginal dryness is a common etiology of painful intercourse, having frank conversations about vaginal moisturizers and lubricants is a solution that is easy to implement.

Water-based lubricants are commonly used in most situations (sensitive skin, condoms, sex toys); however, they are stickier and shorter-lasting than the alternative silicone- or oil-based lubricants. Silicone-based lubricants will feel slicker and last longer than water-based lubricants. In addition, silicone-based lubricants are safe for use during water-based sexual activity (pools, hot tubs, showers, lakes) and also can be used with sex toys. Caution is advised if using with other silicone-based toys as it can impact the integrity of rubber products. It’s also very important to instruct your patients to read labels and understand ingredients as some additives can be caustic to the sensitive vaginal mucosal lining.

Ensure that you take a thorough medical history prior to assuming intercourse is the real problem.

Educate patients that some of the OTC options, whether lubricants or herbal concoctions, are not based in science and can be damaging. For example, vaginal tightening gels are not approved by the US Food and Drug Administration and many may negatively impact the healthy vaginal biome. Many OTC supplements promise re-
sults but often fail on performance and scientific support. Nevertheless, in general, lubrication and sex aids are easy recommendations that any provider can safely make.

**Understand the context of the relationship**
Aside from treating the patient in your office, counsel her that the health of a relationship (or relationships) can significantly impact sexual functioning. Assessing the dysfunction in the context of a partnership can help shed light on the etiology of the issue. An understanding of relationship dynamics, communication styles, and emotional interactions is important when formulating a comprehensive treatment plan. If the patient is willing, an open discussion with her partner can be beneficial and therapeutic. During this appointment, address factors in the relationship that directly relate to sexual dysfunction (unrealistic expectations, different fetishes, etc.), but also lifestyle challenges (shift work, work travel, body changes, etc.).

There is evidence that exercises aimed at improving and enhancing partner communication about sexual wants, needs, and preferences can help alleviate a portion of sexual discomfort. Furthermore, group-based or couples-based cognitive-behavioral therapy can be useful for improving low sexual interest.

**Enlist help**
As women’s health care professionals, we are often the only providers who may discuss sexual health concerns. Few residencies offer in-depth, formalized training about normal and abnormal sexual functioning. While we may want to tackle all issues related to women’s health, appropriate referral to specialists specifically trained in sexual medicine should not be seen as a clinical failure, but rather as a cornerstone of improving a patient’s sexual health.

ACOG recommends connecting patients with health professionals with expertise in sexual dysfunction, such as sex therapists and marriage/relationship counselors, as well as mental health specialists, such as psychiatrists and psychologists. Couples counseling is often a good fit for patients looking to spend time addressing broad relationship issues. A sex therapist may offer help but mainly focuses on sexual concerns, such as negotiating discordant sexual desires and assigning exercises to help overcome dysfunction.

There is emerging scientific data on the efficacy of sex therapy, and the general consensus of sexual medicine experts is that therapy and counseling can significantly improve sexual functioning, relationships, and quality of life. Genital pelvic floor physical therapists may also play a critical role in the treatment of pelvic pain syndromes.

Referral networks may be helpful and include: American Association of Sex Educators Counselors and Therapist (AASECT), The International Society for the Study of Women’s Sexual Health (ISSWSH), North American Menopause Society (NAMS) and ACOG. With the emergence of tele-health and Internet connectivity, even practices in remote areas, tele-medicine can help connect providers to patients. There is less information regarding distance counseling as it pertains to sexual health; however, it is effective for gynecologic care. For male health, tele-sexual health has been used to address concerns such as erectile dysfunction treatment and testosterone replacement, but its role for women and hormonal therapy is currently still being explored. Out-of-pocket cost, fee-for-service models and reimbursement for telemedicine vary, by insurance company and geographic distribution. Patients should be encouraged to investigate their coverage.

Just as the etiology of many sexual dysfunctions is complex, the treatment also requires a multi-faceted, team-based approach. Seeking help from experts is not a clinical failure on the provider’s part. Instead, it should be viewed as an opportunity for medical collaboration that can maximize a patient’s chance to recover and thrive.

**Conclusion**
Sexual dysfunction is an underdiscussed, though prevalent, issue. The aim of this article is to illustrate that there are many ways to help patients struggling with sexual dysfunction. Given the paucity of formal training on sexual health that many ob/gyns receive in residency, understanding the basic options that are available and creating safe, open spaces in which patients feel secure enough about to express their concerns is paramount to starting the process of healing.

**FOR REFERENCES VISIT**
contemporaryobgyn.net/sexual-health
With ongoing aging of the population, incidence of pelvic organ prolapse (POP) is on the increase, and with it the need to increase education for ob/gyns and their patients about proper use of pessaries. A new study underscores the importance of careful device fitting and patient counseling prior to pessary insertion to avoid dislodgement.

Published in Female Pelvic Medicine and Reconstructive Surgery, the research evaluated factors associated with pessary dislodgment in women with advanced POP. The prospective study was conducted in a tertiary urogynecology center from December 2017 and 2018.

The study authors found that presence of advanced apical POP and previous POP surgery are risk factors for ring pessary dislodgment. They advised that physicians guide and counsel patients before pessary insertion.

Women with symptomatic advanced POP—defined as anterior, posterior, or apical stage 3 or 4 in the Pelvic Organ Prolapse Quantification system [POP-Q]—were recruited. Demographic data and history of POP surgery and associated urinary and bowel symptoms were collected.

Prolapse was staged according to the POP-Q, and a ring pessary without support was the only type of pessary in this study. After vaginal pessary insertion, patients were asked to walk and perform Valsalva maneuvers. If the pessary became displaced, reinsertion of the same or next size device was performed, up to three times.

An outpatient visit was scheduled for each patient 3 and 6 months after pessary insertion to assess for symptoms. They were vaginal discharge, bleeding, pain, discomfort, new-onset symptoms—urinary or bowel—and any pessary dislodgement.

To evaluate factors associated with dislodgement, women who had their pessaries dislodged within 6 months were compared with those who retained their pessary. Of 93 women, 78 (83.9%) were able to retain the ring pessary during the 6-month follow-up, and 15 (16.1%) from the pessary dislodgement group failed to retain the device.

Results showed no difference regarding age, body mass index, parity, schooling, race, menopausal status, comorbidities, or sexual activity in women with a dislodged versus a retained VP. However, women with a dislodged VP had significantly more previous reconstructive surgery—specifically anterior colporrhaphy—and more advanced POP-Q C points (apical prolapse) than women who retained the device.

The authors concluded that presence of advanced apical POP and previous POP surgery were risk factors for ring VP dislodgement.

Lindsey Carr is the associate editor for Contemporary OB/GYN.

SOURCE
As you enjoy the print edition of Contemporary OB/GYN, take a minute to go to our updated website for in-depth coverage and timely news and information.

Check out the Spotlight feed in the upper left corner that currently features:

- BV & Sexually Transmitted Infections
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- Laser Treatment for GSM
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- Surgery
- TB Screening

Updated features include:
- Streamlined navigation
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- Faster load speeds to accommodate videos, podcasts, and newsfeeds
This wouldn’t have happened if I was still in Brazil!” exclaimed my patient. Though her face was covered with a mask, her frustration was clear. As a 38-year-old woman who had recently moved to the U.S. with her husband for an exciting job opportunity, she has been taking combined oral contraceptives (COCs) reliably for the past 20 years with no pregnancies. In Brazil, she would simply walk into her neighborhood store and buy a pack of COCs along with her shampoo. She had known for her whole life that she didn’t want children and remained highly motivated to avoid pregnancy, especially now that she is in America and had a chance to further her career beyond what she could achieve in Brazil.

I met her amid this global pandemic, as she had been granted an urgent appointment to our otherwise-closed out-patient clinic due to an early undesired pregnancy. The last physician she saw would only provide her with 1 month of COCs to carry her over until she could be seen for an annual exam. The single pill pack ended as the pandemic reached our state and the stay-at-home order was initiated. She was unable to get a refill from the initial prescribing physician and, though she tried to be careful, ultimately conceived.

The current pandemic has amplified the existing unnecessary barriers to contraception, much to the detriment of women. My patient wasn’t alone in her interest in over-the-counter (OTC) contraception. A survey nearly 10 years ago in the U.S. demonstrated that two-thirds of women were in favor of the concept and one-third would utilize it themselves. A recent survey of over 2,000 women and 500 adolescents in the U.S. revealed that nearly 40% and 30% of each group would be interested in OTC progestin-only pill (POP) access. Now is the time to give women like my patient access to hormonal contraception over the counter.

In the U.S., there are an estimated 43 million women at risk of unintended pregnancy. Prescription-based contraceptive methods are actively used by nearly one-third of contracepting women, and four of five sexually experienced women have used an oral contraceptive (OC) pill at some point in their lifetime. Although physicians are typically most familiar prescribing OCs, the transdermal patch, and the monthly vaginal ring, there is also a self-administered subcutaneous form (104 mg) of depot-medroxyprogesterone acetate (DMPA) that can be directly prescribed to women. With the subcutaneous formulation, women can self-inject their DMPA via a small 3/8-inch needle without requiring an in-person visit for the standard 150mg intramuscular injection (Figure 1).

**Barriers to access**
Unfortunately, women experienced a multitude of barriers to prescription-based contraception long before the pandemic. One large survey of US women currently on prescription methods including OCs, the transdermal patch, and monthly vaginal ring, revealed that one-third of them had experienced access barriers while initiating or continuing their chosen meth-
od. Of the women who reported barriers, the vast majority (62%) were related to the physical need to see a provider in an office to obtain a prescription. Other factors such as cost (25%), pharmacy access (7%), and non-specific barriers (6%) were significantly less common.

Our specialty has successfully overcome the limitations of prescription status on access to reproductive health services, specifically in the context of oral levonorgestrel emergency contraception. Although initially prescription-only when approved by the US Food and Drug Administration in 1998, oral levonorgestrel emergency contraception (EC) was given OTC status in 2006 for women age 18 and above. In 2013, the age restriction was removed so anyone with reproductive potential could access this form of EC. After transitioning to OTC status, adult use of oral levonorgestrel EC increased from 4% of women in 2002 (prior to OTC conversion) to 11% of women by 2010, amounting to a total of 5.8 million women who had ever used this product. Since the day-to-day intricacies of women’s lives vary tremendously, we need a multitude of ways that they can access their preferred contraceptive method. Some women may still prefer in-office visits, but our experience with the OTC transition of oral levonorgestrel EC showed that women need the option to buy contraceptive methods directly off the shelf.

Overcoming access barriers

As an intermediate step toward OTC status, some states have given pharmacists the ability to provide hormonal contraception directly to people without a prescription from a provider. Through this behind-the-counter model, the pharmacist performs a risk assessment and sometimes a blood pressure measurement prior to dispensing combined hormonal contraception (CHC) (COC), transdermal patch, monthly vaginal ring). The most recent tally shows that 13 states along with Washington, D.C., allow pharmacists to directly dispense some types of hormonal contraception. Nuances of behind-the-counter provision vary. Only nine of these states (along with Washington, D.C.,) allow the pharmacist to give the method directly to the patient without any prescriber involvement. Four states actually require a collaborative practice agreement between pharmacists and providers, creating another possible barrier.

Though a step in the right direction, behind-the-counter hormonal contraception still has its limitations. Pharmacists reimbursement for their patient assessment and counseling has also been a logistical obstacle and potential disincentive. These visit costs can get passed down to patients. In addition, we know that women experience pharmacist objection to dispensation of reproductive health products such as EC and this will likely occur with other contraceptive products.

A variety of health care organizations and private companies have tried to address these barriers and created systems of online contraceptive consultation with mail-order products. Women undergo standard health screening, with variation in other requirements like recent blood pressure measurement. Sites also often charge women a separate consultation fee and vary in insurance acceptance. Importantly, women may find it difficult to obtain a clear estimate of insurance coverage. Some sites offer a clear low-cost cash option so women can gauge this option as a back-up if their insurance coverage is limited.

Online hormonal contraceptive access is a convenient option for many women, but there is still a large cohort for whom this is not an option. Access to online hormonal contraception changes depending on which state a woman orders her method from since legal restrictions vary widely. States with restricted online contraceptive access are typically those with restrictive laws regarding in-person contraceptive provision or insurance coverage, so online access cannot totally overcome geographic disparities.

Though most women have Internet

![Image](https://example.com/image.jpg)

**Figure 1. Self-injection of subcutaneous depo medroxyprogesterone acetate 104 mg**

- Gently grasp and squeeze a large area of skin in the chosen injection area between the thumb and forefinger, pulling it away from the body (see image 1).
- Insert the needle at a 45-degree angle so that most of it is in the fatty tissue.
- The plastic hub of the needle should be nearly or almost touching the skin.
- Inject slowly until the syringe is empty (see image 2).
- This should take about 5 to 7 seconds.
- It is important that the entire dose is given.
access to visit these websites, translating the online encounters into actual in-hand contraception can pose additional challenges. Requiring an electronic method of payment may be a barrier to some people. Women and adolescents can have challenges obtaining electronic methods such as credit cards for a wide range of reasons. Privacy is still a risk with obtaining online contraception, whether through the electronic record of the transaction or the risk of a package being opened or intercepted at home. Those facing reproductive coercion or domestic violence are particularly at risk and lose the opportunity to have their method in hand right away so they can take necessary precautions. The need for a stable mailing address also poses a barrier to those with housing instability. In the pandemic, widespread shipping delays can lead to gaps in contraception and thus pregnancy risk. Only OTC availability can give women rapid access to hormonal contraception that they can control immediately.

Support for OTC

Well before the pandemic abruptly exacerbat-ed contraceptive access barriers, the American College of Obstetricians and Gynecologists (ACOG) published a committee opinion in support of OTC hormonal contraception.11 In the realm of oral contraceptive access, the movement has been long in existence, with a broadly inclusive, multidisciplinary OC OTC working group founded over 15 years ago.13 Other professional organizations providing their support include the American Academy of Pediatrics, American College of Nurse-Midwives, American Nurses Association, Association of Physician Assistants in Obstetrics & Gynecology, and Society of Adolescent Health and Medicine.13 A wide range of reproductive health advocacy groups and justice organizations serve as partners in addition to university-based researchers and experts in the field.13 The American Academy of Family Physicians has maintained a clear position statement in favor of OTC hormonal contraception and makes the important distinction that insurance should provide coverage for these medications regardless of prescription or OTC status.14

Despite long-standing interest in OTC hormonal contraception, we are greatly limited in our ability to conduct research due to FDA restriction of these medications as prescription-only. As a result, we draw upon a growing body of literature from international contexts to supplement our domestic survey research. It is important to note that the U.S. is in the minority when it comes to restricting hormonal contraception to prescription-only status, with one global assessment revealing that only 45 of 147 countries have this limitation.15 On a population level, the majority of the world’s population resides in countries with OTC access.15 Although OTC access is a common approach to hormonal contraception, there are important safety considerations as with all medications.

Action needed from drug makers and the FDA

Switching a prescription-only hormonal contraceptive to OTC would require initial action from drug manufacturers. The company would need to submit a new drug application to the FDA that includes a risk assessment of the medication when accessed OTC and a risk-benefit assessment for consumers. Medication label and package inserts will be particularly important with OTC hormonal contraceptives as they would include self-screening instructions along with typical dosing and adverse effect information. Drug manufacturers and the FDA would need to ensure this information is comprehensible based on consumer reading levels and that it translates to correct contraceptive use.16,17

Medical eligibility self-assessment

Hormonal contraceptives are safe for the vast majority of women and adolescents. In a switch from provider-
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Now is the time

As we navigate the pandemic and anticipate our new normal, we need to ensure access to contraception. Reproductive planning is complex at baseline and a person’s interest in becoming pregnant may alter depending on their own personal experience during this time. From financial to medical concerns and everything in between, risk-benefit calculations regarding pregnancy will change. Now is the time for drug companies to pursue OTC status for hormonal contraception. We need to empower people like my patient in their execution of their reproductive goals. With all the uncertainty in the world, access to hormonal contraception should be ensured.

FOR REFERENCES VISIT contemporaryobgyn.net/otc-contraception

guided assessments, OTC provision will require individuals to self-screen for their own eligibility for both progestin-only and combined estrogen/progestin methods.

Venous thromboembolism (VTE) risk is a common safety concern with hormonal contraceptives. Fortunately, progestin-only methods, which include the progestin-only pill and subcutaneous depot-medroxyprogesterone acetate injection, carry no or minimal risk of VTE and do not require any in-person evaluation prior to initiation. Estrogen-containing methods, which include COC, monthly vaginal ring, and transdermal patch, do carry a comparatively increased VTE risk in certain populations. However, the marginal increase in VTE risk among COC users is significantly lower than pregnancy or the postpartum time period.

OTC hormonal contraceptives would contain a checklist that potential purchasers could use to screen for medical conditions that would caution against self-use of these medications, particularly those that contain estrogen (Table 1). Overall, studies have demonstrated that women tend to overestimate the risk of hormonal contraception and are more likely to restrict their own use more than what a medical provider would recommend. In one study, 6.9% of women reported contraindications to combined hormonal contraception while only 2.4% actually had a real contraindication on chart review. Women in one study in the United Kingdom were so accurate in their self-assessment that none of the over 300 women included would have taken hormonal contraception contrary to medical guidelines.

Women could also be provided with guidance to determine whether they can be reasonably certain they are not currently pregnant. Some women may fall outside of these criteria and it is possible that they could start hormonal contraception with a clinically unrecognized pregnancy. Since these methods can alter women’s bleeding patterns and their overall suspicion for pregnancy, women who are not completely certain they aren’t currently pregnant could quick start their method and take a home pregnancy test in 2 weeks. Additional guidance for backup contraception could be provided. Fortunately, if a woman does take hormonal contraception while pregnant, the exogenous hormones should not harm a developing pregnancy if she desires pregnancy continuation.

Other office-visit tasks

Contraceptive visits are often a time to review other aspects of a woman’s health. The Centers for Disease Control and Prevention’s 2016 U.S. Selected Practice Recommendations for Contraceptive Use (SPR) advises against withholding contraception for breast exams, pelvic exams, sexually transmitted infection testing, or cervical cancer screening. Though the SPR does recommend blood pressure measurement prior to starting estrogen-containing methods, women could use assessment from a recent health care visit or perform a self-measurement at a pharmacy or at home.

Cost

Decreased cost could be an additional benefit of OTC hormonal contraception since women would avoid office visit fees. The Affordable Care Act (2010) provided a federal contraceptive coverage guarantee that required private health plans to cover all 18 methods of FDA-approved contraception without co-pay or deductible. General insurance coverage was also extended to dependents under the age of 26, spanning a large number of adolescent and adult contraceptive users. Some states expanded contraceptive coverage, with 20 states and Washington, D.C., requiring insurers to cover dispensation of an extended supply of contraception at one time. Given recent attempts by the current federal administration to weaken the contraceptive coverage guarantee, women may face cost concerns about whether their method is obtained with a prescription, from a pharmacist, or OTC. For policymakers, transitioning hormonal contraception to OTC status should not free it from insurance coverage. The place that a woman accesses her method should not be linked to the amount an insurance company will cover for the same medication.
A South Korean prospective study has concluded that an injection of port-site bupivacaine hydrochloride following gynecologic laparoendoscopic single-site surgery (LSSS) does not provide any additive effect in alleviating postoperative umbilical pain.

The study in Obstetrics & Gynecology Science comprised 200 consecutive patients who underwent LSSS between October 2018 and February 2019 at the National Health Insurance Service Ilsan Hospital in Goyang, South Korea. Patients were alternatively assigned to either the study group, which was 0.25% 10-mL bupivacaine hydrochloride injection at the 1.5-cm umbilical incision site after removal of the wound retractor, or the control group of no injection. In addition, all patients were afforded routine intravenous patient-controlled analgesia (IV-PCA).

The primary outcome was post-operative umbilical pain scores using the visual analog scale (VAS). A trained nurse practitioner blinded to bupivacaine usage collected all the VAS scores.

After adjusting for various confounding variables, differences in post-op umbilical pain scores measured at postop 2 to 3 hours, 6 to 10 hours, 1 day and 3 days were non-significant between the two groups. However, there were significant differences in clinical characteristics between the bupivacaine injection group and the non-injection group: mean age (49.2 and 44.3, respectively), body mass index (BMI) (25.1 and 23.7 kg/m², respectively) and menopausal status (31 menopausal patients vs. 19 non-menopausal patients, respectively).

The most frequently performed surgery was hysterectomy, representing 126 cases, of which 102 were performed with LSSS and 24 with robot-assisted LSSS.

Mean operative time was 99.4 minutes in the bupivacaine injection group and 109.2 minutes in the non-injection group. But there were no differences in blood loss during surgery, perioperative complications, hospital stay after surgery or time of flatus between the two groups.

In subanalysis, postoperative pain scores were compared between LSSS (n = 157) and robot-assisted LSSS (n = 43) procedures. After adjusting for the confounding variables of patient age, BMI, parity, menopausal status, American Society of Anesthesiologist (ASA) score, comorbidities, type of surgery performed, need for additional trocar usage, and bupivacaine injection, the pain score at the time of return to the ward was significantly higher in the robot-assisted LSSS cases than in the LSSS cases: 4.6 vs. 4.0 (P = 0.013).

This difference in pain scores persisted at the evening round on the surgery day: 3.9 for robot-assisted LESS compared to 3.3. for LESS (P = 0.021).

"Previous reports on the effectiveness of trocar-site local anesthetic in-
jection in LSSS included only adnexal procedures lasting less than 1 hour, and the role of port-site bupivacaine injection in more complex surgeries with longer operation times accompanied by comparatively higher postoperative VAS scores remains uncertain,” wrote the authors.

As noted, for the current study, the most commonly performed procedure was hysterectomy, not adnexal surgery, and operative time was longer for cases in the current study than in previous studies of adnexal surgeries.

Although bupivacaine hydrochloride is a relatively safe local anesthetic, cardiotoxic and neurotoxic symptoms may occur.

Further studies of various postoperative pain modulators, including liposomal bupivacaine, might help more effectively manage postoperative pain in LSSS. Meanwhile, the authors caution against routine use of postoperative trocar-site bupivacaine injection as a way to reduce postoperative incisional pain.

Bob Kronemyer is a freelance writer for Contemporary OB/GYN.

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How physician ‘burnout’ gets the real problem wrong

Wendy Dean, MD, the founder of Fix Moral Injury, discusses why the term “burnout” does not encompass the full scope of the problem, and what can be done to address physician career dissatisfaction.

MedicalEconomics.com/view/how-physician-burnout-gets-real-problem-wrong

Dr. Emily Miller of Northwestern Medicine in Chicago has been involved in what may be the most interesting clinical findings to date for the impact of COVID-19 to pregnancy.

BY ANGIE DE ROSA
contemporaryobgyn.net/view/covid-19-and-pregnancy-dr-emily-miller

Dr. Kristina Adams Waldorf of the University of Washington in Seattle is a professor of obstetrics and gynecology there, in addition to being a world-renowned expert on infections in pregnancy.

“Pandemics are with us and emerging pathogens are with us to stay,” Dr. Adams Waldorf has said. “If we can develop systems any infrastructure to study the effect of emerging pathogens on pregnant women and newborns then I think that we will save ourselves some effort for future pathogens.”

BY ANGIE DE ROSA
contemporaryobgyn.net/view/video-series-dr-adams-waldorf-covid-19-pregnancy
Canadian researchers say that prepregnancy elevated levels of hemoglobin A1C—even below thresholds for diabetes mellitus (DM)—may increase risk of severe maternal morbidity. The findings are from a population-based cohort study published in PLoS Medicine.²

The main cohort included 31,225 women aged 16 to 50 with a hospital live birth or stillbirth from 2007 to 2015 who had an A1c measured within 90 days before conception. Of the cohort noted, 90% (28,075) had no known prepregnancy DM.

Cut-points used to diagnose diabetes were A1c < 5.8% for normal, 5.8% to 6.4% for prediabetes, and > 6.4% for DM.

The main outcome was severe maternal morbidity or maternal mortality from 23 weeks’ gestation up to 42 days postpartum. Poisson regression was used to generate relative risks, with adjustment for maternal age, multifetal pregnancy, world region of origin, and tobacco/drug dependence.

Severe maternal morbidity or death occurred in 682 births, with a relative risk (RR) of 1.16 (95% confidence interval [CI] 1.14 to 1.19; P < 0.001) per 0.5 increase in A1c and 1.16 (95% CI 1.13 to 1.18; P < 0.001) after adjusting for the covariates. The adjusted RR was increased among those with and without prepregnancy DM (1.11, 95% CI 1.07-1.14; P < 0.001 and 1.15, 95% CI 1.02 to 1.29; P < 0.001, respectively). The adjusted RRs for body mass index and chronic hypertension and prepregnancy serum creatinine were 1.15, 95% CI 1.11 to 1.20; P < 0.001 and 1.11, 95% CI 1.04 to 1.18; P = 0.002, respectively.

Looking at specific A1c levels, the authors found that in women with a preconception level of 5.8% to 6.4%, the adjusted RR for severe maternal morbidity or death was 1.31 (95% CI 1.06 to 1.62; P = 0.01), for A1c > 6.4% it was 2.84 (95% CI 2.31 to 3.49; P < 0.001), each relative to an A1c < 5.8%. In women with an A1c of > 6.4% who did not have prepregnancy DM, the adjusted RR for severe maternal morbidity or mortality was 3.25 (95% CI 1.76 to 6.00; P < 0.001).

The authors said this research “underscores the importance of identifying women with any degree of prepregnancy hyperglycemia, given their higher risk of severe maternal morbidity.” They noted that their approach was novel, in that they bundled indicators of SMM [severe maternal morbidity] into those likely, possibly, and unlikely to be related to preconception A1c. “Not all indicators have the same association with A1c,” they concluded, “which may direct future research and potential initiatives to reduce SMM.”

Bob Kronemyer is a freelance writer for Contemporary OB/GYN.

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Introducing Dr. Millennial

Bridging the generational gap in the physician workforce

by KRISTA WAGONER, MD

Objective and Gynecology has undergone notable change in the last few decades: advancement in sub-specialties, greater diversity in practitioners, liability, robotics, and much more. The healthcare industry overall is experiencing an historic transformation that is impacting many facets of medicine. Patients’ expectations, communication, access to health information, and desire for transparency and accessibility are just a few of the many aspects that are different today than they were a short time ago.

In the midst of the proliferation of the Internet and related technologies, the Millennial generation emerged in the workforce, and according to the U.S. Bureau of Labor Statistics, Millennials will comprise 75% of employees by 2030. Generational awareness and proactive adaptations are paramount to enhance relationships among providers and patients and to maximize the attributes of each respective workplace age group.

Understanding generations

Generations are defined as cohorts of people born in a span of roughly 15 to 20 years that are influenced and often characterized by the social, economic, and political events that occur during their formative years. These experiences help to shape a common system of beliefs, attitudes, and values held prominently within each group. Generations are often named by pop culture and the media, however, the United States Census Bureau defined one generation, the Baby Boomers.

The current healthcare workforce is composed of members of the Silent Generation (born 1928-1945), Baby Boomers (1946-1964), Generation X (1965-1980), and Millennials (1981-1996). Members of Generation Z (1997-2012) are just beginning to enter medical school and careers in healthcare (Figure 1). Although each generation has stereotyped descriptors, it is important to acknowledge that individual members may not always demonstrate these characteristics or self-identify with their own generation, depending on unique cultural conditions and life experiences.

Figure 2 summarizes the characteristics, experiences, innovations, and workplace attitudes for each generation. Members of the Silent Generation were children of crisis; their formative years occurred during the Great Depression and World War II, and thus birth rates were the lowest of any generation. The Silent Generation came of age in an era of great scarcity and austerity and are known to be hard-working rule-followers who value stability and avoid rocking the boat. Early in their careers, members were thought to be happy to have a secure job, even if it was not the most desirable, and loyalty kept their noses to the grindstone. For many, this loyalty holds fast today.

Baby Boomers were born during social and political upheaval but were also raised during a period of economic prosperity. They are characterized as competitive and ambitious, and are high-achieving, goal-oriented employees. Striving towards and realizing the American Dream was a priority for many. Baby Boomers live to work, and many continue to work beyond the typical retirement age due to the joy they find in their occupations.

Resourceful and self-sufficient, Generation X’ers were dubbed “latch-key kids”; both parents often worked outside the home, so members of this generation looked after themselves

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and their younger siblings. Many saw their mother and father divorce and were raised in single-parent households. Having witnessed the workaholic approaches of their Silent Generation or Baby Boomer predecessors, Generation X’ers have a mantra of “work to live” and value a more flexible work environment.

Millennials are the first generation to have been immersed in digital technology early in life; many had computers in their classrooms and were natural adopters of electronic modes of communication. Their parents tended to be protective and very involved; “helicopter” and “snowplow” parents are widely used descriptors. Millennials are the most educated of any generation; nearly 40% of millennials have a bachelor’s degree or higher, compared with 15% of the Silent Generation. Members of this cohort are marrying later, starting families later, and are the most racially and ethnically diverse generation in the history of the workforce. More than any other generation, Millennials are in search of a work-life integration that grants both personal and professional fulfillment.

Communication/learning

From house calls to smartphones, communication among members of the healthcare team and with patients has varied widely over the last several decades. While members of the earlier generations may recall a time when house calls were not unheard of, the evolution of clinical productivity standards now demands that physicians from all generations embrace email and increasingly text messaging. Even the telephone is quickly becoming obsolete as practitioners seek to both deliver and consume communication asynchronously, sending and receiving when time allows. Millennials who came of age during the smart machine revolution, which began around the turn of the 21st century and is ongoing, strongly prefer and are hastening the adoption of more modern communication regimes. Millennials often expect this type of communication to be the norm, and it is not uncommon for them, when joining a practice, to start a group text thread among partners that they use freely at all hours of the day and night.

Just as the lines of communication are being redrawn, perhaps more uncomfortable for some, the traditional clinical chains of command are being blurred by younger and confident members of later generations. Years ago, it would have been improper for a medical student to address an attending by their first name, but some new attendings actually prefer and invite trainees to dismiss formalities. This type of disregard for hierarchy sends ripple effects throughout academic departments and practices that are tolerated differently based on organizational philosophy and cultural acceptance of change. A side effect of the gradual dissolution of hierarchy may be an exaggeration of ambiguity in how trainees and colleagues of different generations perceive workplace mistreatment by both peers and superiors.

Team-based approaches to learning and problem solving have been hard-wired into newer generations. While most can easily conjure images from childhood of a favorite teacher at the chalkboard espousing wisdom to the masses, Millennials experienced the beginning phases of an ongoing reformation of classroom teaching that more heavily emphasizes problem-based learning in peer groups. Recognizing that collaboration in the healthcare workplace is natural and necessary, many medical schools have trended in this direction, as well. This evolution of teaching and learning has broad implications for how generations of physicians relate and work together. Millennials, for example, may have learned to frequently seek out the opinions of various care-team members while earlier generations might have been trained to make decisions based more on their own understanding and experience.

Work-life integration

What is work and what is life? There are thousands of articles on work-life
“balance,” “fit,” “blend,” and “integration.” The ratios of time and energy spent on personal and professional endeavors may vary not only by generation but also depending on stage of life. The values of any one member of a generation may change as the milestone events of life unfold. What remains constant, however, are the positive professional and personal benefits of sustained maintenance of self-care. Many are familiar with pre-flight instructions that advise passengers to don their own oxygen masks before assisting others; if providers aren’t mentally and physically healthy themselves, how can anyone expect them to care for their patients effectively?

Just as generation and stage of life are important determinants of values, gender cannot be overlooked. Today, more than half of ob/gyns are women, and over 80% of medical students who match into the specialty are female. Compare these numbers to 1970 when 93% of ob/gyns were men. And in 1970, many male physicians were not also responsible for caregiving and domestic duties. Women in medicine are almost twice as likely as men to have partners who are employed full-time (86% of females versus 45% of males). Females in medicine with partners and children reported spending an average of 8.5 hours more on parenting and domestic tasks than their male counterparts each week.

Physicians feel they are being asked to do more with less. There never seem to be enough hours in the day to complete work responsibilities, let alone adequate time for family and pleasure. And while it may be easy for some to dismiss these sentiments as an insufficient work ethic in younger generations, one must carefully consider the disruptive transformation of modern healthcare delivery that is significantly influencing the dynamics of work-life integration. Volumes could be devoted to an exploration of how this topic impacts other vital industries just as acutely as medicine, but take for example the mass exodus of teachers from the K-12 education arena. Only in recent history have regulations led to a demand for student recordkeeping so burdensome that the careers of many educators are extinguished prematurely. The original meaning many teachers sought from a profession once regarded as a cornerstone of our society is being increasingly eroded, and this is a refrain that sounds all too familiar to many physicians today.

Whether symptoms of burnout have actually increased dramatically, or there is now more attention called to exhaustion, or both, job flexibility that allows for some work-life integration is highly valued, especially by younger generations. This begs the question: Is it possible to achieve work-life balance as a physician? Understandably, there will be less of a balance and more of a blend as an ob/gyn, but creative solutions are imperative to ensure the feasibility of fulfilling both home and work responsibilities, within reason. Further, these adaptations play a critical role in preventing exacerbation of the upcoming physician shortage by doctors who don’t maximize their career potential and instead retire early, decrease to part-time or less, or even change careers. One would assume that shifting careers from a physician to a different profession was previously unlikely, but Millennials and likely future generations perceive their careers to be less de-

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<td><strong>Characteristics</strong></td>
<td><strong>Social Experiences</strong></td>
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<tr>
<td>Silent Generation</td>
<td>All work, no play; obedient</td>
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<td>Baby Boomers</td>
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<td>Millennials</td>
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fining of their identities. As mentioned, professional and personal fulfillment are highly regarded by Millennials. As such, opportunities to develop hobbies, devote time to family and friends, and volunteer in the local community and beyond will need to be recognized and supported by employers to ensure satisfaction and stability in the workforce.

Reverse mentorship can offer mentees advice on electronic health record efficiency, template sharing, app utilization, website and social media presence, and more.

Formal mentorships are excellent resources for physicians in every career stage. These relationships can be created in departments and practices, or through utilization of the American College of Obstetricians and Gynecologists Mentor Program, especially when local connections are more limited. As mentors and mentees begin to exchange viewpoints and develop relationships, generational understanding is naturally achieved, reinforced, and enriched.

OFFER FLEXIBILITY
Opportunities for flexibility in scheduling can be employee-friendly and also patient-friendly. Consider offering evening or weekend office hours a few times per month, which are highly desirable to Millennial patients. Members of younger generations may gladly exchange morning hours for evening hours on occasion, as this may afford the opportunity to be involved in school activities for their children or errand-running that is otherwise not possible with a traditional physician schedule.

Similarly, setting up a practice to offer and receive reimbursement for e-visits or video visits is another convenient way to efficiently deliver healthcare. This can allow for occasional windows of time to work outside of the traditional office setting or even from home. Though Obstetrics and Gynecology may be more limited than specialties such as Psychiatry in the visit types that can be offered electronically, opportunities do exist and will become more commonplace as generational demand increases.

Laborist and gynecologic hospitalist models have increased patient safety and can provide unique appeals of acute, inpatient medicine and defined shifts."* Though these models lack the benefit of patient continuity, both junior and senior physicians, as well as many practices, find this to be an attractive alternative to relinquishing obstetric services earlier in a career than desired and can also increase productivity in the office.

CREATE COLLABORATIVE ENVIRONMENTS
Encourage input from all generations when crafting new policies and procedures and in solving problems. Harnessing the creativity of the group is likely to yield different perspectives and invoke innovation. When meeting together, all generations will appreciate a clear agenda with defined and respected start and end times. Consider whether an email or text thread would be just as effective and more efficient than face-to-face contact. Leaders should strive to acknowledge the attributes and perspectives of each generation to achieve harmony and maximize productivity.

As we strive to enhance our relationships with our colleagues and patients, it would benefit us all to consider the values, characteristics, and experiences of every generation. With some effort, generational gaps can be narrowed and ob/gyns of all ages will thrive at home and at work and continue to deliver high-quality care to our patients.

FOR REFERENCES VISIT contemporaryobgyn.net/drmillennial

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A generational divide may seem inevitable; however, gaps can be narrowed with effort.

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Shoulder dystocia: The unpredictable nightmare

This case involves induction of labor for a suspected large for gestational age (LGA) baby in a mother with a normal antepartum course.

A 21-year-old G2P1001 was admitted on July 28 at 38 weeks, 4 days’ gestation for labor induction for a suspected large for gestational age (LGA) baby. The patient’s original estimated date of deliver was Aug. 22. An ultrasound at 19 weeks, 6 days adjusted her date of delivery to Aug. 7. The patient had a normal antepartum course, with normal antenatal screening, and normal glucose screening at 28 weeks’ gestation.

Two years earlier, the patient had given birth to an 8 lb, 10 oz male at term via an uncomplicated vaginal delivery with a three-degree extension.

During the current pregnancy, she was admitted at 33 weeks 0 days for possible preterm labor. Visual exam revealed a friable cervix, with *Trichomonas vaginalis*. The patient was observed for approximately 21 hours, during which she received a dose of subcutaneous terbutaline, which led to diminished contractions, without significant cervical change. She was given a course of steroids and discharged on clindamycin and metronidazole.

On admission for labor induction on July 28, the patient’s diagnosis was advanced cervical dilatation and LGA. The admission history and physical documented a vertex presentation, with a cervix 3-cm dilated, 50% effaced, and a -2 station. The woman’s pelvis was described as “adequate.” Documentation did not include an estimated fetal weight (EFW). Induction proceeded with intravaginal prostaglandins, inserted at 7:30 am, with regular contractions beginning approximately 40 minutes thereafter. Fetal heart tones (FHTs) revealed a Type 1 pattern, with a baseline fetal heart rate (FHR) in the 140s. Augmentation of the patient’s labor with oxytocin was begun, at 2 mU/min. Approximately 4 ½ hours later, at 12:05 p.m., the physician examined the patient. At that time, with oxytocin at 12 mU/min, her contractions were every 1 to 2 minutes, 60- to 70-mmHg in strength, with a continued Type 1 pattern. Her cervix was 4-cm dilated, 50% effaced, at a -2-3 station, with an occiput posterior position. Amniotomy revealed a small amount of clear fluid, and an internal FHR electrode was placed. An epidural was placed shortly thereafter. At 1:55 pm, with oxytocin at 12 mU/min, the patient’s cervix was 7- to 8-cm dilated, 90% effaced, at a 0+1 station. FHTs were in the 140s and, despite minimal variability, no decelerations were observed. At 3:45 pm, examination revealed a cervix with an anterior lip. No mention was made of the fetal station. The patient began pushing at 4:45 pm. FHTs were stable. The physician remained in the room while the patient pushed. Severe variable decelerations to the 60s started at 5 pm and the head was delivered at 5:10 pm and spontaneously rotated from right occiput posterior to occiput anterior position. The body did not immediately deliver. A McRoberts maneuver was used for 2 minutes and various maneuvers were performed to resolve a 6-minute shoulder dystocia. Fundal pressure was applied to assist with delivery of the body, which was

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accomplished at 5:18 pm. An 11 lb, 12 oz (5335 g) male was delivered with Apgar scores of 1, 6, and 8, at 1, 5, and 10 minutes, respectively. The arterial cord gases were pH = 7.19; pO₂ = 23; pCO₂ = 60; base excess = -7.0.

The delivery note, timed at 6:20 pm, documented the following:

- Mediolateral episiotomy
- Anesthesia in room
- Maneuvers (initially all unsuccessful)
  1. McRoberts
  2. Slightest amount of downward traction
  3. Rotated ant shoulder posteriorly
  4. Rotated post shoulder anteriorly
  5. Posterior arm delivered to shoulder
  6. Suprapubic pressure
  7. Attempt to fracture clavicle
  8. Assistant
  9. Aided with delivery of anterior shoulder
  10. Body dystocia
  11. Then, and only then, first application of fundal pressure

Also described was an appropriate repair of a three-degree extension.

Subsequently, placental pathology revealed focal, mild, chronic non-specific chorionitis.

The newborn examination revealed bruising of the baby’s ears, face, chest, and right underarm. The right underarm bruising was consistent with traction to the armpit. There was no movement of the left arm. The left shoulder was noted to be “normal,” while the pediatrician could not rule out a dislocation of the right shoulder. The left shoulder would have been the anterior shoulder at time of delivery. The baby had a low blood sugar at 37 and required an infusion of dextroxx 10% in water.

The baby was transferred to an academic medical center. The admission physical revealed no movement of the left upper or lower arm. Radiologic studies revealed no dislocation of the left or right shoulder. Magnetic resonance imaging revealed avulsion of the nerve roots on the left at C8 to T1, with mild displacement of the cord to the right. There was a possible subarachnoid hemorrhage. A cranial ultrasound was normal. Computed tomography of the head revealed no evidence of intracranial hemorrhage or displacement of the midline sutures. There was swelling on the right side of the face with minor asymmetry of the coronal suture.

A neurology consult confirmed Erb’s palsy, with a significant avulsion injury and complete left brachial plexus palsy. The neurologist opined that other roots may be torn more distally. There was probable right Horner’s syndrome, right torticollis, and a hoarse voice suggestive of laryngeal paresis.

Despite intensive physical therapy, there was no recovery of the function of the left upper extremity over 5 months, associated with mild ptosis of the left eyelid and ipsilateral pupil, consistent with Bernard-Homer Syndrome. The baby was referred to a pediatric neurosurgeon at another academic institution and underwent left brachial plexus exploration and external and internal neurolysis approximately 11 months after birth. Nerve grafting was not performed, as intraoperative electrical stimulation of the musculocutaneous nerve produced some visible and palpable contractions of the biceps brachii, and stimulation of the accessory nerve produced a similar response of the left deltoid muscle. Six weeks after surgery, the child was able to partially extend the elbow and flex his fingers. However, there was no flexion at the elbow or extension of the fingers.

Neurosurgery follow-up 4 months later (5 months postoperatively) identified no further recovery. The child continues with physical therapy.

There was a possible subarachnoid hemorrhage. A cranial ultrasound was normal.

A lawsuit was filed against the obstetrician claiming:

1. Negligence in inducing the patient;
2. Negligence in not offering the patient a primary cesarean delivery;
3. Negligence in management of the shoulder dystocia;
4. Damages including long-term care of the child, required long-term physical and occupational therapy, current and future pain and suffering, loss of future earnings, as well as emotional distress of the parents, and loss of consortium.

Following discovery, the defense elected to proceed with trial, as the case was deemed highly defensible.

At trial, the plaintiff’s experts noted that induction of labor for a LGA baby is not recommended by the American College of Obstetricians and Gynecologists (ACOG). Lack of an estimated fetal weight, either clinically or with ultrasound, was a breach of the standard of care. Had the physician estimated the weight as at least 5000 g, a primary cesarean delivery should have been pursued. Even with an estimated fetal weight > 4500 g, the risk...
of shoulder dystocia is up to 50%. The baby suffered permanent irreversible injuries that will require long-term physical and occupational therapy. The child will never have a normal life.

The defense experts testified that shoulder dystocia cannot be accurately predicted or prevented. None of the risk factors for macrosomia were present in this case, including preexisting diabetes and gestational diabetes, maternal obesity, excessive gestational weight gain, or abnormal antepartum glucose screening. The patient’s first baby weighed 8 lb, 10 oz or 3934 g and was delivered vaginal without difficulty. There was no clinical evidence of macrosomia, noting that the fundal height at 38 weeks was 39 cm.

Although an estimated fetal weight was not documented, the obstetrician deemed that the mother’s pelvis was adequate, evidence that there was consideration of the estimated fetal weight. Clinical and ultrasound estimates of fetal weight are poor indicators of actual fetal weight. Ultrasound is, at best, accurate to within 10% in estimating weight, and worse with larger babies.

Induction of labor is controversial. Earlier studies show an increased cesarean rate without a significant reduction in shoulder dystocia. Recent studies show induction of labor results in a four times reduction in the rate of shoulder dystocia. Regardless, even a primary cesarean delivery does not eliminate the risk of birth trauma and neonatal brachial plexus injury associated with macrosomia.

Further, most macrosomic babies do not experience shoulder dystocia. Finally, brachial plexus injuries can occur as a result of intrauterine positioning, not just a result of a shoulder dystocia.

The patient rapidly entered active labor following induction. She did not experience a prolonged labor, a prolonged second stage, nor was operative delivery required. Once the shoulder dystocia was encountered, all maneuvers were appropriate. The shoulder dystocia lasted 6 minutes, which is not an extended time. The umbilical cord gases were normal, evidence that the baby did not suffer any hypoxic compromise. The clinician’s contemporary documentation was excellent.

During rebuttal, the plaintiff’s experts again criticized the care, particularly the lack of documentation of an estimated fetal weight. If the estimated fetal weight had been less than 5000 g, attempting a vaginal delivery could have been justified. However, had the estimated fetal weight been 5000 g or greater, according to ACOG, a primary cesarean delivery should have been performed. The baby weighed 5335 g and thus, a cesarean delivery should have been performed. Further, in managing the shoulder dystocia, the documentation states, “the slightest amount of downward traction” was applied. Avulsion of the nerves does not occur without the application of excessive, improperly directed force. Avulsion injuries are not a result of intrauterine positioning. The baby has permanent injuries with paralysis of the left arm and distortion of his face, which will result in lack of social acceptance in the future.

Defense experts testified that ACOG only states that a scheduled cesarean delivery may be beneficial and does not mandate that it be performed. The ACOG recommendations are based on expert opinion, not randomized trials. During the reparative surgery, there was evidence of some nerve conduction, thus the current disabilities may still respond to therapy in the future.

After 6 hours of deliberation, the jury found for the plaintiff, awarding $3.5 million.

Case analysis
This case was defensible, except for two major issues: the lack of a preinduction estimated fetal weight and the resulting nerve avulsion. The lack of an estimated fetal weight is not uncommon in shoulder dystocia cases resulting in litigation. Even though inaccurate, a clinical or ultrasound-based estimated fetal weight should be included in the initial assessment of all patients, whether for induction or in labor. Documentation of an estimated fetal weight, even if inaccurate, renders cases more defensible. Lack of such documentation, as in this case, is a major obstacle to successful defense. Avulsion of the nerve roots on the left at C8 to T1 was an additional impediment to successful defense. Plaintiff attorneys who frequently litigate shoulder dystocia cases often pursue only cases with nerve avulsion, as the forces required to cause avulsion have been shown to exceed the forces associated with the typical maneuvers used to manage shoulder dystocia. Further, avulsion injuries rarely recover spontaneously and require early surgical intervention, which if not successful, result in permanent disabilities. Finally, the presence of the child in the courtroom throughout the trial was a constant visual reminder of his life-long disabilities.

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