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OBG MANAGEMENT

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Chaperones for gyn exams?
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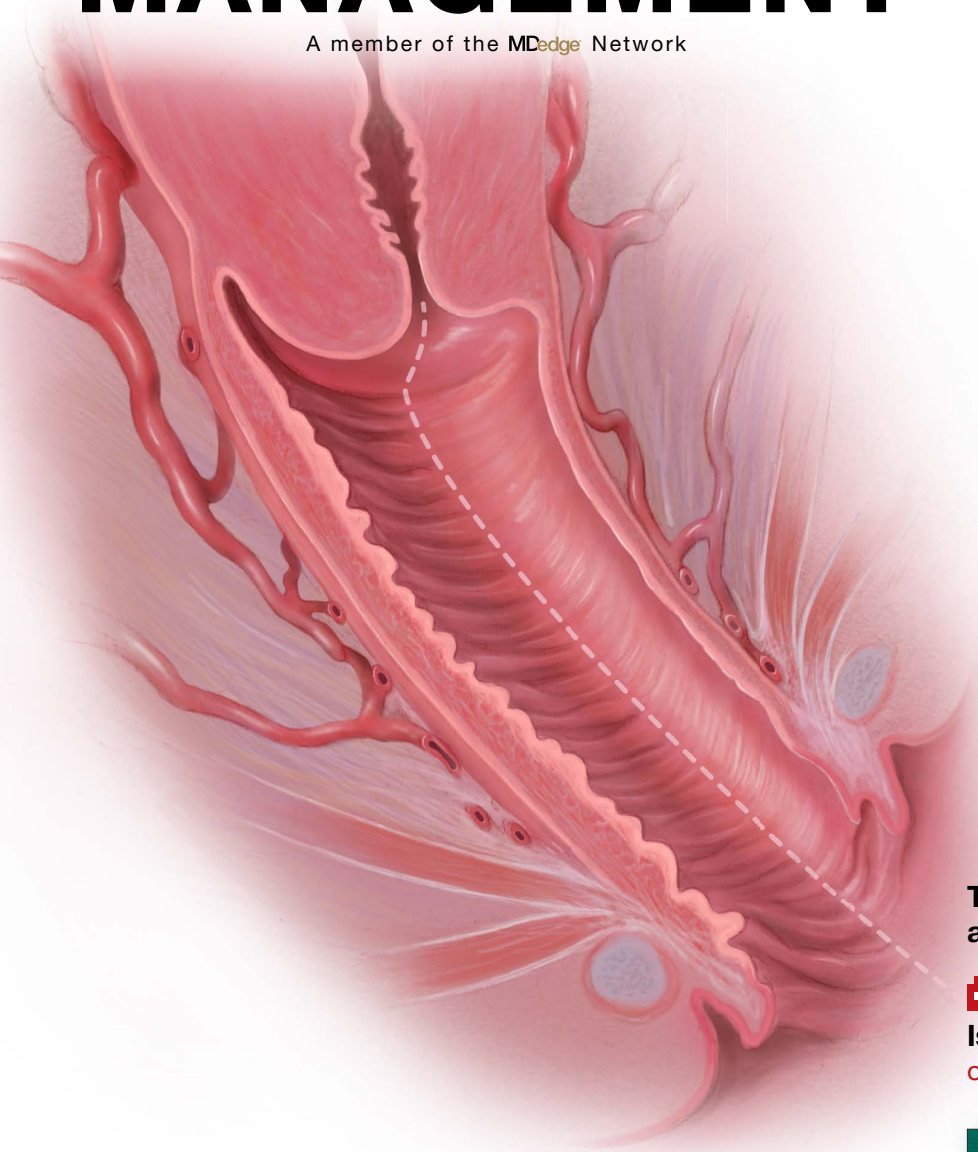
Managing *Trichomonas vaginalis* infection

New ASCCP guidelines: What's in store
Q&A with Warner K. Huh, MD



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New evidence on treatment

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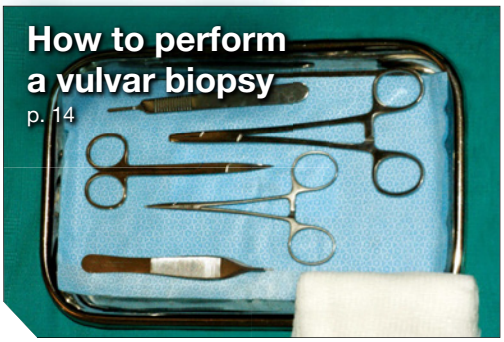

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Cologuard performance when used for repeat testing has not been evaluated or established. Rx only.

[†]In the pivotal study, screening colonoscopy was the reference method.[1]

[‡]Cologuard sensitivity, per stage of cancer: I: 90% (n=29); II: 100% (n=21); III: 90% (n=10); IV: 75% (n=4).[1]

[§]Cologuard specificity: 87% overall specificity, excluding CRC and advanced adenomas, and including all nonadvanced adenomas, nonneoplastic findings, and negative results on colonoscopy. There was 90% specificity in participants with no lesions biopsied on colonoscopy.[1]

[‖]Negative predictive value (NPV) is defined as the probability that disease is absent in those with a negative result; it is highly dependent on the prevalence of the disease. NPV was derived from the patient population evaluated in the Imperiale et al publication.[1]

Reference: 1. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;370(14):1287-1297.

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*Source: Kantar Media, Medical Surgical Study December 2019, Obstetrics/Gynecology Combined Office & Hospital Readers.
†OBG Management recognizes the importance of addressing the reproductive health of gender-diverse individuals.

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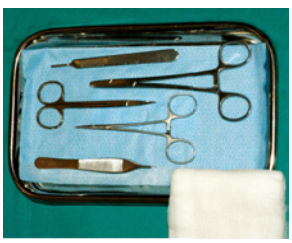

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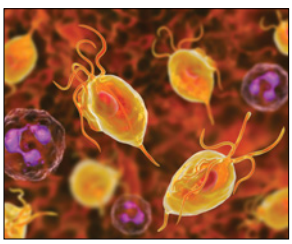

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FAST TRACK is a system to enable you as a reader to move quickly through each issue of **OBG MANAGEMENT**, identifying articles or sections of articles to read in depth.

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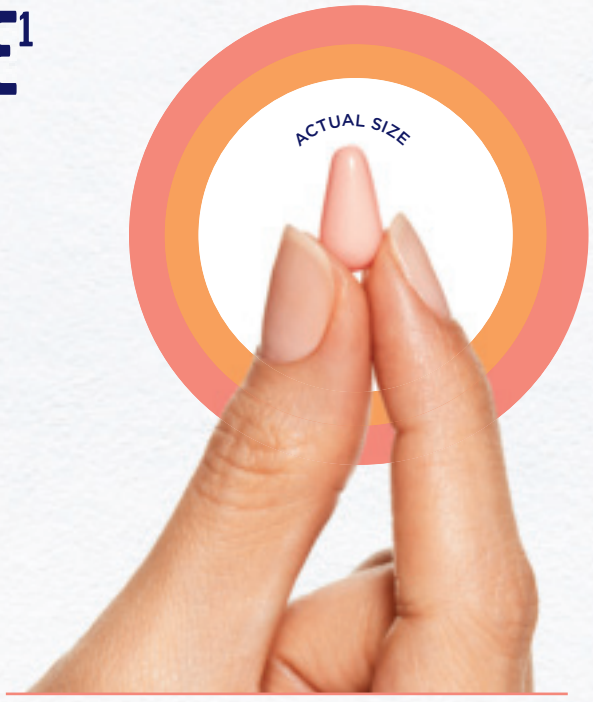

TO LEARN MORE AND REQUEST SAMPLES, VISIT IMVEXXYINFO.COM

INDICATION

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

IMPORTANT SAFETY INFORMATION

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

See full prescribing information for complete boxed warning.

Estrogen-Alone Therapy

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

Estrogen Plus Progestin Therapy

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

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

Please see Brief Summary of the Full Prescribing Information, including BOXED WARNING, on the following page.

References: 1. Imvexxy [package insert]. Boca Raton, FL: TherapeuticsMD, Inc; 2019. **2.** Data on file. Vaginal Estrogen PIs. **3.** Constantine GD, Simon JA, Pickar JH, et al. The REJOICE trial: a phase 3 randomized, controlled trial evaluating the safety and efficacy of a novel vaginal estradiol soft-gel capsule for symptomatic vulvar and vaginal atrophy. *Menopause.* 2017;24(4):409-416.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use **IMVEXXY** safely and effectively. Please visit www.IMVEXXYHCP.com for Full Prescribing Information.

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

Estrogen-Alone Therapy

Endometrial Cancer

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

Cardiovascular Disorders and Probable Dementia

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

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

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

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

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

Estrogen Plus Progestin Therapy

Cardiovascular Disorders and Probable Dementia

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

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

The WHIMS estrogen plus progestin ancillary study of the WHI, reported an increased risk of developing probable dementia in postmenopausal women 65 years of age of older during 4 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women *[see Warnings and Precautions (5.4), Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].*

Breast Cancer

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

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

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

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

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

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Risks from Systemic Absorption

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

Cardiovascular Disorders

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

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

Malignant Neoplasms

Endometrial Cancer

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

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

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

Breast Cancer

In the WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE-alone was not associated with an increased risk of invasive breast cancer [relative risk (RR) 0.80][5] *[see Clinical Studies (14.2) in full prescribing information].*

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

Ovarian Cancer

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

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

Probable Dementia

In the WHIMS estrogen-alone ancillary study of WHI, a population of 2,947 hysterectomized women 65 to 79 years of age was randomized to daily CE (0.625 mg)-alone or placebo.

After an average follow-up of 5.2 years, 28 women in the estrogen-alone group and 19 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE-alone versus placebo was 1.49 (95 percent CI, 0.83-2.66). The absolute risk of probable dementia for CE-alone versus placebo was 37 versus 25 cases per 10,000 women-years[8] *[see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].*

In the WHIMS estrogen plus progestin ancillary study of WHI, a population of 4,532 postmenopausal women 65 to 79 years of age was randomized to daily CE (0.625 mg) plus MPA (2.5 mg) or placebo. After an average follow-up of 4 years, 40 women in the CE plus MPA group and 21 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE plus MPA versus placebo was 2.05 (95 percent CI, 1.21-3.48). The absolute risk of probable dementia for CE plus MPA versus placebo was 45 versus 22 cases per 10,000 women-years[8] *[see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].*

When data from the two populations in the WHIMS estrogen-alone and estrogen plus progestin ancillary studies were pooled as planned in the WHIMS protocol, the reported overall relative risk for probable dementia was 1.76 (95 percent CI, 1.19-2.60). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether these findings apply to younger postmenopausal women[8] *[see Use in Specific Populations (8.5), and Clinical Studies (14.3) in full prescribing information].*

Other Warnings and Precautions include:

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

ADVERSE REACTIONS

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

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

DRUG INTERACTIONS

Inducers and inhibitors of CYP3A4 may affect estrogen drug metabolism and decrease or increase the estrogen plasma concentration.

USE IN SPECIFIC POPULATIONS

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

Geriatric Use

An increased risk of probable dementia in women over 65 years of age was reported in the Women's Health Initiative Memory ancillary studies of the Women's Health Initiative.

Based on IVXY-LAB-20004.2
Revised: 04/2019

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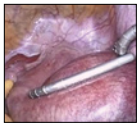

Laparoscopic transabdominal cerclage
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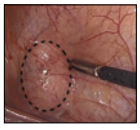
RENAE SHIBATA, MD;
OLIVIA MOSKOWITZ, MD;
GIANNI RODRIGUEZ-AYALA, MD;
AND MICHAEL L. NIMAROFF, MD



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EDITORIAL

In your practice, are you planning to have a chaperone present for all intimate examinations?

The American College of Obstetricians and Gynecologists now recommends that a chaperone be present for all breast, genital, and rectal examinations

Robert L. Barbieri, MD
Editor in Chief, OBG Management
Chair, Obstetrics and Gynecology
Brigham and Women's Hospital
Boston, Massachusetts
Kate Macy Ladd Professor of Obstetrics, Gynecology and Reproductive Biology
Harvard Medical School

Although pelvic examinations may only last a few minutes, the examination is scary and uncomfortable for many patients. To help minimize fear and discomfort, the exam should take place in a comfortable and professional environment. The clinician should provide appropriate gowns, private facilities for undressing, sensitively use draping, and clearly explain the components of the examination. Trained professional chaperones play an important role in intimate physical examinations, including:

- providing reassurance to the patient of the professional integrity of the intimate examination
- supporting and educating the patient during the examination
- increasing the efficiency of the clinician during a procedure
- acting as a witness should a misunderstanding with the patient arise.

Major medical professional societies have issued guidance to clinicians on the use of a chaperone during intimate physical examinations. Professional society guidance ranges from endorsing joint decision-making between physician and patient on the presence of a chaperone to more proscriptive guidance that emphasizes the importance of a chaperone at **every** intimate physical examination.

Examples of professional societies' guidance that supports joint decision-making between physician and patient about the presence of a chaperone include:

- American Medical Association: "Adopt a policy that patients are free to request a chaperone and ensure that the policy is communicated to patients. Always honor a patient's request to have a chaperone."[1]
- Society of Obstetricians and Gynaecologists of Canada: "It is a reasonable and acceptable practice to perform a physical examination, including breast and pelvic examination without the presence of a third person in the room unless the woman or health care provider indicates a desire for a third party to be present." "If the health care provider chooses to have a third person present during all examinations, the health care provider should explain this policy to the woman."[2]
- American College of Physicians: "Care and respect should guide the performance of the physical examination. The location and degree of privacy should be appropriate for the examination being performed, with chaperone services as an option. An appropriate setting and sufficient time should be allocated to encourage exploration of aspects of the patient's life pertinent to health, including habits, relationships, sexuality, vocation, culture, religion, and spirituality."[3]

By contrast, the following professional society guidance strongly recommends the presence of a chaperone for every intimate physical examination:

- United States Veterans Administration: "A female chaperone must be in the examination room during breast and pelvic exams…this includes procedures such as urodynamic testing or treatments such as pelvic floor physical therapy."[4]

- Royal College of Obstetricians and Gynaecologists: "The presence of a chaperone is considered essential for every pelvic examination. Verbal consent should be obtained in the presence of the chaperone who is to be present during the examination and recorded in the notes. If the patient declines the presence of a chaperone, the doctor should explain that a chaperone is also required to help in many cases and then attempt to arrange for the chaperone to be standing nearby within earshot. The reasons for declining a chaperone and alternative arrangements offered should be documented. Consent should also be specific to whether the intended examination is vaginal, rectal or both. Communication skills are essential in conducting intimate examinations."[5]
- American College Health Association (ACHA): "It is ACHA's recommendation that, as part of institutional policy, a chaperone be provided for every sensitive medical examination and procedure."[6]

Trauma-informed care

Sexual trauma is common and may cause lasting adverse effects, including poor health.[1] When sexual trauma is reported, the experience may not be believed or taken seriously, compounding the injury. Sometimes sexual trauma contributes to risky behaviors including smoking cigarettes, excessive alcohol consumption, drug misuse, and risky sex as a means to cope with the mental distress of the trauma.

Trauma-informed medical care has four pillars:

1. Recognize that many people have experienced significant trauma(s), which adversely impacts their health.
2. Be aware of the signs and symptoms of trauma.
3. Integrate knowledge about trauma into medical encounters.
4. Avoid re-traumatizing the person.

Symptoms of psychological distress caused by past trauma include anxiety, fear, anger, irritability, mood swings, feeling disconnected, numbness, sadness, or hopelessness. Clinical actions that help to reduce distress among trauma survivors include:

- sensitively ask patients to share their traumatic experiences
- empower the patient by explicitly giving her control over all aspects of the examination, indicating that the exam will stop if the patient feels uncomfortable
- explain the steps in the exam and educate about the purpose of each step
- keep the patient's body covered as much as possible
- use the smallest speculum that permits an adequate exam
- utilize a chaperone to help support the patient.

Clinicians can strengthen their empathic skills by reflecting on how their own personal experiences, traumas, cultural-biases, and gender influence their approach to the care of patients.

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New guidance from ACOG on trained chaperones

The American College of Obstetricians and Gynecologists (ACOG) recently issued a committee opinion recommending "that a chaperone be present for all breast, genital, and rectal examinations. The need for a chaperone is irrespective of the sex or gender of the person performing the examination and applies to examinations performed in the outpatient and inpatient settings, including labor and delivery, as well as during diagnostic studies such as transvaginal ultrasonography and urodynamic testing."[7]

This new proscriptive guidance will significantly change practice for the many obstetrician-gynecologists who do not routinely have a chaperone present during intimate examinations. The policy provides exceptions to the presence of a chaperone in cases of medical emergencies and if the patient declines a chaperone. ACOG recommends that when a patient declines a chaperone the clinician should educate the patient that a "chaperone is an integral part of the clinical team whose role includes assisting with the examination and protecting the patient and the physician. Any concerns the patient has regarding the presence of a chaperone should be elicited and addressed if feasible. If, after counseling, the patient refuses the chaperone, this decision should be respected and documented in the medical record."[7] ACOG discourages the use of family members, medical students, and residents as chaperones.

Training of chaperones

Chaperones are health care professionals who should be trained for their specific role. Chaperones need to protect patient privacy and the confidentiality of health information. Chaperones should be trained to recognize the components of a professional intimate examination and to identify variances from standard practice. In many ambulatory practices, medical assistants perform the role of chaperone. The American Association of Medical Assistants (AAMA) offers national certification for medical assistants through

Why patients prefer not to have a chaperone present during their pelvic examination—A clinician's perspective

Ronee A. Skornik, MSW, MD

As a female obstetrician-gynecologist trained in psychiatric social work, I have found that some of my patients who have known me over a long period of time find the presence of a chaperone not only unnecessary but also uncomfortable both in terms of physical exposure and in what they may want to tell me during the examination. Personally, I strongly favor a chaperone for all intimate examinations, to safeguard both the patient and the clinician. However, I do understand why some patients prefer to see me without the presence of a chaperone, and I want to honor their wishes. If a chaperone is responsive to the patient's requests, including where the chaperone stands and his or her role during the exam, the reluctant patient may be more willing to have a chaperone. A chaperone who develops a relationship with the patient and honors the patient's preferences is a valuable member of the care team.

an examination developed by the National Board of Medical Examiners. To be eligible for AAMA certification an individual must complete at least two semesters of medical assisting education that includes courses in anatomy, physiology, pharmacology, and relevant mathematics.

Reporting variances that occur during an intimate examination

Best practices are evolving on how to deal with the rare event of a chaperone witnessing a physician perform an intimate examination that is outside of standard professional practice. Chaperones may be reluctant to report a variance because physicians are in a powerful position, and the accuracy of their report will be challenged, threatening the chaperone's employment. Processes for encouraging all team members to report concerns must be clearly explained to the chaperone and other members of the health care team. Clinicians should be aware that deviations from standard practice will be reported and investigated. Medical practices must develop a reporting system that ensures the reporting individual will be protected from retaliation.

In addition, the chaperone needs to know to whom they should report a variance. In large multispecialty medical practices, chaperones often can report concerns to nursing leaders or human resources. In small ambulatory practices, chaperones may be advised to report concerns about a physician to the practice manager or medical director. Regardless, every practice should have the best process for reporting a concern. In turn, the practice leaders who are responsible for investigating reports of concerning behavior should have a defined process for confidentially interviewing the chaperone, clinician, and patient.

Even when a chaperone is present for intimate examinations, problems can arise if the chaperone is not trained to recognize variances from standard practice or does not have a clear means for reporting variances and when the practice does not have a process for investigating reported variances.

Sadly, misconduct has been documented among priests, ministers, sports coaches, professors, scout masters, and clinicians. Trusted professionals are in positions of power in relation to their clients, patients, and students. Physicians and nurses are held in high esteem and trust by patients. To preserve the trust of the public we must treat all people with dignity and respect their autonomy. The presence of a chaperone during intimate examinations may help us fulfill Hippocrates' edict, "First, do no harm." ●

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

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medicem

COMMENTARY

‘I didn’t train for this’: Take cues from elite athletes to maintain stamina during the COVID-19 crisis

We can train ourselves to develop mental toughness to get us through challenging times

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I am not an elite athlete. Never have been, never will be. But as I contemplated how to support my colleagues at my hospital during the COVID-19 pandemic—knowing that we face more weeks of social distancing, probable virus outbreaks as business opens up, and myriad changes in how we will practice medicine—I wondered how Olympic athletes focus their mental and physical stamina to respond to the challenges of competition.

In this article, I offer some pointers, gleaned from techniques used by exceptional athletes, on how we can maintain our stamina during the COVID-19 marathon.

Train your mind

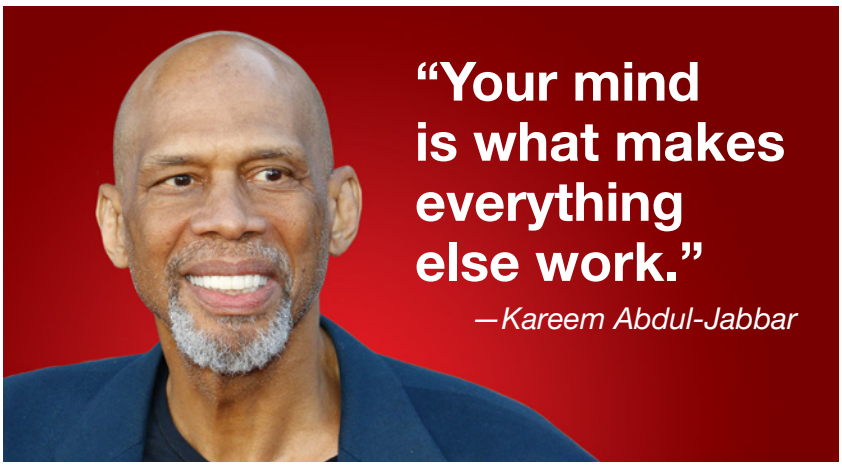
Elite athletes understand that what will take them to the top of their sport is less about their physical gifts (all elite athletes have superior athletic talent) and more about how they train their minds to achieve their goals. As basketball great Kareem Abdul-Jabbar said, “Your mind is what makes everything else work.” Not surprisingly, athletes who train to be mentally “tough” have a better chance to reach the podium.

One definition of mental toughness is the “ability to perform toward the upper range of your talent and skill” regardless of external circumstances.[1] Mental toughness involves an unshakable self-belief, resilience, motivation, focus, and ability to perform under pressure and manage physical and emotional pain.

Like me, most of you probably are not elite athletes, but you can train your mind to be tougher and increase your stamina using some of the following techniques.

Think positively

Do you find yourself dealing with an inner monologue of fear, self-doubt, and feelings of worthlessness? That is the Obnoxious Roommate in your head as described in a HuffPost



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CONTINUED FROM PAGE 10

article and based on the pioneering work of psychiatrist Aaron Beck, MD, the father of cognitive-behavioral therapy.[2,3] Such thoughts negatively affect one's sense of self-efficacy, which is the mental state of believing that you can meet the challenges you face. Elite athletes pay particular attention to their self-talk and replace negative thoughts with positive ones. These may include affirmations of your strengths or cue words that pump you up or help you manage your nerves.

To begin this practice, first observe what you are telling yourself. You may be saying, "I can't do this. This is too hard." This is an important step because you may have lived with the Obnoxious Roommate for so long that these thoughts are automatic and seem like a part of you. If, however, you first observe the thought and acknowledge it, you can begin to replace negative thoughts with supportive ones: "This is hard, but I can do this. I am intelligent, strong, capable, and ready." While practice and repetition are required, thinking positively eventually will become a habit of self-support. Elite athletes know that to reach the top, they need to become their own best friend.[4]

Use visualization

Elite athletes visualize their events in such meticulous detail that they can actually *feel* their feet on the track, their muscles tensing, the starter pistol going off, the roar of the crowd. Research shows that the part of the brain that is activated in a race is also activated when one *visualizes* the race. It is as though the race is happening in real time.[5] Physicians could use this approach to visualize the day ahead, picturing the procedures in detail and the clinical encounters going well.

In the current crisis, we frequently need a way to calm down quickly. One suggestion is to find a quiet space and sit for a few minutes, allowing the chair to support you. Then imagine a beautiful, calm, soothing place. Relax there and take in that feeling. Or, imagine a past achievement when you felt good about yourself. See yourself in that moment, remember how you felt, and take it in.

Plan for setbacks

All elite athletes have setbacks: Marathon runners hit a wall, golfers hit into the rough. But they don't spin out of control at setbacks. They expect them, and they have practiced skills to restore their confidence and re-center themselves.[6] For example, some athletes calm themselves by performing a ritualized series of movements. Others use a specific phrase (that positive self-talk again!) that reminds them of their goals or skills, while others play specific songs on their media player, or in their head, to return to their center.

Another technique is to use deep, rhythmic, diaphragmatic breathing for about 30 seconds to bring yourself back to your body.

The point is to have a plan in place to respond to setbacks in a positive manner and get back on track. Don't waste time on self-criticism.

Manage stress

Not all stress is negative. Everyone has a "sweet spot," a level of activation from which we operate best.[1] If we go too far over that level, though, we can panic. If we aren't stressed enough, it is hard to get going at all.

If you need to be pumped up to function at your best, try playing music that energizes you. If you work best when you are calm, take deep breaths and attend to the exhalation while you engage in positive self-talk.

Another way to manage stress levels during the COVID-19 pandemic is to employ the ESCAPE mnemonic:

- **E**xercise. Research shows that regular aerobic exercise is a potent stress reliever; it raises endorphin levels, provides a general sense of well-being, and improves immune function.[7] If you exercise regularly, do everything possible to keep doing so. If you do not have an exercise routine, try taking walks. Get out into the fresh air, pay attention to your surroundings, and work to be present in your body as you move.
- **S**leep. Getting adequate sleep, 7 to 9 hours a night for most people, is important for maintaining physical and emotional health.[8] Elite athletes pay particular attention to sleep because they know that their bodies need to recharge. The COVID-19 crisis has affected sleep for many, and we need to consciously attend to sleep hygiene. This includes limiting use of screen time to no more than 2 hours before bed. As well, limit your intake of the news and definitely avoid it right before bedtime. Take a warm shower, drink a cup of herbal tea, or read a less-than-stimulating journal article. Make sure your bedroom is cool and dark. Keep a regular bedtime and wake up at a regular time.
- **C**onnect. Despite the current need for physical distancing, do not neglect your need to connect to those you love and care about. Whatever modality works for you—telephone, e-mail, video conferencing—if you feel lonely, reach out. Friends and families are concerned about us, and it makes them feel useful to support us. Allow that.
- **A**ppreciate/cultivate gratitude. Look for causes for celebration in your life, whether that is your family, friends, or that you have a job and a

home. Perhaps it is the cleaner air or the beauty of nature. Whatever you are grateful for, acknowledge it, perhaps by writing it down in a journal. Remembering these things can serve as an antidote to the stress created by the COVID-19 crisis.

- **P**lay. Seek out things that make you laugh.[9] Find your inner goofiness. Get creative and paint, sing, garden, golf, play an instrument, dance, do puzzles, or play games. We need to remember the pleasures in life when times are dark. Find whatever feels like joy.
- **E**xhale. If you have a meditation practice continue to do it. If not, consider starting. Try yoga as a way to center yourself in your body. Elite athletes use meditation and yoga to harness their minds and bodies to feel more in control.[10] When so many things feel out of our control and unpredictable, it can be immensely soothing to connect to yourself in this way and realize you can reliably relax.

Self-care is a necessity

While we are in a marathon not of our choosing, we can use the techniques of elite athletes to think positively, visualize scenarios to achieve our goals or to simply relax, plan for setbacks so that we can bounce back, and manage stress productively. Self-care is paramount as we continue to care for others. Let's not neglect ourselves, and we will cross the finish line together. ●

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How to perform a vulvar biopsy

Tips for honing in on your vulvar biopsy skills and communicating clearly with your pathologist

Kathryn C. Welch, MD; Hope K. Haefner, MD; and Natalie A. Saunders, MD

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Many benign, premalignant, and malignant lesions can occur on the vulva. These can be challenging to differentiate by examination alone. A vulvar biopsy often is needed to appropriately diagnose—and ultimately treat—these various conditions.

In this article, we review vulvar biopsy procedures, describe how to prepare tissue specimens for the pathologist, and provide some brief case examples in which biopsy established the diagnosis.

Ask questions first

Prior to examining a patient with a vulvar lesion, obtain a detailed history. Asking specific questions may aid in making the correct diagnosis, such as:

- How long has the lesion been present? Has it changed? What color is it?
- Was any trigger, or trauma, associated with onset of the lesion?
- Does the lesion itch, burn, or cause pain? Is there any associated bleeding or discharge?
- Are other lesions present in the vagina, anus, or mouth, or are other skin lesions present?
- Are any systemic symptoms present, such as fever, lymphadenopathy, weight loss, or joint pain?
- What is the patient's previous treatment history, including over-the-counter medications and prescribed medications?
- Has there been any incontinence of urine or stool? Does the patient use a pad?
- Is the patient scratching? Is there any nighttime scratching? It also can be useful to ask her partner, if she has one, about nighttime scratching.
- Is there a family history of vulvar conditions?
- Has there been any change in her use of products like soap, lotions, cleansing wipes, sprays, lubricants, or laundry detergent?
- Has the patient had any new partners or significant travel history?

Preprocedure counseling points

Prior to proceeding with a vulvar biopsy, review with the patient the risks, benefits, and alternatives and obtain patient consent for the procedure. Vulvar biopsy risks


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include pain, bleeding, infection, injury to surrounding tissue, and the need for further surgery. Make patients aware that some biopsies are nondiagnostic. We recommend that clinicians perform a time-out verification to ensure that the patient's identity and planned procedure are correct.

Assess the biopsy site

A wide variety of lesions may require a biopsy for diagnosis. While it can be challenging to know where to biopsy, taking the time to determine the proper biopsy site may enhance pathology results.

When considering colored lesions, depth is the important factor, and a punch biopsy often is sufficient. A tumor should be biopsied in the thickest area. Lesions that are concerning for malignancy may require multiple biopsies. An erosion or ulcer is best biopsied on the edge, including a small amount of surrounding tissue. For most patients, biopsy of normal-appearing tissue is of low diagnostic yield. Lastly, we try to avoid biopsies directly on the midline to facilitate better healing.[1]

A photograph of the vulva prior to biopsy may be helpful for the pathologist to see the tissue. Some electronic medical records have the capability to include photographs. Due to the sensitive nature of these photographs, we prefer that a separate written patient consent be obtained prior to taking photographs. We find also that photos are a useful reference for progression of disease at follow-up in a shared care team.

Anesthesia procedure and instrument kit

Some patients may benefit from the application of topical lidocaine 4% cream (L.M.X.4) prior to the injection of a local anesthetic for tissue biopsy. Ideally, topical lidocaine should be placed on the vulva and covered with a dressing such as Tegaderm or cellophane up to 30 minutes before the anticipated biopsy procedure. The anesthetic effect generally lasts for about 60 minutes. Many patients report stinging for several seconds upon application. Due to clinic time restrictions, we tend to reserve this method for a limited subset of patients. If planning a return visit for a biopsy, the patient can place the topical anesthetic herself.

FIGURE 1 Premade vulvar biopsy instrument kit

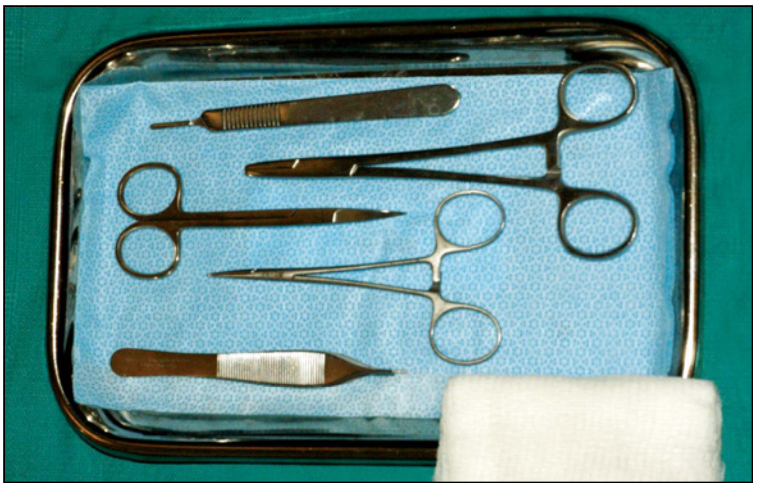

Image courtesy of Hope Haefner, MD.

For the anesthetic injection, we recommend lidocaine 1% or 2% with epinephrine in all areas of the vulva except for the glans clitoris. For a punch biopsy, we draw up 1 to 3 mL in a 3-mL syringe and inject with a 21- to 30-gauge needle, using a lower gauge for thicker tissue. We have not found buffering the anesthetic with sodium bicarbonate to be of particular use. For the glans clitoris, lidocaine without epinephrine should be utilized.

Equipment. Depending on your office setting, having a premade instrument kit may be preferred to peel-pack equipment. We prefer a premade tray that contains sterile gauze, a hemostat, iris scissors, a needle driver, a scalpel handle, and Adson forceps (**FIGURE 1**).

FAST TRACK

A photograph of the vulva prior to biopsy may be helpful for the pathologist to see the tissue

Types of biopsy procedures

Punch biopsy. We recommend a 4-mm Keyes biopsy punch. As mentioned, we use a biopsy kit to facilitate the procedure. After the tissue is properly anesthetized and prepped, we test the area via gentle touch to the skin with the hemostat or Adson forceps. To perform the punch biopsy, gentle, consistent pressure in a clockwise-counterclockwise

FIGURE 2 Stitch biopsy with suture placed around the biopsy area

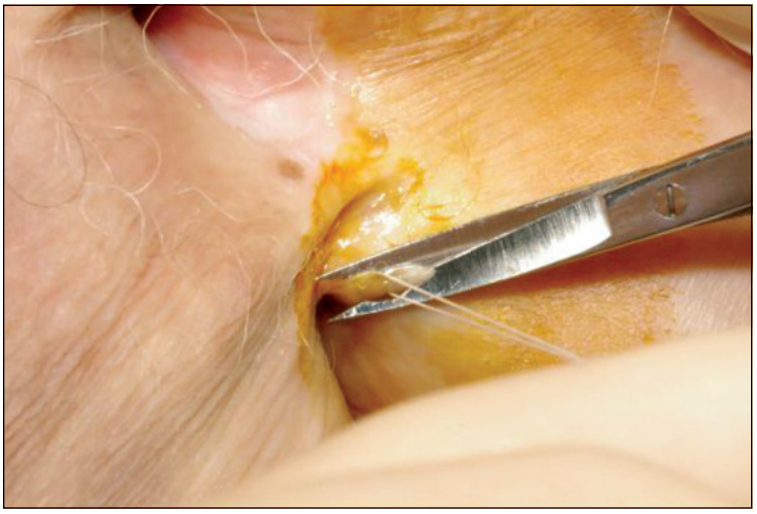

Image courtesy of Hope Haefner, MD.

FAST TRACK

A stitch biopsy can be very useful given the architecture of the vulva, and a relatively large sample can be obtained

fashion yields the best results. The goal is to obtain a 5-mm depth for hair-bearing skin and a 3-mm depth for all other tissue.[2] The tissue should then be excised at the base with scissors, taking care not to crush the specimen with forceps.

Punch biopsy permits sampling of the epidermis, dermis, and subcutaneous tissue. Hemostasis is maintained with either silver nitrate, Monsel's solution (ferric sulfate), or a dissolvable suture such as 4-0 Monocryl (poliglecaprone 25) or Vicryl Rapide (polyglactin 910).

Stitch biopsy. We find the stitch biopsy to be very useful given the architecture of the vulva. A modification of the shave biopsy, the stitch biopsy is depicted in **FIGURE 2**. A 3-0 or 4-0 dissolvable suture is placed through the intended area of biopsy. Iris scissors are used to undermine the tissue while the suture is held on tension. The goal is to remove the suture with the specimen. Separate sutures are used for hemostasis. The stitch does not cause the crushing artifacts on prepared specimens. Depending on the proceduralist's comfort, a relatively large sample can be obtained in this fashion. If the suture held on tension is inadvertently cut, a second pass can be made with suture; alternatively, care can be used to remove remaining tissue with forceps and scissors, again avoiding crush injury to the tissue.

Excisional biopsy. Often, a larger area or margins are desired. We find that with adequate preparation, patients tolerate excisions in the office quite well. The planned area for excision can be marked with ink to ensure margins. Adequate anesthesia is instilled. A No. 15 blade scalpel is often the best size used to excise vulvar tissue in an elliptical fashion. Depending on depth of incision, the tissue may need to be approximated in layers for cosmesis and healing.

When planning an excisional biopsy, place a stitch on the excised tissue to mark orientation or pin out the entire specimen to a foam board to help your pathologist interpret tissue orientation.

The box on page 18 provides 6 case examples of vulvar lesions and the respective diagnoses confirmed by biopsy.

Preparing tissue for the pathologist

Here are 5 tips for preparing the biopsied specimen for pathology:

- Include a question for the pathologist, such as "rule out lichen sclerosus or lichen simplex chronicus." The majority of specimens should be sent in formalin. At times, frozen sections are done in the operating room.
- Double-check that the proper paperwork is included with every specimen and be very specific regarding the exact location of the lesion on the vulva. Include photographs whenever possible.
- Request that a dermatopathologist or a gynecologic pathologist with a special interest in vulvar dermatology, when feasible, review the tissue.
- Check your laboratory's protocol for sending biopsies from areas around ulcerated tissue. Often, special medium is required for immunohistochemistry stains.
- Call your pathologist with questions about results; he or she often is happy to clarify, and together you may be able to arrive at a diagnosis to better serve your patient.[3]

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How to perform a vulvar biopsy

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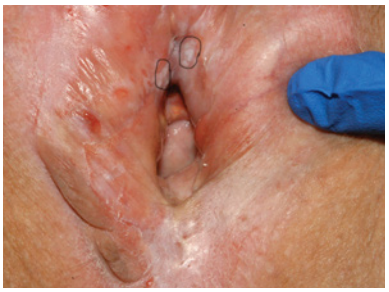
Vulvar biopsy established the diagnosis in these cases

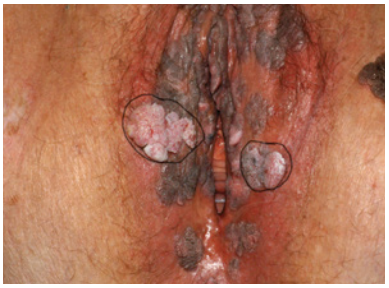


Case 1

A 62-year-old woman with a history of vulvar lichen sclerosus presents for examination reporting symptoms of perianal irritation. Vulvar examination is consistent with lichen sclerosus, with an area of erosion on the right labium majus. In addition, thickened tissue firm to the touch raises concern. The clinician recommends a vulvar biopsy to evaluate for lichen sclerosus, differentiated vulvar intraepithelial neoplasia (dVIN), and vulvar cancer.

Biopsies were obtained of the areas highlighted in the photo. Pathology shows dVIN.

Image courtesy of Hope Haefner, MD.

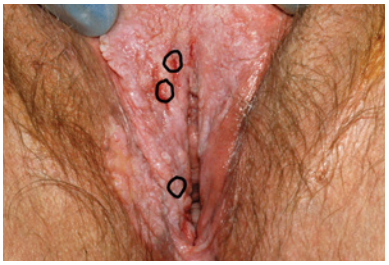


Case 2

A 22-year-old woman presents with concerns of raised bumps on the vulva. The bumps can be itchy and irritating but are not painful. They seem to have grown and spread since she first noticed them.

The examination is consistent with condylomata acuminata and biopsy is recommended with a 4-mm punch. Biopsy results are consistent with condylomata acuminata.

Image courtesy of Hope Haefner, MD.

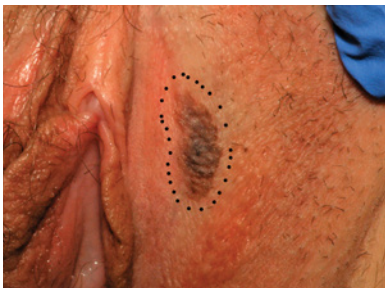


Case 3

A 30-year-old woman presents with concern of a raised area on the vulva. It is itchy and sometimes painful. Acetic acid is applied to the vulva and acetowhite changes are noted. 4-mm punch biopsies are obtained in multiple areas.

The final pathology shows high-grade squamous intraepithelial lesions (HSIL) of the vulva.

Image courtesy of Hope Haefner, MD.



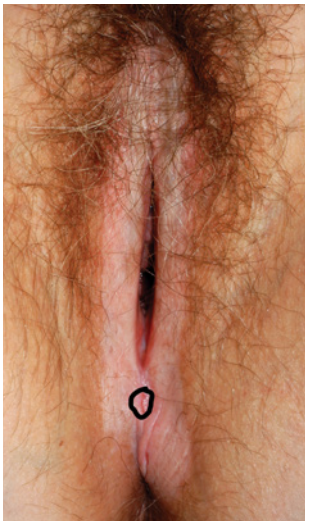
Case 4

A 19-year-old woman presents with concerns of a pigmented, darkened area on the vulva. She is not sure how long the lesion has been present. It is not itchy and does not cause pain or irritation.

This presentation is an excellent opportunity for an excisional biopsy of the vulva. A marking pen is used to draw margins. A No. 15 blade is used to outline and then undermine the lesion, removing it in its entirety.

Final pathology shows a compound nevus of the vulva.

Image courtesy of Hope Haefner, MD.

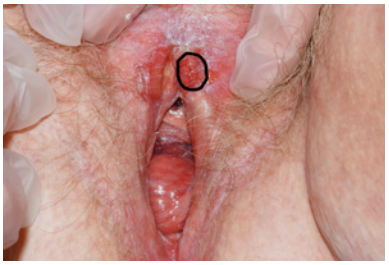


Case 5

A 56-year-old woman presents with a 2-year history of vulvar irritation, burning, and itching. Examination reveals vulvar paleness in an hourglass configuration. There is loss of the labia minora and phimosis of the prepuce overlying the clitoris.

A 4-mm punch biopsy result is consistent with a diagnosis of lichen sclerosus.

Image courtesy of Hope Haefner, MD.



Case 6

A 65-year-old woman with a long history of lichen sclerosus presents with painful bleeding and a raised lesion on the vulva. Examination reveals a firm raised area that is friable to touch.

A 4-mm punch biopsy result reveals that the pathology is significant for squamous cell carcinoma.

Image courtesy of Hope Haefner, MD.

Complications and how to avoid them

Bleeding. Any procedure has bleeding risks. To avoid bleeding, review the patient's medication list and medical history prior to biopsy, as certain medications, such as blood thinners, increase risk for bleeding. Counseling a patient on applying direct pressure to the biopsy site for 2 minutes is generally sufficient for any bleeding that may occur once she is discharged from the clinic.

Infection. With aseptic technique, infection of a biopsy site is rare. We use nonsterile gloves for biopsy procedures. This does not increase the risk of infection.[4] If a patient has iodine allergy, dilute chlorhexidine is a reasonable alternative for skin cleansing. Instruct the patient to keep the site clean and dry; if the biopsy proximity is close to the urethra or anus, use of a peri-bottle may be preferred after toileting. Instruct patients not to pull sutures. While instructions are specific for each patient, we generally advise that patients wait 4 to 7 days before resuming use of topical medications.

Scarring or tattooing. Avoid using dyed suture on skin surfaces and counsel the patient that silver nitrate can permanently stain tissue. Usually, small biopsies heal well but a small scar is possible.

Key points to keep in mind

- Counsel patients on biopsy risks, benefits, and alternatives. Counsel regarding possible inconclusive results.
- Take time in choosing the biopsy site and consider multiple biopsies.
- Have all anticipated equipment available; consider using premade biopsy kits.
- Consider performing a stitch biopsy to avoid crush injury.
- Take photographs of the area to be biopsied and communicate with your pathologist to facilitate diagnosis. ●

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1. Edwards L, Lynch PJ. *Genital Dermatology Atlas and Manual.* 3rd ed. Philadelphia, PA: Wolters Kluwer; 2018.
2. American College of Obstetricians and Gynecologists. Practice bulletin no. 93: Diagnosis and management of vulvar skin disorders. *Obstet Gynecol.* 2008;111:1243-1253.
3. Heller DS. Areas of confusion in pathologist-clinician communication as it relates to understanding the vulvar pathology report. *J Low Genit Tract Dis.* 2017;21:327-328.
4. Rietz A, Barzin A, Jones K, et al. Sterile or non-sterile gloves for minor skin excisions? *J Fam Pract.* 2015;64:723-727.

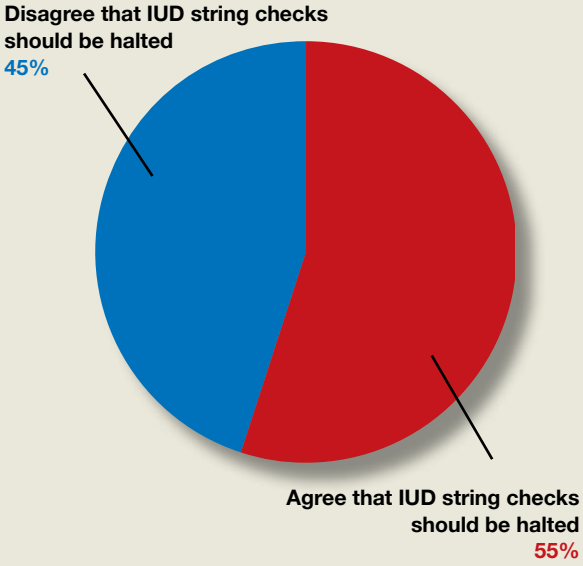
Do ObGyns agree that the practice of in-office IUD string checks should be halted?

In their Break This Practice Habit column, "The IUD string check: Benefit or burden?" (March 2020), Kathryn Fay, MD, and Lori Gawron, MD, MPH, argued that it is time to discontinue routine office visits and self-checks for IUD strings postinsertion as the practice is unsupported by data and costly. OBG MANAGEMENT polled readers: "Should the practice of counseling patients to present to the office for a string check after IUD insertion be halted?"

Poll results

A total of 93 readers cast their vote:

- **55% (51 readers) said yes**
- **45% (42 readers) said no**



PART 2 OF 3

Telemedicine: Common hurdles and proper coding for ObGyns

Hurdles to the effective delivery of telemedicine may seem to abound, but vaulting such hurdles as cost, complexity, coding, and compensation can be easier than you would think

Mickey Karram, MD, and Neil Baum, MD

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Since the COVID-19 pandemic began, many significant changes have occurred that have made the implementation of telemedicine easier and more attractive for gynecologic practices. In the first article in this series, we discussed the benefits of telemedicine to physicians and patients, how to get started using telemedicine, and implementing a workflow. This article will discuss the common hurdles in the process and the proper coding to use to insure reimbursement for services rendered.

Barriers to implementing telemedicine

Incorrect assumptions

Latecomers to telemedicine often assume that patients prefer face-to-face visits when, in fact, many may prefer the convenience of virtual visits. More than 50% of patients who are surveyed about their experience with telemedicine say that online tools have helped improve their relationship with their providers.[1] Telemedicine has grown astronomically during the COVID-19 pandemic to the point where many patients now *expect* their health care providers to be able to conduct virtual visits. Practices that do not offer telemedicine may find their patients seeking services elsewhere. Nearly two-thirds of health care professionals expect their commitment to telemedicine to increase significantly in the next 3 years.[2] Of those providers who have not yet adopted the practice, nearly 85% expect to implement telemedicine in the near future.[3] COVID-19 has motivated the increased use of telemedicine to enhance the communication with patients, making it possible for patients to have enhanced access to health care during this pandemic while minimizing infectious transmission of COVID-19 to physicians and their staff.[4]

Admittedly, telemedicine is not appropriate for all patients. In general, situations that do not lend themselves to telemedicine are those for which an in-person visit is required to evaluate the patient via a physical

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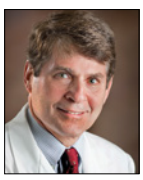
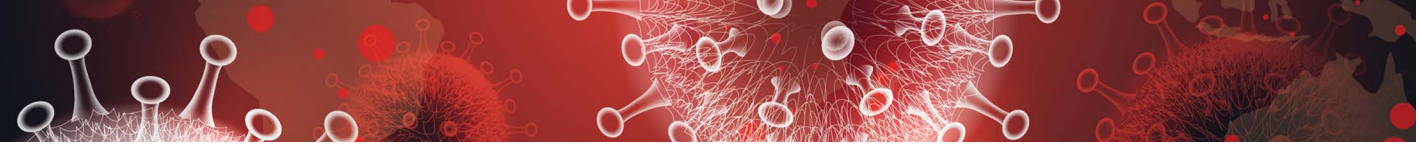


Dr. Baum is Professor of Clinical Urology, Tulane Medical School, New Orleans, Louisiana.

The authors report no financial relationships relevant to this article.



examination, to perform a protocol-driven procedure, or provide an aggressive intervention. Additional patients for whom telemedicine may be inappropriate include those with cognitive disorders, those with language barriers, those with emergency situations that warrant an office visit or a visit to the emergency department, and patients who do not have access to the technology to conduct a virtual visit.

Cost and complexity

The process of implementing electronic health records (EHRs) left a bitter taste in the mouths of many health care professionals. But EHRs are complicated and expensive. Implementation often resulted in lost productivity. Because the learning curve was so steep, many physicians had to decrease the number of patients they saw before becoming comfortable with the conversion from paper charts to an EHR.

Telemedicine implementation is much less onerous and expensive. Telemedicine is available as a cloud-based platform, which requires less information technology (IT) support and less hardware and software. The technology required for patients to participate in telemedicine is nearly ubiquitous. According to the Pew Research Center, 96% of Americans own a cell phone (81% have a smart phone), and more than half (52%) own a tablet, so the basic equipment to connect patients to providers is already in place.[5]

On the provider side, the basic equipment required for a telemedicine program is a computer with video and audio capabilities and a broadband connection that is fast enough to show video in real time and to provide high-quality viewing of any images to be reviewed.

The growth in telemedicine means that telemedicine options are now more diverse, with many more affordable solutions. However, most telemedicine programs do require the purchase and set-up of new technology and equipment and the training of staff—some of which may be outside the budgets of health care providers in smaller independent practices. Many gynecologists have technology budgets that are already stretched thin. And for patients who do not have access to a smartphone or computer with Internet access, real-time telemedicine may be out of reach.

But with new guidelines put forth by the Centers for Medicare and Medicaid Services (CMS) in March 2020, connectivity can take place inexpensively using free platforms such as Google Hangouts, Skype, Facetime, and Facebook Messenger. If a non-HIPAA-compliant platform is used initially, conversion to a HIPAA-compliant platform is recommended.[6] These platforms do not require the purchase of, or subscription to, any expensive hardware or software. The disadvantages of these programs are the lack of documentation, the failure to be Health Insurance Portability and Accountability Act (HIPAA)-compliant, and the lack of encryption; however, these disadvantages are no longer an issue after the new CMS guidelines.

Depending on the magnitude of the program, IT assistance may be needed to get started. It is imperative that the telemedicine program is interoperable with the EHR and the billing program. Otherwise, double and

Resources

- COVID-19 and Telehealth Coding Options as of March 20, 2020. https://www.ismanet.org/pdf/COVID-19andTelehealthcodes3-20-2020Updates.pdf.
- Federation of State Medical Boards. US States and Territories Modifying Licensure Requirements for Physicians in Response to COVID-19. Last updated May 26, 2020. https://www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declarations-licensures-requirementscovid-19.pdf.
- Center for Connected Health Policy. Current State Laws and Reimbursement Policies.
- https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies.
- Centers for Medicare and Medicaid Services. List of Telehealth Services. Updated April 30, 2020. https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
- American Medical Association. AMA quick guide to telemedicine in practice. Updated May 22, 2020. https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice.

FIGURE 1 Sample consent form for telemedicine services

PATIENT NAME: _____

LOCATION OF PATIENT: _____ DATE OF BIRTH: _____

MEDICAL RECORD #: _____ PHYSICIAN NAME: _____

LOCATION: _____ CONSULTANT NAME: _____

LOCATION: _____ CONSULTANT NAME: _____

LOCATION: _____ DATE CONSENT DISCUSSED: _____

Introduction

Telemedicine is the delivery of health care services through the use of technology when the health care provider and patient are not in the same physical location. Providers may include primary care practitioners, specialists, and/or subspecialists. Electronically-transmitted information may be used for diagnosis, therapy, follow-up, and/or patient education, and may include any of the following:

- patient medical records
- medical images
- interactive audio, video, and/or data communications
- output data from medical devices and sound and video files.

The interactive electronic systems used will incorporate network and software security protocols to protect the confidentiality of patient identification and imaging data and will include measures to safeguard the data and to ensure its integrity against intentional or unintentional corruption.

Potential Benefits:

1. Improved access to medical care by enabling a patient to remain in his/her physician's office (or at a remote site) while the physician obtains test results and consults with healthcare practitioners at distant/other sites.

2. Obtaining the expertise of a distant specialist.

Potential Risks:

As with any medical procedure, there are potential risks associated with the use of telemedicine. These risks include, but may not be limited to:

1. Information transmitted may not be sufficient (eg, poor resolution of images) to allow for appropriate medical decision-making by the physician and consultant(s).

2. The consulting physician(s) is not able to provide medical treatment to the patient through the use of telemedicine equipment nor provide for or arrange for any emergency care that may be required.

3. Delays in medical evaluation and treatment could occur due to deficiencies or failures of the equipment.

4. Security protocols could fail, causing a breach of privacy of personal medical information.

5. A lack of access to complete medical records may result in adverse drug interactions or allergic reactions or other medical judgment errors.

triple entry will erase the efficiency provided by conducting a virtual visit.

Licensing

Another concern or barrier is a license to participate in telemedicine. The March 15, 2020, approval of telemedicine states that physicians who are licensed in the state where the patient is located do not require any additional license or permission to conduct virtual visits.[7]

FIGURE 1 Sample consent form for telemedicine services (continued)

By signing this form, I understand and agree to the following:

1. The laws that protect the privacy and confidentiality of medical information also apply to telemedicine. No information obtained during a telemedicine encounter that identifies me will be disclosed to researchers or other entities without my consent.

2. I have the right to withhold or withdraw my consent to the use of telemedicine during the course of my care at any time. I understand that my withdrawal of consent will not affect any future care or treatment, nor will it subject me to the risk of loss or withdrawal of any health benefits to which I am otherwise entitled.

3. I have the right to inspect all information obtained and recorded during the course of a telemedicine interaction, and may receive copies of this information for a reasonable fee.

4. A variety of alternative methods of medical care may be available to me, and I may choose one or more of these at any time. My physician has explained the alternative care methods to my satisfaction.

5. Telemedicine may involve electronic communication of my personal medical information to other medical practitioners who may be located in other areas, including out-of-state.

6. I may expect the anticipated benefits from the use of telemedicine in my care, but no results can be guaranteed or assured. My condition may not be cured or improved, and in some cases, may get worse.

Patient Consent To The Use of Telemedicine

I have read and understand the information provided above regarding telemedicine, have discussed it with my physician or such assistants as may be designated, and all of my questions have been answered to my satisfaction.

I hereby give my informed consent for the use of telemedicine in my medical care. I hereby consent to and authorize _____ (name of gynecologist) to use telemedicine in the course of my diagnosis and treatment.

Signature of Patient (or person authorized to sign for Patient):_____

Date: _____

If authorized signer, relationship to Patient:

Witness: _____Date: _____

I have been offered a copy of this consent form (patient's initials) _____

CMS has temporarily waived the requirement that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. For questions regarding licensure, contact your State Board of Medicine or Department of Health for information on requirements for licenses across state lines (see "Resources," page 21).

Informed consent

Just like with any other aspect of providing care for patients, obtaining informed consent is paramount. Not only is getting informed patient consent a recommended best practice of the American Telemedicine Association (ATA), but it is actually a legal requirement in many states and could be a condition of getting paid, depending on the payer. To check the requirements regarding patient consent in your state, look at The National Telehealth Policy Resource Center's state map (see "Resources," page 21).

Some states do not have any requirements regarding consent for a virtual visit. Others require verbal consent. Even if it is not a legal requirement in your state, consider making it a part of your practice's policy to obtain written or verbal consent and to document in the patient's record that consent was obtained prior to the virtual visit so that you are protected when using this new technology.

CONTINUED ON PAGE 24

CONTINUED FROM PAGE 23

Because telemedicine is a new way of receiving care for many patients, it is important to let them know how it works including how patient confidentiality and privacy are handled, what technical equipment is required, and what they should expect in terms of scheduling, cancellations, and billing policies. A sample consent form for telemedicine use is shown in **FIGURE 1**.

Liability insurance

Another hurdle that must be considered is liability insurance for conducting virtual visits with patients. Gynecologists who are going to offer telemedicine care to patients should request proof *in writing* that their liability insurance policy covers telemedicine malpractice and that the coverage extends to other states should the patient be in another state from the state in which the gynecologist holds a license. Additionally, gynecologists who provide telemedicine care should check with liability insurers regarding any requirements or limitations to conducting a virtual visit with their patients and should document them. For example, the policy may require that the physician keep a written or recorded record of the visit in the EHR. If that is the case, then using Skype, Facebook, or Google for the virtual visit, which do not include documentation, would be less desirable.

FAST TRACK

When offering telemedicine care, request written proof that your liability insurance policy covers telemedicine malpractice and that the coverage extends to other states

Privacy

Certainly, there is concern about privacy, and HIPAA compliance is critical to telemedicine success. Because of the COVID-19 emergency, as of March 1, 2020, physicians may now communicate with patients, and provide telehealth services, through remote communications without penalties.[8] With these changes in the HIPAA requirements, physicians may use applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Skype, to provide telehealth without risk that the Office for Civil Rights will impose a penalty for noncompliance with HIPAA rules. The consent for patients should mention that these "public" applications potentially introduce privacy risks. This is a motivation for gynecologists to consider one of the programs that promises encryption, privacy, and HIPAA compliance, such as Updox, Doxy.me, and Amazon Chime. It is also important to recognize that a virtual visit could result in colleagues (if the patient is in an office setting) or family members (if the patient is in the home environment) overhearing conversations between the health care professional and the patient. Therefore, we suggest that patients conduct virtual visits in locations in which they feel assured of some semblance of privacy.

Compensation for telemedicine

Perhaps the biggest barrier to virtual health adoption has been compensation for telemedicine visits. Both commercial payers and CMS have been slow to enact formal policies for telemedicine reimbursement. Because of this, the common misconceptions (that providers cannot be reimbursed for telemedicine appointments or that compensation occurs at a reduced rate) have persisted, making telemedicine economically unappealing.

The good news is that this is changing; legislation in most states is quickly embracing virtual health visits as a result of the COVID-19 pandemic.[9] In fact, as of January 1, 2020, telemedicine services are no longer considered "optional" coverage in Medicare Advantage plans.[10] Nor are they required to have an additional fee. Instead, CMS now allows telemedicine as a standard, covered benefit in all plans, enabling beneficiaries to seek care from their homes rather than requiring them to go to a health care facility.[11] In the past, telemedicine was restricted for use in rural areas or when patients resided a great distance from their health care providers. Starting March 6, 2020, and for the duration of the COVID-19 public health emergency, Medicare will make payment for professional services furnished to beneficiaries in all areas of the country in all settings regardless of location or distance between the patient and the health care provider.[12]

In addition, since March 15, 2020, CMS has expanded access to telemedicine services

for all Medicare beneficiaries—not just those who have been diagnosed with COVID-19.[13] The expanded access also applies to pre-COVID-19 coverage from physician offices, skilled nursing facilities, and hospitals. This means that Medicare will now make payments to physicians for telemedicine services provided in any health care facility or in a patient's home, so that patients do not need to go to the physician's office.

The facts are that there are parity laws and that commercial payers and CMS are required by state law to reimburse for telemedicine—often at the same rate as that for a comparable in-person visit. On the commercial side, there has been an increase in commercial parity legislation that requires health plans to cover virtual visits in the same way they cover face-to-face services. With the new guidelines for reimbursement, every state and Washington DC has parity laws in place. (To stay abreast of state-by-state changes in virtual health reimbursement, the Center for Connected Health Policy and the Advisory Board Primer are valuable resources. See "Resources," page 21.) As long as the provider performs and documents the elements of history and decision-making, including the time spent counseling, and documents the visit as if a face-to-face visit occurred, then clinicians have a billable evaluation and management (E&M) visit.

Virtual services for Medicare patients

There are 3 main types of virtual services gynecologists can provide to Medicare patients: Medicare telehealth visits, virtual check-ins, and e-visits.

Medicare telehealth visits. Largely because of the COVID-19 pandemic, Medicare patients may now use telecommunication technology for any services that previously occurred in an in-person communication. The gynecologist must use an interactive audio and video telecommunications system that permits real-time communication between the physician and the patient, and the patient should have a prior established relationship with the gynecologist with whom the telemedicine visit is taking place. The new guidelines indicate that the US Department of Health and Human Services (HHS) will not conduct audits to ensure that such a prior relationship exists for claims submitted during this public health emergency.[14]

The Current Procedural Terminology (CPT) codes for virtual visits using synchronous audio/visual communication are:

- 99201-99295, *Office visit for a new patient*
- 99211-99215, *Office visit for an established patient.*

Important modifiers for telemedicine visits include:

- modifier 02 for POS (place of service) for telehealth Medicare
- modifier 95 for commercial payers.

(A list of all available CPT codes for telehealth services from CMS can be found in "Resources," page 21.)

Virtual check-ins. Established Medicare patients may have a brief communication with gynecologists the traditional way using a telephone or via live video. These brief virtual services, usually 5 to 10 minutes in duration, are initiated by the patient. The purpose of the virtual check-in is to determine if an office visit or a test or procedure is indicated.

Medicare pays for these "virtual check-ins" (or brief communication technology-based services) for patients to communicate with their physicians and avoid unnecessary trips to the office. These brief virtual check-ins are only for established patients. If an existing patient contacts the gynecologist's office to ask a question or determine if an office visit is necessary, the gynecologist may bill for it using code G2012.

E-visits. Established Medicare patients may have non–face-to-face patient-initiated communications with their gynecologists without going to the physician's office. These services can be billed only when the physician has an established relationship with the patient. The services may be billed using CPT codes 99421 to 99423. Coding for these visits is determined by the length of time the gynecologist spends online with the patient:

- 99421: *Online digital evaluation and management service, for an established patient* 5 to 10 minutes spent on the virtual visit

FAST TRACK

The 3 main types of virtual services gynecologists can provide to Medicare patients are Medicare telehealth visits, virtual check-ins, and e-visits

- 99422: 11 to 20 minutes
- 99423: ≥ 21 minutes.

Many clinicians want to immediately start the communication process with their patients. Many will avail themselves of the free video communication offered by Google Hangouts, Skype, Facetime, and Facebook Messenger. Since the March 15, 2020, relaxation of the HIPAA restrictions for telemedicine, it is now possible to have a virtual visit with a patient using one of the free, non–HIPAA-compliant connections. This type of visit is no different than a telephone call but with an added video component. Using these free technologies, a gynecologist can have an asynchronous visit with a patient (referred to as the store and forward method of sending information or medical images), which means that the service takes place in one direction with no opportunity for interaction with the patient. Asynchronous visits are akin to video text messages left for the patient. By contrast, a synchronous or real-time video visit with a patient is a 2-way communication that provides medical care without examining the patient.

FAST TRACK

A scribe or medical assistant can be used to document a physician-patient encounter when a virtual visit tool does not allow for documentation

Using triangulation

There are some downsides to telemedicine visits. First, virtual visits on Skype, FaceTime, and other non–HIPAA-compliant methods are not conducted on an encrypted website. Second, no documentation is created for the doctor-patient encounter. Finally, unless the physician keeps a record of these virtual visits and submits the interactions to the practice coders, there will be no billing and no reimbursement for the visits. In this scenario, physicians are legally responsible for their decision-making, prescription writing, and medical advice, but do not receive compensation for their efforts.

This can be remedied by using "triangulation," which involves: 1. the physician, 2. the patient, and 3. a scribe or medical assistant who will record the visit. Before initiating the virtual visit using triangulation, it is imperative to ask the patient for permission if your medical assistant (or any other person in the office who functions as a scribe) will be listening to the conversation. It is important to explain that the person is there to take accurate notes and ascertain that the notes are entered into the EHR. Also, the scribe or assistant will record the time, date, and duration of the visit, which is a requirement for billing purposes. The scribe may also ascertain that the visit is properly coded and entered into the practice management system, and that a bill is submitted to the insurance company. By using triangulation, you have documentation that consent was obtained, that the visit took place, that notes were taken, and that the patient's insurance company will be billed for the visit (see **FIGURE 2** for a sample documentation form).

Which CPT codes should I use?

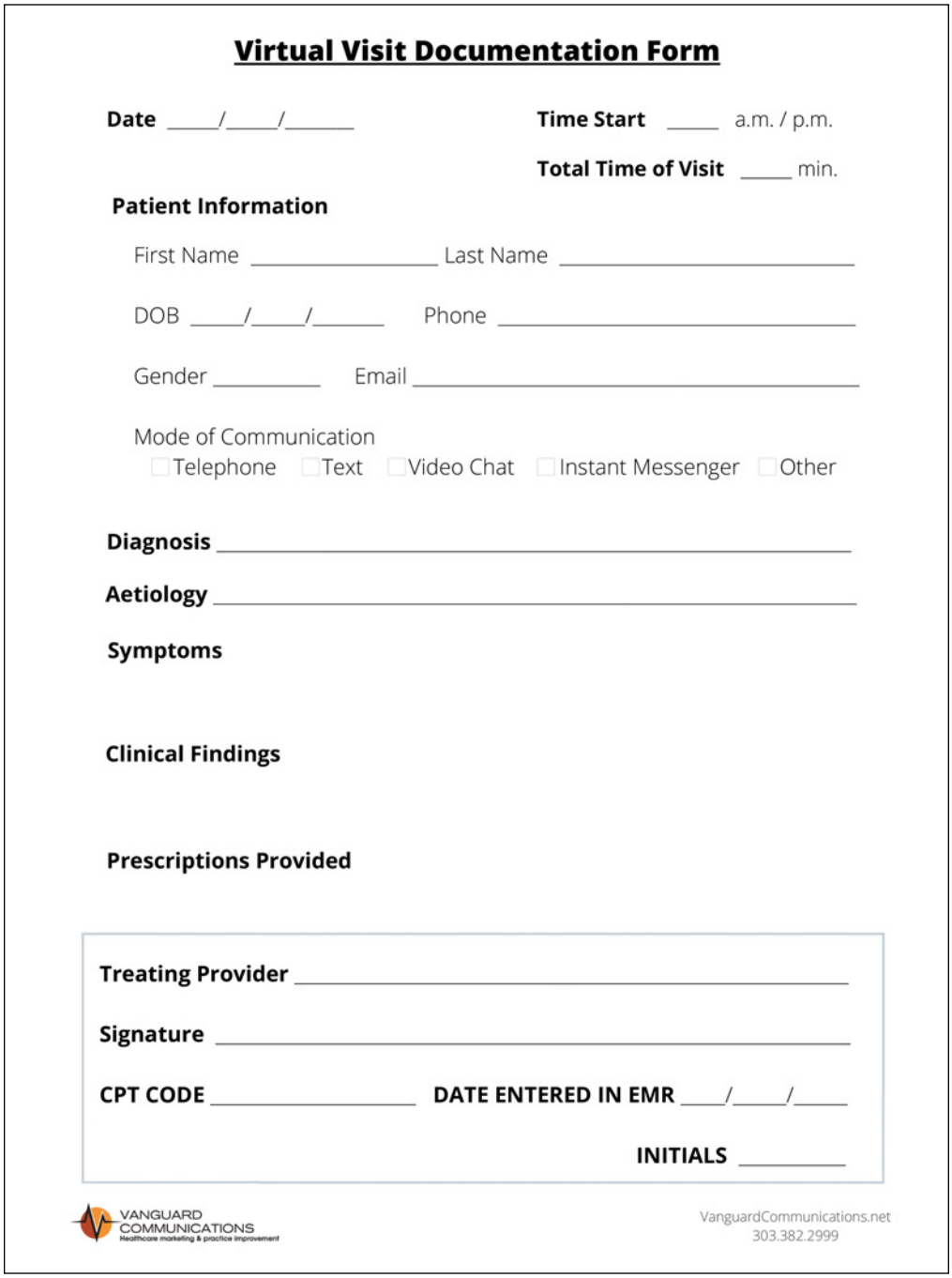
The answer depends on a number of factors, but a good rule of thumb is to use the same codes that you would use for an in-person appointment (CPT codes 99211-99215 for an established patient visit and 99201-99205 for a new patient visit). These are the most common CPT codes for outpatient gynecologic office visits whether they take place face-to-face or as a synchronous virtual visit (via a real-time interactive audio and video telecommunications system).

For example, the reimbursement for code 99213 has a range from $73 to $100. You may wonder how you can achieve the complexity requirements for a level-3 office visit without a physical examination. Whether as a face-to-face or virtual visit, documentation for these encounters requires 2 of 3 of the following components:

- expanded problem-focused history
- expanded problem-focused exam (not accomplished with telemedicine)
- low-complexity medical decision-making OR
- at least 15 minutes spent face to face with the patient if coding is based on time.

If a gynecologist reviews the results of a recent lab test for an estrogen-deficient patient and adjusts the estrogen dosage, writes a prescription, and spends 15 minutes communicating with the patient, he/she has met the complexity requirements for a code 99213. Because Level 3 and 4 visits (99214

FIGURE 2 Virtual visit documentation form



Virtual Visit Documentation Form

Date ____/____/_____ **Time Start** _____ a.m. / p.m.

Total Time of Visit _____ min.

Patient Information

First Name _____ Last Name _____

DOB ____/____/_____ Phone _____

Gender _____ Email _____

Mode of Communication

☐ Telephone ☐ Text ☐ Video Chat ☐ Instant Messenger ☐ Other

Diagnosis _____

Aetiology _____

Symptoms

Clinical Findings

Prescriptions Provided

Treating Provider _____

Signature _____

CPT CODE _____ **DATE ENTERED IN EMR** ____/____/____

INITIALS _____

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and 99215) require a comprehensive physical examination, it is necessary to document the time spent with the patient (code 99214 requires 25 to 39 minutes of consultation and code 99215 requires ≥ 40 minutes).

Some final billing and coding advice

Always confirm telemedicine billing guidelines *before* beginning to conduct telemedicine visits. Consider starting a phone call to a payer armed with the fact that the payer is

required by law to offer parity between telemedicine and face-to-face visits. Then ask which specific billing codes should be used.

Until you and your practice become comfortable with the process of, and the coding and billing for, telemedicine, consider using a telemedicine platform that has a built-in rules engine that offers recommendations for each telemedicine visit based on past claims data. These systems help gynecologists determine which CPT code to use and which modifiers are appropriate for the various insurance companies. In other words, the rules engine helps you submit a clean claim that is less likely to be denied and very likely to be paid. There are some vendors who are so confident that their rules engine will match the service with the proper CPT code and modifier that they guarantee full private payer reimbursement for telemedicine visits, or the vendor will reimburse the claim.

Watch for the third and final installment in this series, which was written with the assistance of 2 attorneys. It will review the legal guidelines for implementing telemedicine in a gynecologic practice and discuss the future of the technology. ●

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Coming soon...

- **Update on abnormal uterine bleeding**
  Howard Sharp, MD
- **Telemedicine, part 3: Navigating legal issues**
  Neil Baum, MD; Nadia de la Houssaye, JD; and Anjali Dooley, JD
- **Evidence-based management of early pregnancy loss**
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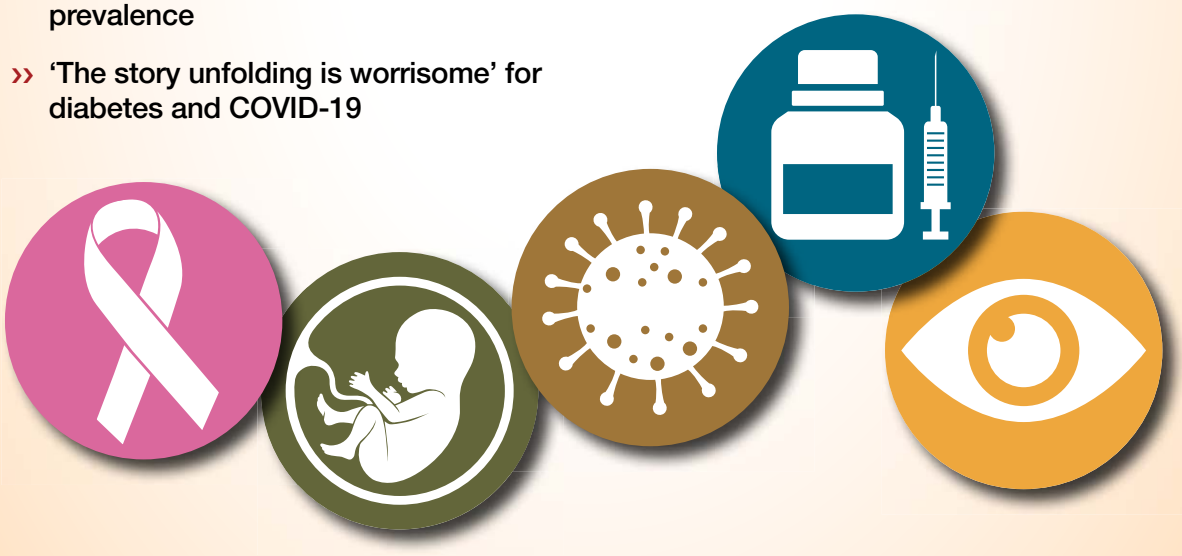

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UPDATE Menopause

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Dr. Kaunitz reports that he is a consultant to Pfizer and has received grant or research support from AbbVie and Endoceutics. Dr. Pinkerton and Dr. Manson report no financial relationships relevant to this article.

Recent studies show low-dose vaginal estrogen to be a highly effective, and safe, treatment for genitourinary syndrome of menopause, while promising RCT results are emerging for vaginal laser therapy

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The term genitourinary syndrome of menopause (GSM) refers to the bothersome symptoms and physical findings associated with estrogen deficiency that involve the labia, vestibular tissue, clitoris, vagina, urethra, and bladder.[1] GSM is associated with genital irritation, dryness, and burning; urinary symptoms including urgency, dysuria, and recurrent urinary tract infections; and sexual symptoms including vaginal dryness and pain. Vulvovaginal atrophy (VVA) represents a component of GSM.

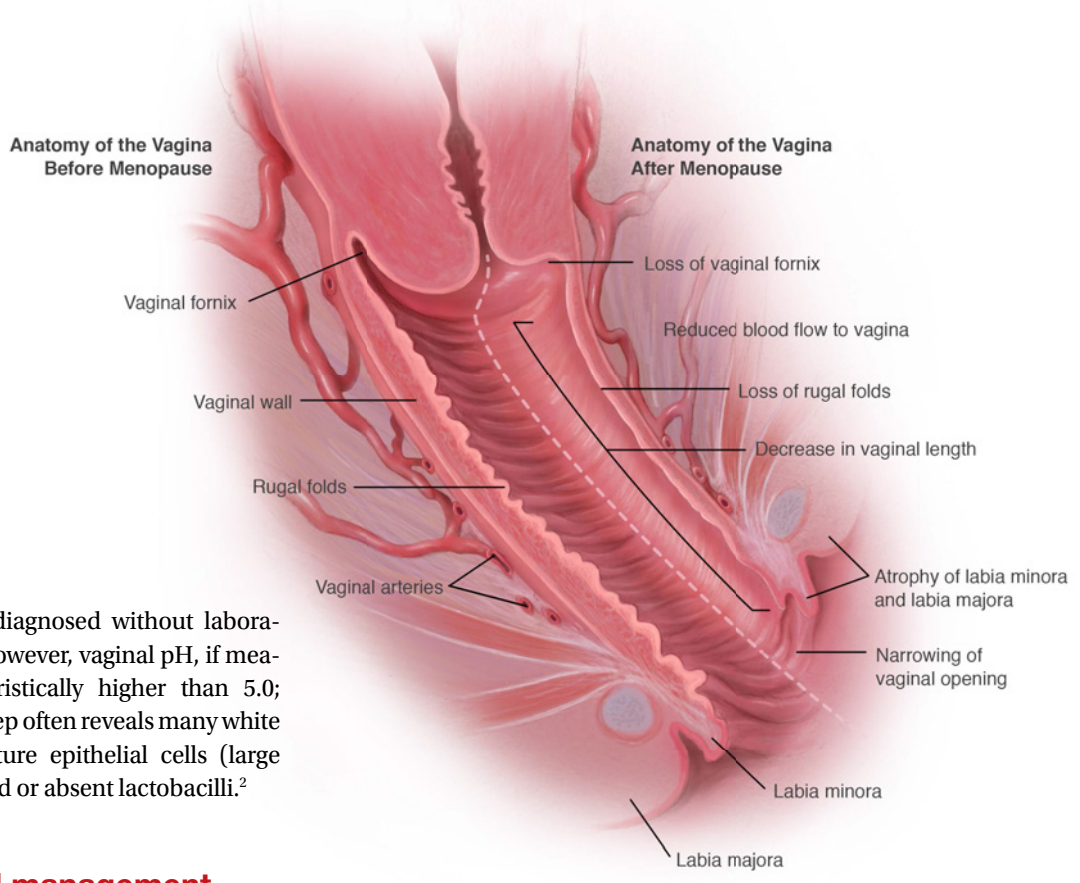
GSM is highly prevalent, affecting more than three-quarters of menopausal women. In contrast to menopausal vasomotor symptoms, which often are most severe and frequent in recently menopausal women, GSM commonly presents years following menopause. Unfortunately, VVA symptoms may have a substantial negative impact on women's quality of life.

In this 2020 Menopause Update, I review a large observational study that provides reassurance to clinicians and patients regarding the safety of the best-studied prescription treatment for GSM—vaginal estrogen. Because some women should not use vaginal estrogen and others choose not to use it, nonhormonal management of GSM is important. Dr. JoAnn Pinkerton provides details on a randomized clinical trial that compared the use of fractionated CO2 laser therapy with vaginal estrogen for the treatment of GSM. In addition, Dr. JoAnn Manson discusses recent studies that found lower health risks with vaginal estrogen use compared with systemic estrogen therapy.

Diagnosing GSM

GSM can be diagnosed presumptively based on a characteristic history in a menopausal patient. Performing a pelvic examination, however, allows clinicians to exclude other conditions that may present with similar symptoms, such as lichen sclerosus, *Candida* infection, and malignancy.

During inspection of the external genitalia, the clinician may note loss of the fat pad in the labia majora and mons as well as a reduction in labia minora pigmentation and tissue. The urethral meatus often becomes erythematous and prominent. If vaginal or introital narrowing is present, use of a pediatric (ultrathin) speculum reduces patient discomfort. The vaginal mucosa may appear smooth due to loss of rugation; it also may appear shiny and dry. Bleeding (friability) on contact with a spatula or cotton-tipped swab may occur. In addition, the vaginal fornices may become attenuated, leaving the cervix flush with the vaginal apex.



GSM can be diagnosed without laboratory assessment. However, vaginal pH, if measured, is characteristically higher than 5.0; microscopic wet prep often reveals many white blood cells, immature epithelial cells (large nuclei), and reduced or absent lactobacilli.[2]

Nonhormonal management of GSM

Water, silicone-based, and oil-based lubricants reduce the friction and discomfort associated with sexual activity. By contrast, vaginal moisturizers act longer than lubricants and can be applied several times weekly or daily. Natural oils, including olive and coconut oil, may be useful both as lubricants and as moisturizers. Aqueous lidocaine 4%, applied to vestibular tissue with cotton balls prior to penetration, reduces dyspareunia in women with GSM.[3]

Vaginal estrogen therapy

When nonhormonal management does not sufficiently reduce GSM symptoms, use of low-dose vaginal estrogen enhances thickness and elasticity of genital tissue and improves vaginal blood flow. Vaginal estrogen creams, tablets, an insert, and a ring are marketed in the United States. Although clinical improvement may be apparent within several weeks of initiating vaginal estrogen, the full benefit of treatment becomes apparent after 2 to 3 months.[3]

Despite the availability and effectiveness of low-dose vaginal estrogen, fears regarding the safety of menopausal hormone therapy have resulted in the underutilization of vaginal estrogen.[4,5] Unfortunately, the package labeling for low-dose vaginal estrogen can exacerbate these fears.

FAST TRACK

When nonhormonal management does not sufficiently reduce GSM symptoms, use of low-dose vaginal estrogen enhances thickness and elasticity of genital tissue and improves vaginal blood flow

Nurses' Health Study report provides reassurance on long-term safety of vaginal estrogen

Bhupathiraju SN, Grodstein F, Stampfer MJ, et al. Vaginal estrogen use and chronic disease risk in the Nurses' Health Study. Menopause. 2018;26:603-610.

Bhupathiraju and colleagues published a report from the long-running Nurses' Health prospective cohort

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Results from Bhupathiraju and colleagues' analysis of data from the Nurses' Health Study on the 3-year safety of vaginal estrogen use encourage clinicians to recommend and women to use this safe and effective treatment for GSM.

study on the health outcomes associated with the use of vaginal estrogen.

Recap of the study

Starting in 1982, participants in the Nurses' Health Study were asked to report their use of vaginal estrogen via a validated questionnaire. For the years 1982 to 2012, investigators analyzed data from 896 and 52,901 women who had and had not used vaginal estrogen, respectively. The mean duration of vaginal estrogen use was 36 months.

In an analysis adjusted for numerous factors, the investigators observed no statistically significant differences in risk for cardiovascular outcomes (myocardial infarction, stroke, deep vein thrombosis, and pulmonary embolism) or invasive cancers (colorectal, endometrial, ovarian, or breast).

Findings uphold safety of vaginal estrogen

This landmark study provides reassurance that 3 years of use of vaginal estrogen does not increase the risk of cardiovascular events or invasive breast cancer, findings that hopefully will allow clinicians and women to feel comfortable regarding the safety of vaginal estrogen. A study of vaginal estrogen from the Women's Health Initiative provided similar reassurance (see page 34). Recent research supports guidance from The North American Menopause Society and the American College of Obstetricians and Gynecologists that vaginal estrogen can be used indefinitely, if indicated, and that use of concomitant progestin is not recommended in women who use vaginal estrogen and have an intact uterus.[6,7]

I agree with the authors, who point out that since treatment of GSM may need to be continued long term (even indefinitely), it would be helpful to have data that assessed the safety of longer-duration use of vaginal estrogen.

FAST TRACK

This landmark study provides reassurance that 3 years of use of vaginal estrogen does not increase the risk of cardiovascular events or invasive breast cancer

How CO2 fractionated vaginal laser therapy compares with vaginal estrogen for relief of GSM symptoms

Paraiso MF, Ferrando CA, Sokol ER, et al. A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: the VeLVET trial. Menopause. 2020;27:50-56.

Up to 50% to 60% of postmenopausal women experience GSM symptoms. However, many fewer receive treatment, either because they do not understand that the symptoms are related to menopause or they are not aware that safe and effective treatment is available. Sadly, many women are not asked about their symptoms or are embarrassed to tell providers.

GSM affects relationships and quality of life. Vaginal lubricants or moisturizers may provide relief. US Food and Drug Administration (FDA)–approved therapies include low-dose vaginal estrogen, available as a vaginal tablet, cream, suppository, and ring; intravaginal dehydroepiandrosterone (DHEA); and oral ospemifene, a selective estrogen replacement modulator. If women have an estrogen-sensitive breast or uterine cancer, an oncologist should be involved in decisions about vaginal hormonal therapy.

Energy-based devices such as vaginal lasers appear to induce wound healing;

stimulate collagen and elastin fiber formation through increased storage of glycogen; and activate fibroblasts, which leads to increased extracellular matrix and restoration of vaginal pH.

These lasers are FDA approved for use in gynecology but not specifically for the treatment of GSM. In July 2016, the FDA issued a safety alert that energy-based devices, while approved for use in gynecology, have not been approved or adequately tested for menopausal vaginal conditions, and safety concerns include reports of vaginal burns.[8] Lacking are publications of adequately powered randomized, sham-controlled trials to determine if laser therapy works better for women with GSM than placebos, moisturizers, or vaginal hormone therapies.

Recently, investigators conducted a multicenter, randomized, single-blinded trial of vaginal laser therapy and estrogen cream for treatment of GSM.

Details of the study

Paraiso and colleagues aimed to compare the 6-month efficacy and safety of fractionated CO2 vaginal laser therapy with that of estrogen vaginal cream for the treatment of vaginal dryness/GSM.

Participants randomly assigned to the estrogen therapy arm applied conjugated estrogen cream 0.5 g vaginally daily for 14 days, followed by twice weekly application for 24 weeks (a low-dose vaginal estrogen therapy). Participants randomly assigned to laser therapy underwent 3 vaginal treatments at a minimum of 6 weeks apart.

Sixty-nine women were enrolled in the trial before enrollment was closed because the FDA required that the sponsor obtain and maintain an investigational device exemption. Of 62 women who completed 6 months' treatment, 30 received 3 laser treatments and 32 received estrogen cream.

The primary outcome compared subjective improvement in vaginal dryness using the visual analog scale (VAS) between the 2 groups at 6 months. Secondary outcomes included comparisons of the vaginal health index (VHI) and vaginal maturation index (VMI), the effect of GSM on quality of life, the effect of treatment on sexual function and urinary symptoms, and patient satisfaction.

Study findings

Efficacy. Laser therapy and estrogen therapy were found to be similarly effective except on the VMI, which favored estrogen. On patient global impression, 85.8% of laser-treated women rated their improvement as "better or much better" and 78.5% reported being either "satisfied or very satisfied," compared with 70% and 73.3%, respectively, in the estrogen group, a statistically nonsignificant difference.

On linear regression, the investigators found a nonsignificant mean difference in female sexual function index scores. While VMI scores remained higher in the estrogen-treated group (adjusted $P = .02$), baseline and 6-month follow-up VMI data were available for only 34 participants (16 laser treated, 18 estrogen treated).

Regarding long-term effectiveness, 20% to 25% of the women in the laser-treated group needed further treatment after 1 year while the estrogen cream continued to work as long as it was used as prescribed.

Adverse effects. The incidence of vaginal bleeding was similar in the 2 groups: 6.7% in the laser group and 6.3% in the estrogen group. In the laser therapy group, 3% experienced vaginal pain, discharge, and bladder infections, while in the estrogen cream group, 3% reported breast tenderness, migraine headaches, and abdominal cramping.

Takeaways. This small randomized, open-label (not blinded) trial provides pilot data on the effectiveness of vaginal CO2 laser compared with vaginal estrogen in treating vaginal atrophy, quality-of-life symptoms, sexual function, and urinary symptoms. Adverse events were minimal. Patient global impression of improvement and satisfaction improved for both vaginal laser and vaginal estrogen therapy.

Study strengths and limitations

To show noninferiority of vaginal laser therapy to vaginal estrogen, 196 study participants were needed. However, after 38% had been enrolled, the FDA sent a warning letter to the

FAST TRACK

Vaginal laser therapy and vaginal estrogen therapy were found to be similarly effective except on the VMI, which favored estrogen

Evidence points to different benefit-risk profiles for vaginal estrogen and systemic estrogen therapy

JoAnn E. Manson, MD, DrPH, NCMP

Having more appropriate, evidence-based labeling of low-dose vaginal estrogen continues to be a high priority for The North American Menopause Society (NAMS), the International Society for the Study of Women's Sexual Health (ISSWSH), and other professional societies.

NAMS and the Working Group on Women's Health and Well-Being in Menopause had submitted a citizen's petition to the US Food and Drug Administration (FDA) in 2016 requesting modification of the label—including removal of the "black box warning"—for low-dose vaginal estrogen products. The petition was, disappointingly, denied in 2018.[1]

Currently, the class labeling, which was based on the results of randomized trials with systemic hormone therapy, is not applicable to low-dose vaginal estrogen, and the inclusion of the black box warning has led to serious underutilization of an effective and safe treatment for a very common and life-altering condition, the genitourinary syndrome of menopause (GSM). This condition affects nearly half of postmenopausal women. It tends to be chronic and progressive and, unlike hot flashes and vasomotor symptoms, it does not remit or decline over time, and it affects women's health and quality of life.

While removal of the black box warning would be appropriate, labeling should include emphatic reminders for women that if they have any bleeding or spotting they should seek medical attention immediately, and if they have a history of breast cancer or other estrogen-sensitive cancers they should talk with their oncologist prior to starting treatment with low-dose vaginal estrogen. Although the text would still inform women of research results on systemic hormone therapy, it would explain the differences between low-dose vaginal estrogen and systemic therapy.

Studies show vaginal estrogen has good safety profile

In the last several years, large, observational studies of low-dose vaginal estrogen have suggested that this treatment is not associated with an increase in cardiovascular disease, pulmonary embolism, venous thrombosis, cancer, or dementia—conditions listed in the black box warning that were linked to systemic estrogen therapy plus synthetic progestin. Recent data from the Nurses' Health Study (see page 31), for example, demonstrated that 3 years of vaginal estrogen use did not increase the risk of cardiovascular events or invasive breast cancer.

Women's Health Initiative. In a prospective observational cohort study, Crandall and colleagues used data from participants in the Women's Health Initiative Observational Study to determine the association between use of vaginal estrogen and risk of a global index event (GIE), defined as time to first occurrence of coronary heart disease, invasive breast cancer, stroke, pulmonary embolism, hip fracture, colorectal cancer, endometrial cancer, or death from any cause.[2]

Women were recruited from multiple clinical centers, were aged 50 to 79 years at baseline, and did not use systemic estrogen therapy during follow-up. The study included 45,663 women and median follow-up was 7.2 years. The investigators collected data on women's self-reported use of vaginal estrogen as well as the development of the conditions defined above.

In women with a uterus, there was no significant difference between vaginal estrogen users and nonusers in the risk of stroke, invasive breast cancer, colorectal cancer, endometrial cancer, pulmonary embolism, or deep vein thrombosis. The risks of coronary heart disease, fracture, all-cause mortality, and GIE were lower in vaginal estrogen users than in nonusers (GIE adjusted hazard ratio [HR], 0.68; 95% confidence interval [CI], 0.55–0.86).

In women who had undergone hysterectomy, the risks of the individual GIE components and the overall GIE were not significantly different in users of vaginal estrogen compared with nonusers (GIE adjusted HR, 0.94; 95% CI, 0.70–1.26).

The investigators concluded that the risks of cardiovascular disease and cancer were not increased in postmenopausal women who used vaginal estrogen. Thus, this study offers reassurance on the treatment's safety.[2]

Meta-analysis on menopausal hormone therapy and breast cancer risk. Further evidence now indicates that low-dose vaginal estrogen is not linked to chronic health conditions. In a large meta-analysis published in 2019, investigators looked at different types of hormone therapies—oral estrogen plus progestin, transdermal estrogen and progestin, estrogen alone, low-dose vaginal estrogen—and their relationship to breast cancer risk.[3]

Information on individual participants was obtained from 58 studies, 24 prospective and 34 retrospective. Breast cancer relative risks (RR) during years 5 to 14 of current hormone use were assessed according to the main hormonal contituents, doses,

Foundation for Female Health Awareness, which required obtainment of an investigational device exemption for the laser and addition of a sham treatment arm.[9] Instead of redesigning the trial and reconsenting the participants, the investigators closed the study, and analysis was performed only on the 62 participants who completed the study; vaginal maturation was assessed only in 34 participants.

The study lacked a placebo or sham control, which increases the risk of bias, while small numbers limit the strength of the findings. Longer-term evaluation of the effects of laser therapy beyond 6 months is needed to allow assessment of the effects of scarring on vaginal health, sexual function, and urinary issues.

Discussing therapy with patients

Despite this study's preliminary findings, and until more robust data are available, providers

and modes of delivery of the last-used menopausal hormone therapy. For all systemic estrogen-only preparations, the RR was 1.33 (95% CI, 1.28–1.38), while for all estrogen-progestogen preparations, the RR was 2.08 (95% CI, 2.02–2.15). For transdermal estrogen, the RR was 1.35 (95% CI, 1.25–1.46). In contrast, for vaginal estrogen, the RR was 1.09 (95% CI, 0.97–1.23).[3]

Thus, the analysis found that in all the studies that had been done to date, there was no evidence of increased risk of breast cancer with vaginal estrogen therapy.

The evidence is growing that low-dose vaginal estrogen is different from systemic estrogen in terms of its safety profile and benefit-risk pattern. It is important for the FDA to consider these data and revise the vaginal estrogen label.

On the horizon: New estradiol reference ranges

It would be useful if we could accurately compare estradiol levels in women treated with vaginal estrogen against those of women treated with systemic estrogen therapy. In September 2019, NAMS held a workshop with the goal of establishing reference ranges for estradiol in postmenopausal women.[4] It is very important to have good, reliable laboratory assays for estradiol and estrone, and to have a clear understanding of what is a reference range, that is, the range of estradiol levels in postmenopausal women who are not treated with estrogen. That way, you can observe what the estradiol blood levels are in women treated with low-dose vaginal estrogen or those treated with systemic estrogen versus the levels observed among postmenopausal women not receiving any estrogen product.

With the reference range information, we could look at data on the blood levels of estradiol with low-dose vaginal estrogen from the various studies available, as well as the increasing evidence from observational studies of the safety of low-dose vaginal estrogen to better understand its relationship with health. If these studies demonstrate that, with certain doses and formulations of low-dose vaginal estrogen, blood estradiol levels stay within the reference range of postmenopausal estradiol levels, it would inform the labeling modifications of these products. We need this information for future discussions with the FDA.

The laboratory assay technology used for such an investigation is primarily liquid chromatography with tandem mass spectrometry, the so-called LC-MS/MS assay. With use of this technology, the reference range for estradiol may be less than 10 picograms per milliliter. Previously, a very wide and inconsistent range—about 5 to 30 picograms per milliliter—was considered a "normal" range.

NAMS is championing the efforts to define a true evidence-based reference range that would represent the range of levels seen in postmenopausal women.[5] This effort has been spearheaded by Dr. Richard Santen and colleagues. Using the more sensitive and specific LC-MS/MS assay will enable researchers and clinicians to better understand how levels on low-dose vaginal estrogen relate to the reference range for postmenopausal women. We are hoping to work together with researchers to establish these reference ranges, and to use that information to look at how low-dose vaginal estrogen compares to levels in untreated postmenopausal women, as well as to levels in women on systemic estrogen.

Hopefully, establishing the reference range can be done in an expeditious and timely way, with discussions with the FDA resuming shortly thereafter.

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should discuss the benefits and risks of all available treatment options for vaginal symptoms, including over-the-counter lubricants, vaginal moisturizers, FDA-approved vaginal hormone therapies (such as vaginal estrogen and intravaginal dehydroepiandrosterone), and systemic therapies, such as hormone therapy and ospemifene, to determine the best treatment for the individual woman with GSM.

In a healthy postmenopausal woman with bothersome GSM symptoms not

WHAT THIS EVIDENCE MEANS FOR PRACTICE

For GSM that does not respond to lubricants and moisturizers, many FDA-approved vaginal and systemic therapies are available to treat vaginal symptoms. Vaginal laser treatment is a promising therapy for vaginal symptoms of GSM that needs further testing to determine its efficacy, safety, and long-term effects. If discussing vaginal energy-based therapies with patients, include the current lack of FDA approval for specific vaginal indications, potential adverse effects, the need for ongoing retreatment, and out-of-pocket costs.

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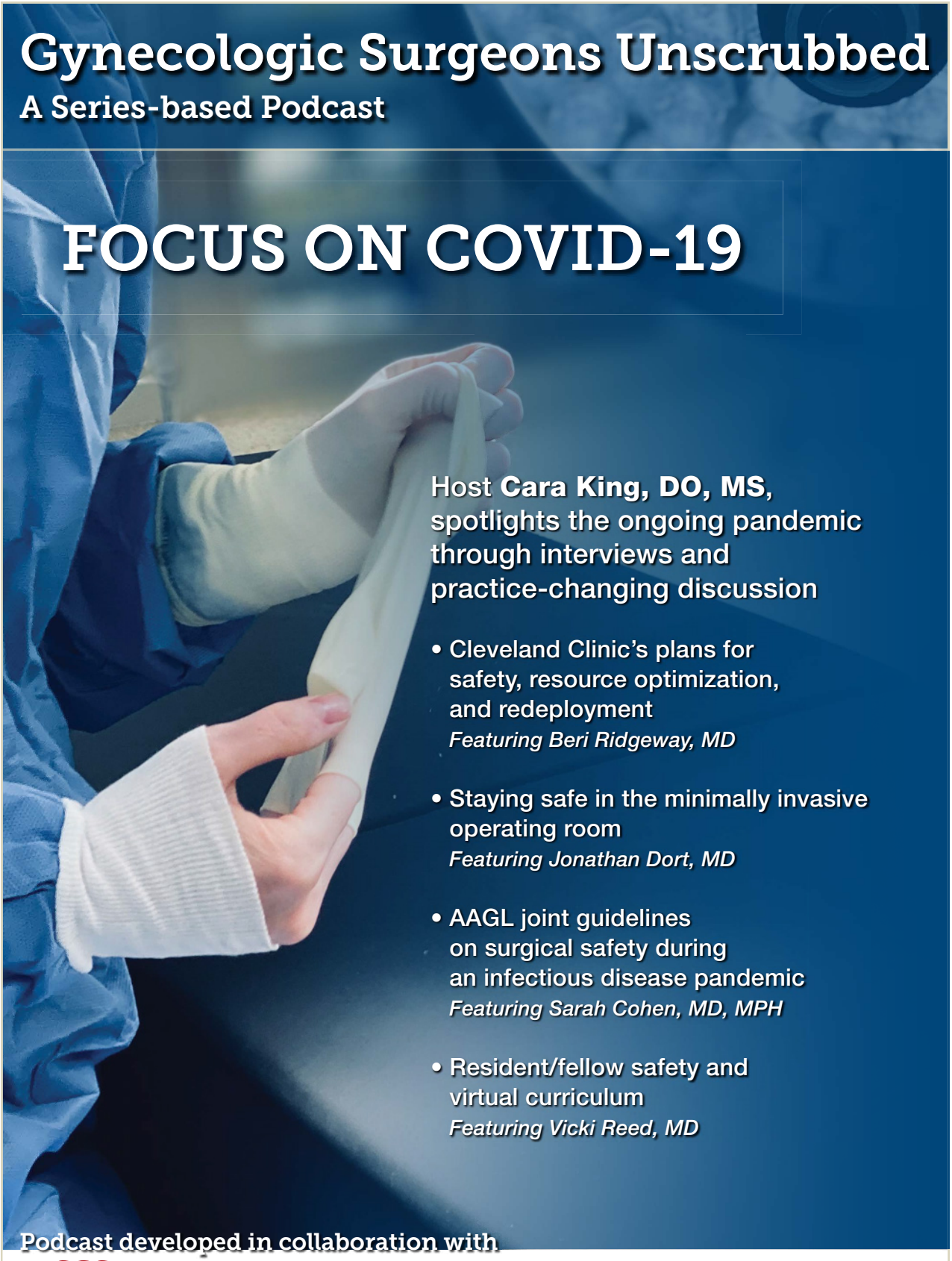

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Managing *Trichomonas vaginalis* infections

Prevalent and nonreportable, trichomonas infection, when left untreated, can cause complications in women, men, and infants, and co-infection with other STIs increases concerns

Emily S. Edwards, MS, CCRP, and Patrick Duff, MD

CASE Woman with malodorous vaginal discharge

A 26-year-old nulligravid woman with 2 current sexual partners requests evaluation because she has a yellow-green frothy vaginal discharge that is slightly malodorous. One of her sexual partners has noted a similar discharge from his urethra. On physical examination, the clinician notes that the patient's discharge emanates from the vaginal mucosa, and the exocervix has multiple punctate hemorrhages. Considerations in this case include:

- What is the most likely diagnosis?
- How should this patient be evaluated and treated?
- Should the patient's sexual partners be treated?

This clinical scenario is most consistent with a trichomonas infection, although other conditions, including bacterial vaginosis, gonorrhea, and chlamydia infection, must be considered in the differential diagnosis.

In this article, we examine the microbiology, epidemiology, clinical manifestations, and diagnosis and treatment of this common sexually transmitted infection (STI).

The causative microbe

Trichomonas vaginalis is a free-living flagellated protozoan that accounts for almost half of all nonviral STIs globally. It has a predilection for the mucosal epithelium of the genitourinary tract, including the vagina and urethra. Humans are the only known host for *T vaginalis*. The infection is transmitted through sexual intercourse, and the

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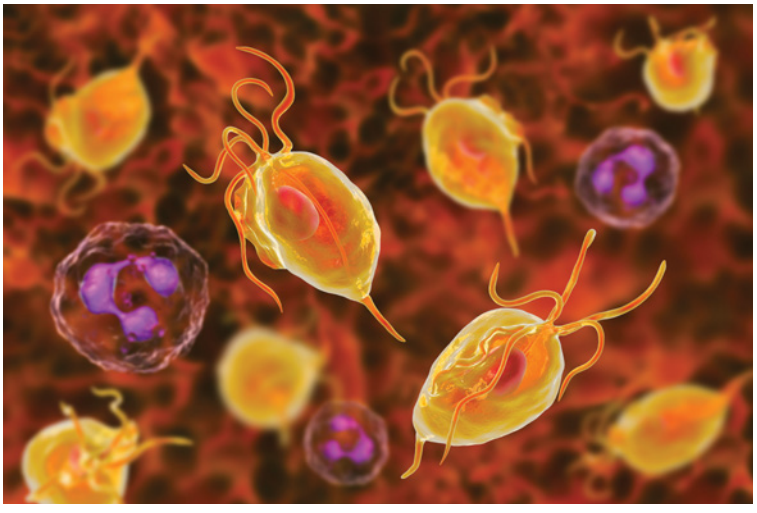

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The authors report no financial relationships relevant to this article.

organism reproduces through binary fission in the lower genital tract of women and in the urethra and prostate of men.

This anaerobic trophozoite has 4 flagella anteriorly and 1 flagellum that projects posteriorly, with an undulating membrane that gives its characteristic motile appearance on saline microscopy.[1] *T vaginalis* infection causes major mechanical stress on epithelial cells, which results in disruption of the plasma cell membrane and, ultimately, cell death. The necrotic cell fragments are then phagocytosed by trichomonads, thus accelerating the infection.[2]

Groups at risk

Trichomonal infections are not reportable to public health authorities, which makes assessing the true prevalence of infection difficult.

The World Health Organization estimated the incidence of infection to be more than 156 million cases globally in 2016, with a prevalence of 110.4 million people at any one time.[3]

The 2013-2014 National Health and Nutrition Examination Survey tested 4,057 men and women aged 18 to 59 years for *T vaginalis* and found a prevalence of 0.5% among men and 1.8% among women.[4] The prevalence increased with age. There was a disproportionate burden of trichomonas infections in the non-Hispanic black population, with 4.2% of black men and 8.9% of black women affected.[4]

Targeted screening of urogenital samples for *T vaginalis* in a population of US women undergoing *Chlamydia trachomatis/Neisseria gonorrhoeae* screening demonstrated prevalence rates of 8.7%, 6.7%, and 1.7% for *T vaginalis, C trachomatis,* and *N gonorrhoeae,* respectively.[5]

Differences in prevalence estimates may be due to differences in the varying sensitivity of each testing modality and patient populations. In one study, nucleic acid amplification testing (NAAT) for *T vaginalis* detected rates as high as 11.3% in women and 6.1% in men undergoing evaluations at STI clinics.[6]

FAST TRACK

Complications of trichomonal infection in women include infections of the adnexa, endometrium, and vestibular glands, as well as cervical neoplasia and increased co-infection rates with other STIs

Clinical manifestations of infection

Most cases of *T vaginalis* remain in an asymptomatic carrier state, with up to 85% of women and 77% of men reporting no clinical symptoms.[1] However, approximately one-third of asymptomatic carriers will experience symptoms within 6 months of infection acquisition. This latency in appearance of clinical symptoms certainly contributes to the high transmission rate of *T vaginalis.*

Infected men may experience purulent urethritis, dysuria, and postcoital pruritus. Common clinical symptoms in women include abnormal vaginal discharge that may be malodorous, purulent, thin, frothy, and yellow-green, as well as symptoms of dyspareunia and vulvar irritation. Punctate hemorrhages in the cervix (colpitis macularis) and vaginal walls (macular vaginitis) give the characteristic "strawberry appearance," but these findings are seen in only 2% of affected women.[7]

Complications in ObGyn patients

Although *T vaginalis* once was regarded as more of an annoyance than a public health issue, awareness of the infection's ramifications has increased in recent years. Because of these complications, treatment of both symptomatic and asymptomatic patients is clearly indicated.

Complications of trichomonal infection in men include balanoposthitis, epididymitis, prostatitis, urethritis, and infertility.[7] In women, complications include infections of the adnexa, endometrium, and vestibular glands, as well as cervical neoplasia and increased co-infection rates with other STIs, such as bacterial vaginosis, chlamydia infection, gonorrhea, syphilis, and herpes simplex virus type 2.[1]

Infection in pregnancy. Adverse outcomes in pregnant women with *T vaginalis* infections at mid-gestation include low birth weight, preterm premature rupture of membranes, preterm delivery, and postpartum endometritis.[8] A disproportionately larger share of the low birth weight rate associated

with *T vaginalis* infections occurs in black women compared with white and Hispanic women.[8] Perinatal transmission to newborns can cause fever; respiratory difficulties; urinary tract infections; nasal discharge; and, in female infants, vaginal discharge.[9,10]

Co-infection concerns. The increased rate of co-infection with human immunodeficiency virus type 1 (HIV-1) and *T vaginalis* is a major concern.[11] One study found a higher concentration of HIV-1 in semen samples from men with *T vaginalis* and symptomatic urethritis.[12] Further, *T vaginalis* was found in 17.4% of women with HIV screened at a public clinic in California, with almost 38% of black women affected.[13] Trichomoniasis can increase the risk of HIV-1 acquisition by 1.52-fold (95% confidence interval, 1.04- to 2.24-fold), pointing toward a potential amplifying effect of *T vaginalis* on HIV transmission rates.[14] This association may be based at least in part on the organism's ability to cause microulcerations in the genital and urinary tract epithelium, thus creating pathways for other microorganisms to enter the vascular system.

Making the diagnosis

The nonspecific symptoms of *T vaginalis* create a wide differential to consider. Vaginal discharge may be due to bacterial vaginosis, vulvovaginal candidiasis, physiologic discharge, atrophy, and nonspecific inflammation. The presence of malodorous and discolored discharge increases the likelihood of bacterial vaginosis or *T vaginalis* infection. Pruritus often is associated with candidiasis co-infection.

The diagnosis of trichomoniasis can be confirmed in the outpatient office with the use of saline microscopy, an inexpensive test that is based on observation of motile trichomonads in a wet mount of vaginal fluid. The sensitivity of the wet mount ranges from 44% to 68% compared with culture. Culture, traditionally using Diamond's medium, has a sensitivity of 81% to 94% and was long the gold standard; however, culture has been replaced largely by molecular and antigen testing.

Three US Food and Drug Administration (FDA)-approved NAATs for *T vaginalis* currently are on the market; all can detect co-infection with gonorrhea and chlamydia from the same specimen. These tests include the Aptima *T vaginalis* rRNA target assay (Hologic, Bedford, Massachusetts) and the BD ProbTec *T vaginalis* Q^{x} (TVQ) amplified DNA assay (BD Diagnostics, Baltimore, Maryland), both of which require up to 8 hours to yield results. The Xpert *T vaginalis* (TV) assay (Cepheid, Sunnyvale, California) is the first NAAT that is FDA approved for use with male urine (in addition to female urine), and it yields results in 60 to 90 minutes. Sensitivity for these NAAT assays ranges from 88% to 100%.[15]

Point-of-care testing is preferred for rapid diagnosis and for helping the clinician provide same-visit treatment for STIs. The Solana trichomonas assay (Quidel, San Diego, California) detects *T vaginalis* DNA and can yield results within 40 minutes, but it requires specialized equipment for running the samples. The AmpliVue trichomonas assay (Quidel, San Diego, California) is similar to the Solana assay but it is contained within a small handheld cartridge that does not require additional equipment. Sensitivities are 92% to 98% for Solona and 90.7% to 100% for AmpliVue. The OSOM trichomonas rapid test (Sekisui, Framingham, Massachusetts) uses antigen-detection immunochromatography to provide results in 10 to 15 minutes, with 83% to 92% sensitivity and 99% specificity for vaginal specimens.[15,16]

The **TABLE** on page 40 provides a summary of the clinical performance of the various tests for *T vaginalis*.[15-18]

Treatment options

The 5-nitroimidazole agents, which include metronidazole and tinidazole, are the preferred agents for the treatment of trichomoniasis.

Dosing regimen. While a single oral dose of metronidazole 2 g has long been the mainstay of treatment for *T vaginalis,* this regimen recently has been questioned, at least in women, due to the high posttreatment positive

FAST TRACK

Point-of-care testing is preferred for rapid diagnosis and for helping the clinician provide same-visit treatment for STIs

TABLE Commonly used diagnostic tests for *Trichomonas vaginalis*[15-18]

Test	Time	Specimen source	Sensitivity
Wet mount microscopy	Varies	Vaginal and endocervical secretions	44%–68%
InPouch Culture	Up to 7 days	Vaginal and endocervical secretions and female urine, male urine	96.9%–98.7%
InPouch Culture	Up to 7 days	Male urine and urethral secretions	No data available
Aptima	8 hours	Vaginal and endocervical secretions and female urine	88%–100%
BD ProbTec *T vaginalis* Q^x assay	8 hours	Vaginal and endocervical secretions and female urine	98.3%
Xpert TV assay	60–90 minutes	Vaginal and endocervical secretions and female urine	99.5%–100%
Xpert TV assay	60–90 minutes	Male urine	97.2%–99.9%
AmpliVue	45 minutes	Vaginal secretions and female urine	90.7%–100%
Solana	40 minutes	Vaginal secretions and female urine	92%–98%
OSOM	10–15 minutes	Vaginal secretions	83%–92%

Abbreviation: TV, *Trichomonas vaginalis*.

rate of *T vaginalis,* which ranges from 5% to 37%.[19,20] These cases may be due to reinfection by untreated sexual partners. They also may result from treatment failure, however, specifically inadequate treatment time.[21] Overall, patients treated with single-dose metronidazole are 1.87 times more likely to experience treatment failure compared with those treated with a multidose regimen.[19] Since many cases of *T vaginalis* infection are associated with bacterial vaginosis co-infection, recommending metronidazole 500 mg twice daily for 7 days is beneficial because this course provides optimal treatment for both infections.

Treatment during pregnancy. In the minds of some investigators, treatment of *T vaginalis* in asymptomatic pregnant women is problematic. One study demonstrated a similar to slightly increased risk of preterm delivery for metronidazole-treated patients compared with a placebo-treated group.[22] Limitations of the study included atypical treatment dosing (2 doses of metronidazole 2 g given 48 hours apart at 16 to 23 weeks' gestation and repeated at 24 to 29 weeks' gestation) and a latency between the last dose of metronidazole and preterm delivery.[22]

We believe that all pregnant women, symptomatic or asymptomatic, should be treated because of the sexually transmitted nature of the infection and the probability that most asymptomatic carriers ultimately become symptomatic.

Cost of treatment. Generic oral metronidazole is very inexpensive. The approximate retail price for 14 metronidazole 500-mg tablets is $15.69 (www.goodrx.com). By contrast, a single-dose course of tinidazole (four 500-mg tablets) costs approximately $45. Accordingly, we reserve tinidazole for patients who have experienced a treatment failure with metronidazole or who cannot tolerate metronidazole.

Drug-alcohol interaction. With both metronidazole and tinidazole, patients must abstain from alcohol during treatment and for 72 hours after completing therapy because these drugs have a disulfiram-like reaction with ethanol. ●

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UPDATE menopause

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responsive to lubricants and moisturizers, I recommend FDA-approved vaginal therapies as first-line treatment if there are no contraindications. For women with breast cancer, I involve their oncologist. If a patient asks about vaginal laser treatment, I share that vaginal energy-based therapies, such as the vaginal laser, have not been approved for menopausal vaginal concerns. In addition to the possibility of adverse events or unsuccessful treatment, there are significant out-of-pocket costs and the potential need for ongoing therapy after the initial 3 laser treatments. ●

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ASCCP guidelines for managing abnormal cervical cancer tests: What's new?

They've traded in algorithms for risk, and there will soon be a new app to streamline navigation of the guidelines

Q&A with Warner K. Huh, MD

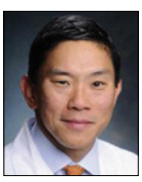
The 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors Consensus Guidelines, which represent a consensus of nearly 20 professional organizations and patient advocates, are a culmination of almost 10 years of research.[1] With the last version issued in 2012,[2] these latest guidelines offer the most recent recommendations regarding safely triaging women with abnormal cervical cancer screening results.

According to the consensus, research has shown that risk-based management allows clinicians to better discriminate women who will likely develop precancer from those who can safely continue with routine screening. As you will hear from guidelines coauthor Dr. Warner Huh, one of the most important differences between these guidelines and the 2012 version is a new emphasis on the principle of "equal management for equal risk." Essentially, this insures that all women who have the same amount of risk for progression to precancer or cancer are managed the same.

The guidelines were once again published in the *Journal of Lower Genital Tract Disease*, and the tables they reference are publicly available. Additionally, ASCCP is developing a new management guidelines app to facilitate the use of the guidelines on smartphones and computers. With the publicly available risk tables, and the ASCCP navigation app, the guidelines will more easily accommodate updates as new information and technology become available.

OBG MANAGEMENT: The latest ASCCP guidelines, published in April, represent a "paradigm shift" from results to risk-based guidelines. Can you explain what this means and why the shift was undertaken?

Warner K. Huh, MD: Yes, the shift occurred because we needed to focus less on algorithms and more on risk. We started promulgating a concept of "equal management for equal risk" back in 2012. What this means is that if we have a method to look up a risk score based on relevant test results and other pieces of information, then all patients with that score should be managed in the same



Dr. Huh is Division Director, Gynecologic Oncology and Vice-Chair, Gynecology, University of Alabama at Birmingham and Senior Medical Officer, O'Neal Comprehensive Cancer Center.

The author reports being a consultant to Inovio, Zilico, and Altum.

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manner. We wanted that to be the underlying principle.

Focusing on risk tables also makes it easier to incorporate any future technologies used for risk estimation without having to rebuild algorithms from scratch. ASCCP is developing a new management guidelines app to streamline navigation of the guidelines. This app makes them easier for clinicians to use; they simply plug in certain variables from the patient's history and receive 1 of 5 outputs: treatment, colposcopy, or surveillance at 1, 3, or 5 years.

The only drawbacks, if you view them as such, are that the clinician must plug in all the variables, and then must sit back and trust in what we have done. Clinicians have to trust that the system works and will simplify the clinical decision making.

We spent a lot of time determining what the risk thresholds should be. Some may argue they are arbitrary, but the decisions were data-driven, and carefully, thoughtfully vetted; we deliberated about whether the cut points actually made sense clinically to a practicing clinician base. The clinical action thresholds refer to a specific percentage below which a woman falls into one bucket and above which she falls into another bucket.

The other element that is unique about the guidelines is that instead of looking at the patient's current screening result in isolation, the user sees it along with the prior one because prior history dictates subsequent risk.

It's important that clinicians understand why this system is so markedly different from what we have done previously, and why risk-based guidelines make infinitely more sense than algorithmic ones. It's because: 1) they can be easier to use; 2) they incorporate new data more efficiently and effectively than algorithm-based guidelines; and 3) they can incorporate future technologies seamlessly rather than having to create yet another algorithm.

FAST TRACK

Risk-based guidelines have the advantages of being easier to use, incorporating new data efficiently and effectively, and allowing for future technologies

OBG MANAGEMENT: What do clinicians need in order to execute the guidelines?

Dr. Huh: Nothing. All of the information needed—the guidelines article and risk tables—are publicly available. However, to make navigation of the guidelines easier, the plan is for the app that I mentioned. I have the app on my phone and am actively beta testing it now. We're planning on creating a web-based application as well, that will allow users to access the Internet and their electronic health record system so that they can plug in information directly from patient charts. The web-based app will be similar to the web-based Breast Cancer Surveillance Consortium's Risk Calculator (https://tools.bcsc-scc.org/BC5yearRisk/calculator.htm). You will pull it up, plug in the requested information, including the patient's age; their Pap smear and genotyping results; and their previous screening history.

OBG MANAGEMENT: When will the app be available for users?

Dr. Huh: Soon. Hopefully no later than this summer.

OBG MANAGEMENT: Were HPV vaccination levels incorporated into the new guidelines?

Dr. Huh: We initially looked at them because human papillomavirus (HPV) vaccination hugely influences outcomes but, no, we did not include them in the guidelines. The reason is that it's really challenging to prove whether a woman has been vaccinated. You have to have access to vaccine records. Then there is also the issue of whether a patient has had 1, 2, or 3 doses. That is a really sticky variable. So, since it is not part of the guidelines, ASCCP also did not include it as a part of the app or the website. But we do recognize that HPV vaccination plays an important role in outcomes.

OBG MANAGEMENT: Have recommendations regarding colposcopy changed?

Dr. Huh: Not really. About 3 years ago, we created basic colposcopy guidelines—the ASCCP Colposcopy Standards—so everything about colposcopy references back to those guidelines. Those colposcopy standards covered terminology and risk-based

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colposcopy, which actually aligns beautifully with these guidelines.

OBG MANAGEMENT: To narrow in on some changes from the prior guidelines, can colposcopy be deferred in certain patients?

Dr. Huh: Yes. Not everyone who has an abnormal screening test needs to come back for colposcopy.

OBG MANAGEMENT: How has guidance for expedited treatment or treatment without colposcopic biopsy changed?

Dr. Huh: This was heavily debated within not only the treatment group that I co-chaired with Richard Guido, MD, but also within the entire steering committee. The recommendation is that if the patient has an immediate risk of CIN 3 that is >60%, the patient should go straight to treatment without a colposcopic biopsy. The main reason for this is that you do not want to biopsy a patient and then lose them to follow-up.

When a woman has >60% immediate risk of CIN 3, we are fairly certain that colposcopy is not going to change management ultimately, so we recommend that patients receive treatment right away. We have already been doing this for 15 to 20 years, so this is not a new concept. It is just more formally codified here by assigning a percentage to the risk. Those who have between 25% and 60% immediate risk of CIN 3 should receive immediate colposcopy. We realize that not all clinicians have the ability to do this, so if clinicians can't treat immediately, we recommend they do whatever they can to prevent losing the patient to follow-up.

OBG MANAGEMENT: How should a positive primary HPV screening test be managed?

Dr. Huh: If a woman has a positive primary HPV screening test, genotyping should be performed. If genotyping reveals HPV 16 or 18, then the patient should proceed to colposcopy. If genotyping reveals other forms of HPV, reflex cytology or a Pap smear should follow. ●

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Out of the pipeline: Remdesivir

What do we know about this drug, recently FDA approved under emergency use authorization to treat COVID-19, and how can it be used safely in pregnant women?

Robert L. Barbieri, MD

Although the US Food and Drug Administration (FDA) has granted emergency use authorization of remdesivir (Gilead Sciences, Inc., Foster City, California) to treat COVID-19, the disease caused by SARS-CoV-2, the drug is considered an investigational agent, not yet formally approved by the FDA and whose efficacy and safety has not yet been fully characterized. Remdesivir has been shown to be effective in reducing the time to recovery of people with COVID-19 disease. It has not been tested in a large controlled clinical trial of pregnant women with COVID-19; however, remdesivir has been given to pregnant women infected with COVID-19 in a compassionate use protocol. For pregnant women, the drug should only be used if the potential benefit justifies the potential risk to the mother and fetus.[1]

Pharmacology. Remdesivir is a nucleoside RNA polymerase inhibitor. It has a molecular formula of $C_{27}H_{35}N_6O_8P$ and a molecular weight of 602.6 g/mol.[1]

Mechanism of action. From FDA's fact sheet: "Remdesivir is an adenosine nucleotide prodrug that distributes into cells where it is metabolized to form the pharmacologically active nucleoside triphosphate metabolite. Metabolism of remdesivir to remdesivir triphosphate has been demonstrated in multiple cell types. Remdesivir triphosphate acts as an analog of adenosine triphosphate (ATP) and competes with the natural ATP substrate for incorporation into nascent RNA chains by the SARS-CoV-2 RNA-dependent RNA polymerase, which results in chain termination during replication of the viral RNA. Remdesivir triphosphate is a weak inhibitor of mammalian DNA and RNA polymerases with low potential for mitochondrial toxicity."[1]

Treatment protocols

Remdesivir is authorized for treatment of **hospitalized** patients with severe COVID-19 disease, defined as patients with **an oxygen saturation ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO)**. The optimal dose and duration of treatment of COVID-19 with remdesivir is unknown.[1]

Prior to initiating treatment, the estimated glomerular filtration rate should be documented to be ≥30 mL/min. An excipient used in the remdesivir formulation—sulfobutylether-ß-cylcodextrin sodium salt—is renally cleared and accumulates in patients with decreased renal function.

Baseline liver function tests should be performed prior to treatment and daily during the course of treatment. Remdesivir should not

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Pregnancy risk summary
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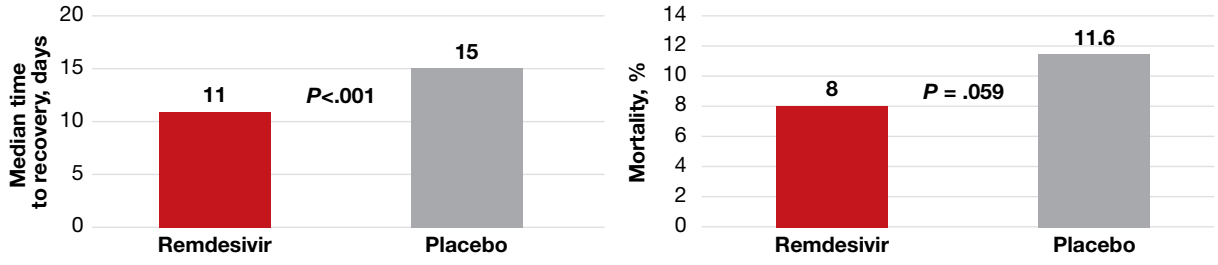
The author reports no financial relationships relevant to this article.

TABLE **Adaptive COVID-19 Treatment Trial time to recovery and mortality results**[1]



FAST TRACK

A randomized, multicenter study suggested that patients receiving 10 days of remdesivir had similar improvement in clinical status compared with those receiving a 5-day treatment course

be initiated in patients with an alanine aminotransferase (ALT) level ≥5 times the upper limit of normal at baseline. Remdesivir should be discontinued in patients who develop an ALT level ≥5 times the upper limit of normal or in patients who develop elevated ALT levels and have increased bilirubin, alkaline phosphatase, or international normalized ratio.[1]

In one open-label study (GS-US-540-5773), remdesivir treatment was discontinued due to an adverse event in 5% of patients on a 5-day regimen and in 10% of patients on a 10-day regimen.[1]

Under the emergency use authorization, two treatment protocols have been proposed depending on the clinical severity of the COVID-19 infection[1]:

- Protocol 1: For people with COVID-19 requiring mechanical ventilation and/or ECMO, the duration of therapy is 10 days, beginning with a loading dose of remdesivir 200 mg infused intravenously for 30 to 120 minutes on day 1 followed by a once-daily dose of 100 mg for 9 days.
- Protocol 2: For people with COVID-19 disease not requiring mechanical ventilation and/or ECMO, the duration of therapy is 5 days, beginning with a loading dose of remdesivir 200 mg infused intravenously for 30 to 120 minutes on day 1 followed by a once-daily dose of 100 mg for 4 days. If the patient does not show clinical improvement, treatment may be extended for an additional 5 days.

Randomized placebo-controlled trial results

The Adaptive COVID-19 Treatment Trial (ACTT), sponsored by the National Institute of Allergy and Infectious Diseases, is a randomized, double-blind, placebo-controlled trial conducted by Gilead Sciences. The study began in February and evaluated up to 10 days of remdesivir treatment—200 mg IV once daily for 1 day followed by 100 mg IV once daily for 9 days in hospitalized adult patients with COVID-19. Patients were enrolled in a 1:1 manner to remdesivir or placebo, and time to recovery within 28 days after randomization was the trial's endpoint. According to preliminary analysis of 606 recovered patients, recovery took a median of 11 days in the remdesivir group and 15 days in the placebo group (hazard ratio, 1.31; 95% confidence interval ([CI], 1.12–1.54; *P*<.001). Mortality rates were 8.0% and 11.6% in the remdesivir and placebo groups, respectively (*P* = .059) (**TABLE**).[1]

5 vs 10 days of remdesivir treatment

The Gilead Sciences–sponsored study GS-US-540-5773 was a randomized, open-label multicenter trial of patients with severe COVID-19. A total of 197 adult patients received 10-day remdesivir treatment (200 mg IV once daily for 1 day followed by 100 mg IV once daily for 9 days). An additional 200 adult patients received 5-day remdesivir treatment (200 mg IV once daily followed by 100 mg IV for 4 days). Both groups also received standard of care. Results suggested that patients receiving 10 days of remdesivir had similar improvement in clinical status compared with those receiving a 5-day treatment course (10-to-5 day odds ratio, 0.76; 95% CI, 0.51–1.13, on day 14).[1] Improvement in clinical status was defined as an improvement of 2 or more points from baseline on a

predefined 7-point scale that ranged from hospital discharge to increasing levels of oxygen support to death. Clinical recovery was achieved if patients ceased the need for oxygen support or were discharged.[1]

The time to clinical improvement for 50% of patients was similar in each treatment group (10 days in the 5-day group versus 11 days in the 10-day group). By day 14, observed clinical improvement rates were 65% and 54% in the 5- and 10-day treatment groups, respectively. Clinical recovery rates were 70% and 59% in the 5- and 10-day treatment groups and mortality rates were 8% and 11%.[1]

Adverse events

The use of remdesivir is contraindicated in patients who are hypersensitive to the drug. Its infusion may cause hypotension, nausea, vomiting, diaphoresis, and shivering. If signs of a clinically significant infusion reaction are observed the infusion should be discontinued. As noted above, elevation in ALT levels occurs with remdesivir treatment.[1]

Reporting serious adverse events. If a serious and unexpected adverse event occurs and appears to be associated with the use of remdesivir, the prescribing health care provider and/or the provider's designee should complete and submit a MedWatch form to the FDA using one of the following methods[1]:

- complete and submit the report online: www.fda.gov/medwatch/report.htm
- return form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) to the FDA by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-0178).

Gilead requests that all FDA MedWatch forms also be returned to Gilead Pharmacovigilance and Epidemiology: fax: 1-650-522-5477 726; e-mail: Safety_fc@gilead.com.

Drug interactions

Remdesivir has not been thoroughly evaluated for drug-drug interactions in humans. The clinical relevance of in vitro drug interactions also has not been established. According to the FDA, remdesivir is a substrate for the drug metabolizing enzymes CYP2C8, CYP2D6, and CYP3A4, and is a substrate for organic anion transporting polypeptides 1B1 (OAPT1B1) and P-glycoprotein (P-gp) transporters. In vitro, remdesivir inhibits CYP3A4, OATP1B1, OATP1B3, BSEP, MRP4, and NTCP.[1]

Pregnancy risk summary

Remdesivir has not been studied adequately in pregnant women and only should be used during pregnancy if the potential benefit of the drug justifies the potential risk to both mother and fetus. Nonclinical animal studies that included systemic exposure of the predominant circulating metabolite of remdesivir in pregnant rats and rabbits (at 4 times the recommended dose of human exposure) demonstrated no adverse effect on embryofetal development.[1]

Breastfeeding

The only information regarding breastfeeding and remdesivir comes from animal studies. The drug and its metabolites were detected in the plasma of nursing rat pups whose mothers were given intravenous remdesivir daily from gestation day 6 to lactation day 20. Measured on lactation day 10, remdesivir exposure in the pups was about 1% that of maternal exposure.[1]

"Because of the potential for viral transmission to SARS-CoV-2-negative infants and adverse reactions from the drug in breastfeeding infants, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for remdesivir and any potential adverse effects on the breastfed child from remdesivir or from the underlying maternal condition."[1] ●

FAST TRACK

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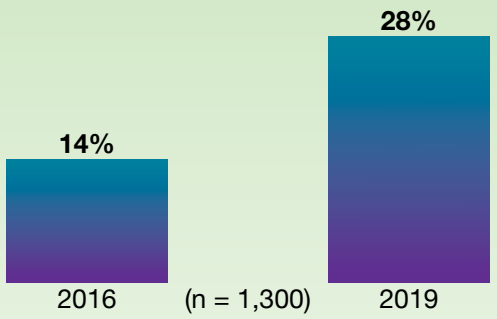
Reference

1. US Food and Drug Administration. Fact Sheet for Health Care Providers Emergency Use Authorization (UA) of Remdesivir (GS-5734)™. https://www.fda.gov/media/137566/download. Accessed May 19, 2020.

Telemedicine growth in the United States

Progress was underway before COVID-19 became a reality

From 2016 to 2019 the number of physicians reporting televisits doubled



In 2018, 47.6% of 4,711 hospitals reported providing telehealth-based services

In 2019,

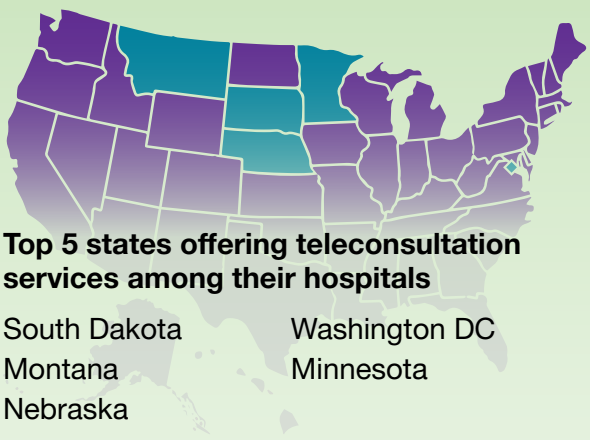
58%

of multispecialty groups were using or had plans to use televisits within the year

In 2019,

47%

of hospitals had plans to begin televisits within or beyond a year



Top 5 states offering teleconsultation services among their hospitals

South Dakota
Montana
Nebraska
Washington DC
Minnesota

In March 2020, the COVID-19 Telehealth Program, as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, was passed, including $200 million for health services connectivity improvement

Sources:

American Medical Association. Physicians' motivations and requirements for adopting digital health. Adoption and attitudinal shifts from 2016 to 2019. February 2020. https://www.ama-assn.org/system/files/2020-02/ama-digital-health-study.pdf. Accessed May 26, 2020.

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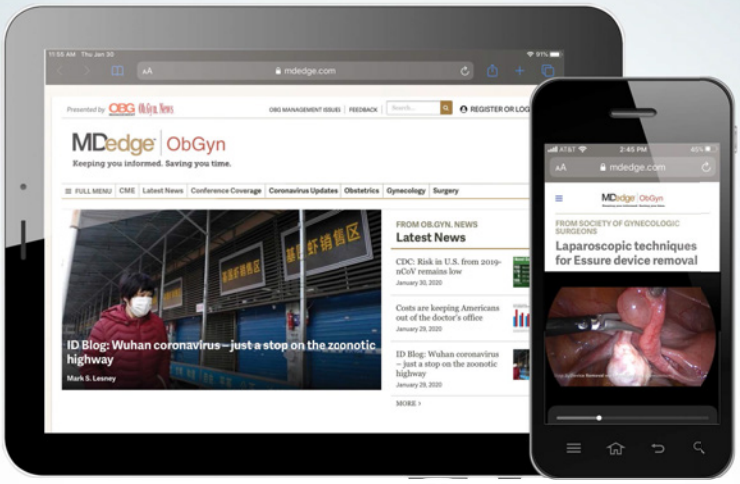

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- ✓ Conserve critical resources
- ✓ Reduce potential COVID-19 exposure

fFN testing can help identify patients at low risk of imminent sPTB who can safely remain at home.

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- Limit TVUS cervical length to positive fFN results only avoiding potential COVID-19 exposure of patients & staff
- Collect fFN specimens in the OB provider office
- Collaborate with hospitals and laboratories to perform fFN testing STAT for outpatient specimens to reduce patients sent into hospital OB triage

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Reference: 1. Rapid fFN for the TLi$_{iq}$ System [package insert]. AW-04196, Sunnyvale, CA: Hologic, Inc.; 2017.