GYNECOLOGY

Surgical simulators
A roundtable discussion

WITH

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THE EDITORS ARE PLEASED TO ANNOUNCE the availability of our new parent company’s continuing education activities. We’ve picked this one especially for our readers - http://bit.ly/LeveragingImmunogenicity

Let us know what you think: Email us at COGEditorial@mmhgroup.com
Fake news in ob/gyn

As patients are exposed to more and more misinformation, ob/gyns have a responsibility to not just treat but also educate.

"Facts" about women’s health that are simply untrue can wreak havoc with the doctor/patient relationship but ob/gyns can help protect women from taking clickbait.

The term “fake news” has dominated our political landscape for the past 3 years, but it has a long and infamous history. The “yellow journalism” that infested the coastal cities in New York and California at the turn of the 20th century was believed to have led to the US entry into the Spanish-American War.1 The remnants of this type of sensational print reporting can still be seen in supermarket tabloids, with ludicrous headlines about alien abductions and other nonsense.

The new normal for many of us is that we get our daily information about the world around us from our personal computers, those devices that are always, always attached to us and that can also make phone calls. The sites from which we seek information often require minimal to no verification. To continue to exist, they must maximize their “hits” to generate advertising revenue. The site and the advertisers, depending upon exactly how we have logged in, next use our pattern of clicks to feed us more and more information geared to our apparent personal tastes, as deciphered by a machine-learning algorithm. The eventual result is a barrage of information that contains variable and unknown amounts of disinformation—“fake news”—that we either sift through and try to verify (very rarely), accept and await verification from a second source (hazardous when your content is being curated by a computer that is trying to give you what it thinks you want see), or sink into a funk of cynicism and disbelieve of everything and disengage (common response).

Our inherent belief in our rational ability to sort information, especially when it is now vast and readily accessible, is not well founded.2 We are, therefore, all vulnerable to defective processing and acquisition of “facts” that are simply untrue. As we become further and further insulated within our Internet-curated bubble of beliefs, we may also choose to call unwanted information feeds “fake news” even when they are true, because they don’t appear representative of all else we have been reading. Clearly, the hazards of these patterns of behavior are evident in many walks of life and are considered responsible for our current deeply divided political atmosphere.

Obstetrics and gynecology is a very personal and powerful field. We are privy to the most private details of our patients’ lives and have the ability to influence future generations with actions that we take today. The trust relationship that we have with our patients is essential to our effectiveness. The ability of fake news to wreak havoc with this trust relationship is a threat to our life’s work that can be, at times, simply annoying, but can take some very negative turns. What follows are a few examples that illustrate “fake news” in its various forms.

1 Women no longer have to endure the ravages of menopause! (Part 1)

Just a few weeks ago, The Guardian published a story online touting a new medical procedure that “could delay menopause by 20 years”.3 Two smiling, jogging midlife women are shown. The procedure promises to
FAKE NEWS

improve women’s lives by “delaying the onset of more common symptoms of the menopause, which range from low mood, anxiety and difficulty sleeping, to hot flushes, night sweats and a reduced sex drive.” But that’s not all! “Doctors claim the operation could benefit thousands of women who experience serious health problems, such as heart conditions and bone-weakening osteoporosis, that are brought on by the menopause.”

WAIT, WHAT?!? Something has gone wrong in the worldwide race for clicks if we are talking about creating a world where menopause occurs at age 70+. Prolonged lifetime exposure to estradiol and progesterone is associated with increased risks of breast and endometrial cancer—risks that have been appreciated for many decades. Cardioprotection from extended ovarian function is far from proven. How can a responsible news source overstate the benefits of such a procedure? How many women would—seriously—want to undergo ovarian transplantation, which includes two surgical procedures, to delay menopause? What if the ovaries are replaced in a position where they might result in pregnancy? And decades more of menstrual periods? Ahem, no thank you.

2 Women no longer have to endure the ravages of menopause! (Part 2)
The Wonderful World of “Bioidentical Hormones” is another area where “fake news” abounds unfettered by any reality. Due to the lack of regulation and oversight for compounded hormones (which were exempted from being considered pharmaceuticals but rather are considered dietary supplements, thanks to the Dietary Supplement Health and Education Act of 1994—thank you, Senator Orrin Hatch), there is almost no need whatsoever to provide any proof of claim, and penalties for false advertising are rarely imposed. Here are some claims made by various websites:

- Synthetic hormones have a variety of negative side effects, but our approach to bioidentical hormone therapy, also known as BHRT, can help you avoid these.
- Many women begin to feel the negative effects of hormone imbalances years before menopause…Our goal is to relieve the unwanted symptoms of aging caused when hormone levels are unbalanced.

WAIT, WHAT??!?!? The “bioidentical hormone” (BHRT) industry is arguably the first and one of the most effective “fake news” enterprises in medicine. Capitalizing on the wake of the Women’s Health Initiative (WHI), which debunked the myth that estrogen and progesterone were powerful anti-aging drugs and would prevent disease, a proliferation of alternatives were born, reinventing the myth by claiming that the hormones used in the WHI were simply the wrong hormones, and the alternative products being sold had no such side effects and would, indeed, prevent aging. This marketing has been so effective that it is estimated that BHRT is currently one-third to half of the national use of menopausal hormone therapy.

3 HPV vaccines are bad for you…and the medical establishment is covering up!
The human papillomavirus (HPV) vaccine is one of the most effective weapons in the medical armamentarium against cervical cancer, and has already demonstrated unanticipated benefits in reducing anal and oral cancers. The perfect storm of “anti-vaxxers” and religious conservative forces, who fear that vaccinating a young woman against HPV will encourage sexual promiscuity, has impeded the effective implementation and widespread use of this life-saving strategy, aided and abetted by “fake news”—some of which is promulgated by politicians.

The digital era has made the rapid propagation of “fake news” more efficient than ever. By offering up emotionally charged campaigns, based on powerful anecdotes that are repeated over and over again, fake news gets our attention. Logic and facts are, well, boring when pitted against sensational clickbait. Truth gets replaced with “truthiness”: something that seems or feels like it is true (thank you, Stephen Colbert), so we just go with it.

How can we and our patients protect ourselves from the clickbait?

1. ENCOURAGE GOOD HABITS. Direct your patients to reputable sources of information at the outset of a web search. Rather than reading the first item that comes up, assuming it is the most important one, it helps to bookmark reputable websites. The

CONTINUED ON PAGE 6
AI: Coming to a clinical scenario near you

As artificial intelligence increases its presence in medicine, ob/gyns are welcoming the technology with both excitement and trepidation.

Artificial intelligence (AI) is already all around us in our daily lives. It enables smartphones to sort our pictures based on face recognition algorithms, it helps Google guess what you’re going to search for the second you start typing and it helps Uber figure out what you are willing to pay for various services.

AI is also entering medicine. That is, in part, enabled by the large amount of high-resolution digital data that are collected in electronic medical records and from images, genetic screening, and laboratory tests. The other vital component is the ever-increasing capacity of computers to analyze large amounts of data and create a solution on their own, a process called machine learning. Once implemented, machine learning algorithms can continuously improve their performance by using outcomes to improve the fit of the model. These methods have the potential to help with diagnostic accuracy, outcome prediction, cost-effectiveness assessment, and real-time decision-making in surgery.

In this issue, Han et al discuss use of AI in ob/gyn ultrasound and its potential there. As they point out, AI is especially helpful in image detection and automation. It has the potential to reduce clinician errors and help detect rare anomalies, especially among less skilled providers, thereby reducing clinician variability in terms of performance. AI also has a lot of other potential applications in our field and in all of medicine. A recent systematic review identified nine articles that spanned multiple medical subjects, including retinal diseases, skin cancers, pulmonary nodules, and brain tumors. All of these articles compared the performance of clinicians and AI and found a consistent theme. Current AI algorithm development has a diagnostic performance comparable to that of medical experts, especially in image recognition-related fields. This is especially impressive, given how fairly recently AI has been applied to medical decision-making. It seems inevitable that this technology will improve rapidly over the next few years, which should improve accuracy significantly.

This does not mean that clinicians are not needed anymore. AI is not meant to replace clinicians (at least not yet), but rather, to augment their diagnostic and therapeutic capacity. One of the major concerns for using AI in medicine is the lack of transparency about how decisions are generated and the inherent risk of bias if the training database is skewed. Some recent advances in the field aim to mitigate those risks. For example, some of the newest diagnostic machine learning algorithms are able to create saliency...
Fake news in ob/gyn CONTINUED FROM PAGE 04

American College of Obstetricians and Gynecologists, of course, is an outstanding resource, as are the Centers for Disease Control and National Institutes of Health. Many academic medical centers have readily accessible web posts on a broad range of topics in women’s health. For specialty information, the North American Menopause Society, the American Society for Reproductive Medicine, the American Society for Gynecologic Oncology, and the Hormone Health Network provide excellent, fact-based information.

2. REITERATE THE PRINCIPLES OF CRITICAL THINKING. Educate your patients on how to tell if a source is reliable. Are the data referenced and peer reviewed? Are clinical studies described? If they are described, were the studies registered under clinicaltrials.gov? Are the authors in the bibliography of a scientific piece all the same, small group of authors? This suggests an internally concatenating alternative reality may be behind the thinking.

3. BE PROACTIVE. I like to provide my patients with specific information sources on sensitive topics prone to disinformation campaigns. I anticipate that they will be consulting “Dr. Google” as soon as they leave my office. If you have an electronic medical record, you can create dot phrases for commonly asked questions and avoid rewriting this for every similar patient scenario. Having patient education materials available in your office waiting room can also be an effective way to direct your patients to reliable sources of information.

4. FIGHT BACK. Highlight for your patients some of the more outrageous examples of viral information that were subsequently proven to be untrue (e.g., the Hillary Pizzagate Conspiracy), and alert them to be critical of stories that elicit a strong emotional response. Give them tools to sort out the real from the fake (snopes.com is an excellent website for this purpose).

Like it or not, the information highway of the Internet can be a “disinformation highway” that is not under our control, but it is here to stay. Alerting patients to the pitfalls inherent in information access in this era of plentiful information may make them better at sorting it out. And like it or not, that task has now become part of our daily work if we are to promote the health of our patients. I’m off to check my Facebook feed for the week, and I hope I won’t be accosted by too many trolls!

DR. SANTORO is Professor and E Stewart Taylor Chair of Ob/Gyn, University of Colorado School of Medicine, Aurora.

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FOR REFERENCES VISIT contemporaryobgyn.net/ObGynFakeNews
What is the role of surgical simulators?

Interview by LINDA MARIE WETZEL, RN

In gynecologic surgery, surgeons are expected to acquire high levels of experience before performing surgeries, but they need to perform surgeries in order to gain experience. One proposed solution to this paradox is using surgical simulators. Here, four physicians discuss the merits of incorporating simulators into surgical training.

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**MS. WETZEL:** How do surgical simulators work and can they take the place of actual surgical procedures in training and certification?

**DR. EINARSSON:** I think simulators have potential to be very useful in training. Low-fidelity simulators—box trainers—are perfectly adequate but the science of simulation is somewhat lacking. Studies show that learner skills do improve after practice with a simulator, compared with results prior to use of the technology. To me, that’s not very surprising. I would be much more interested in knowing whether learners retain knowledge and skills gained from simulators over the long term and if that translates into superior clinical outcomes. Those are important questions and
I understand that in medicine, we use intermediate outcomes for teachability sake, but I think we need better science in simulation.

**DR. MUNRO:** I agree that the science needs to be better. Many people think that surgical simulation means going into a virtual environment and simulating an entire operation. However, we are nowhere close to having realistic immersive simulation in which a learner can actually work on a virtual patient with a spectrum of virtual anatomical and pathological circumstances. Instead much of what we have is simple technology that simulates parts of the task or skill that we believe are useful, circumstances that may reflect something about the physical abilities of the individual. And this sort of simulation doesn’t take into account surgical judgment. Truly meaningful outcomes with simulation would include the impact of simulation-based training on safety, efficacy, quality of life, cost reduction, or some combination of those. But assessing these outcomes would be quite expensive. So important questions facing us right now include: Who are the stakeholders for surgical simulation and where is the funding going to come from to study real-world outcomes?

**DR. MOAWAD:** I have a different perspective on simulation. Simulations are not going to create the surgeon but they can help enhance hand/eye coordination and ambidextrous surgery, among other things, and facilitate the learning curve and help with team-building and managing complications. I believe that the value of simulation lies in shortening the learning curve for the learner and providing a safe environment in which it’s permissible to make mistakes, explore what went wrong, and ask questions.

**DR. MUNRO:** Where possible, we also have to try to determine outcomes for simulation training that are meaningful and that will guide us in designing the technology and the way in which it’s used. Simulation is a part of an overall change in the training paradigm that spans a range of components of care such as determining who to operate on and how the surgeon should be prepared to execute the technical aspects of performing the procedures. Our disease state management is basically that of uterine and adnexal disease so our training has to be in that context.

**MS. WETZEL:** What kind of simulators are currently available and what do practitioners need to know about using them? Which simulators do you prefer and why?

**DR. EINARSSON:** A lot of different simulators are available. The simplest are low-fidelity trainers that are basically a box with a small camera and a light, into which instruments can be placed to practice. The box trainer most widely used right now is the FLS Trainer. And then you have virtual reality (VR) trainers that try to simulate more procedures than the actual intraoperative environment. I really like the box trainers because they’re relatively inexpensive and can be used in different places and under varying conditions to gain dexterity and experience with techniques such as intracorporeal and extracorporeal mopping. Developing VR trainers that are meaningful is money- and resource-intensive. We had a VR trainer at our simulation center and every time I used the ectopic pregnancy module, the patient bled to death. I’ve never had a patient bleed to death in real life from an ectopic pregnancy. So, I think that there’s still some developmental work that needs to be done on VR surgical trainers.

**DR. MUNRO:** I think the first consideration is framing what is it that you’re simulating. In gynecologic surgery, we have abdominal access, both laparotomic and laparoscopic approaches, the latter done with and without microprocessor assistance. Vaginal approaches include hysteroscopic technique and surgery on the cervix and,
hysterectomy when removal of the uterus is necessary. Should all of those aspects be simulated for residency training? The American Board of Obstetrics and Gynecology (ABOG) has acknowledged the importance of simulation-based training in laparoscopy by requiring that residents in obstetrics and gynecology graduating after May 31, 2020 pass the Fundamentals of Laparoscopic Surgery (FLS) examinations developed jointly by the Society of American Gastrointestinal and Endoscopic Surgeons and the American College of Surgeons. Many residency programs, however, have trouble affording a surgical simulator unless it’s inexpensive. But there is really no evidence that VR laparoscopy trainers do a better job at what is being measured than the low-fidelity systems.

On the hysteroscopy side, VR is actually more realistic and more attainable. There are a number of quite decent VR systems for hysteroscopy and one of the reasons that it’s easier to engineer those in that the environment is like being in a small room. In the laparoscopy environment, in contrast, you have to simulate interaction with the bowel and the level of complexity is exponentially greater. Simulation is hardly being done for vaginal hysterectomy and it remains a very low morbidity procedure with no abdominal incisions, but one that requires certain skills. Simulation should be considered for the multiple approaches to and processes associated with vaginal hysterectomy to see what the likely benefit of the procedure might be. We’ve examined two low-fidelity surgical simulation systems—one for hysteroscopy and one for laparoscopy. Both can be used reasonably well by novices, mid-level trainees, people without extra training in gynecologic surgery, and people who have done a 2-year fellowship in it. Low-fidelity simulation is quite feasible, and quite usable.

**DR. MOAWAD:** If we’re going to devise surgical simulation, first we need to determine its goal. If we’re looking at training for depth perception, hand-to-hand coordination and ambidexterity, which are the basic principles of surgery, I believe that low-fidelity simulators are always the best. What they lack is the feel of real tissue and plane dissection. The latter can be learned by watching realistic videos. I think virtual simulation has a role if we’re looking at the efficiency of movements and how to maximize it. Calculations can be done about the number of unnecessary moves to establish how efficient a surgeon is.

But virtual simulations are being marketed as depicting procedures so super-realistic that training on them will give someone the ability to do the real surgery in real life. But they’re very far away from reality in many metrics. I think each simulator adds something but we need a combination of them. For example, using a bell pepper for hysteroscopy, chicken for laparoscopy, and beef tongue for suturing or tissue extraction are really very valuable in terms of immersing trainees in actively performing surgical steps on real tissue.

**DR. ASCHER-WALSH:** A few years ago, we started a research project with our insurance carrier with the eventual goal of trying to find a simulator for use for credentialing or for continuation of privileges. We tried a lot of simulators and decided on the Surgical Science simulator because we thought it was as close to real life, at that time, as we could find. But, there’s really nothing that mimics real surgery, although some of the newer simulators have tactile feedback. My perception is that simulation is good for learning the steps of a procedure, and it may help people who didn’t grow up playing video games to develop the hand/eye coordination necessary for laparoscopy. However, we’re far from using it learn the intricacies of surgery and create talented surgeons. Things like tissue planes, which experienced surgeons see innately don’t really exist within simulation at this point.

**DR. MUNRO:** I think we may potentially be able to use simulation to help identify who should or shouldn’t be admitted to surgical training programs. Ability to use a surgical simulator could be a criterion for entry, either into residency or into a fellowship. For years now, in North America, dentists have had to demonstrate manual dexterity in order to get into dental school. I don’t know what evidence the dentists had when that criterion was introduced, but it doesn’t matter how smart you are if you can’t do a good job with manual skills. Simulation-based testing also could function as a formative examination for surgical skill, a skill-based component of the CREOG in-training exam (ITE). The ITE is administered to residents annually to evaluate their cognitive abilities.
knowledge but we have no equivalent for surgery. As was previously mentioned, ABOG will now be requiring that residents in obstetrics and gynecology pass the FLS examinations that were designed for general surgeons. But the only component of gynecologic surgery that’s tested under FLS is laparoscopy and, if we’re restricted to that, then we’re creating one-arm surgeons. There is no testing for hysteroscopy, vaginal surgery, or laparotomy. Maintenance of certification also is another possibility for simulation-based testing. And simulation could be used to train gynecologists on use of new equipment and new techniques that are introduced, much as is done by the US military or in civil aviation. For example when new fighter aircraft are built, training and credentialing systems also are created for that machinery and are used as critical and essential hurdles to the overall process of certification. In my opinion surgical simulation based training and testing should ultimately be used in a similar fashion for surgeons of any discipline.

**DR. EINARSSON:** I think the simulators that offer the biggest bang for the buck, so to speak, are the low-fidelity simulators, which could be used to help residents pass the FLS test that will soon be a requirement for graduation. I think both graduating residents and physicians in practice should become familiar with the low-fidelity simulators. They should be made available in every ob/gyn residency program rather than virtual reality trainers, which are more expensive.

**DR. EINARSSON:** When I was a resident, I made my own simulator out of a cardboard box, a video camera - there were no iPhones then - and a flashlight. And it worked quite well. So a simulator doesn’t have to be very fancy to be useful.

**DR. EINARSSON:** I think that the most exciting thing that’s on the horizon is really the launch of the Essentials in Minimally Invasive Gynecology (EMIG) test, which has been in development for some time now by AAGL, ABOG, and CREOG. EMIG is a three-part program designed to aid and evaluate the acquisition of manual and cognitive skills in hysteroscopic and laparoscopic surgery. It includes a curriculum, written examination, and manual skills test. I hope EMIG will be integrated into clinical practice in the near future and hopefully represent a minimum standard of proficiency in hysteroscopy and laparoscopy that providers should have to meet to have the privilege of operating on patients.

**MS. WETZEL:** What other options for simulation are on the horizon and do you see simulators being integrated more completely into your own clinical practices?

**DR. EINARSSON:** The laparoscopic component of EMIG is performed the FLS box trainer, with exercise and instructions that have been adapted in a way that we believe is appropriate for gynecologic trainees - from novices to mid-level trainees to board-certified ob/gyns and also those who are training for FMIGS and other surgical fellowships. We’ve also created a relatively simple box trainer for hysteroscopy but we’re still challenged...
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LOS, length of stay; MED, morphine equivalent dose; TAP, transversus abdominis plane.

\(^1\) The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

\(^2\) A prospective, 8-site, multicenter, randomized clinical trial of 183 patients who underwent a C-section with a multimodal pain management protocol including a TAP block using either 20 mL EXPAREL, 266 mg, 20 mL 0.25% bupivacaine HCl, and 20 mL normal saline (50 mL volume on each side) for a total volume of 60 mL, or 20 mL 0.25% bupivacaine HCl and 40 mL normal saline (30 mL volume on each side) for a total volume of 60 mL.

\(^3\) Single-center retrospective trial of 201 patients who underwent C-section with either a multimodal pain management protocol including a TAP block with 20 mL EXPAREL 266 mg, 30 mL 0.25% bupivacaine HCl, and 30 mL normal saline; or a multimodal pain management protocol alone. Mean hospital LOS was 2.9 days with EXPAREL (n=97) vs 3.9 days without EXPAREL (n=89). Time to ambulation was 18.7 hours with EXPAREL (n=67) and 30.7 hours without EXPAREL (n=60).

\(^4\) Single-center retrospective trial of 201 patients who underwent C-section with either a multimodal pain management protocol including a TAP block with 20 mL EXPAREL 266 mg, 30 mL 0.25% bupivacaine HCl, and 30 mL normal saline; or a multimodal pain management protocol alone. Mean hospital LOS was 2.9 days with EXPAREL (n=97) vs 3.9 days without EXPAREL (n=89). Time to ambulation was 18.7 hours with EXPAREL (n=67) and 30.7 hours without EXPAREL (n=60).

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As general guidance in selecting the proper dosing, two examples of infiltration dosing are provided:

- In patients undergoing bunionectomy, a total of 106 mg (8 mL) of EXPAREL was diluted with 10 mL of saline, for a total of 20 mL, into which 10 mg of dexamethasone was added prior to administration of the bupivacaine. This resulted in a final dose of 2 mg/mL.
- In patients undergoing paracervical block anesthesia for obstetric patients in the third trimester of pregnancy, EXPAREL was administered in a total dose of 25 mg/mL (0.5 mL) for a total of 10 mL, into which 10 mg of dexamethasone and 10 mg of epinephrine were added prior to administration of the bupivacaine. This resulted in a final dose of 2 mg/mL.

Recommended Dosing in Adults

Local Anesthesia via Infiltration

The recommended dose of EXPAREL for interstitial brachial plexus nerve block adults is in 133 mg (10 mL), and is based upon one study of patients undergoing upper extremity surgery.

Compatability Considerations

Syringes and other drugs other than bupivacaine HCI prior to administration is not recommended.

Non-bupivacaine based local anesthetics, including lidocaine, may cause an increase in the duration of action when administered together locally. The administration of EXPAREL may fail the administration of lidocaine after a delay of 20 minutes or more.

When a topical antiseptic such as povidone iodine (e.g., Betadine®) is applied, the site should be allowed to dry before EXPAREL is administered into the skin. The use of Betadine® for skin disinfection may result in the formation of a transient surface film that may interfere with antibiotic contracts such as povidone iodine in solution.

Studies conducted with EXPAREL demonstrated that the most common immediate and adverse reactions (paresthesia, nausea, and vomiting) are not affected by the presence of EXPAREL any more than they are when EXPAREL is used alone. EXPAREL may be administered immediately before EXPAREL as long as the ratio of the milligram dose of bupivacaine to EXPAREL does not exceed 1:2.5.

The recommended dose of EXPAREL for interstitial brachial plexus nerve block in adults is 133 mg (10 mL), and is based upon one study of patients undergoing upper extremity surgery.

Non-interchangeability with Other Formulations of Bupivacaine

Different formulations of bupivacaine are not bioequivalent even if the milligram dosages is the same. Therefore, it is not possible to convert dosing from one formulation of bupivacaine to EXPAREL and vice versa.

Non-interchangeability or requirements may substantially affect a drug’s functional properties relative to those of the unencapsulated or non-encapsulated associated drug. In addition, different lipophilic or lipoprotein products may behave differently in the chemical composition and physical form of the lipid product. Such differences may affect functional properties of these drug products. Do not substitute.

CLINICAL PHARMACOLOGY

Pharmokinetics

The Cmax of EXPAREL results in significant systemic plasma levels of bupivacaine, which can persist for 48 hours after local infiltration and 120 hours after interstitial brachial plexus nerve block. In general, peripheral nerve blocks do not result in systemic plasma levels high enough to cause systemic toxicity when compared to local infiltration. Systemic plasma levels of bupivacaine following local infiltration with EXPAREL are not correlated with local efficacy.

PATIENT COUNSELING

Inform patients that use of local anesthetics may cause methemoglobinaemia, a rare but potentially life-threatening complication. Advise patients or caregivers to seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale skin, blue or grayish skin (cyanosis), headache, rapid heart rate, shortness of breath, electrolyte imbalance, or fatigue.

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November 2018
by the expenses of having the scope, light source, and camera, and there is currently no way to adapt the trainer for the iPhone or similar easily accessible monitors. We don’t yet have a simulator for laparotomic or vaginal surgery. Hysteroscopy is strikingly missing from a lot of the discussions about simulation on a national level – an omission which is concerning. It is lesions in the endometrial cavity such as polyps and myomas that most often are responsible for infertility and abnormal uterine bleeding, and the hysteroscopic surgeon is the one often best equipped to deal with them in a minimally invasive fashion. And of course, the hysteroscopic surgeon and the laparoscopic surgeon should be one and the same, making decisions on the technique based upon optimal training and skill rather than what they are comfortable with based on limited training. As Dr. Einarsson has said, gynecologic surgeons need to be adept at hysteroscopic, laparoscopic, and vaginal procedures to call themselves gynecologic surgeons. So, the next step in introducing simulation to our trainees is to make them applicable to the two endoscopic approaches we use.

**DR. ASCHER-WALSH:** For me the only way I see simulation getting integrated into clinical practice is for surgeons who don’t operate very much. For high-volume surgeons, simulation in its current state, which is really not very lifelike, doesn’t help us in our clinical practice. But for surgeons who do a dozen cases a year, simulation may be helpful in credentialing or assessing whether to continue privileges. For those low-volume surgeons, I would see simulation as part of their clinical practice in maintenance of skills.

**DR. MOAWAD:** Where I see simulation, not only for the novice surgeon but also for the experienced surgeon, is integration of case-specific simulation. For example, anatomy could be reconstructed in three dimensions (3D) based on imaging and then the trainer, the mentor and the learner could use it to review that specific case. We might use it to simulate models for incision of fibroids or to test scenarios for addressing a complex case in a different way. In the future, 3D printing and reconstruction combined with case-specific simulation may prove very helpful before the case itself.

**DR. MUNRO:** I agree. There are certain circumstances in which a case may be so challenging that 3D reconstruction could help identify who you need in the room, what resources, and even where to dissect. For example, for complex neurosurgery, surgeons are increasingly using 3D reconstruction using of MRI volumes and 3D printers have been used to assess vascularity and other factors, allowing the surgeons to understand how to dissect in a very difficult field. As Dr. Ascher-Walsh said, we aren’t even remotely close to that but I think one of the potential advantages of a true virtual reality immersive experience, is the opportunity to actually practice the operation and be a little bit closer to what happens, like commercial or fighter aircraft simulation, where it really is a realistic immersive experience. In fact, the simulation systems for fighter aircraft are so sophisticated, that training planes are no longer made – the pilot goes straight from the simulator to solo flying in aircraft worth hundreds of millions of dollars.

**DR. EINARSSON:** Until we are there, I think using low-fidelity simulators and watching videos can be very, very helpful for surgeons. I want to put a small plug in for the SurgeryU platform that the AAGL has developed. It has a lot of very high-quality surgical videos that AAGL members can access. There are other sources of surgical videos available as well. I think that those two components are most easily accessible currently and then hopefully this will evolve into a more sophisticated offering in the near future or maybe the far future.
DR. MUNRO: To go back to the EMIG program, I’d like to emphasize that it isn’t just manual skills. There is an entire cognitive program that comprises 80 training videos which encompass the spectrum of hysteroscopic and laparoscopic surgery procedures and patient preparation. There is an accompanying didactic component is designed to measure judgment that will be mounted on the AAGL’s SurgeryU (https://surgeryu.com/landing) website. The cognitive exam that has been validated and, in an ongoing fashion is modified and revalidated using high quality, psychometrician supported methodology. This examination, meant to evaluate judgement, is paired with the manual skills exam to provide an overall assessment of progress. So the EMIG system is more comprehensive than just an assessment of manual skills.

MS. WETZEL: In conclusion, please sum up for our readers where you see surgical simulation today and what’s on the horizon in terms of simulation science.

DR. EINARSSON: Simulation is still somewhat in its infancy. The low-fidelity simulators are the most easily usable and are probably going to be more integrated with the FLS test and then hopefully the EMIG test. I think we need better science and also probably better technology in the area of surgical simulation.

DR. MOAWAD: The most important point about surgical simulation, for me, is that use of simulation in isolation from any teaching method will furnish the learner with some skills but the best time and place to learn most of the skills will still be the traditional way, in the operating room (OR). In addition, surgical judgment is really hard to learn and I think simulation could provide a safe environment in which to learn how things can go wrong and how to readress them. Simulation could help gynecologic surgeons build confidence to enable you to apply those kind of competencies in a real OR.

DR. ASCHER-WALSH: Where we’ve had some early success with simulation is in establishing credentialing. We’ve done some projects with a very large health system looking at a few hundred attendings and correlating their surgical skills on the simulator with their case experience. We were able to find some correlation between the two and we’re now comparing it to actual surgical videos with the hope of being able to use it as a credentialing tool. I think, as everybody else was saying, we’re sort of far away in using simulation as an advanced surgical training tool. I agree that the low-fidelity simulators are the best tools for the surgeon early in training. For low-volume surgeons, it also may be a way to maintain their skills. I hope that in the next decade, as the science improves, we’ll be able to have more realistic simulation, but we’re not there now.

DR. MUNRO: In gynecology, we are awkening to the notion that we have an increasingly complex challenge in the disease states that we are entrusted to manage. That challenge has to be taken into consideration when developing a structured approach to training and evaluation of residents and fellows at a spectrum of benchmark times in the training process. It’s both a moral and legal imperative. We need to improve how we train gynecologic surgeons, and simulation is only part of the answer. Right now, simulation is only a nascent adjunct to training, and, at least in present forms, the low-fidelity simulators are at least equivalent to expensive virtual reality systems. The future requires science, investment, creativity, and an understanding that ultimately the patient expects that her physician and surgeon have a consistent and predictable level of skills. The patient’s level of trust should be similar to that vested in the pilot of the commercial aircraft of her selected airline. Finally, simulation isn’t just for laparoscopy. Simulation and surgical training involves hysteroscopic, laparoscopic, laparotomic and vaginal approaches, because all are essential skills for the contemporary gynecological surgeon.
Migraine headache and hormonal contraception

Many factors must be considered before prescribing hormones to this population.

by Charisse Loder, MD, MSC, and Raina Advani, BA

Women with no significant medical history have many medically appropriate forms of contraception from which to choose. The options narrow when counseling a woman with episodic or chronic health conditions such as headache disorders. Hormonal options are the most widely used forms of contraception among US women; over 40% of women aged 15 to 44 use hormone-containing forms of birth control, including the pill, intrauterine device, implant, injectable, ring, or patch.1 With up to 20% of reproductive-aged women affected by migraine, it is important for ob/gyns to understand the risks and benefits of contraceptive hormone use in this population.2

Migraine characteristics

Migraine must be distinguished from other types of headaches, such as tension-type headache, prior to contraceptive counseling (Table 1). Migraine headaches are diagnosed clinically and are classified as a recurrent disorder. The International Headache Society (IHS) provides diagnostic criteria for migraine using the IHS Classification of Headache Disorders III criteria (Table 2).3 Migraine without aura is the

**CASE**

A 27-year-old G1P1 presents for initiation of contraception. She has no significant medical history but on review of systems, reports experiencing headaches twice monthly. Prior to her headache onset, the patient sometimes sees shimmering lines and other shapes in her vision. Her headaches last 4 to 6 hours and she has associated nausea and occasional vomiting. The woman’s headaches resolve after she lies in a dark quiet room and sleeps. She has a 1-year-old son, is no longer breastfeeding, and would like to wait 1 to 2 years before another pregnancy, and is hoping to start combined hormonal oral contraceptive pills. Which of the patient’s symptoms would cause you to recommend against estrogen-containing contraceptive methods?

A. Photophobia  B. Length of time of headache  C. Vomiting  D. Shimmering lines

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Dr. Loder is Assistant Professor, Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor.

Ms. Advani is a medical student at University of Michigan Medical School, Ann Arbor.
MIGRAINES

**TABLE 1**  
**Characteristics of migraine vs. tension headache**

<table>
<thead>
<tr>
<th></th>
<th>Migraine headache</th>
<th>Tension headache</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td>Usually unilateral (side may vary from one episode to another)</td>
<td>Usually bilateral (often forehead or back of the head and neck)</td>
</tr>
<tr>
<td><strong>Descriptors</strong></td>
<td>Throbbing, pulsating, severe</td>
<td>Pressure, tightness, squeezing</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>Hours to days</td>
<td>Variable: minutes to days</td>
</tr>
<tr>
<td><strong>Associated symptoms</strong></td>
<td>Photophobia, phonophobia, nausea, vomiting +/- aura (see above)</td>
<td>Fatigue, muscle tenderness, +/- nausea</td>
</tr>
<tr>
<td><strong>Common triggers</strong></td>
<td>Alcohol, chocolate, cheese, sleep deprivation, stress</td>
<td>Stress</td>
</tr>
</tbody>
</table>


Most common subset of migraine, with a 1-year prevalence in women of 11%. Migraine with aura includes all of the outlined migraine criteria, with the addition of a variety of neurological symptoms that can occur immediately before or with onset of the headache. Aura symptoms are reversible and can include visual, sensory, speech, language, motor, brain-stem, and retinal symptoms. Though less common, migraine with aura has a 1-year prevalence of 5% in females (Table 3).

**Stroke risk**

**MIGRAINE**

Migraine is a risk factor for ischemic stroke. Though the overall absolute risk of stroke in reproductive-aged women is low—between 3.5 and 19.0 per 100,000—migraine may be the only risk factor for stroke in younger women. Women older than 35 years are likely to have other classic risk factors for stroke, such as hypertension, diabetes, and hyperlipidemia that contribute more to stroke risk than migraine alone. Migraine with aura is associated with an elevated relative risk of stroke when compared to migraine without aura. A meta-analysis of 11 case control studies demonstrated that migraine with aura had a relative risk of 2.27 (95% CI, 1.61–3.19) for ischemic stroke, while migraine without aura had a relative risk of 1.83 (95% CI, 1.06–3.15). The overall stroke risk is still low, with only 3.8 additional cases of stroke per year per 10,000 women attributed to migraine with aura. A complete medical and social history can help elucidate all potential risk factors for stroke before contraception is prescribed.

**HORMONAL CONTRACEPTION**

The association between hormonal contraception and stroke risk is estrogen dose-dependent. It has been demonstrated that lower-dose estrogen-containing oral contraceptive pills (OCPs) (<50 ug ethinyl estradiol) are not independently associated with increased risk of stroke, but formulations with high levels of estrogen are. Use of the patch and ring also may result in an increased risk of stroke. Neither level nor type of progestin in combined OCPs appears to contribute to stroke risk. There is no evidence that progestin-only contraceptives increase risk of stroke and they are considered safe for use in women with stroke risk factors, including migraine with aura.

**ESTROGEN-CONTAINING HORMONAL CONTRACEPTION**

In addition, use of combined hormonal contraception increases risk of stroke in women with any type of migraine. Multiple studies have indicated an increased odds ratio, ranging from 2 to 14, for ischemic stroke in...
women with migraine (not separated by subtype) who use combined hormonal contraceptives, as compared to women without migraine who use the drugs. Risk of ischemic stroke is further magnified in migraineurs who smoke and use combined hormonal contraceptives, with odds ratios ranging from 3.7 to 34.4. More recently, a meta-analysis of nine studies suggested that even women younger than age 45 who are migraineurs have an increased relative risk (3.6-7.0) of stroke when using combined hormonal contraception. However, much data supporting these findings do not reflect new formulations of OCPs. Because low-dose (20- to 30-μg of ethinyl estradiol) and ultra-low-dose (10- to 15-μg of ethinyl estradiol) formulations conceivably have less stroke risk, further research needs to be undertaken on these formulations.

When type of migraine is further delineated, it appears that the combination of migraine with aura and combined hormonal contraception maximizes risk of stroke. One study found risk of ischemic stroke to be increased by six-fold in women with migraine with aura on combined hormonal contraceptives compared to those without aura—demonstrating safety concerns when prescribing combined hormonal contraception in migraineurs with aura. Thus, assessment of migraine type when performing contraceptive counseling is a clinical necessity.

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**TABLE 2**

**International Classification of Headache Disorders III Diagnostic Criteria for Migraine**

### Migraine without aura

Recurring headache with at least five attacks fulfilling the following criteria:
- Attacks last 4-72 hours (untreated or unsuccessfully treated)
- At least two of the following:
  - Unilateral location
  - Pulsating quality
  - Moderate or severe pain intensity
  - Aggravation by or causing avoidance of routine physical activity
- At least one of the following symptoms during the headache:
  - Nausea and/or vomiting
  - Photophobia and phonophobia
  - Not attributed to another disorder

### Migraine with aura

Must fulfill criteria for migraine listed above

At least two attacks fulfilling the following criteria:
- One or more of the following reversible aura symptoms:
  - Visual
  - Sensory
  - Speech and/or language
  - Motor
  - Brainstem
  - Retinal

At least three of the following six characteristics:
- At least one aura symptom spreads gradually over ≥ 5 minutes
- Two or more aura symptoms occur in succession
- Each individual aura symptom lasts 5-60 minutes
- At least one aura symptom is unilateral
- At least one aura symptom is positive
- The aura is accompanied by, or followed within 60 minutes by, migraine headache

### Recommendations

Given the increased risk of ischemic stroke in women with migraine with aura—and added risk when combined with hormonal contraceptive

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The US MEC chart is available online and useful to keep in clinic for reference. 8 ½” by 14” charts can be printed double sided, laminated, and used by health care providers when counseling women.

MIGRAINES

The American College of Obstetricians and Gynecologists (ACOG) and the Centers for Disease Control and Prevention (CDC) US Medical Eligibility Criteria (US MEC) have listed migraine with aura as an absolute contraindication to using combined hormonal contraception (Table 4).\textsuperscript{17-19} The US MEC is a helpful resource when providing contraceptive counseling services to women with a history of or existing medical conditions. The summary chart risk-stratifies different forms of contraception based on current and past medical conditions into four different categories. Categories 1 and 2 suggest that the advantages of the method usually outweigh the risk and that a method is safe. Category 3 suggests that the risks outweigh the benefits of using a contraceptive method. Category 4 indicates that there is an unacceptable risk to the patient. Common medical conditions used in the chart include headaches, hypertension, diabetes, and depression.

Combined hormonal contraception is acceptable in women with migraine without aura who have no additional risk factors for stroke.\textsuperscript{17-19} Moreover, ACOG’s recommendations are based on data using old formulations of combined hormonal contraception that include more than 35 μg of ethinyl estradiol (Table 4). Many of today’s popular formulations contain less than 30 μg of ethinyl estradiol and are not independently associated with stroke risk.

The International Headache Society has more lenient guidelines for use of combined hormonal contraception in patients with migraine with aura and recommends an individualized assessment of risk depending on the number of other risk factors a woman has for ischemic stroke (including age > 35, tobacco use, hypertension, obesity, diabetes, and hyperlipidemia). Per these guidelines, patients with migraine with aura who smoke should quit smoking prior to starting combined hormonal contraceptives and those with risk factors such as hypertension, diabetes, and hyperlipidemia should be treated for these conditions prior to starting combined hormonal contraceptives.\textsuperscript{14} Similarly, the American Headache Society indicates that use of low-dose estrogen-containing formulations can be individualized based on patient risks and benefits because the absolute risk of stroke is low.\textsuperscript{20}

It is always important to compare the risk of unintended pregnancy in patients with chronic medical conditions with the risk of contraceptives. Patients should be adequately counseled and the discussion should be documented in the medical record.\textsuperscript{21} In all cases, once a woman with mi-
Graines has been started on a method of combined hormonal contraception, if her migraines worsen or she develops new-onset aura, the formulation should be discontinued.

**Migraine medication interactions**

During contraceptive counseling, it is important to consider possible medication interactions in women who have headaches. Many classes of medications are used for migraine prophylaxis, including beta blockers, calcium channel blockers, tricyclic antidepressants, and antiepileptic drugs (AEDs). Some AEDs specifically alter the efficacy of combined hormonal contraception through the Cytochrome P450 system. They act as P450 inducers and increase metabolism of contraceptive steroids. Topiramate is a commonly used migraine prophylaxis agent that also decreases efficacy of contraceptives by reducing the circulating dose of ethinyl estradiol. Specifically at doses > 200 mg daily, topiramate decreases efficacy of combined hormonal contraceptives, as well as of progestin-only pills and the progestin implant.22

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

Which of the patient’s symptoms would cause you to recommend against estrogen-containing contraceptive methods?

**ANSWER:**

D. Shimmering lines

For references visit contemporaryobgyn.net/Migraines&Contraception

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Case study
Joanna is a 17-year-old G2P1 living in Garden City, Kansas who sought a pregnancy test after missed menses and learned that she was 11 weeks pregnant despite placement of an intrauterine device 9 months ago. She moved out of her parents’ home due to domestic violence and lives with her grandmother. They depend on Social Security, Medicaid and Joanna’s part-time job to raise her baby as she works to complete high school. Joanna talked extensively with her grandmother and decided to pursue an abortion. Due to the barriers she encountered (Table 1), Joanna eventually presented to a clinic in New Mexico at 19 weeks for her abortion and paid $2,000 for her care, plus travel costs and time missed from her job and school.

The case study here is not atypical for many women seeking second-trimester abortion, as barriers mount to abortion care access throughout the country. Women face many obstacles to first-trimester abortion; challenges to second-trimester abortion are even greater, with fewer trained and willing providers, increased costs, and gestational age limits. As of July 1, 2019, 17 states had “20-week” abortion bans. Access to abortion, including in the second trimester, is critical to maintaining women’s health and autonomy. The timing of a second-trimester abortion may be related to delays in care access, fetal anomalies, or health and life-threatening patient conditions. In this article, we discuss the epidemiology of second-trimester abortion, medical techniques including complex clinical scenarios, and the current status of abortion access in the United States.

Epidemiology
Second-trimester abortions account for only a small fraction of all abortions in the United States; as of 2015, 7.6% of all abortions occurred between 14 and 20 weeks and only 1.4% occurred at 21 weeks or more. Induced abortion is safer than childbirth, and complications of the procedure are very low even in the second trimester. While most abortions occur in the first trimester, women like Joanna who seek second-trimester abortion face obstacles such as transportation, financial difficulties, delayed diagnosis (of pregnancy and of fetal abnormalities), and lack of knowledge about how to access the desired procedure.

Abortion options
Second-trimester abortion can be performed via standard dilation and evacuation (D&E) or through medi-
cal induction with mifepristone and misoprostol. When reviewing the two options, most women prefer D&E.6,7 Few randomized studies directly compare induction to D&E because women are generally unwilling to be randomized; overall D&E is less painful and more acceptable than induction.7

**DILATION AND EVACUATION**

D&E is the most common method of second-trimester pregnancy termination in the United States, accounting for more than 98% of all such procedures and nearly 95% of all abortions after 21 weeks.2 The procedure can be safely performed in the outpatient setting with appropriately trained providers and staff; hospital care is not necessary for most low-risk patients.4 D&E comprises two steps: cervical preparation and uterine evacuation.

The Society of Family Planning recommends cervical preparation in the second trimester to facilitate safe uterine evacuation.8 Cervical preparation can be accomplished with osmotic dilators, medications, or both in combination; the necessary amount of dilation depends on factors such as gestational age and parity. Cervical preparation decreases rates of uterine perforation and cervical laceration, especially in later gestations.8

In the early second trimester, misoprostol, a synthetic prostaglandin E1 analog, administered the same day as the D&E is usually sufficient for cervical preparation. It induces uterine contractions and cervical softening. Following misoprostol administration, the cervix is mechanically dilated with dilators, such as Pratt or Hegar dilators at the discretion and preference of the physician, until dilation is adequate for safe uterine evacuation. Common misoprostol regimens include 400 or 600 mcg administered 1.5 to 4 hours prior to the procedure by vaginal, buccal, or sublingual route.8

As gestational age advances, cervical osmotic dilators either alone or in combination with misoprostol are required for adequate cervical dilation. Osmotic dilators or tent are small, thin rods that radially expand as they absorb fluid. The proximal end of the dilator is placed through the internal os with the distal end visible at the external os. The most well-known osmotic dilator is the dehydrated sterilized seaweed Laminaria japonicum, commercially available in standard sizes. One or more Laminaria tents are retained at least 12 hours, usually overnight, to achieve full dilation. More Laminaria tents and serial sets of dilators may be needed for abortions at more advanced gestational ages. The synthetic hygroscopic dilator Dilapan-S expands more quickly and is used for same-day or multiple-day cervical preparation. Dilapan-S dilators are more expensive than Laminaria tents, although fewer Dilapan-S are needed to accomplish the same cervical dilation. The choice and number of dilators is at the discretion of the surgeon as no minimum number, standard or preferred combination of osmotic dilators has been established for any gestational age.8

Mifepristone, an antiprogestogen that causes cervical softening and di-

### TABLE 1 Barriers Joanna faced in accessing abortion care in Kansas

- “Abortion clinic” search engine results link to facilities that do not offer abortion (so-called “crisis pregnancy centers”), leading to lack of expected care and delays in obtaining desired care
- Closest abortion clinic 3½-hour drive from Garden City
- Lack of insurance coverage for abortion care
- 24-hour waiting period between counseling and the procedure
- Two parents’ written consent required to obtain abortion care
- Cumbersome judicial bypass procedure for minors that requires:
  - An initial visit to the abortion clinic accompanied by an adult over 21 years old (and cannot be the partner) for a pregnancy options discussion
  - Clinic notification of the court, which provides a list of attorneys to assist with the process
  - A hearing with a judge, the client and the attorney in which the client is questioned to determine her maturity and ability to make an informed decision for herself and that it would not be in her best interests to have her parents involved
  - A 48-hour window within which the Judge decides and issues the client an “order” giving permission for the abortion
- Written medically inaccurate materials about the association of abortion with breast cancer, future fertility risk, fetal pain, and negative psychological effects
- Written description of fetal development and that personhood begins at conception
SECOND-TRIMESTER ABORTION

Routine intraoperative ultrasound guidance decreases rates of uterine perforation, especially in the training setting.

RATIONALE, is a potent addition to cervical preparation. A combination of mifepristone and osmotic dilators is often used in the late second trimester; beyond 19 weeks, mifepristone 200 mg orally at the time of dilator placement increases ease of the D&E procedure.9 Mifepristone is better tolerated than adjunctive misoprostol, which may cause pain, fever, and chills.9 Although the complication of infection with surgical abortion is low, antibiotic prophylaxis reduces the risk; the American College of Obstetricians and Gynecologists recommends a single dose of doxycycline 200 mg orally at the time of surgical abortion, typically administered when dilators are placed.10

D&E is performed after adequate cervical dilation is achieved, either the same day or up to 2 days later, depending on the extent of cervical preparation needed. A large suction cannula, usually a size 14 or 16 at and after 16 weeks’ gestation, is used to drain the amniotic fluid and the pregnancy tissue is removed using a combination of instruments and suction. Bierer or other modified ovum forceps facilitate uterine evacuation. Risk of significant bleeding during D&E is reduced by adding vasoconstrictive agents such as vasopressin to a paracervical block and by administering oxytocin 30 units intravenously over 15 minutes during the procedure.11,12 Routine intraoperative ultrasound guidance decreases rates of uterine perforation, especially in the training setting.13

MEDICAL INDUCTION
Just as with use of mifepristone for cervical preparation for D&E, pre-treatment with mifepristone 200 mg orally 24 to 48 hours prior to induction prepares the cervix and improves success rates of medical abortion in the second trimester. Compared with simultaneous administration or placebo, mifepristone pretreatment leads to much shorter (up to 50%) induction times; 95% of women deliver within 24 hours of starting the induction.14,15 Placement of cervical osmotic dilators at the time of induction does not shorten overall procedure time.16

Misoprostol is the most commonly used medication for second-trimester induction abortion. While several regimens have been studied, a frequent misoprostol dosing interval of every 3 hours shortens the overall induction time; 400 mcg appears to be the minimum effective dose. Vaginal and sublingual routes of misoprostol are superior to oral administration.16 Reported rates of intervention for bleeding or retained placenta vary; with these evidence-based medication regimens, the rate of retained placenta is as low as 6%.15

Special considerations
PRE-PROCEDURE MEDICATIONS FOR FETAL DEMISE
It is not medically necessary to induce fetal demise prior to a second-trimester abortion.17,18 Feticide does not decrease D&E procedure time or complications.19,20 Digoxin injection prior to D&E is associated with increased rates of infection, hospital admission, and spontaneous expulsion.20 For induction abortion, limited evidence suggests feticide injection may shorten induction-to-delivery time.17,21 When asked, patients report discomfort and difficulty with feticide injections, but also reassurance.22

Digoxin or potassium chloride may be administered as a feticide injection. Complications with digoxin are unusual; when shared decision-making results in use of digoxin, it is administered as a dose of 1 to 2 mg injected into the fetus or into the amniotic fluid on the first day of osmotic dilator placement. Intrafetal digoxin injection is more likely to cause fetal asystole within 24 hours than intra-amniotic injection; doses lower than 1 mg are less likely to cause asystole.23,24 Potassium chloride is more commonly used for selective fetal reduction and must be administered directly into the umbilical cord or into a fetal cardiac chamber, requiring more technical skill to administer than digoxin. The dose of potassium chloride required for effectiveness varies between 6 and 20 mEq.17

PRIOR UTERINE SURGERY
History of cesarean delivery is one of the most common conditions potentially complicating second-trimester abortion. The placenta should be evaluated for all women with prior uterine surgery and specialist referral is indicated in cases where there is concern for morbidly adherent placenta. D&E is safe for women with prior uterine surgery and normal placenta. Two or more cesarean deliveries increases the risk of major complications with D&E compared with one or no cesareans.25
Uterine rupture with second-trimester abortion with misoprostol is a rare event, with a risk of less than 0.5% in women with one prior cesarean delivery compared with less than 0.1% with no uterine surgery.26 Risk of uterine rupture for women with two or more cesarean deliveries (2.5%) is significantly increased compared with no prior uterine surgery.26 For women with a history of one or more cesarean deliveries, risk of retained placenta and of needing blood transfusion is also increased during induction abortion.20

Regimens for misoprostol dosing can be modified based on gestational age, with use of higher doses early in the second trimester and lower doses between 24 and 28 weeks.

Abortion access in the United States

The 1973 Roe v. Wade Supreme Court decision established the constitutional right to abortion. In 1992, the Supreme Court allowed states to create restrictions that did not place an "undue burden" on women's access to abortion. Since Roe, 1200 restrictions have been enacted; recently the pace of abortion restrictions has accelerated, and the nature of the restrictions more severely curtails access.33 Nearly 60% of US women live in a state with significant abortion restrictions.33 As Joanna found (Table 1), many restrictions target the woman seeking abortion.

Other restrictions focus on limiting abortion provision, including facility and provider requirements. A case study of the impact of abortion provision restrictions occurred in Texas with the passage of House Bill 2 (HB2) in 2012. HB2, an omnibus law, required admitting privileges at a nearby hospital for physicians providing abortions and required clinics to meet ambulatory surgical center standards for all abortions, including medication abortions. HB2 also banned most abortions after 20 weeks and imposed medically unnecessary restrictions on medication abortion. The impact was dramatic: by 2014, only 19 of the previous 43 clinics remained open. Although key parts of HB2 were reversed by a Supreme Court decision in 2016, the damage was done; few closed clinics have been able to reopen.

Restrictions targeting patients, providers, and facilities have already created significant barriers that reduce abortion access in many states. Furthermore, the true intent of recent aggressive anti-abortion legislation is less likely than in the past to be cloaked as improving patient safety; current proponents of restrictive legislation articulate the purpose of eliminating legal abortion. Illegal abortion is highly associated with maternal mortality, both in the United States pre Roe v Wade and throughout the world where abortion is illegal.34 It is no surprise that our leading US medical journals have published cautionary editorials sounding the alarm about the ramifications of gutting or reversing Roe v Wade.33,35 We echo these calls to action and strongly support continued access to safe, legal, and equitable abortion, including evidence-based patient-centered second-trimester abortion care.

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

FOR REFERENCES VISIT contemporaryobgyn.net/SecondTrimesterabortion

WE WANT TO HEAR FROM YOU! Let us know what you thought of this month’s feature. Or tell us about your experience with second-trimester abortion and what you learned from it. Email COGeditorial@mmhgroup.com
How menopause influences multiple sclerosis

A study evaluating the impact of menopause during the course of multiple sclerosis (MS), including disease activity and disability progression, has found that after menopause there is a reduced relapse rate, but that disability progression continues at a similar rate, compared to the premenopausal period.

The retrospective, longitudinal cohort study in the journal *European Neurology* also concluded that these findings persisted in the subgroup of patients without changes in disease-modifying treatment (DMT) or a diagnosis of at least one vascular comorbidity (including smoking, hypertension, diabetes or dyslipidemia) during the observation period.

"Hormonal variations are known to influence the course of MS," wrote the Portuguese authors.

The study enrolled 37 women, all older than 44, who were postmenopausal (mean age at the time of menopause of 49.8 years), and had a diagnosis of MS at least 1 year before menopause. The investigators assessed the impact of menopause during the course of MS by comparing clinical and radiologic outcomes within 5 years before and after menopause.

The analysis was repeated in the subgroup of patients without changes in DMT or in comorbidities detected during the observation period because these factors could also influence MS outcomes. Patients were evaluated every 3 to 6 months, along with requested magnetic resonance imaging by the assistant physician.

Slightly more than half the study patients (54.1%) switched to DMT during the observation period; however, only 18.9% of patients changed to DMTs after menopause. Median duration of the premenopausal and postmenopausal periods was 5.0 years.

Within 5 years following menopause, there was a decrease in the annualized relapse rate: 0.37 premenopause vs. 0.08 postmenopause \((P \leq 0.001\), compared with the same period before menopause.

However, the progression rate of the Expanded Disability Status Scale (EDSS) remained stable: 0.13 EDSS point/year for both premenopause and postmenopause \((P = 0.935\). Similarly, EDSS progression events frequency was similar before and after menopause: 37.8% vs. 48.6%, respectively \((P = 0.424)\).

In the subgroup of patients with a disease duration \(\leq 14\) years, there was a decrease in annualized relapse rate after menopause: 0.46 premenopause vs. 0.15 postmenopause \((P = 0.001)\). On the other hand, EDSS progression was similar for the subgroup: 1.74 premenopause vs. 2.82 postmenopause \((P = 0.243)\).

Frequency of EDSS progression events also did not change significantly: 36.8% premenopause vs. 42.1% postmenopause. In patients with disease duration longer than 14 years, there was also a decrease in the annualized relapse rate after menopause: 0.27 premenopause vs. 0.01 postmenopause \((P = 0.002)\). But neither EDSS progression nor frequency of EDSS progression events changed meaningfully in this group of patients.

“Our results are consistent with the proposed mechanisms of action of estrogen and the effect of its reduction,” the authors wrote. “The estrogen decay might account for the reduction of inflammation, which might relate to the reduction in disease activity observed after menopause, but also for the loss...
Female adult bicyclists who reported genital pain and genital numbness were much more likely to have sexual dysfunction than those who did not report the symptoms, according to a study in The Journal of Sexual Medicine.

“Bicycle seat pressure on the perineum may impair arousal and clitoral erection, likely contributing to genital pain and numbness experienced by female cyclists,” wrote the study authors from Stanford University School of Medicine and the University of California, San Francisco.

A total of 335 female cyclists participated in the study, of whom 178 (58.1%) completed an online survey using the Female Sexual Function Index (FSFI). The average age of all participants was 48.1 years and the average riding experience of survey participants was 17.1 years, mostly using a road bike (98.1%). Overall, 53.9% of survey participants met the diagnostic criteria for female sexual dysfunction (FSD), along with 58.1% reporting genital numbness and 69.1% reporting genital pain.

Women over age 60 (comprising 22.7% of the survey population) were less likely to report numbness during their ride (odds ratio [OR] 0.3; 95% confidence interval [CI]: 0.1 to 0.9; \( P = 0.02 \)). On the other hand, cyclists who rode an average of over 10 hours per week were more likely to report pain (OR 2.4; 95% CI: 1.1 to 5.2; \( P = 0.03 \)). But cyclists using a wide-cut saddle were less likely to report pain (OR 0.3; 95% CI: 0.1 to 0.8; \( P = 0.02 \)).

Women who reported experiencing genital numbness at least half the time while cycling were significantly more likely to have FSD (adjusted OR [aOR] 6.0; 95% CI: 1.5 to 23.6; \( P = 0.01 \)), particularly if localized to the clitoris (aOR 2.5; 95% CI: 1.2 to 5.5; \( P = .02 \)), after adjusting for age, body mass index, relationship status, smoking history, comorbidity and average time spent cycling per week.

Women who reported genital pain half the time or more while cycling also were much more likely to have FSD (aOR 3.6; 95% CI: 1.2 to 11.1; \( P = .02 \)). In addition, cyclists experiencing genital pain within the first hour of riding were more likely to have FSD (aOR 12.6; 95% CI: 2.5 to 63.1; \( P = .002 \)).

“Analysis of FSFI domains found that the frequency of numbness was correlated with decreased arousal, orgasm, and satisfaction during intercourse, whereas the frequency of pain significantly reduced arousal, orgasm, and genital lubrication,” wrote the authors. However, average distance cycled per week, average time riding per week, years of riding experience and number of long rides (at least 3 hours in duration) per month did not significantly correlate with any of the FSFI domains.

A limitation of the study is its cross-sectional survey design. The authors said future studies are needed to determine if alleviating genital pain and numbness while cycling can reduce the impact of cycling on FSD.

Meanwhile, researchers and bicycle manufacturers are increasingly developing ergonomic saddles and cycle modifications to reduce genital pain and numbness. Using a correct bicycle size with a professional fitting and standing in the saddle have also shown to have a modest benefit on genital discomfort.

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

SOURCE
A study in the Journal of Physiology and Pharmacology confirms a strong connection between nutrient intake and gastrointestinal disorders in women with endometriosis. As a result, the German authors believe a dietary intervention by a professional nutritionist may help reduce the disease burden of endometriosis in affected women.

Recent studies indicate that nutrition impacts endometriosis onset and progression. However, because data about the actual nutrient intake of endometriosis patients are sparse, the investigators examined the actual nutrient intake and potential influencing factors in these women.

The retrospective case-control study comprised 156 women with endometriosis and 52 age-matched controls. All study participants completed a validated food frequency questionnaire of their nutrient intake over the past 12 months, along with a disease-related questionnaire to determine disease status, clinical symptoms and comorbidities.

Women with endometriosis suffered significantly more from diet-related comorbidities than the control group, such as for food intolerances (25.6% vs. 7.7%; P = 0.009) and allergies (57% vs. 31%; P < 0.001). Gastrointestinal symptoms, including constipation, flatulence, pyrosis, diarrhea or frequent defecation, were also higher in the endometriosis group (77% vs. 29%; P < 0.001).

In addition, the nutrient intake of patients with endometriosis varied significantly from controls, with a notable lower ingestion of organic acids (P = 0.006), maltose (P = 0.016), glycogen (P = 0.035), tetradecenoic acid (P = 0.041), methionine (P = 0.046), lysine (P = 0.048), threonine (P = 0.046) and histidine (P = 0.049).

Similarly, the total intake of animal proteins was significantly lower among women with endometriosis compared to controls (P = 0.047).

The endometriosis group also showed a decreased intake of vitamin C (P = 0.031), vitamin B_{12} (P = 0.008) and magnesium (P = 0.043) compared to controls. The lower intake of vitamin B_{12} in the endometriosis group could be attributed to a lower intake of animal protein in this group because the vitamin is mostly found in animal products.

The endometriosis group also failed to attain the recommended daily intake of 300 µg folate. About 77% of the women in the endometriosis group said they suffered from gastrointestinal symptoms, namely constipation and flatulence, versus 29% in the control group (P < 0.001).

Besides disease localization, therapeutic treatment like gynecological surgeries and medications may impact gastrointestinal symptoms.

The current study found hysterectomy and ovariectomy impaired indigestion, in particular constipation, flatulence and diarrhea in the endometriosis group. The investigators also observed a significantly higher portion of celiac disease and gluten sensitivity in women with endometriosis compared to controls, "which may explain the positive effect of a gluten-free diet in the management of pelvic pain in these patients."

Initiating studies to assess the prevalence of food intolerance in relation to endometriosis might help manage pain and gastrointestinal symptoms, such as through dietary interventions. "Considering the described gastrointestinal symptoms and food intolerances, endometriosis patients probably have a different nutritional behavior compared to women without endometriosis," the authors wrote.

Organic acids, such as citric or sorbic acid, may benefit endometriosis because of their anti-oxidative and antimicrobial properties. These acids have also shown anti-inflammatory effects in animal experiments.

Dietary supplementation of vitamin C or magnesium might also be part of nutritional therapy for endometriosis.

**About 77% of women in the endometriosis group said they suffered from gastrointestinal symptoms.**

**Nutrient intake and gastrointestinal comorbidities with endometriosis**

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

**SOURCE**

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Although breast cancer represents a major risk to older women, the benefit of screening mammography for women over 75 years is unclear. A recent study in The Journal of the National Cancer Institute aimed to determine the 10-year cumulative incidence of breast cancer versus death from causes other than breast cancer according to comorbidity and age in the Medicare-linked Breast Cancer Surveillance Consortium (BCSC).

The study included women aged 66 to 94 without a history of breast cancer who underwent screening mammography between 1999 and 2010. Participants were continuously enrolled in fee-for-service Medicare for 12 months before and after mammography. Information on breast cancer diagnoses and tumor characteristics was obtained by linking BCSC data to pathology services, regional Surveillance, Epidemiology, and End Results (SEER) programs, and/or state registries.

For the study, the primary exposure of interest was the Charlson Comorbidity Index (CCI), which is a weighted index that predicts 1-year risk of death using Medicare Part B procedure and diagnostic claims data. CCI is calculated using the sum of weighted conditions and given scores of 1, 2, or 3 based on diagnoses with any of 16 disease conditions. Primary outcomes of interest were incident breast cancer (invasive or ductal carcinoma in situ [DCIS]) diagnoses and other cause death.

The study cohort included 222,088 women who were followed for a median of 107 months (interquartile range [IQR]: 65-120). Overall, participants were mostly white (84.8%), had a high school diploma or less (50.7%), reported no family history of breast cancer (82.5%), and had scattered fibroglandular density in their breast tissue (54.6%). By the end of follow-up, 7,583 women were diagnosed with invasive breast cancer and 1,742 were diagnosed with DCIS. Furthermore, 471 women died from breast cancer and 42,229 died from other causes.

According to the study results, 10-year cumulative incidence of invasive breast cancer did not change with increasing CCI but actually decreased slightly with age: ages 66-74 (CCI 0 = 4.0% (95% CI 3.9-4.2%) vs CCI ≥ 2 = 3.9% (95% CI, 3.5-4.3%)), ages 75-84 (CCI 0 = 3.7% (95% CI 3.5-3.9%) vs CCI ≥ 2 = 3.4% (95% CI 2.9-3.9%)), and ages 85-94 (CCI 0 = 2.7% (95% CI, 2.3-3.1%) vs CCI ≥ 2 = 2.1% (95% CI 1.3-3.0%)).

On the other hand, 10-year cumulative incidence of other causes of death increased with increasing CCI and age: ages 66-74 (CCI 0 = 10.4% (95% CI, 10.3-10.7%) vs CCI ≥ 2 = 43.4% (95% CI 42.2-44.4%)), ages 75-84 (CCI 0 = 29.8% (95% CI, 29.3-30.2%) vs CCI ≥ 2 = 61.7% (95% CI, 60.2-63.3%)), and ages 85-94 (CCI 0 = 60.3%, (95% CI, 59.1-61.5%) vs CCI ≥ 2 = 84.8% (95% CI, 82.5-86.9%)).

The 10-year cumulative incidence of breast cancer death was small and did not vary by age.

The authors believe their findings suggest that cumulative incidence of other cause death was much higher than breast cancer incidence and death, although that varied by comorbidity and age. Therefore, older women with favorable life expectancies would benefit more from continued screening mammography than those with increased comorbidity.

Ben Schwartz is the associate editor for Contemporary OB/GYN.

SOURCE
Pubic hair grooming and STI risk

Newly published research in PLOS One contradicts earlier findings about pubic hair grooming as a risk factor for sexually transmitted infection (STI). Earlier studies suggested an association between the practice and higher STI rates, but that might not be the case, at least in young, wealthier, white women.

The study objective was to evaluate the association between self-reported extreme grooming and laboratory-confirmed prevalence of gonorrhea and Chlamydia trachomatis (GC/CT) among female university students. The participants, who presented at one of two walk-in STI testing sites on the campus of a large university from April 2017 to April 2018, completed a questionnaire on demographics, sexual behavior, STI risk factors and pubic hair grooming.

Extreme grooming was defined as removal of pubic hair either at least weekly in the past 12 months or ≥ 6 times in the past 30 days. The authors also used two logistic regression models to determine whether odds of GC/CT varied by extreme groomer status for either time interval.

Prevalence of GC/CT was 9.8% among the 214 women in the study. Most of them were white (75.2%), single (72.0%) and reported a parental or guardian income of $60,000 or higher. Almost all of the participants who reported ever grooming (98.1%), 53.6% were extreme groomers in the past year and 18% in the past month. Nearly two-thirds (63.3%) had experienced a grooming injury, and the mean number of lifetime grooming injuries was 4.9 (SD = 3.8).

In both unadjusted and adjusted models, the authors found no difference in the odds of GC/CT between women who were extreme groomers within the past 12 months and those who were not extreme groomers (OR=0.8, 95% CI = 0.3-1.9; adjusted OR = 0.6, 95% CI 0.3-2.0, respectively). Unadjusted and adjusted associations between extreme grooming within the past month and prevalent GC/CT were slightly stronger but were still non-significant (unadjusted OR = 0.5, 95% CI = 0.1-2.0; adjusted OR = 0.4, 95% CI 0.1-1.9).

Although these findings conflict with the results of earlier studies, the authors note that this study was limited by its population, both in terms of the number of participants and their homogeneity. Still, the authors believe their finding do not support the need for public health or clinical interventions to address pubic hair grooming as a risk factor for GC or CT. Future studies should focus on using a larger, more representative sample, the researchers said, to gather more precise estimates and wider generalizability.

Ben Schwartz is the associate editor for Contemporary OB/GYN.

SOURCE

How menopause influences multiple sclerosis

of the neuroprotective properties of estrogen, which might contribute to the persistent disability progression following menopause.”

Because all women in the study were at least in their mid-40s, the authors were unable to separate the effect of aging and suppression of ovarian function.

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

SOURCE

CONTACT US! Email comments and article ideas to Linda Wetzel at lwetzel@mmhgroup.com
Ever wonder how self-driving cars recognize a ball in the road? How about when Amazon magically knows what items you need before you do? This is all thanks to pattern recognition of artificial intelligence (AI). Analytical AI refers to the general process by which machines or computers replicate and replace human tasks and cognition. Machine learning is a branch of AI in which algorithms, inspired by the human brain, encourage the computer to continue recognizing patterns automatically (Figure 1). A further subset is deep learning in which massive amounts of neuronal networks interpret and use large amounts of data for deeper “cognitive” capabilities. It has also been called a convolutional neural network (CNN) in part due to its resemblance to the neurons and connections in our cerebral cortices. Deep learning has led to breakthroughs in healthcare, specifically in radiologic image recognition.

Use of AI in medical imaging
One of the most common uses of AI in healthcare is computer-aided diagnosis (CAD) which has already been widely studied in many fields including prostate, breast and cardiac imaging. Many AI applications are used to develop and implement protocols, thereby shortening imaging time, optimizing staffing, and reducing costs. They also have become instrumental in helping physicians make decisions about patient care. Ob/gyn, while late to the game, given the ubiquitous involvement of ultrasound in care of nearly every reproductive-aged woman in the modern world, has the potential to climb the ranks as the specialty most instrumental to use and development of AI.

Use of AI in ob/gyn imaging
“T’ll believe you have to calculate all those measurements yourself. Doesn’t
the machine recognize the baby’s head?” —asks an inquisitive patient. A Tesla automobile costs roughly the same as a Voluson E10, yet the former can recognize multiple and simultaneous moving objects in the road but the latter has yet to reliably figure out how to recognize fetal organs, which are more or less identical in 97% of fetuses. While the initial task of learning to perform fetal ultrasound requires dexterity and rote hand skills, it seems plausible that a semi-trained sonographer can learn to place the probe in the correct location and computer aid can help identify the correct plane, prompt organ identification, and calculate many of the measurements automatically.

In many new machines, automatic image recognition is already being used during biometric measurement of the fetal biparietal diameter (BPD), head circumference (HC), femur length (FL) and abdominal circumference (AC). In these instances, the sonographer is responsible for identifying the proper landmarks in the plane of choice, and once prompted, the machine will label and measure the desired biometric value. If correct, this saves time. On the contrary, if the image quality is poor, due to fetal position or maternal obesity for example, it may erroneously over or under measure the organ. One study compared 100 manual biometric measurements to 100 automated measurements and showed a time-saving of about 20 seconds and seven steps on each 20-minute anatomic survey. While the time-saving in each individual patient encounter may be insignificant, at the end of a busy day, every second counts towards improving sonographer efficiency and decreasing fatigue.

Three- and four-dimensional (3D/4D) ultrasound have further revolutionized the ability to acquire and process images, especially in the arena of CAD and image recognition. Many major ultrasound manufacturers have developed their own software, such as VOCAL (Virtual Organ Computer-aided Analysis) from GE or S-Detect for breast imaging from Samsung. Image recognition has boomed in fetal ultrasound with groups studying virtually every plane and fetal organ.

One of the earliest interests was 3D computer-aided analysis of the fetal heart. One study showed that satisfactory views of the four-chamber heart, outflow tracts, and stomach were only obtained in 43% to 65% of cases, and less in settings of obesity or fetal spine up. More recently, spatiotemporal image correlation (STIC) volume data sets have been used to identity nine standard fetal echocardiographic views with up to 98% sensitivity for screening congenital heart disease. Other examples include the fetal thymus, for which CAD has assisted with border identification and accurate volume measurement of this complex pyramidal structure in 77% of cases. CAD has even been studied for identification of key characteristics of placenta accreta spectrum and cervical length, funneling, and sludge to predict preterm labor in patients with short cervix. Gestational age is no longer a limiting factor as these techniques have expanded to the first trimester in volume NT by Samsung and SonoNT by GE.

FetalHQ is another software that uses speckle tracking to analyze the motion of multiple points on the fetal heart to provide information on its size, shape, and function. Calculation of this complex algorithm requires a simple 2D video clip of the beating four-chamber view and 3 minutes of post-production analysis, with the results potentially yielding a volume of information on fetal cardiac function.

Newly emerging software includes SoNoCNS Fetal Brain (Figure 2) developed by GE Healthcare and 5D CNS+ by Samsung. Both use deep learning application to take one 3D sweep of the fetal brain and automatically recognize and measure the essential structures through the posterior fossa, ventricles, BPD, and HC. As it stands now, however, most providers use image recognition as a second pass or confirmation to increase their
diagnostic accuracy and are not looking for replacement of their clinical acumen and years of training.

The future of AI in ob/gyn ultrasound

Data and a lot of it is the fundamental requirement for creating a successful deep learning application. One of the practical limitations of software developers is ethically and efficiently obtaining de-identified patient data to create such a thing. One of the biggest players on the AI block is the UK-based company Intelligent Ultrasound, which acquired over 1 million high-quality images from real obstetric scans to develop algorithms for the software ScanNav. The goals of ScanNav are to provide real-time guidance to sonographers by automatically capturing the six correct images as recommended by the UK fetal anomaly-screening program and provide an audit showing that all the images were obtained. In a sense, this provides a layer of quality improvement to ensure that optimal patient care is being delivered.

The software is still in development and some limitations include real-time guidance for probe placement, especially with unique patient considerations such as obesity. A crucial aspect to consider in these situations is patient privacy. While individual data may be de-identified, further advances in machine learning may be able to identify individuals if appropriate safety measures aren’t taken with data security.15

At the end of 2018, SonoScape medical (Shenzhen, China) announced development of their S-fetus algorithm, designed for the S60 ultrasound system, which will scan the entire fetus with a single cine loop. Thousands of real images were used to develop algorithms to identify appropriate landmarks and accurate measurements. In addition, in true deep learning fashion, the system continues to fine-tune its analysis with each additional exam it performs. The S-fetus software will select the best images and automatically measure key growth components. This software will consolidate the multistep process of obtaining fetal biometry to a single push of a button. In addition to saving an immense amount of time and keystrokes for each patient, it will alert the sonographer if manual adjustments or measurements do not meet image standards, thus providing the sonographer feedback and resulting in better images.

Fetal ultrasonography is a mainstay of routine prenatal care. Significant advancements have been made over the years to improve image quality and diagnostic accuracy while maintaining the ease, reproducibility, and efficiency for sonographers performing and physicians interpreting the images. One of AI’s greatest benefits is removing its dependency on the operator and standardizing our approach to improve patient safety, especially in low-resources settings where expertise may otherwise be lacking. Keep your eyes and ears open as the data and hype about this technology are only going to skyrocket in our field. The preliminary schedule for ISUOG in Berlin in October of this year includes courses on how large data and AI may impact our field, and the sessions are sure to be well attended. AI and deep learning certainly warrants all the buzz and energy surrounding it, but realistically, is not yet sophisticated enough to replace obstetricians, maternal-fetal medicine specialists or radiologists. Rest assured, we don’t have to worry about our job security quite yet.

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

FOR REFERENCES VISIT contemporaryobgyn.net/UltrasoundAI
The other difficult delivery

Although residency teaches doctors to deliver babies, how to deliver bad news must also be a part of the curriculum.

by LUKE BURNS, MD

At the start of my inpatient Maternal Fetal Medicine rotation last month, I was called to triage to counsel a mother with monochorionic, diamniotic twins.

This particular patient, unemployed and underserved, had had very little prenatal care. She knew how far along she was and that she was having twin girls, but the high-risk chorionicity of her pregnancy had been missed at her initial prenatal visit, and she had not undergone an ultrasound since. It was only now, presenting to our triage with a painfully distended abdomen, that she learned her fetuses actually shared a single placenta. Because of this missed diagnosis, the woman had not had the regular ultrasound surveillance that might have detected the twin-twin transfusion syndrome now affecting her pregnancy.

The patient was so polyhydramniotic, she was having difficulty breathing. She was in shock. We discussed that her condition was now considered Stage IV, and the twins were unlikely to survive. We offered her an amniocentesis, knowing that removing the excess fluid in the remaining amniotic sac would relieve some of the discomfort of her swollen abdomen, but she declined.

The woman asked us to scan her abdomen a final time. One of her fetuses was hydropic, while the other was severely growth restricted. She sobbed quietly, and her boyfriend, sitting on a chair by the bed, played tinny music from her phone to comfort her. After the scan we stepped out of the room, letting the patient rest a while.

An hour or so later, an urgent phone call brought me back to triage. Our patient had gotten up to use the restroom when her water broke. Now she was bleeding, hemorrhaging onto her bed. I launched into emergency mode, frantically directing the various people in the room.

“Place a second IV! Have you called anesthesia? We’ll need to make sure she’s typed and crossed for four units. When was her last CBC? Is OR 3 ready?”

Amid the chaos occurring in this tiny room, I felt a tap on my shoulder. It was my attending, who leaned toward me and asked calmly, “Have you told her what’s happening?”

In medical school, they tried to teach us how to deliver bad news. Find a quiet room, make sure you’re sitting down, look earnest, begin with a warning shot: the results are back and I’m afraid they are not good.

In reality, I find it impossible to have this much control over my environment in the hospital, especially in the midst of an evolving crisis. In clinic recently, I was asked by a midwife to help troubleshoot a malfunctioning ultrasound machine. I managed to fix the technical problem, but in doing so, I noticed that the fetus had no heartbeat. And so it was me, a stranger this couple had never met but the one caught holding the ultrasound wand, who told them they had had a miscarriage.

This is not surprising in a profession that oscillates so rapidly between good and bad news. One of my attendings uses the phrase psychological whiplash to describe it. It is the idea that an ob/gyn can enter a room to deliver a baby, taking part in all the joy of that ecstatic, high-energy process and moments later, cross the hall and deliver a stillborn child while whispering commiserations to a grieving couple. Entering and leaving each room without clinging to the residue of emotion from either encounter is incredibly difficult and mentally taxing.

Back in triage, with my patient hemorrhaging on the bed in front of me, my attending asked me again. “Have you told her what is happening?”

In all the frenzied panic, in ordering the chaos around me, I had completely forgotten about the patient. I had forgotten what she must be going through, what was likely going through...
her mind, how she must feel at the sight of so much of her own blood.

I was frozen, inarticulate, uncertain of exactly how I could explain what was happening. I wanted to say that when her water broke the placenta had likely abrup ted, peeling off the uterine wall. This would most certainly lead to the death of her fetuses and, if we did not act quickly, would be life-threatening for her too. I wanted to sit down next to her, to console her. Here again was another imperfect opportunity, another time-critical moment to comfort this patient, to be the one to gently convey this terrible news.

But I was silent. I was stuck in place. After so much heartache and tragedy already, in the middle of this horrendous scene, I could only think of the next steps needed to keep this patient alive. In the quiet room, tinny music still played from the cell phone.

Finally, my attending stepped in, leaning close to the patient to explain what was happening. She held her hand all the way to the operating room and was beside her when she returned.

So far, my training has taught me to be an excellent resident. I can place orders, respond to consults, and write progress notes. I can recite the antihypertensive regimen necessary to control severe-range pressures or the Amel's criteria for diagnosis of bacterial vaginosis.

But I am still hoping residency will train me to be an excellent doctor. I am still hoping it will teach me to adapt, to see through the rigid guidelines to the terrified patient beneath. I hope that in the midst of an emergency, I can not only be level-headed and calm and make the right decisions, but also make them with warmth, generosity, and compassion.

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<td>2. In-County Paid/Requested Mail Subscriptions Stated on PS Form 3541</td>
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<td>3. Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS</td>
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4. **Requested Copies Distributed by Other Mail Classes Through the USPS**
   **Total Paid and/or Requested Circulation (Sum of 15b (1), (2), (3), and (4))**
   **Non-requested Distribution**
   1. **Outside County Non-requested Copies Stated on PS Form 3541**
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      | 0 | 0 |
   3. **Non-requested Copies Distributed Through the USPS by Other Classes of Mail**
      | 0 | 0 |
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   5. **Total Non-requested Distribution (Sum of 15f (1) and (2))**
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   7. **Total (Sum of 15f and g)**
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   **Requested and Paid Electronic Copies**
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How to get patients to stop smoking

by JAMES F. SWEENEY

The patient, a smoker for 50 years, told her doctor she was afraid quitting would kill her.

Her mother had smoked her entire life, the patient explained, finally quit, then died of a heart attack 3 months later. Quitting cigarettes had killed her mother, the patient believed, and she was sure the same thing would happen to her.

Her doctor, Richard Bryce, DO, could have given up in the face of that illogical stubbornness, but he persisted. And, after a year of treatment and encouragement, the patient quit.

Treating the compulsion

Smoking rates have been declining for decades and those who do smoke are smoking less. Smoking bans in public and private places means smoking has become less of an annoyance for non-smokers. The opioid crisis gets more headlines and congressional hearings than smoking does.

But smoking is still one of the most serious health problems in the nation.

According to the Centers for Disease Control and Prevention (CDC), cigarette smoking is responsible for more than 480,000 deaths a year in the United States, more than 10 times the number of opioid deaths in 2017. Nearly 38 million American adults, or 15.5%, smoked in 2016 and the CDC reports tobacco use is on the rise among middle and high school students, largely due to vaping.

For decades, physicians have been scolding, educating, and pleading in an effort to get their smoking patients to quit, but it doesn’t always work. So, what should a doctor do? Frank Leone, MD, MS, thinks physicians who try to scare patients into quitting are going about it the wrong way.

“The message has been to turn up the heat on the patient. Constantly reiterating the negative effects of smoking—no one should expect it to make a difference,” says the director of the University of Pennsylvania’s Comprehensive Smoking Treatment Program.

Most smokers know smoking is bad for them and want to quit, Leone says, but they’re unable to because the compulsion to smoke, which is largely due to nicotine addiction, is simply too strong.

The solution, he says, is to separate the compulsion from the smoking and treat the compulsion as an addiction.

Doctors should treat smoking the same as they would any other addiction, which means anticipating incremental progress with inevitable setbacks and sporadic improvement, he says. Too often, Leone says, smoking cessation is treated as an all-or-nothing proposition, rather than a treatment program like those designed for chronic conditions like asthma or diabetes.

“It’s not an event; it’s a process,” Leone says. “There is no such thing as failure in this system.”

Ideally, he says, there would be three levels of care for smokers: primary care physicians, community- and health system-based programs and intervention specialists who understand the chemistry of addiction.

Scold or encourage?

According to a 2015 report in Morbidity and Mortality Weekly, 68% of adult smokers wanted to stop smoking and 55.4% had attempted to quit in the past year.

“Nagging never works. It just makes people mad,” says Windel Stracener, MD, a family practitioner in Richmond, Ind. “I think our job is to encourage them in quitting. Reassure them that they’re not the only ones to relapse and then help them get back on track.”

Doctors say they try to understand why patients smoke and address those reasons, if possible. Stracener says he will not nag a smoker who’s not ready to quit.
to quit, but will keep revisiting the subject. “One of those times you go to the well you might get what you’re looking for,” he says. “When I’ve had success, it’s been when I’ve used a positive approach.”

Bryce says the key to success is to not be discouraged by the patient’s inevitable relapse, but to keep providing encouragement and never abandon a smoker as a lost cause. “Even if the success rate is only one percent, it’s worth my time,” he says.

And patients do listen, says Steve Schroeder, MD, director of the Smoking Cessation Leadership Center at the University of California, San Francisco. While smokers probably have been told numerous times to stop smoking, research shows they are twice as likely to do so if they hear it from their doctor, he says. “People trust physicians,” he says. “We carry a lot more impact than their mothers-in-law.”

Doctors differ on whether to wait until patients say they want to quit to begin treating them. Stracener says a smoker will not quit until ready, but Leone says anti-smoking medication can within weeks bring patients to the point where they’re ready to stop. “The idea of ‘Are you ready to quit?’ is a big obstacle,” he says. “Create the readiness.”

Getting outside help
Helping patients stop smoking can be a long, frustrating and time-consuming process for physicians, not all of whom have the time to manage it or the patience for the inevitable relapses and setbacks. However, that doesn’t excuse inaction on the part of physicians. “To do nothing is malpractice,” says Schroeder.

Some physicians use office staff to check in with patients who are in the process of quitting. Others refer them to the numerous online cessation programs and organizations like the American Cancer Society and American Lung Association. Stracener has referred patients to social workers in the Federally Qualified Health Center where he works.

Busy physicians often advise smokers to call 1-800-QUIT-NOW. Available in all 50 states, the quit lines are staffed by National Cancer Institute-trained counselors who take patient histories, create personalized cessation programs and offer ongoing counseling.

Nicotine therapy
There are two types of anti-smoking medications: controllers that prevent cravings, such as varenicline tartrate (Chantix), bupropion (Zyban) and nicotine patches (Nicoderm); and relievers that fight immediate urges by delivering nicotine through less harmful methods than smoking. These include gum (Nicorette) and lozenges, as well as prescription inhalers and nasal sprays.

Doctors should not give up hope if a single medication doesn’t work, Leone says, adding that it often takes a combination of medicines or medicines and therapy to succeed.

Vaping
E-cigarettes and vaping devices have not been around long enough to generate the body of research that smoking has, but those in the field say there is reason to worry about their addictive properties.

Like regular cigarettes, e-cigarettes deliver doses of nicotine but, unlike cigarettes, their use is increasing dramatically. A 2016 study found that 10.8 million adults in the United States are vaping and more than half also were smoking tobacco cigarettes. Use among teens also is increasing.

According to the CDC, vaping went up among middle and high school students from 2011 to 2018. Nearly one of every 20 middle school students (4.9%) reported in 2018 that they had used electronic cigarettes in the past 30 days. That figure was 20.8 percent for high school students.

Vaping also could make it more likely that users graduate to tobacco cigarettes. A 2017 study from the University of Southern California found that 40% of teens who vaped started smoking tobacco cigarettes, compared to 10% of the youth who did not smoke at all.

Vaping is hard to quit, Leone says, because the devices are good at delivering nicotine. His treatment center has just started seeing high school students who want to quit vaping and who are surprised they are unable to.

Mr. Sweeney is a freelance writer in Cleveland, Ohio. He is a former newspaper and magazine reporter and editor.

DISCLOSURES The author reports no potential conflicts of interest with regard to this article.
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Motivational interviewing
Benefits and advice for busy physicians

A few techniques can help ob/gyns communicate more effectively and better convince their patients to follow advice.

by DEBRA SHUTE

To improve health outcomes, today’s physicians must be able to communicate effectively with their patients. One approach many experts encourage physicians to use is motivational interviewing (MI), a series of techniques to get at the root of patient concerns and help encourage them to make healthy behavior changes.

These techniques are based on the work of William R. Miller, PhD, who originally came up with the concept to address problem drinking. Miller later teamed up with Stephen Rollnick to write a book on the subject, which is now in its third edition.

The promise of MI, according to interviews with experts, is for physicians to cease wrestling with their patients to adhere to their advice, and begin to feel they are dancing as partners.

“There’s a lot to motivational interviewing, but when it’s done well without taking too much time, it can help a busy healthcare provider ‘come alongside’ the patient,” says William H. Polonsky, Ph.D., CDE, president of the Behavioral Diabetes Institute and associate clinical professor at the University of California-San Diego. “When the physician and patient feel they are on the same side, everything gets a little easier. Patients will be more willing to probably tell their doctors the truth, and maybe more willing to follow recommendations on things like taking medication.”

Benefits to physicians

This transformation does not occur overnight, but it can have a profound effect not only on patients’ health, but on physician satisfaction, says Damara Gutnick, MD, an internist and the medical director of the Montefiore Hudson Valley Collaborative. Introduced to MI while taking part in a chronic disease depression collaborative at Bellevue Hospital, Gutnick began applying MI-based techniques for goal setting and action planning with her patients.

“At this point in my career, I was quite burnt out,” she says, explaining that her population was quite sick, yet patients continued to keep drinking, smoking, or failing to take their medications. “When I learned motivational interviewing, I changed the way I was with my patients, and as a result my patients changed.”

This change was also reflected in Gutnick’s physician report card for diabetes control and other measures. “Mine were all in the green. It was the same patient...
panel that used to frustrate me and not take their medication, but it all changed when I did,” she says. It also vastly alleviated her feelings of burnout.

“Motivational interviewing gave me the opportunity to connect with patients again, which is what I loved most about medicine,” she says.

‘The listening is the doing’
The concept of OARS offers a snapshot of the skills involved in MI:

O - Open-ended questions
A - Affirmations of the patient’s inner strength
R - Reflective statements
S - Summary statements

Open-ended questions can be anything that requires more than a yes or no response, but there are some that are especially useful in getting to the heart of the matter. Polonsky, a diabetes psychologist for more than 30 years, always asks patients to identify at least one thing that really bothers them about their disease. “I may not be able to solve it, but it changes the tone of the interaction in an important way. You’re going to see your patient differently, and they’re going to see you differently because you’re interested in them as something more than a number, such as their A1c or blood pressure.”

Affirmation and reflection are equally useful, says Gutnick. “If you reflect back and say, ‘You’ve been through a lot. You’re a survivor,’ you’re picking up on the strength of the individual, and that’s an act of doing something,” she says. Even if a clinician can’t directly solve a problem the patient identifies, such as an emotional or psychosocial issue, it’s a valuable interaction. “It’s an act of doing what matters, because you’re meeting the person where they’re at, and you’re acknowledging that they’re struggling. The listening is the doing.”

Summary statements are helpful to use at transition points in the conversation as well as at the end of the visit. Experts recommend phrasing such as, “Here’s what I’ve heard. Tell me if I’ve missed anything.”

John Cullen, MD, a family physician in Valdez, Alaska, has been employing motivational interviewing techniques throughout his 25-year career. “Don’t get too caught up in the terminology,” he suggests. “It’s also important to close the computer in order to be present and empathetic. I would recommend being truthful, yet positive and supportive.”

“Patients will be more willing to probably tell their doctors the truth, and maybe more willing to follow recommendations on things like taking medication.”

Capturing the spirit of motivational interviewing
Another useful mnemonic is CAPE, which Gutnick says captures the spirit of the motivational interviewing philosophy.

“If you put a cape on somebody, such as when they’re graduating, it’s a sign of respect,” she says. “If it’s raining, it keeps them warm and dry. Or they become a superhero.

You can use CAPE to empower your patients to make changes for themselves,” she says.

COMPASSION. The entire interaction is driven by the best interest of the patient.

ACCEPTANCE AND RESPECTING AUTONOMY. Individuals have the right to change or not change, says Gutnick. “If somebody is not ready, you respect that and you don’t push. You might use some skills to try to guide them toward change, but if you’re hearing a lot of resistance and you have four patients waiting, you don’t push that visit,” she says.

PARTNERSHIP. The physician is not telling the patient what to do. Instead, “You’re helping the patient move toward change, but you’re equals,” Gutnick says.

EVOCATION. This means pulling ideas for change out of the patient. “As a doctor, I know a lot of reasons why you should quit smoking, but only you know what’s most important to you,” Gutnick says.

This mindset can help neutralize patients’ natural reflex to come up with reasons to not do something when it comes in the form of “doctor’s orders,” Gutnick explains. It’s also important to note that it’s not a dead end if a patient isn’t ready to change. “Pushing is just going to make you more frustrated,” she says. Rather, she recommends physicians ask the patient if it would be okay to revisit the topic at a future visit.

During that next meeting, it may be possible to draw more substance from the patient. For example, a clinician could say, “I know that you might not be interested in quitting smoking, but tell me a bit about what the advantages might be if you did quit,”
MOTIVATIONAL INTERVIEWING

Gutnick suggests.

The key is identifying what’s important to the individual, which often isn’t a reason that would be brought up by a clinician, Gutnick explains. “The science is that when people start to talk about their reasons for change that are important to them, it increases the chances of them changing.”

**Ways to learn technique**

There are many ways physicians can familiarize themselves with motivational interviewing skills, including articles, online modules, and workshops. However, Damara and Gutnick, who are both members of the Motivational Interviewing Network of Trainers, advise that these modalities are best used as an introduction, and that ongoing training is a must.

Polonsky says in-person training is necessary to really grasp the concept. “Studies have found that training that’s online and brief doesn’t really stick. As healthcare providers, what we all do is go back to our old habits. Live and ongoing support is most effective.”

And even when one-off trainings truly inspire clinicians, they’re unlikely to implement the skills without a framework that allows them to practice them with feedback, Gutnick says. “Any behavior change is really hard. People might have the desire, but if you don’t have the milieu that allows you to try it, then it’s going to be very hard to implement.”

**Caveats and challenges**

The biggest obstacle physicians face in learning and practicing motivational interviewing skills is time. Even though this form of communication can be more efficient and productive in the long run, it takes a great deal of practice to do it well.

A frequent mistake that clinicians make, for example, is rushing into creating an action plan with a patient before he or she is truly ready to change, says Polonsky. “You want to capture a patient’s commitment and enthusiasm about saying, ‘I see this as a priority for myself, I feel less ambivalent than before, and I’m raring to go.’”

When patient’s aren’t quite ready to change, it’s the rough equivalent of a man or woman standing at the altar and saying they might take the other person to be their wedded husband or wife rather than they will, says Gutnick. The way to identify an adequate threshold of readiness is to listen for “change talk,” she says.

Change talk indicates that a person has already taken steps toward change, such as buying walking shoes or setting a quit date. However, especially when pressed for time, doctors have a tendency to rush into the nitty-gritty of action planning when patients may still have ambivalent feelings, Polonsky says.

When the physician doesn’t spend enough time getting a true “I will” from patients and rushes into asking patients what actions they’re going to take the next day—How? What time?—patients might begin to give lip service to plans with which they won’t follow through, he explains. “Sometimes we move forward into antagonizing people about taking action before they’re ready to do so,” Polonsky says.

Cullen reiterates that patience is essential. “There is great satisfaction in finding that interventional moment that will allow a patient to change their behavior,” he says. “For some of my patients, it has taken decades.” Other attributes of motivational interviewing include willingness to be silent, to let patients talk, and to be present for them, Cullen says.

Debra Shute is a contributor for Medical Economics.

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

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**When owner relationships fall apart**

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

contemporaryobgyn.net/OwnerRelationships

**Recession preparation for physicians**

Prudent ob/gyns can take steps to ensure their practices can withstand a downturn.

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Fibroids, polyps, scar tissue, uterine malformations: in practices focused on fertility issues, the hysteroscope is an invaluable tool allowing clinicians to both diagnose and treat conditions of uterine abnormality.

This Contemporary OB/GYN podcast features Charles Miller, MD, FACOG as he reviews causes of infertility, assesses the value of using hysteroscopy for certain patients, and describes his hysteroscopic techniques for endometrial polyps, retained products of conception, and small fibroids.

Listen to the podcast at contemporaryobgyn.net/hysteroscopy-cast
pelvis was then filled with irrigation fluid and no air leak was identified upon filling the colon with air. Evicel was placed over the operative sites and peritoneal dissection sites with excellent hemostasis noted. Ancillary ports were removed with decreased pneumoperitoneum and there was no bleeding.

On admission to the Postoperative Acute Care Unit (PACU) at 4:20 PM the patient’s vital signs were stable. Surgical incision was well-approximated with scant serosanguinous drainage. At 5:00 PM, an RN noted the patient’s complaints of abdominal pain/discomfort at 6/10 intensity. Fentanyl 25 mcg intravenous (IV) push was given. By 5:15 PM the patient reported partial relief from fentanyl and complained of 6/10 abdominal pain. At 5:30 PM her vital signs were blood pressure (BP) 119/77, pulse 105, and an additional dose of fentanyl (25 mcg IV push) was given. By 5:45 PM the patient reported partial relief, and by 8:45 PM, confirmed relief of pain (with a rating of 2/10 at rest and activity) at which time she voided 400 mL. At that time, her vital signs were 110/65, pulse 88.

At discharge, she was instructed to notify her physician about persistent vaginal bleeding, nausea or vomiting; inability to urinate or a fever greater than 100.4°F; and to follow up in the clinic on July 8. The patient left the hospital at approximately 9:00 PM accompanied by family.

A few hours after being discharged...the patient presented to the ED

A few hours after being discharged from the PACU, the patient presented to the ED complaining of severe lower abdominal pain with radiation to her shoulder, unrelieved by pain medications, as well as a fever of 101°F recorded at home. Her admitting lab work was notable for an elevated white blood count (WBC) of 11.0 which later rose to 15.2. At 10:00 PM a computed tomography (CT) scan of the abdomen/pelvis with contrast was performed and revealed, “post-surgical changes in the abdomen including free intraperitoneal air; a moderate amount of complex free pelvic fluid; and no abscess.” The report noted subcutaneous gas in the right abdominal wall extending towards the pelvis and around the umbilicus which was felt to be consistent with laparoscopy port sites. These findings were not deemed suspicious by the radiologist and no further imaging or workup was suggested.

The patient was ultimately admitted to the gynecology service and seen by residents during the night who were in contact with Dr. A. She was medicated for pain but continued to complain of throbbing, constant abdominal pain. At 4:28 AM her vital signs were 120/40, pulse 116; temperature 97.9°F. At 4:45 AM the patient reported no improvement from the last dose of ketorolac although she acknowledged that her pain was currently less intense in her shoulder. On exam the patient appeared uncomfortable although she was sitting up and walking around. The resident noted that an abdominal ultrasound revealed a small amount of fluid around Monsen’s pouch, though she was “unable to determine if it was new or post-operative as seen on CT.” On exam, the woman’s abdomen was described as “soft” and appropriately tender; her incisions were clean dry and intact. The resident ordered additional lab work and indicated that she discussed her plan of continued analgesia and monitoring of vital signs with Dr. A.

A 7:00 AM the RN noted the patient “reported high level of pain partially relieved by morphine. Guarding, grimacing and moaning.” At 8:21 AM the patient was examined by a PGY-4, who noted that the patient was still complaining of abdominal pain at 5/10.
Her physical exam was notable for “voluntary guarding,” no rebound, and mid-abdominal bruising at the site of greatest pain. The resident felt the pain was likely secondary to “insufflated air and small hematoma at port site.” She ordered acetaminophen plus oxycodone and ketorolac on a prn basis and encouraged ambulation with possible discharge if the woman’s pain improved.

At 10:15 AM the patient was evaluated by Dr. A who agreed with the resident’s assessment and treatment plan. Dr. A described the woman’s pain as improved; she had passed flatus. On exam the woman’s abdomen was soft, appropriately tender, non-distended with no rebound or guarding; an area of ecchymosis was noted. Dr. A advised initiation of oral pain medications, ambulation, and discharge planning. There were no further Progress Notes by a physician in the record.

At 10:19 AM the patient was medicated with ibuprofen 600 mg. At 12:20 PM she received ibuprofen 2 tabs. At 4:30 PM she received ibuprofen 2 tabs and ondansetron 4 mg po. In her final entry at 4:37 PM the RN documented, “Explained to patient that pain is normal post-op, encouraged to take pain meds OTC, eat small frequent meals with pain meds, drink plenty of water and increase ambulation when at home.” At 5:22 PM the patient was discharged.

On June 25, 2015 at 11:16 AM the patient presented to the ED complaining that since her surgery, she had been experiencing radiating abdominal pain, primarily lower; back pain; nausea and vomiting; and shortness of breath when the pain became severe. Two days prior to admission, she started to notice bright red blood with each bowel movement, but denied black tarry stools. She also had fever and chills with a highest temperature of 101.9°F, but denied chest pain, dizziness or urinary symptoms.

On exam, she was alert and oriented and noted to be in “severe” distress. Her abdomen was soft, with minimal diffuse tenderness to palpation, but no rebound or guarding. A pelvic exam revealed a non-tender bladder; no adnexal tenderness bilaterally; a normal uterus; no rectal tenderness or hemorrhoids but blood in the vault; and abdominal scars from the laparoscopy which were clean, dry, and intact.

A CT scan with contrast (compared with a the post-op study of June 20) revealed: “a large volume pneumoperitoneum, out of proportion to expected post-surgical findings and consistent with perforated viscus; ascites, some complex, with peritoneal enhancement present consistent with peritonitis; a large multi-loculated collection of fluid and gas (abscess) is noted in the cul-de-sac, with an adjacent small collection along the pelvic sidewall and containing debris within the first (collection), of uncertain etiology; infection or fistula is not excluded.” The woman was admitted to the ob/gyn service to “rule out anemia and post-op complications.”

In her 5:00 PM Progress Note, Dr. A noted she had examined the patient and discussed the CT scan finding of a “large free air pelvic collection” with her and her family. Dr. A noted the patient’s complaints of increased pain and rectal bleeding since June 23, 2015, which she felt was “likely a delayed thermal injury to the descending colon and rectal area.” Dr. A noted that the colorectal surgeon would be evaluating the patient for surgery and she discussed with the patient and family the need for possible laparoscopy/ laparotomy and repair of primary bowel/bowel resection or diverting colostomy, noting that all questions and concerns were addressed. Dr. A also indicated she would be present during surgery.

On June 25 the colorectal surgeon performed an emergency exploratory laparotomy for ruptured viscus and a worsening clinical picture. According to the Operative Report, the findings included a 5-cm longitudinal tear in the anterior rectal wall with purulent material and a small amount of stool in the pelvis with a small abscess. An anterior bowel resection with end-to-end anastomosis and diverting ileostomy was performed. The patient was transferred to the PACU in critical but stable condition. Culture and gram stain of the pelvic fluid and wound revealed many (4+) Gram-positive rods and WBCs.

Postoperatively the patient remained in the surgical intensive care unit, with a nasogastric tube (NGT) in place, a Foley catheter, IV fluids, IV patient-controlled analgesia (PCA), and antibiotics. On postoperative day #4, she was transferred to the floor and PCA was restarted for...
pain control. She was also started on leuprolide for endometriosis following a discussion with the patient and her family about the risks/benefits of same. On July 2, a CT scan with contrast (compared with study of June 25) revealed an irregular pelvic abscess. On July 5, the NG tube was removed and the patient was started on a clear diet. On July 8, a repeat CT scan with contrast ordered for persistent elevated WBC count and “known pelvic abscesses” (compared with the study of July 2) revealed a “partial proximal small bowel obstruction with transition in the left abdomen; significant interval decrease in fluid collection in the pelvis; a decrease in the tiny collection previously identified in the right lower abdomen; a resolution of the small fluid collection in the left hemi-abdomen; interval removal of the left surgical drain; and slight increase in bilateral pleural effusions, right greater than left.”

A later CT scan with contrast (compared with the study of July 8) demonstrated that the patient was “s/p low anterior resection with expected post-surgical findings; no intra-abdominal fluid collection or free intra-peritoneal air; and a mildly increased right effusion.” Repeat blood and urine cultures from July 13 proved negative. On July 24, she underwent thoracostomy with chest tube placement under IV sedation. On July 26, the chest tube was removed. On July 28, the patient was discharged home to continue on a 2-week course of amoxicillin plus clavulanic acid. At discharge she was ambulating with assistance, tolerating a low-residue diet, voiding adequately, and her ileostomy was functioning well.

The patient returned on September 8 for closure and reversal of her ileostomy and was discharged home on September 16, 2015.

The patient returned a day later complaining of abdominal pain, nausea and vomiting. Physical exam was notable for severe abdominal tenderness on palpation with rebound and guarding. Admitting lab work abnormalities included a WBC of 11.0. A CT scan of the abdomen suggested a small obstruction over the ileus. The colorectal surgeon performed an exploratory laparotomy with lysis of adhesions and diverting loop ileostomy. Operative findings included a distal small bowel obstruction secondary to adhesions; a stool-filled colon without evidence of obstruction; and a patent colorectal anastomosis. The patient’s postoperative course was uneventful. On July 23, at the request of the patient and her family, she was transferred to another hospital.

On December 3, 2015, the patient underwent an ileostomy takedown, appendectomy, resection of prior ileal anastomosis and creation of a new hand-sewn ileo-ileostomy. Her weight was 90 lb, 2.7 oz, and her appetite was “great.”

**DISCOVERY**

The plaintiff’s ob/gyn expert reported that the patient described being in constant pain for which she used medical marijuana daily. She reported not getting her period at this time. She had experienced significant weight loss, weighing 84 lbs at the time of the exam, which she attributed to chronic difficulty with bowel movements that made it uncomfortable and difficult for her to eat. Her normal weight before her surgery was 120 lbs. Recent studies indicated that both fallopian tubes were now blocked. The expert believed that the main contributing factor to the woman’s fallopian tube disease/bilateral blockage was the rectal perforation and subsequent fecal peritonitis, and although the endometriosis was felt to be a contributing factor, he

**ALLEGATIONS**

The patient alleged that the defendants failed to protect her intraabdominal organs during the June 19 surgery, resulting in a 5-cm bowel/rectal perforation, which was not detected intraoperatively because of a purported failure to properly inspect prior to closing. She also claimed a failure to timely diagnose and treat the perforation postoperatively resulting in prolonged exposure to fecal material in the pelvis, causing infection, abscesses and adhesions and requiring four surgeries to correct. A lack of informed consent was also alleged as was bilateral fallopian tube blockage and impaired ability to conceive; post-traumatic stress response; anxiety; depression; and loss of enjoyment of life. The patient claimed to be in constant pain for which she ingested medical marijuana twice a day, impacting her cognition and her ability to work.

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The patient alleged that the defendants failed to protect her intraabdominal organs during the June 19 surgery, resulting in a 5-cm bowel/rectal perforation, which was not detected intraoperatively because of a purported failure to properly inspect prior to closing. She also claimed a failure to timely diagnose and treat the perforation postoperatively resulting in prolonged exposure to fecal material in the pelvis, causing infection, abscesses and adhesions and requiring four surgeries to correct. A lack of informed consent was also alleged as was bilateral fallopian tube blockage and impaired ability to conceive; post-traumatic stress response; anxiety; depression; and loss of enjoyment of life. The patient claimed to be in constant pain for which she ingested medical marijuana twice a day, impacting her cognition and her ability to work.
believed that complications of the June 19, 2015 surgery caused the worsening. He also believed that the tubal disease was a permanent condition which could not be fixed and that surgical removal of the dilated tube would be necessary to increase the likelihood of success with in vitro fertilization. In addition, he believed that the small bowel obstruction requiring emergency surgery with diversion ileostomy was secondary to abdominal adhesions caused by the undiagnosed and untreated fecal peritonitis. He also believed that the woman remained at risk for recurrent small bowel obstructions.

The defendant ob/gyn expert believed that this case involved a “classic” delayed thermal injury which occurred during the June 19 surgery, during removal of the endometrial masses. He described it as a rare, yet known risk which happens in the best of hands and is not an indication of medical malpractice. He noted that the patient was a candidate for the surgery because she had chronic symptomatic painful endometriosis that had not responded to conservative management.

The ob/gyn expert also believed the patient was appropriately discharged the evening of June 19, 2015. She reported pain relief, she had voided and her vital signs were stable. When she returned to the ED the next day, a CT scan was performed which revealed normal non-concerning postsurgical changes in the abdomen. The expert reported that if Dr. A had created a longitudinal tear in the anterior rectal wall during the June 19 surgery it would have been apparent on the CT scan on June 20 and there would have been “tons of air” and purulent material in the pelvis. Moreover, if a frank perforation had occurred during the surgery, stool would have been seen immediately, the air/leak test performed prior to closure would have shown it, and the patient would have developed peritonitis within a few hours of closure.

The defendant colorectal surgery expert doubted that the patient had an immediate perforation because she passed the “leak test” that Dr. A performed prior to closure. The woman’s admitting lab work was notable for an elevated WBC of 11.0 but at discharge it was 9.6. He opined that the WBCs did not support a finding of a perforation, especially since the woman was not on antibiotics. He also believed that if she had been taken to the OR on June 21, she would have had the same surgery that was performed on June 25.

The defendant radiology expert conducted a blind review of the pertinent films. Overall, she did not see a bowel perforation on the June 20 CT scan but she felt that the one performed on June 25 strongly suggested one.

The patient had some potential culpable conduct in delaying surgery (she was first advised to undergo surgery in October 2014). This allowed her ovarian cysts to enlarge thus complicating the surgery. The woman testified that she may have been taking excessive quantities of ibuprofen, which may have contributed to the surgical complications and alleged injuries. With respect to informed consent, the patient provided helpful testimony in that, due to endometriosis, her periods were so painful that it caused her to get fired from her job and it adversely impacted her activity level, making it unreasonable to presume she would have refused surgery irrespective of the potential risks.

With respect to damages, the patient provided helpful testimony in that she got married in July 2016; traveled to Atlantic City for her bachelorette party and, thereafter, travelled on a cruise and to Miami in 2017. The patient admitted that her wedding videos and photos showed her dancing. Thus, her claims that she had restricted motion due to the alleged malpractice were undermined. The woman’s claims of diminished fertility were mitigated by her long history of endometriosis, which is known to adversely impact fertility.

**TRIAL:**
Prior to the start of the trial, the patient’s attorney initially demanded $12 million to settle and then came down to a “firm” $1.5 million demand. The trial commenced with testimony of Dr. A who performed as well as could be expected under aggressive examination. The patient’s radiology expert then testified and was subjected to blistering cross-examination during which he became extremely combative and made references to multiple theories under duress in order to support his opinions, which were not supported by the record. Thereafter, opposing counsel voiced a desire to attempt to settle within reason and the case eventually settled for $885,000.
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Facts
The patient presented to the defendant hospital gyn clinic on May 6, 2015. She reported continuous bilateral pelvic pain in the right and left quadrants somewhat relieved by oral contraceptives, but said she was taking ibuprofen “around the clock.” She was examined by Dr. A, counseled regarding treatment options, given a referral for magnetic resonance imaging (MRI) and told to follow up in 3 weeks to discuss whether surgery was indicated. In a Progress Note, Dr. A indicated that she discussed the causes of pelvic pain with the patient, advising her she likely had endometriosis for which an MRI could determine the extent of the disease and surgical planning.

An MRI done on May 21, 2015 revealed bilateral endometriomas. A left hematosalpinx/hemosalpinx or pelvic endometrial implant also was noted posterior to the uterus.

The patient was seen by Dr. A to discuss the results of her MRI. She reported she was still taking ibuprofen “around the clock,” and was requesting surgery as both she and her family felt the pain was directly affecting the quality of her life. Dr. A documented that she discussed the surgical approach, risks, benefits and alternatives with the patient and her family.

The patient presented for surgery on June 16, 2015. Dr. A’s Preoperative Note listed the indications for surgery as a history of dysmenorrhea, pelvic pain, bilateral cysts, and suspected endometriosis. The patient and Dr. A executed a Surgical Consent authorizing the performance of a hysteroscopy, dilation and curettage, laparoscopic bilateral ovarian cystectomy, possible salpingectomy, treatment of endometriosis, and possible cystoscopy. Hysteroscopy revealed a normal uterine cavity with some discoloration in the endometrium and possibly adenomyosis. Both ovaries were adherent to pelvic sidewall and the posterior cul-de-sac, peritoneum, and on the uterus. A 3-cm uterine mass was noted on the posterior superfi cial myometrium of the uterus, and the rectum was pulled to the mass. Endometrial curettings were obtained from the posterior uterine wall and sent to pathology.

The laparoscopic portion of the procedure was performed via umbilical incision. Two right ovarian cysts were incised, enucleated, and removed. Hemostasis was secured. The left ovary was mobilized from the pelvic side wall with hydroadissection; a left ovarian chocolate cyst was incised, enucleated, and removed. Hemostasis was secure. Adhesions from the posterior uterus to the recto-sigmoid colon were taken down with hydro dissection and blunt dissection. The posterior uterine mass, which was about 3 cm, was grasped using the laparoscopic shears; the serosa was electro-dissected and the mass removed using a specimen bag. Peritoneal lesions were excised from the right uterosacral ligaments and posterior cul-de-sac using traction and hydroadissection. Chromotubation with methylene blue was performed and spillage noted from the left fallopian tube. No spillage was noted on the right side.

At the conclusion of the procedure, Dr. A noted: “…air was pushed into the rectum with a syringe. The
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2. The International Healthcare Worker Safety Center (University of Virginia Health System)