Clinical Journal for Nurse Practitioners in Women's Health

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Message From the Editor



Dear Colleagues,

I am pleased to welcome you to the prelaunch issue of our new peer-reviewed online journal, *Clinical Journal for Nurse Practitioners in Women's Health (CJNPWH)*. *CJNPWH* is the new official journal of the National Association of Nurse Practitioners in Women's Health (NPWH).

We are excited to partner with our new publisher, Springer Publishing Company. I want to share some of the reasons we chose them. Springer is well-established in the women's and gender-related health field, as demonstrated by their numerous journals and books. We are already discussing how valuable connections and collaborations can be made to further the reach of essential insights and knowledge with a broader audience. Springer values authors and has committed to providing resources to help them receive better recognition for their work.

This prelaunch issue features articles from authors who have been eagerly waiting to be part of the new journal. We thank them for their patience and for providing a great example of what we bring to the readers of *CJNPWH*. I also want to thank our peer reviewers, who have remained active this past year, providing expertise and thoughtful feedback to ensure the articles we publish in our new journal are the very best.

CJNPWH will be published online quarterly, with the debut issue for our first full year in January 2025. Although we are starting with four issues each year, we are expanding content in each issue to match what you have received each year previously with six issues. We will include two continuing education articles in each issue that are available free to NPWH members and for a fee to nonmembers. Springer will provide an early view of articles on the journal website. This early view is another great benefit for authors to reach our readers so they can access articles prior to publication in a journal issue.

Springer uses an online platform for manuscript submission and for peer reviewers. We will ensure you have easy-to-follow instructions and that we will be available to answer questions.

The mission of *CJNPWH* is to provide nurse practitioners and other advanced practice registered nurses who provide women and gender-related health care with relevant clinical, policy, and professional development content as a critical resource to stay informed about the latest advancements in the field. In choosing articles for publication, we keep in mind the diversity of our readers in areas such as population served, clinical setting, specialty care, geographic location, and years of experience. *CJNPWH* intentionally seeks to publish articles that contribute to eliminating health disparities and achieving health equity.

Please take some time to meet our *CJNPWH* editorial advisory board (EAB) members. Their short bios are available on the www.npwh.org. I am committed to expanding our EAB to represent the relevant variety of expertise and diversity that will allow us to meet our journal's mission. Watch for the call for NPWH members to submit EAB applications for 2025.

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https://doi.org/10.1891/CJNPWH-2300-ED

We want to hear from you as readers, authors, or potential authors what you want from the journal. Please be sure to complete the CJNPWH reader survey coming to you soon.

I am incredibly honored to be the editor-in-chief of *CJNPWH*. Springer, NPWH, our EAB, and I are committed to excellence in the content we bring you and our support for authors and peer reviewers. Watch for upcoming tutorials and webinars on writing for publication, submitting a manuscript, and what to expect in the peer review process. I will continue to send biannual newsletters to our peer reviewers with tips to help them in their role. As we finish 2024 and move forward into 2025, so much good work is happening at NPWH, and *CJNPWH* is definitely a part of this!

Beth

Beth Kelsey, EdD, APRN, WHNP-BC, FAANP

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https://doi.org/10.1891/CJNPWH-2300-ED

Message From NPWH



Dear NPWH Community,

I am thrilled to announce the launch of the *Clinical Journal for Nurse Practitioners in Women's Health*, a new publication dedicated to advancing the practice and professional growth of certified women's health nurse practitioners (WHNP-BCs) and advanced practice registered nurses (APRNs) who are at the forefront of women's and gender-related health care. This journal marks a significant milestone in our ongoing efforts to elevate the profile of certified WHNPs and APRNs and to highlight the critical role they play in providing comprehensive, evidence-based care across an individual's lifespan.

This exciting initiative is made possible through our partnership with Springer Publishing, a renowned leader in health care education and academic publishing. With Springer's extensive reach and respected platform, the *Clinical Journal for Nurse Practitioners in Women's Health* will bring our authors' expert insights and innovative practices to a broader audience than ever before. This journal will serve as a vital resource not only for nurse practitioners in women's and gender-related health care but also for educators, students, researchers, and policymakers who are shaping the future of health care.

Our mission at the National Association of Nurse Practitioners in Women's Health (NPWH) has always been to advocate for the essential contributions of WHNPs and other APRNs. By showcasing your work in this new journal, we are amplifying the voice of your profession and ensuring that the expertise and impact of certified WHNPs are recognized and celebrated on a national and global stage.

What makes this launch so special is knowing that it is your work—your dedication, your passion, and your commitment to excellence—that will fill these pages. This journal will be a place where our community can come together to share knowledge, learn from one another, and continue pushing the boundaries of what is possible in women's and gender-related health.

I encourage you to engage with this journal—whether by submitting your manuscript, sharing your clinical insights, or using it as a resource to stay at the forefront of women's and gender-related health care. Together, we will continue to advance the women's health field, fostering innovation and excellence in every aspect of your practice. This journal is just one more way we are making sure that the essential contributions of certified WHNPs and all APRNs are recognized and valued.

Thank you for being such a vital part of this journey. I am excited to see the *Clinical Journal for Nurse Practitioners in Women's Health* become a cornerstone of NPWH and the WHNP profession, showcasing the incredible work you do every day. This journal will stand as a powerful testament to our collective dedication and the exceptional contributions of our members.

With warm regards,

Heather L. Maurer, MA, CAE
Chief Executive Officer
National Association of Nurse Practitioners in Women's Health

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https://doi.org/10.1891/CJNPWH-2301-ED

Sexual Dysfunction in Patients With Breast or Gynecologic Cancer: What Women's Healthcare Providers Need to Know

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Continuing Education Approval

This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH) for 1.0 continuing education contact hour, including 0.25 contact hours of pharmacology content, now through December 31, 2026. NPWH is accredited as a provider of continuing education by the California State Board of Nursing, Provider Number CEP 13411.

Educational Objectives

At the conclusion of this educational activity, participants should be able to

1. Discuss the pathophysiology of sexual dysfunction as it relates to breast and gynecologic cancers,
2. Describe communication, assessment, and diagnostic considerations for sexual dysfunction as it relates to individuals with breast and gynecologic cancers, and
3. Discuss nonpharmaceutical and pharmaceutical treatment approaches to sexual dysfunction particularly as it relates to individuals with breast and gynecologic cancers.

Disclosure

The authors have no actual or potential conflicts of interest in relation to the contents of this article.

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Commercial Support

This activity did not receive any commercial support.

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Successful completion of this activity, J-24-02, requires participants to do the following:

1. "Sign in" at the top right-hand corner of the page https://www.pathlms.com/npwh/courses/75636 if you have an NPWH account. You must be signed in to receive credit for this course. If you do not remember your username or password, please follow the "Forgot Password" link and instructions on the sign-in page. If you do not have an account, please click on "Create an Account."
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https://doi.org/10.1891/CJNPWH-2421

Sexual Dysfunction in Patients With Breast or Gynecologic Cancer: What Women's Healthcare Providers Need to Know

Many individuals with breast or gynecologic cancer experience sexual dysfunction. Providing sexual health care to patients with or who are survivors of breast or gynecologic cancer can be challenging. This article describes the pathophysiology of sexual dysfunction, most specifically as it relates to breast and gynecologic cancers, as well as communication, assessment, and management strategies that can be used by health care providers practicing in gynecologic and primary care settings to better address these issues.

Keywords: sexual dysfunction, breast neoplasms, female genital neoplasms

Breast and gynecologic cancers accounted for over 400,000 cancer diagnoses in women in the United States in 2023.[1] These cancers, along with their treatment, can lead to a plethora of adverse effects, with impact on sexual health being one of them.[2,3] Studies demonstrate that between 50% and 85% of patients with breast or gynecologic cancer experience some sexual health issue during or after diagnosis or treatment.[4–7] These sexual health issues range from impairments in sexual function to overall issues with body image, sexuality, and intimacy.

To begin, it is crucial to understand the differences between sexual health and sexual function. Sexual health is defined as:

> a state of physical, emotional, mental, and social well-being in relation to sexuality, not merely the absence of disease, dysfunction or infirmity, [and] a positive and respective approach to sexuality, sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences.[8]

Sexual function, on the other hand, refers to the physical ability to engage in sexual activities and includes the domains of desire, arousal, orgasm, and lubrication.[9] Sexual dysfunction occurs when there are persistent and recurrent issues with sexual function that cause distress.

Sexual dysfunction can occur through a variety of mechanisms and conditions.[10] In patients with breast or gynecologic cancer, the diagnosis itself, the cancer treatment, or the culminating symptoms can lead to sexual dysfunction. The type of cancer, location, stage, and sites of metastasis can all impact sexual health. The context of cancer in the life trajectory and its influence on one's relationships and body image can also play a role. Surgery can affect sexual health, and chemotherapy can lead to ovarian failure, causing a multitude of hypoestrogenic symptoms similar to those in menopause. Hormonal therapies, such as tamoxifen and aromatase inhibitors (AIs), can lead to vaginal dryness and significant dyspareunia.[11] Radiation to the breast can lead to skin and sensory changes, whereas pelvic radiation can lead to ovarian failure or vaginal stenosis.[12]

Communication and assessment skills are crucial to the diagnosis and management of sexual health issues in patients with breast and gynecologic cancers. The purpose of this article is to describe communication techniques, assessment strategies, and diagnostic and management approaches.

Communication Techniques

Researchers have noted that, while important to patients with cancer, providers do not ask about sexual dysfunction nor is it brought up by the patients.[7,13] As women's health care providers, it is essential to lead the way in addressing the sexual health of survivors of breast and gynecologic cancers. An important first step is to break the silence. Health care providers can start with simple questions about sexual health that can open up the conversation and help establish initial rapport. Successful conversations encompass the use of clear and concise language and questions, avoiding vague terminology, using proper anatomic terms, open-ended communication, and employing active listening skills.

Assessment Strategies

Sexual function issues typically arise in five broad categories associated with the physiologic functions of sexual

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response: desire, arousal, lubrication, orgasm, and satisfaction. While obtaining history and conducting physical exam, it can be helpful to think through these five categories to identify in which area or areas the patient may be experiencing problems.

When performing an assessment focused on sexual health in a patient with breast or gynecologic cancer, it is important to review their cancer history. Cancer history includes the cancer diagnosis, age at diagnosis, and types of treatment (eg, surgery, radiation, chemotherapy, combination).[7] Conduct a typical sexual history and ascertain if the patient has had any sexual health issues prior to cancer. Cancer history and sexual health history provide key information that may help the health care provider determine if sexual health issues have a psychological cause, physiologic cause, or both. Asking the patient if they are interested in being sexually involved in the future is important for goal setting.[7] The gynecologic exam should include an external and internal examination. The vulva should be assessed for swelling, excoriations, lesions, edema, and scarring.[14] The labia, clitoris, introitus, and perineum should also be assessed. A cotton-tipped applicator can be used to further evaluate localized complaints of vulvar pain. A digital vaginal exam allows assessment of possible vaginal stenosis and shortened vaginal length and the level of any vaginal discomfort or pain prior to initiating a speculum exam. A vaginal speculum exam is performed with an appropriate-sized speculum (pediatric or adult Pederson speculum) to assess the vagina for scarring, edema, atrophy, and infection. Pelvic floor muscle assessment is important in evaluating the ability to effectively contract and relax the pelvic floor and in assessing for dysfunction.[10,14]

Diagnostic Considerations

The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (*DSM-5*) criteria for sexual dysfunction help health care providers distinguish between the different symptoms and diagnoses. To meet the *DSM-5* diagnostic criteria for sexual dysfunction categories, the dysfunction cannot be due to a medical condition and must be experienced at least 75% of the time, present for at least 6 months, and cause significant distress to the individual. The dysfunction can be primary (lifelong) or secondary (acquired) and can be generalized or situational. It is essential to assess for psychological causes of dysfunction and recognize that comorbidities (eg, body image disturbance, depression, anxiety) associated with cancer or its treatment may meet the diagnostic criteria outlined in the *DSM-5*.[15,16]

The *DSM-5* diagnostic criteria for a genito-pelvic pain or penetration disorder include at least one of the following: difficulty with vaginal penetration, pain with vaginal penetration, fear of vaginal penetration, fear of pain during vaginal penetration, and pelvic floor muscle dysfunction. The *DSM-5* combines difficulties with desire and arousal into one diagnosis: female sexual interest/arousal disorder. The criteria for this diagnosis include complete lack of, or significant reduction in, sexual interest or sexual arousal during sexual activity or sexual/erotic thoughts or fantasies; reduced initiation of sexual activity and being unreceptive to their partner's sexual initiation attempts; and absent/reduced sexual interest or arousal in response to any sexual/erotic cues, or absent/reduced sensation during sexual activity in almost all sexual encounters. Female orgasmic disorder (FOD) is defined as delayed, infrequent, or absent orgasm, or markedly decreased orgasm intensity.

Because most of these sexual health problems in cancer patients are related to the medical condition or its treatment, the *DSM-5* diagnosis of sexual dysfunction may not be applicable. In these cases, diagnoses with the appropriate International Classification of Diseases-10 (ICD-10) code can be used in conjunction with their cancer diagnosis. Examples of ICD-10 codes that are potential causes of sexual health problems in patients with current or history of cancer include vulvovaginal dryness, vaginal stenosis, dyspareunia, or decreased libido.[17] In some situations, there are no diagnostic codes that appropriately address the medical causes of sexual function problems. For example, a diagnosis of anorgasmia in a patient with a cancer diagnosis in whom the clitoris has been removed as part of a complete radical vulvectomy would not classify as a sexual dysfunction according to the *DSM-5* because it is related to a medical condition, but there is not an appropriate ICD-10 code that can be used.

Treatment Approaches

The EX-PLISSIT Framework

After establishing initial rapport with the patient, consider incorporating the EX-PLISSIT framework, an extended form of the PLISSIT model used when assessing and managing sexual health issues. EX-PLISSIT uses the same steps as the original PLISSIT (Permission, Limited Information, Specific Suggestions, Intensive Therapy) but is feedback-oriented. With EX-PLISSIT, the health care provider incorporates questions to elicit patient feedback with each step.[18]

Addressing Difficulties With Lubrication and Sexual Pain

The treatment for sexual pain focuses on treating the underlying cause. Survivors of breast and gynecologic cancer commonly experience dyspareunia due to vaginal dryness, which can affect the entire sexual response cycle.[19,20] Vaginal moisturizers and vaginal lubricants are first-line therapies for pain caused by vaginal atrophy.[19] Vaginal moisturizers are nonhormonal and are inserted into the vagina several times a week to improve vaginal

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health. A few vaginal moisturizers bind to the vaginal epithelium, hydrating the underlying cells and resulting in maturation of the epithelium, while others (eg, hyaluronic acid) lubricate and hold water.[7,20] Various types (eg, liquid, lotion, suppositories) can benefit patients with consistent usage.[7] Vaginal lubricants are liquids or gels applied to the genital area prior to and during sexual activities. Water and silicone lubricants are typically recommended over others. Both should be used for maximum effectiveness, as moisturizers several times a week, and as lubricants during sexual activities.[7]

The use of hormonal therapy to treat dyspareunia caused by vaginal atrophy should be considered in coordination with the patient's oncologist. Systemic estrogen hormone therapy is never considered appropriate in patients with an estrogen-dependent cancer. This includes estradiol acetate vaginal ring, which delivers systemic levels of estrogen. In patients in whom vaginal moisturizers and lubricants do not effectively alleviate pain, low-dose vaginal estrogen, such as estrogen vaginal cream (ie, 17B-estradiol, conjugated equine estrogen, estrone), may be used as systemic levels typically remain in the postmenopausal range.[19] Systemic absorption of estradiol soft gel inserts (4 g and 10 g) also remains in the postmenopausal range. Localized estrogen can also be delivered with a low-dose vaginal ring (17B-estradiol) or vaginal tablet (estradiol hemihydrate).[21]

There is support for the use of dehydroepiandrosterone (DHEA) in women with a history of breast cancer who are unresponsive to vaginal moisturizers and lubricants.[22,23] Vaginal DHEA is approved by the U.S. Food and Drug Administration (FDA) for treatment of moderate to severe dyspareunia due to menopause. It is converted to androstenedione, which converts through aromatization to estrogen and androgens, including testosterone. Although the manufacturers of DHEA have not studied this product in women with breast cancer, studies have shown that those on AI had no change in estrogen serum concentrations. However, there was an increase in serum concentrations in those not on AI in the higher vaginal DHEA dose (6.5 mg). The vaginal DHEA product label states exogenous estrogen is contraindicated in women with known or suspected breast cancer.[24]

Ospemifene is the only nonestrogen oral medication approved by the FDA for moderate to severe dyspareunia due to atrophy in postmenopausal women. It is a selective estrogen receptor modulator (SERM) that improves vaginal tissue health. SERMs exhibit agonistic activity in some tissues and antagonistic activities in other tissues. Ospemifene exhibits estrogen receptor agonistic activity in vaginal tissues and estrogen receptor antagonistic activity in breast tissues.[24] Ospemifene is approved in Europe for women with breast cancer who have completed their cancer treatment. However, the long-term effects have not been studied, and the FDA advises against the use of ospemifene in women with breast cancer, as well as those with known or suspected estrogen-dependent neoplasms.

Dyspareunia can also be associated with pelvic surgery or radiation, or anything that causes atrophy or strictures of the vagina that result in shorter vaginal length, vaginal or vulvar scarring, or stenosis. Use of a vaginal dilator is necessary in patients treated with pelvic radiation and is also useful in other patients as an intervention to prevent vaginal stenosis. Generally, use of a vaginal dilator is initiated within 1 month postradiation. The patient is instructed to insert the appropriately sized, lubricated dilator for 10–20 minutes at least two to three times a week.[7,14]

Patients with sexual dysfunction following treatment for gynecologic cancers can benefit from pelvic floor physical therapy (PFPT).[25] Treatments can result in alterations in pelvic tone from loss of tissue elasticity, which increases vulvovaginal pain with intercourse. In PFPT, patients are taught pelvic floor muscle exercises with electromyography biofeedback; manual therapy techniques (ie, trigger point therapy, stretching) can also be incorporated to relax and strengthen control of the pelvic floor muscles, resulting in improved sexual function. Furthermore, PFPT has been shown to decrease pain anxiety and pain with intercourse and to improve body image concerns.[25]

Addressing Issues With Desire and Arousal

Medical, psychological, and relationship factors can negatively affect sexual desire and arousal of many survivors of cancer.[7] Identifying and managing the factors affecting a patient's sexual health may alleviate the effects on the sexual desire and arousal. Women experiencing depression related to their cancer diagnosis and treatment may be taking antidepressants such as selective serotonin reuptake inhibitors (SSRIs), which are known to decrease sexual desire.[26] Switching to a different medication may resolve the issue if this is an option for the patient. If not, a 2-day reprieve from taking an SSRI (with the exclusion of fluoxetine) prior to a planned sexual activity has been shown in a small trial to increase desire, arousal, and overall sexual satisfaction with no significant adverse effects.[27] Certain treatments that impact desire/arousal in patients with breast and gynecologic cancers cannot be altered, so other strategies may need to be considered. Sexual desire and subsequent arousal in women are found to be more responsive to sexual cues than to occur spontaneously.[26] Sexual response involves the interplay of sexual excitement and sexual inhibition. Certain situations can either accelerate or inhibit sexual interest.[26] Physical attraction and intimate touch are excitatory mechanisms that can accelerate interest or desire, leading to arousal. Incorporating quality time with a partner and touching in nonsexual ways (ie, kissing, holding hands, cuddling) can positively affect relationship connection, improving desire/arousal.

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Psychosocial factors such as stress, anxiety, and partner relationship issues are common in most cancer survivors. When health care providers normalize them as common concerns, patients are more likely to address them. Psychotherapy, mindfulness therapy, cognitive behavioral therapy, and other stress reduction and healthy coping techniques may be beneficial.[28] The use of sexual arousal devices (eg, vibrators, air pulsation devices, dildos) can help increase sensation, especially when used with mindfulness therapy. Mindfulness therapy focuses on sexual arousal and excitement and results in a desire to continue the sexual activity. If nonpharmacologic strategies for addressing desire/arousal issues are unsuccessful, pharmacologic therapies may provide benefit to the patient. These include flibanserin, bremelanotide, and other drugs that may be used off-label (Table).[26,29]

Table. Pharmacologic Management of Female Desire/Arousal Disorder[26,29]

DRUG	MECHANISM OF ACTION	DOSE	COMMENTS
Flibanserin	Serotonin type 1A agonist and serotonin type 2A receptor antagonist that decreases serotonin but raises dopamine and norepinephrine	100 mg orally at bedtime every night; discontinue if not effective in 8 weeks	• It is FDA-approved for premenopausal women only. • Clinical trials found increased sexual desire, decreased sexual distress, and an increased number of satisfying sexual encounters. • There is boxed warning to wait 2 hours after alcohol consumption to take flibanserin. • Although not FDA-approved for postmenopausal women, improvements have been found in sexual desire, the number of satisfying sexual events, and a decrease in sexual desire distress.
Bremelanotide	Alpha-melanocyte stimulating hormone analog that enhances release of dopamine and oxytocin	1.75 mg subcutaneously in the abdomen or thigh as needed, 45 minutes prior to sexual activity Limit to only one dose per 24 hours and only eight doses per month	• It is FDA-approved for premenopausal women only. • Clinical trials found an increase in sexual desire and decrease in sexual desire distress. • Side effects include mild to moderate nausea, flushing, and headache. • It is contraindicated in uncontrolled hypertension or cardiovascular disease.
Bupropion	Increases dopamine and norepinephrine levels in the brain	150–450 mg maximum per day orally	• It is FDA-approved for major depressive disorder and aid in smoking cessation. • It is used off-label for sexual dysfunction. • Sexual side effects include increased libido, sexual arousal, and orgasm. • Side effects include dry mouth, nausea, and insomnia. • It is contraindicated in those with seizure and eating disorder.
Buspirone	Serotonin type 1A receptor agonist similar to flibanserin	20–60 mg/day orally, flexible dosage	• It is FDA-approved for generalized anxiety disorder. • It is found to decrease SSRI-induced sexual dysfunction and enhance the effects of testosterone in some women.
Trazodone	Similar to flibanserin	3.5–19.2 mg extended-release per day orally or 1.2–6.4 mg immediate-release three times a day, minimum effective dosage for improving sexual desire and arousal	• It is FDA-approved for major depressive disorders.

Abbreviations: FDA, Food and Drug Administration; SSRI, selective serotonin reuptake inhibitor.

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Addressing Difficulties With Orgasm and Satisfaction

It is well-recognized that psychosocial issues involving relationships, intimacy, and body image can affect orgasm and sexual satisfaction. Body image concerns are commonly seen in survivors of breast cancer and they should be offered adaptive devices (eg, wigs, breast prostheses) as these may help restore body positivity.[30] Treatments for gynecologic cancer may result in vaginal/vulvar scarring, vaginal shortening/stenosis, and atrophy issues that can result in pain or damage to the clitoris. Pain affects the ability to enjoy sexual activities and achieve orgasm, and damage to the clitoris or injury to the sacral/pelvic nerves impairs sensation, leading to decreased/absence of orgasms. The use of vaginal lubricants, moisturizers, and dilators may be beneficial to those with pain, and clitoral stimulation (eg, vibrators, clitoral suction devices) may be helpful to those with sensory changes.

Management of FOD focuses on treating the underlying cause if possible. Whether or not FOD is associated with a physical or medical reason, psychotherapy, including cognitive behavioral therapy and couples counseling if appropriate, may be helpful. A first-line therapy for treatment of FOD is directed masturbation, a cognitive behavioral and mindfulness-based technique that allows the individual to explore sensations from self-stimulation of the genital area. This can improve sexual attention to stimulation, increasing comfort with the use of vibrators and increasing arousal with erotic materials.[28,31]

Conclusion

Survivors of breast and gynecologic cancers commonly experience sexual dysfunction that may impact some or all areas of the sexual response cycle (eg, desire, arousal, orgasm). Sexual dysfunction can be a result of psychological factors or may be caused by physical changes related to cancer treatment (ie, surgery, radiation, chemotherapy, hormonal therapy). Management begins with treating the underlying cause if possible. Holistic care includes a comprehensive assessment, effective communication techniques, and treatment. Treatment varies based on the type and severity of dysfunction. Women's health care providers can utilize psychotherapy, including cognitive behavioral therapy and mindfulness techniques, as well as devices, pelvic physical therapy, and medications, to improve the sexual health of cancer survivors.

Disclosure

The authors have no actual or potential conflicts of interest in relation to the contents of this article.

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https://doi.org/10.1891/CJNPWH-2421

Depot Medroxyprogesterone Acetate and Adolescents

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Continuing Education Approval

This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH) for 1.0 continuing education contact hour, including 1.0 contact hours of pharmacology content, now through December 31, 2026. NPWH is accredited as a provider of continuing education by the California State Board of Nursing, Provider Number CEP 13411.

Educational Objectives

At the conclusion of this educational activity, participants should be able to

1. Describe current evidence about the safety and effectiveness of depot medroxyprogesterone acetate (DMPA),
2. Discuss barriers and facilitators for adolescents' use of DMPA, and
3. Describe anticipatory guidance about potential side effects to improve continuation rates.

Disclosure

The authors have no actual or potential conflicts of interest in relation to the contents of this article.

Disclaimer

Participating faculty members determine the editorial content of the Continuing Education (CE) activity; this content does not necessarily represent the views of the NPWH. This content has undergone an anonymized peer review process for validation of clinical content. Although every effort has been made to ensure that the information is accurate, clinicians are responsible for evaluating this information in relation to generally accepted standards of care and integrating the information in this activity with that of established recommendations of other authorities, national guidelines, and individual patient characteristics.

Commercial Support

This activity did not receive any commercial support.

Successful Completion of the Activity

Successful completion of this activity, J-24-03, requires participants to do the following:

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2. Read the learning objectives, disclosures, and disclaimers.
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4. Complete the evaluation.
5. Print out the CE certificate after you have completed the evaluation.

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https://doi.org/10.1891/CJNPWH-2401

Depot Medroxyprogesterone Acetate and Adolescents

Depot medroxyprogesterone acetate (DMPA) is an effective method of contraception that may be underutilized due to lack of information or access. This article updates clinicians on current evidence about the safety and potential side effects of DMPA. Logistic and financial barriers to use are identified, along with a discussion of opportunities to address them. Attention to these barriers from the outset along with anticipatory guidance can improve method uptake, patient satisfaction, and method continuation, particularly in the adolescent population.

Keywords: DMPA, adolescent, unintended pregnancy, long-acting contraceptive, user-administered

Depot medroxyprogesterone acetate (DMPA) is an injectable progestin-only contraceptive method that was approved by the U.S. Food and Drug Administration (FDA) in 1992. It was first available as an intramuscular (IM) injection. In 2004, a subcutaneous (SC) formulation was approved by the FDA. In either formulation, it is recommended that DMPA be administered every 13 weeks, with a typical use failure rate of 4%.[1] Unlike some other hormonal contraceptive methods, the efficacy of DMPA is not weight-dependent, and there are very few contraindications to its use.[2]

Despite its safety and efficacy, DMPA may be underprescribed due to actual or perceived barriers. These barriers include misunderstanding or miseducation of both clinicians and potential users regarding the medication's effect on bone mass; scheduling and cost issues; lack of understanding of, or comfort with, the quick start method of initiation; concern about potential side effects of the medication, including those associated with bleeding, weight, and mood; and patient fear of needles.

While each of these barriers is a consideration for individuals of any age, they may be particularly relevant to adolescents. As of 2019, nearly one in five female adolescents who reported having sex with a male partner reported using DMPA as their contraceptive method at some point.[3] Although the rate of adolescent unintended pregnancy has decreased in recent years, the persistence of any unintended pregnancies presents an opportunity for improvement in contraception education and provision.

The purpose of this article is to update clinicians on the current evidence about the safety of DMPA and the barriers to and facilitators of adolescents' use of this contraceptive method. Management of potential side effects and suggestions for sharing anticipatory guidance with patients are discussed. The information provided may be helpful to clinicians as they consider biases they may have in providing contraception counseling for adolescents. The authors acknowledge challenges in shared decision-making around contraception, given the inherent power differentials present with adolescent patients that may include age, race, sex, gender, sexual orientation, gender identity, income, and ability.

Safety

In 2004, the FDA began requiring a "black box warning" on DMPA packaging indicating a risk of loss of bone mineral density secondary to the use of DMPA. This led to clinicians limiting the use of DMPA to no more than 2 years and, in some cases, requiring bone density testing as part of the continuation of the method. However, even then, most research demonstrated that bone density is multifactorial and is recoverable following discontinuation of DMPA, regardless of the duration of use. In a 2014 Committee Opinion, the American College of Obstetricians and Gynecologists affirmed that concerns about bone density should not prevent extended use of DMPA, especially if the patient did not have another preferred method of contraception.[4] The U.S. Medical Eligibility Criteria for Contraceptive Use (USMEC) lists DMPA as a category 2 contraceptive from menarche to 18 years, meaning the method can be used by most individuals and that the advantages generally outweigh the risks.[5] Adolescents can achieve peak bone mass after DMPA use, regardless of the duration of use, and there is no evidence of increased bone density-related fracture risk after extended DMPA use in adolescents.[5]

The USMEC lists only one condition, breast cancer within the past 5 years, as a category 4 exclusion criterion for DMPA. Category 4 indicates an unacceptable health risk if a woman with that condition uses the contraceptive.[5] There are only a few category 3 conditions listed for DMPA. These include severe hypertension, other

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significant atherosclerotic disease risk factors, autoimmune disorders including rheumatic disease and lupus erythematosus, unexplained vaginal bleeding, past breast cancer and no evidence of current disease for 5 years, and severe vascular or liver disease. Category 3 indicates that the theoretical or proven risks usually outweigh the benefits, and the method is not usually recommended unless more appropriate methods are not available or acceptable.[5] Importantly, no specific tests or examinations are indicated before the initiation of DMPA, and dosing and efficacy of DMPA are not weight-dependent. Progestin-only contraceptives do not affect blood pressure or other vital signs; therefore, screening is also not necessary for method initiation or continuation. A physical exam, including a pelvic exam, does not provide any information that could affect the use of DMPA. Finally, while contraceptive visits can be an opportunity to screen for sexually transmitted infections and vaccine utilization, neither of these is clinically relevant to the administration of DMPA.[2]

Scheduling and Cost Considerations

Clinicians are discouraged from requiring multiple visits before initiating contraception, as this leaves the patient at risk of unintended pregnancy while awaiting method initiation. One way to reduce visits is by utilizing the quick start method for same-day method initiation whenever the clinician can be "reasonably certain" the patient is not pregnant. Notably, with this method, a pregnancy test is not required. The person seeking contraceptive care simply needs to meet at least one of the criteria listed in Box 1.[6] If the patient is amenorrheic due to recent use of a different method, they can be advised to use a backup contraceptive if they plan to engage in intercourse with a male partner in the subsequent 7 days.[7]

Box 1. How to be reasonably certain that a woman is not pregnant.[6]

A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- <7 days after the start of normal menses;
- Has not had sexual intercourse since the start of the last normal menses
- Has been correctly and consistently using a reliable method of contraception
- <7 days after spontaneous or induced abortion
- Within 4 weeks postpartum
- Fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [>85%] of feeds are breastfed, amenorrheic, and <6 months postpartum)

Centers for Disease Control and Prevention. How to be reasonably certain that a woman is not pregnant. Last reviewed March 27, 2023. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/notpregnant.html.

For follow-up visits, the manufacturer of DMPA recommends repeat administration at 13-week intervals, which leads some clinicians to require another negative pregnancy test or waiting period before repeat administration if it has been more than 13 weeks since the previous injection. The U.S. Selected Practice Recommendations for Contraceptive Use (USSPR) states that there can be as many as 15 weeks between injections without concern for ovulation. If a patient is more than 15 weeks from their most recent injection, the clinician can use the quick start method again.[2] The Centers for Disease Control and Prevention (CDC) states that even when the clinician cannot be certain a user is not pregnant, the benefits of starting DMPA will likely outweigh any potential risk. It is reasonable, in this circumstance, for the patient to start DMPA and plan to take a pregnancy test in 2–4 weeks.[7] Use of a reminder system, such as the Bedsider.org reminder application (https://www.bedsider.org/reminders_app), may help adolescents remember to schedule for their next injection.

Patients with private insurance are often required to visit a clinician for a prescription for DMPA, then visit a pharmacy and utilize their pharmacy benefits to retrieve the medication, and subsequently make another visit to the clinician's office for administration of the drug. The visit to the pharmacy and the subsequent visit to the clinician's office recur with each repeat administration. This return visit burden may be unavoidable for privately insured patients in many settings.

For some individuals, cost can be a barrier to the utilization of DMPA. Facilities with Title X funding can source and provide DMPA at a lower cost. Therefore, reproductive health care providers in these facilities may be more apt to prescribe DMPA to adolescents.[8,9] In many subsidized settings, patients can pay at the time of each injection (every 12–15 weeks) and can often utilize a sliding scale fee schedule if a government-sponsored health plan does not cover them.

Bleeding Changes

Extended bleeding or spotting is common with initiation of DMPA. Over time, this bleeding typically tapers, and many users will experience sporadic light to moderate bleeding, while others will become amenorrheic. Clinicians can counsel patients that a change in bleeding is an expected side effect of the medication and not indicative of a health problem. Furthermore, patients should be informed that once the method is discontinued, they will eventually return to their baseline menstrual pattern and fertility. Irregular or unexpected bleeding may cause embarrassment to adolescents or limit their ability to participate in activities, as well as impact their sexual relationships. Some research indicates that appropriate anticipatory guidance about side effects can improve continuation rates.[10]

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In addition to education, clinicians may consider medications used short term to mitigate bleeding.[1] Mitigating unwanted bleeding with DMPA initiation can improve the method continuation rate. Empirically, some clinicians have utilized estrogen, including combined oral contraceptives, to relieve some of the bleeding experienced with the initial use of DMPA. Studies have examined the efficacy of nonsteroidal anti-inflammatory drugs in treating abnormal bleeding with mixed results. Doxycycline, tranexamic acid, mifepristone, and tamoxifen have also shown some efficacy in decreasing unwanted bleeding, but their use may be limited due to issues with access and cost. There is insufficient evidence to demonstrate that routine use of any of these approaches has an overall benefit, but again for the individual patient, a treatment that mitigates bothersome bleeding may result in method continuation and overall increased acceptance of the method.[12]

Weight Changes

One study found that weight gain with DMPA was more common based on younger age at initiation, making it difficult to differentiate from the expected changes in weight during young adolescence due to growth.[13] Another study found weight changes occurred in users of DMPA, the levonorgestrel (LNG) implant, and inexplicably the copper intrauterine device (IUD). Not all users of these methods gained weight and some experienced weight loss. The study did not demonstrate the effect of age on weight gain or loss, nor were there any data about weight changes more than 18 months or after discontinuation of the method.[14] There is insufficient evidence to confirm an association between DMPA and weight gain. However, weight gain is a frequently cited reason patients discontinue this method. Because of this, clinicians should counsel about the possibility of weight gain and may choose to monitor weight at subsequent visits if this is desired by the patient.

Mood Changes

Current literature does not provide evidence of mood changes with progestin-only contraceptives. However, the USMEC notes that this evidence is based on a comparison of the frequency of hospitalization in patients with bipolar disorder or depression, which does not account for day-to-day mood lability or the most common depressive and anxiety symptoms.[11] One study found the lowest incidence of depression in DMPA users relative to users of a progestin-containing IUD or LNG implant at 1 year following initiation, while a systematic review found no evidence of an increase in depressive symptoms in adolescents using DMPA relative to the general population and no reason to withhold this method of contraception due to concerns about depressive symptoms.[15,16] There is insufficient evidence on the use of progestin-only contraceptive methods in patients of any age with preexisting depression. The World Health Organization does not support the withholding of any contraceptive method due to preexisting depressive symptoms.[11] As with any potential side effect, decision-making should include the patient's wishes and values and consider their fears about worsening of any condition.

Fear of Needles

Adolescents, in particular, may have anxiety about receiving injections due to fear of needles. Many adolescents have nose, naval, and ear piercings. Anecdotally, one of the authors has found that comparing the experience of a piercing with the DMPA injection can eliminate some of this fear because DMPA administration is a fast injection that does not require the healing time of a piercing. Further, the SC DMPA injection may be more acceptable to some adolescents due to the smaller needle and the ability to self-administer.

Parental Involvement and Privacy

DMPA use may necessitate parental involvement in more ways than other methods, given that this method often requires the use of insurance to purchase the medication and transportation to the pharmacy and clinician's office. However, some adolescents can obtain DMPA independently through Title X or other public health or sliding scale clinics and may utilize public transportation to obtain the necessary care. For some adolescents, DMPA can be more discreet than a more user-dependent method such as the pill, patch, or ring because the patient does not carry or store any contraceptive supplies at home.

Subcutaneous DMPA

SC DMPA contains 104 mg of medroxyprogesterone acetate, a lower dose than the IM formulation, with the same efficacy and recommended injection frequency timing every 13 weeks. It is dispensed in prefilled syringes that can be stored at room temperature. In 2021, the CDC updated the recommendations in the USSPR to support the self-administration of SC DMPA as an alternative to provider-administered DMPA.[17] The CDC acknowledged that the FDA labeling requires administration by a health care professional and indicated that self-administration could be an off-label use of the drug.[17] Coverage and reimbursement for SC DMPA remain a barrier to its full utilization in practice. Coverage can vary from state to state and between public and private insurers. Some insurers do not cover SC DMPA through pharmaceutical benefits, which forces patients to access this medication through provider administration during an office visit. Greater awareness of and access to SC DMPA could be an essential component of improving adolescent contraceptive uptake. For this to occur, cost and accessibility need to be addressed.

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Box 2. Resources related to SC DMPA.

- This Is How I Teach: Self-Injection DMPA-SC
  Bixby Center for Global Reproductive Health
  https://www.innovating-education.org/2020/06/this-is-how-i-teach-self-injection-dmpa-sc/
- A Toolkit for User Administration of Subcutaneous Depot Medroxyprogesterone Acetate
  National Clinical Training Center for Family Planning
  https://www.ctcsrh.org/wp-content/uploads/User_Administration_DMPA-SC_Toolkit.pdf
- Injectables
  U.S. Selected Practice Recommendations for Contraceptive Use
  https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/injectables.html

Abbreviations: DMPA, depot medroxyprogesterone acetate; SC, subcutaneous.

However, excellent tools are already available for clinicians and patients who can access SC DMPA (Box 2).

Conclusion

DMPA remains an important contraceptive option for adolescents. Many common concerns that patients, parents, and clinicians express can be mitigated with education and anticipatory guidance. Clinicians are advised to develop trusting relationships with adolescents and their parents when appropriate and to use counseling and education strategies that center the patient's values while providing accurate information about methods that meet their stated contraceptive goals. Details on minimizing side effects can also increase method continuation.[10] Furthermore, increasing access to SC DMPA may improve overall contraceptive uptake among adolescents.

Disclosure

The authors have no actual or potential conflicts of interest in relation to the contents of this article.

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https://doi.org/10.1891/CJNPWH-2401

Trauma-Informed Perinatal Care

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A history of childhood maltreatment, previous traumatic birth or loss, prior medical or sexual trauma, and discriminatory or inequitable care are all believed to have the most significant impact on the perinatal period. Specific obstetric complications associated with trauma exposure include low birth weight, preterm birth, substance use during pregnancy, placental abruption, fetal death, perinatal depression, and anxiety. A trauma-informed approach to perinatal care promotes resilience among trauma survivors and minimizes the risk of retraumatization.

Keywords: trauma, trauma-informed care, perinatal care, PTSD, reproductive trauma, maternal health care

There is no one definition of trauma, but a helpful framework provides the following concept:

> Individual trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual wellbeing.[1]

Reproductive trauma is described as any trauma that occurs with a reproductive event (Table 1). The most prevalent forms of reproductive trauma include infertility, miscarriage, stillbirth, fetal distress during birth, fetal distress during pregnancy, and premature birth.[2] Infertility is not always associated with a physical death but rather the death of a dream or desire for parenthood. Women who experience first-trimester pregnancy loss or fail to achieve conception despite numerous and extensive therapies can experience grief and depression, feelings of isolation, and shame. An estimated 20%–30% of women will have a birth that they will describe as psychologically traumatic.[3] Reasons include labor complications, a birth experience that does not meet prior expectations, a lack of control, disaffirmation by the health care team, or not feeling supported. Adverse outcomes associated with traumatic birth experiences include low self-esteem, difficulty breastfeeding, postnatal depression, and impaired maternal–infant bonding, and up to one in four women with a traumatic birth experience will develop posttraumatic stress disorder (PTSD).[2,4–6]

Table 1. Forms of Reproductive Trauma[2,7]

• Infertility
• Miscarriage
• Stillbirth
• Fetal distress during pregnancy
• Premature birth
• Emergency intervention: cesarean delivery/assisted vaginal delivery
• Any shocking or unexpected experiences during birth
• Having procedures performed without informed consent
• Feeling out of control or forced to make decisions about care

The very nature of obstetric care can be retraumatizing, and traumatic events/experiences may be related to reproduction. Adoption of a trauma-informed care approach in perinatal care settings promotes resilience and minimizes the risk of retraumatization. This article explores the significance of trauma for the perinatal population, presents a three-tier continuum of care system for trauma-informed care in perinatal settings, and describes trauma-informed practices specific to perinatal care settings.

Trauma Overview

The three "Es" of trauma are event(s), experience of event(s), and the effect of the experience.[1] A multitude of factors determine how the event is experienced, including cultural beliefs, availability of social support, and the individual's age. The adverse effects of the event may manifest immediately or at a later time. The individual may or may not recognize the link between the event and the effect. Following a traumatic event, the ability of

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https://doi.org/10.1891/CJNPWH-2405

an individual to cope with everyday stresses, engage in meaningful relationships, regulate behavior, and express emotion may be negatively impacted. The adverse effects may range from hypervigilance to numbing and avoidance.

Experiencing traumatic events may negatively affect long-term physical and mental health outcomes. Unhealthy coping mechanisms may include eating disorders, substance use, or self-harm. Trauma survivors have an increased incidence of mental health conditions, including anxiety, depression, PTSD, and suicide attempts.[7,8] A history of trauma may impact the survivor's attitude toward medical care. Trauma creates feelings of powerlessness, fear, and hopelessness, as well as shame, guilt, rage, isolation, and disconnection.[1] Survivors have low rates of preventive care utilization and high rates of emergency care utilization. Anxiety about medical examinations and procedures is common among individuals who have experienced trauma. A history of trauma is associated with chronic diseases, including hypertension, obesity, cardiovascular disease, elevated triglycerides, and autoimmune disease. Specific to women's health, trauma exposure is associated with chronic pelvic pain, sexually transmitted infections, unintended pregnancy, conflicted feelings about pregnancy and sexuality, and difficulty with infant attachment postpartum.[7]

Significance of Trauma to Perinatal Population

The experience of pregnancy and prenatal care, labor and birth, breastfeeding, and care of the infant for women with a history of trauma may be empowering, feel challenging, or trigger reminders of past trauma.[9] Obstetric complications associated with trauma exposure include low birth weight, preterm birth, substance use during pregnancy, placental abruption, fetal death, perinatal depression, and anxiety.[10,11] A history of childhood maltreatment, previous traumatic birth or loss, prior medical or sexual trauma, and discriminatory or inequitable care are all believed to have the most significant impact on the perinatal period.[12]

Adverse childhood experiences (ACEs) are a compilation of traumatic experiences that include physical abuse, sexual abuse, family dysfunction, parental physical or substance abuse, and parental death or incarceration that are experienced in childhood.[13] Having experienced four or more ACEs is correlated with the presence of alcohol and drug abuse, depression, and suicide attempts.[13] Women who experience one or more categories of ACE are more likely to participate in high-risk sexual behaviors that can result in unintended pregnancies and sexually transmitted infections. This behavior may be present due to low self-esteem, impaired perception of sexual behavior, and feelings of self-worthlessness, which are common traits found in adult survivors of ACE.[14] Depression and PTSD are common comorbidities in survivors of ACEs. Manifestation of PTSD symptoms during the perinatal period is associated with adverse outcomes, including ectopic pregnancy, preterm birth, and fetal death, believed to be due to alterations in the neuroendocrine system among individuals with PTSD.[15] Women with PTSD are at risk of increased alcohol and drug use in pregnancy. Pregnancy is a time of emotional, physical, and biological change, and increased substance use may be an effort to cope with these changes.[16] Women with a history of ACE may delay prenatal care secondary to the presence of drug or alcohol abuse or fear of the intimate physical exams required.

The cumulative effect of long-term exposure to the traumas of racism, political marginalization, housing and food insecurity, lack of health care access, and ecological stressors (fire, flood) contributes to early and ongoing health deterioration, including adverse pregnancy and birth outcomes.[9] Racism, sexism, and other forms of oppression contribute to economic marginalization, a risk factor for perinatal depression.[17] Rates of PTSD are higher in perinatal care settings serving a predominately Black population and a population with limited resources as compared with settings serving a predominately White population and a population with greater resources.[12] For marginalized populations, interactions with the health care system may be discriminatory. Negative interactions with the health care system, including coercion to accept certain interventions and disrespectful treatment by health care professionals, are part of the lived experience and often result in a general mistrust of the health care system.[6]

Principles of Trauma-Informed Care

The Substance Abuse and Mental Health Services Administration's (SAMHSA) trauma-informed approach to care includes four key assumptions and six key principles.[1] According to the SAMHSA, optimization of outcomes for trauma survivors and avoidance of retraumatization are dependent on a trauma-informed approach to care by a program, organization, or system. The four assumptions include realizing the impact of trauma and paths to recovery, recognizing the signs and symptoms of trauma, responding with a trauma-informed care approach, and resisting retraumatization. A trauma-informed care approach shifts the questions from "What is wrong with you?" to "What happened to you?" The six key principles of a trauma-informed approach include physical and psychological safety; trustworthiness and transparency; peer support; collaboration and mutuality; empowerment, voice, and choice; and recognition and response to cultural, historical, and gender issues.

A trauma-informed approach to care is recommended for all providers of health care. A three-tier continuum of care system for trauma-informed care in perinatal settings incorporates the SAMHSA's framework and guiding principles.[12]

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The continuum includes universal trauma-informed care offered to all patients, trauma-specific interventions that are targeted practices and programs, and trauma-focused treatment provided by specialists. The prevalence of traumatic experiences requires all staff to adopt a universal trauma-informed care approach to include screening for a history of trauma. The second tier of the continuum directs clinicians and paraprofessionals to identify perinatal triggers, adopt trauma-specific practices, create trauma-specific birth plans, and develop trauma-specific programs at the practice, hospital, or community level for those who self-identify as trauma survivors. Examples of programs include offering doulas who have trauma training and psychoeducation about PTSD during childbearing and early parenting.[12] The first and second tiers of the continuum are within the scope of care of perinatal care providers. The third tier, specialist treatment, requires referral for psychotherapy and/or medication.

Trauma-Informed Practices Specific to Perinatal Care Settings

A universal trauma-informed care approach recognizes the prevalence of trauma, understands the role these lived experiences may play in a patient's life, recognizes the signs and symptoms of traumatic stress, and accepts and supports survivors of trauma to improve patient participation, treatment adherence, and health.[18] The application of the SAMHSA's six key principles begins during pre-pregnancy care or the first prenatal visit (Table 2). When obtaining the history, listen attentively and respectfully to create a psychologically safe environment.[6,9] Emphasize physical, psychological, and emotional safety to create an environment where the survivor can rebuild a sense of control and empowerment.[7,18] To ensure safety, screen for current trauma or intimate partner violence and screen for adversity, past trauma, strengths, and resilience.[7,9] Convey

Table 2. SAMHSA's Six Core Principles of Trauma-Informed Care[1]

	TRAUMA-SPECIFIC PRACTICES IN PERINATAL CARE SETTINGS
Safety	• Provider listens attentively and respectfully • Patient screened for current trauma or IPV • Patient's seat faces door to exam room • Patient remains fully clothed for interviews • Option for chaperone/support person during the exam offered
Trustworthiness and transparency	• Provider sits at eye level for interviews • Provider invites introductions • Repetitive questioning/screenings by multiple providers avoided • Patient disclosures kept confidential/safe • Providers and staff communicate effectively • Patient oriented to obstetric care model • Every step of exams/procedures explained • Time reserved for patient questions • Thorough explanations provided
Peer support	• Current social support network promoted • Options explored for: ◦ Peer support group ◦ Doula
Collaboration and mutuality	• Necessity of care described • Information shared • Options offered (obstetric care model, route of birth, infant feeding method) • Prenatal plan, birth plan, and postpartum plan developed
Empowerment, voice, and choice	• Patient allowed to tell their story without judgment or interpretation • Patient agency and strength (resiliency) acknowledged • Provider asks for permission to begin exam/continue exam • Alternatives to exam offered (self-swabs) • Modifications to exam offered (alternative positioning, patient insertion of speculum)
Cultural, historical, and gender identity	• Patient pronouns determined • Professional interpreter provided when necessary • Patient goals for each visit determined • Culturally specific childbirth traditions recognized

Abbreviations: IPV, intimate partner violence; SAMHSA, Substance Abuse and Mental Health Services Administration.

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the universality of screening through framing statements: "Trauma is prevalent and may impact physical and mental health, so we screen all our patients for a history of trauma." Develop policies and practices to keep disclosures safe and avoid repetitive questioning/screenings by multiple staff and providers.[6] Current models of care with multiple providers contribute to difficulty building trust. Orient patients to the model of care, adopt an organization-wide trauma-informed care approach, and facilitate good communication among staff and providers.

Screening for adversity, past trauma, strengths, and resilience may take place during a visit when trust has been established, not during the initial prepregnancy visit or first prenatal visit.[9] There is no one established format for screening: use open-ended questions, structured survey measures, or both. With awareness that not all survivors will disclose a personal history of trauma, observe and respond to signs and symptoms of distress from a triggering event. Signs and symptoms of distress include body tension, restlessness, poor eye contact, aggressive behavior, easily startled, sudden sweating, feeling disconnected or numb, difficulty trusting, difficulty concentrating, irritability, and rapid breathing.[4,7] Recognize that high-risk behaviors may be an attempt to self-regulate and cope with posttraumatic stress symptoms.[6]

The trauma-informed continuum of care includes targeted practices to avoid common triggers and retraumatization. Trauma-informed practices are a clinician's therapeutic response to an individual's identified or expressed need.[12] During encounters, invite introductions, maintain eye contact, sit at eye level, allow time for questions, and provide thorough explanations.[6,7] Allow patients to remain fully clothed for interviews, sit where they feel most comfortable, and provide the option to sit facing the exam room door.[10] Determine the need for a professional interpreter, elicit their pronouns and personal goals for the visit, and explore culturally specific childbirth traditions.[19] If the individual chooses to share their story, a previous traumatic birth experience, sexual assault, or an adverse childhood event, listen and respond without judgment or interpretation.

Among individuals who have experienced trauma, common triggers are not being in control, not being respected, unwelcome touch or body positioning, feelings of fear or dread, and situations in which they are vulnerable.[12] Use a trauma-informed approach during physical exams to avoid triggering and retraumatization. When possible, offer alternatives to an exam, such as self-swabs. Shift the power dynamic, allow patients to choose if they want an exam, and before the exam ask if there are parts of the exam that may trigger anxiety.[6,7,19] Offer a chaperone or support person and allow the patient to wear as much personal clothing as possible. Give permission to openly express discomfort. Ask permission and continue to ask permission throughout the exam. Offer modifications during the exam to include patient placement of the speculum and alternate positioning. Explain each step of the exam and any procedures.[10] Recognize signs and symptoms of distress and agree to halt the exam if necessary.[7] If the patient appears to dissociate and seems frozen and unresponsive to communication, stop the exam, allow the patient to get dressed, and consider moving the patient to an alternate location. A physical change in location may help the patient reengage with staff and providers.

A trauma-informed care approach incorporates individual choice in decision-making and planning for ongoing care. Describe the necessity of care; share information; offer options; and consider the patient's goals, preferences, knowledge, and skills.[4] A trauma-informed prenatal care approach promotes individual choice, autonomy, and a sense of control through prenatal plans, birth plans, and postpartum plans.[4,6,7] Ensure decisions are patient-centered, including choices about obstetric care model (midwifery or physician model), location of intrapartum care (birth center or hospital), route of birth, and infant feeding method.[19] Prepare ahead of time for labor-specific triggers or stressors such as bright lights and vaginal exams and suggest modifications. Identify and promote the patient's current social support network and explore other options, such as a peer support group or doula care. Recognize high-risk behaviors and increasing levels of stress and refer for specialist care with a mental health provider.

A trauma-informed approach to the postpartum visit requires the provider to review the birth record and discharge summary before the patient encounter.[6] During the initial postpartum encounter, elicit and acknowledge the woman's perception of the birth experience so that it is considered in postpartum care planning. Begin the visit by determining patient priorities and consider using a postpartum previsit checklist, such as the tool developed by the Fourth Trimester Project (https://newmomhealth.com). The tool focuses on patients' priorities for the visit and prompts discussion of what is going well. Start the conversation with more neutral topics like physical recovery. Then, approach more emotionally charged discussions such as infant feeding, emotional adjustment to parenting, and partner/family support at home. The availability of a member of the intrapartum team to discuss traumatic birth experiences and answer questions may be protective against PTSD exacerbation related to birthing and facilitate healing.[6,9] Support resilience by suggesting the patient write a narrative about their birth experience and acknowledging the patient's agency and strength exhibited through the birth process.

Conclusion

A universal trauma-informed care approach recognizes the prevalence of trauma, understands the role these lived experiences may play in a patient's life, recognizes the signs and symptoms of traumatic stress, and accepts and

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supports survivors of trauma with the goal of improving patient participation, treatment adherence, and health. The three-tier continuum of care system in perinatal settings includes universal trauma-informed care offered to all patients, trauma-specific interventions that are targeted practices and programs, and trauma-focused treatment provided by specialists. The prevalence and potential negative impact of trauma on long-term physical and mental health outcomes, as well as perinatal outcomes, require perinatal settings to adopt a universal trauma-informed approach to care. The SAMHSA's six key principles guide the identification of trauma-specific interventions/practices in perinatal care settings. Trauma-informed perinatal care providers recognize a history of trauma and offer referrals for specialist care. A trauma-informed approach to perinatal care promotes resilience and minimizes the risk of retraumatization.

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The authors received no specific grant or financial support for the research, authorship, and/or publication of this article.

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https://doi.org/10.1891/CJNPWH-2405

Improving Preexposure Prophylaxis Accessibility for Women: Role of Nurse Practitioners

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Women in the United States receive the fewest prescriptions for HIV preexposure prophylaxis (PrEP) despite their disproportionate rate of new HIV infections. Unclear and conflicting guidelines have partially contributed to the underutilization of HIV PrEP in women. Nurse practitioners who provide women and gender-related health care have a vital role in increasing women's accessibility to PrEP and in helping meet the U.S. Department of Health and Human Services' goal of ending new HIV infections in the United States by 2030. This article reviews the current recommendations and guidelines for prescribing PrEP. Inequalities in PrEP prescribing and use are described, including unique barriers, needs, and implications for women.

Keywords: human immunodeficiency virus, HIV, preexposure prophylaxis, PrEP, nurse practitioners, infections, syndrome

Preexposure prophylaxis (PrEP) is a preventive approach where HIV-negative persons take oral or injectable antiviral medications to reduce the risk of acquiring the virus.[1] PrEP use, when taken as prescribed, can reduce the risk of HIV infection among men who have sex with men (MSM) and transgender women by up to 99%.[1,2] The efficacy rate is lower for cisgender women and intravenous (IV) drug users at 77% and 74%, respectively.[3] The first oral HIV PrEP medication approved by the U.S. Food and Drug Administration (FDA) in 2012 was emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg.[1] Two additional drugs were later approved for prophylaxis: emtricitabine 200 mg/tenofovir alafenamide 25 mg for men and transgender women in 2019; and cabotegravir 200 mg, a bimonthly injectable formulation for all PrEP candidates, in 2021.[1,4] The introduction of an injectable PrEP formulation addresses concerns about the oral formulary's risk for renal toxicity, reduces the need for laboratory assessments, and eases the burden of remembering to take daily medications in the absence of an HIV diagnosis.[1,5]

Unclear and conflicting guidelines have partially contributed to the underutilization of HIV PrEP. This confusion has impeded progress toward the goal of the U.S. Department of Health and Human Services of ending new HIV infections by 2030.[6–8] As primary care providers (PCPs), nurse practitioners (NPs) can lead efforts to end new HIV infections by integrating PrEP with education about condom use and safer sex practices.[9,10] PrEP is especially important to women, who often find it hard to negotiate safe sex due to socioeconomic power imbalances in sexual partnerships.[3,11] PrEP gives them the autonomy to choose safer sex without negotiating with a partner.[11,12] The purpose of this article is to review the current recommendations and guidelines for prescribing PrEP and to focus on the role of NPs, who are uniquely positioned to provide women and gender-related health care, and therefore increase the accessibility of PrEP.

History of PrEP Eligibility

The FDA approved the first oral PrEP formulary in 2012 based on two randomized clinical trials: one in MSM and the other in heterosexual serodiscordant couples (a relationship where one partner is HIV-negative [seronegative] and the other is HIV-positive [seropositive]).[1] Greater efficacy was shown among the former, but the heterosexual arm of the study was not completed due to high attrition

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https://doi.org/10.1891/CJNPWH-2403

rates and low adherence.[12] PrEP eligibility guidelines were released by the Centers for Disease Control and Prevention (CDC) in 2014 and tailored toward individuals with perceived high-risk behaviors, such as individuals with IV drug use, individuals with multiple sex partners, and MSM.[3,11,13] The 2014 CDC guidelines had stricter eligibility criteria for women.[3] To be eligible for PrEP at that time, women were expected to know their partners' sexual risks, including the presence of a sexually transmitted infection or treatment, within the last 6 months.[14,15]

Current PrEP Prescribing Guidelines and Recommendations

Between 2015 and 2021, 1.1 million adults across three transmission risk groups (individuals with IV drug use, individuals with multiple sex partners, and MSM) were reported to qualify for PrEP use.[1] PrEP was not approved for adolescent use until 2018 and may be underreported in this number.[4]

In 2021, the PrEP eligibility guidelines were updated. Both the U.S. Preventive Services Task Force and the CDC make clear that all sexually active adults and adolescents are now eligible for PrEP regardless of their ability or willingness to explain HIV risk awareness.[1] These guidelines address major hindrances to PrEP adoption for prescribers and users. For example, instead of emphasizing eligibility based on high-risk behaviors, PrEP eligibility is based on being a sexually active adult or adolescent of at least 13 years of age and weighing at least 35 kg.[1] Offering PrEP to all sexually active individuals regardless of knowledge of personal or partner risk reduces stigmatization and makes it easier for providers to offer PrEP (Figure).[1]

Inequalities in PrEP Prescribing and Use

There have been consistent yearly increases in PrEP utilization since it was first approved, with a 20% increase from 2021 to 2022.[16] Yet data from the interactive online HIV mapping tool AIDSVu[a] illustrate that significant inequalities exist in the prescribing and use of PrEP.

In 2022, 14% of Black people used PrEP while accounting for 40% of new HIV diagnoses. Hispanic/Latinx people had the lowest rate of PrEP use among all races and ethnicities despite accounting for 27% of new HIV diagnoses. While 69% of PrEP recipients were MSM in 2022, Black and Latino MSM received the fewest of these PrEP prescriptions.[16]

Although an estimated 170,000 women are at risk of HIV infection and 18% of new HIV diagnoses are in women, only 8% of PrEP users in 2022 were women.[13] These data, combined with data that show Black women are diagnosed with HIV 16.6 times that of White women, point to an even greater unmet need among Black women.[8,13]

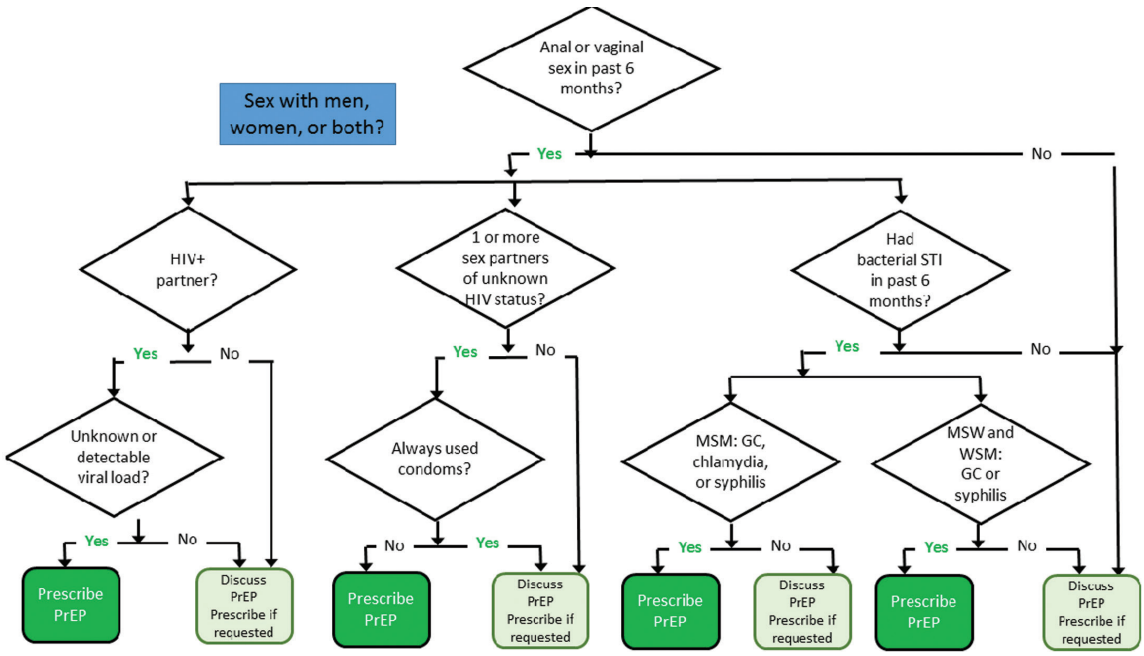

Figure. Assessing indications for PrEP in sexually active persons.

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Abbreviations: GC, gonorrhea; MSM, men who have sex with men; MSW, men who have sex with women; PrEP, preexposure prophylaxis; STI, sexually transmitted infection; WSM, women who have sex with men.

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Of HIV diagnoses, 20% are made in adolescents and young adults (aged 13–24 years).[13] They have the greatest unmet need for PrEP among all age groups.[16,17] Of note, the highest numbers of HIV diagnosis are for those aged 20-24 years. The number of adolescents who have been prescribed PrEP has increased significantly to 76.2% between 2018 and 2021 since its approval for this age group, with a notable 29% of these prescriptions stemming from pediatricians.[18]

Table shows the recent data on the number of new HIV infections and the number of PrEP prescriptions provided as a PrEP-to-need ratio (PNR) by sex assigned at birth, race and ethnicity, and age. PNR serves as a measurement of whether PrEP use appropriately reflects the need for HIV prevention, with lower PNRs indicating higher unmet needs. Female individuals, Black individuals, and those aged 13-24 years have the highest unmet need for PrEP.[16]

According to the CDC, in 2021, 30% of the newly estimated 1.2 million people who could benefit from PrEP were prescribed PrEP versus 13% in 2017. Increased PrEP use, more accessible HIV testing, and improved treatments have contributed to an overall 12% decline in new infections, from 36,500 in 2017 to 32,100 in 2021.[1] However, PrEP prescribing and uptake remain suboptimal.

Table. PrEP-to-Need Ratio (PNR)[16]

	PNR
Sex	
Male	13.63
Female	5.09
Race/ethnicity	
Black	4.08
Hispanic/Latinx	7.25
White	30.97
Age (years)	
13–24	8.09
25–34	13.04
35–44	14.15
45–54	11.81
55+	12.05

PNR is the ratio of the number of PrEP users in 2022 to the number of people newly diagnosed with HIV in 2021. PNR serves as a measurement of whether PrEP use appropriately reflects the need for HIV prevention. A lower PNR indicates more unmet needs. The overall PNR is 12.06.

Abbreviation: PrEP, preexposure prophylaxis.

Currently, health care providers report low HIV risk perceptions for their patients even in the context of greater actual risk.[19] They often do not give enough information or do not present PrEP as an effective option to prevent HIV.[19] They may believe that prescribing PrEP outside the traditional risk behaviors of IV drug use, multiple sex partners, and MSM is unnecessary unless a partner has an HIV diagnosis.

Efforts must go further and faster to reach all populations equitably and to achieve the national goal of 50% of eligible people using PrEP by 2025.[2,21] All health care providers regardless of specialty or setting can introduce PrEP to patients and follow current guidelines for prescribing and follow-up.

PrEP Prescribing Practices in Primary Care

The "purview paradox" is a phenomenon in which PCPs historically believed that prescribing PrEP is the responsibility of HIV experts.[22,23] HIV experts do not generally see HIV-negative individuals for whom PrEP would be appropriately recommended unless they are in a serodiscordant relationship.[22,23] A gradual shift is occurring, and PCPs, who see the greatest number of patients, including nonsick visits, are beginning to offer PrEP.[23] A group effort among providers across a variety of specialties and settings is needed to increase PrEP prescribing.

PCPs come from different disciplines, educational backgrounds, and practice environments. Compared with physicians, NPs report less knowledge of PrEP at baseline; however, they are more likely to prescribe PrEP once they acquire this knowledge.[24,25] Previous studies of PrEP knowledge, beliefs, attitudes, perceptions, and practices have failed to explore differences between physicians and NPs and have not differentiated the roles of NPs from physician assistant roles.[6] Current primary care trends, which include dwindling numbers of physicians and an increase in NPs, suggest that a closer look at PrEP perspectives and practice habits is warranted.[26] Experts have recommended PrEP provider-related research with providers who are not physicians to advance knowledge of HIV care and prevention.[6] To date, only one published report has explored the beliefs, attitudes, perceptions, and related PrEP prescription practices for women among NPs.[24]

PrEP use gives women the autonomy to protect themselves from HIV infection, which they may lack with partner-centered preventive methods due to power imbalances in society and intimate relationships.[15] PrEP adherence has successfully protected more than 90% of women in serodiscordant relationships before and during pregnancy.[3,8] Despite its clinical success, some providers are reluctant to prescribe PrEP to women, partly due to a lack of efficacy studies and high attrition rates during clinical trials. Heterosexual women comprise 18% of all new HIV infections, yet MSM continue to be the target population of most HIV-related studies concerning PrEP

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Box. Highlights of the components included in the CDC's PrEP 2021 clinical practice guideline.[1]

- Identifying indications for PrEP
- Initial PrEP prescription visit for all patients
- HIV testing and STI screening prior to starting PrEP
- Laboratory tests for patients being considered for oral PrEP (e.g., renal function, screening for hepatitis B infection, lipid profile)
- Prescribing oral PrEP
- Drug interactions with oral PrEP
- Follow-up care for patients on oral PrEP (eg, managing side effects, laboratory testing schedule, medication adherence drug monitoring, and discontinuing oral PrEP or restarting)
- Prescribing cabotegravir PrEP injections
- Drug interactions with PrEP injections
- Follow-up care for patients on cabotegravir PrEP injections (e.g., injection schedule, HIV and STI screening schedule, and discontinuing PrEP injections or restarting)
- Women who become pregnant or who breastfeed while taking PrEP
- Considerations for transgender persons taking PrEP

Abbreviations: CDC, Centers for Disease Control and Prevention; PrEP, preexposure prophylaxis; STI, sexually transmitted infection.

use.[3,11] The adoption of PrEP prescribing by NPs has been problematic in clinical practice, especially for women.[9,10] Providers such as NPs may hesitate to prescribe PrEP to women due to perceptions that it encourages multiple partners, as well as concerns about toxicity, especially in the absence of efficacy studies in women, and patients' lack of ability to pay for the drug.[12] Resources are available for NPs to increase their knowledge about HIV risk factors, risk assessment, patient counseling, and PrEP prescribing. The Box highlights the components included in the CDC's PrEP 2021 clinical practice guideline.[1] PrEP is a preventive service with medication and related services covered by almost all Affordable Care Act health insurance plans, most private health insurance plans, and Medicaid expansion coverage plans. In some states, the traditional Medicaid program also covers PrEP. Patient assistance programs are available through some drug manufacturers for people who do not have insurance. A few states also have PrEP assistance programs. Links to resources for coverage are accessible at Pre-Exposure Prophylaxis at HIV.gov.[b]

Conclusion

Harnessing their expertise, accessibility, and integrated educational background, NPs can revolutionize HIV prevention efforts, help reach underserved communities, break down barriers to care, and ultimately end new infections. There is a need to advocate for policy changes that recognize and maximize the invaluable contributions of NPs in the fight against HIV to ensure a healthier and more equitable future.

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Web Resources

A. https://aidsvu.org
B. https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

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https://doi.org/10.1891/CJNPWH-2403

Using Pharmacogenetics to Tailor Cardiovascular Treatment in Women

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At the forefront of precision medicine, integrating pharmacogenetics into clinical practice holds promise for increasing treatment efficacy and reducing adverse drug reactions. By understanding the relationship between medications and genetic variability, pharmacogenetics can help tailor cardiovascular treatment in women, avoiding the trial-and-error approach and improving cardiovascular health outcomes. This article provides a review of factors that influence the therapeutic benefit of drugs and the risks for toxic effects. Pharmacogenetics, as one of these factors, is highlighted with examples of its role in the use of three common medications (clopidogrel, warfarin, and HMG-CoA [3-hydroxy-3-methylglutaryl-CoA] reductase inhibitors, commonly known as "statins") for treatment of cardiovascular disease.

Keywords: cardiovascular pharmacogenetics, pharmacogenomics, precision medicine, women's cardiovascular health, nurse practitioners, primary care

Cardiovascular disease (CVD) continues to be the leading cause of death in women globally.[1] At least two out of three women in the United States possess one significant risk factor for coronary disease and 34.6% of deaths in women were from CVD-related causes in 2019.[1,2] CVD refers to a number of complex genetically diverse and environmentally influenced conditions that affect the heart and blood vessels, including atherosclerosis, coronary artery disease (CAD), myocardial infarction (MI), ischemic and hemorrhagic stroke, peripheral vascular disease, rheumatic and congenital heart disease, conduction abnormalities, cardiomyopathies, valvular disorders, and clotting disorders.[2-4] Between 2015 and 2018, 44.4% of adult women had CVD, with the highest prevalence in non-Hispanic Black women at 58.8%.[5] Being one of the most common risk factors for CVD, 40.4% of adult women have elevated total cholesterol levels of 200 mg/dL or greater.[4,5] Rates of hypertension increase dramatically in women after the age of 65, with 80% of women aged 75 or older having hypertension.[3,5] Of the 9.1 million women living with CAD, 3 million have had an MI. In 2019, 57.1% of individuals who died of stroke were women.[5] Early identification, prevention, and intervention are crucial to reduce morbidity and mortality.

Women have faced disparities in the treatment of CVD due to underrepresentation in research and the generalization of results from men to women, resulting in the use of treatment modalities for women that may not be as appropriate or effective as they are when used to treat men.[2,6] For example, women experience higher in-hospital mortality from an MI than men and a higher post-MI 5-year mortality of 47% compared with men at 36%.[5,6] There are differences in cardiac remodeling post-MI among women and men. Cardiac remodeling is defined as the structural, molecular, and interstitial changes that occur as a result of an injury to the heart that manifest clinically as changes in size, shape, and function of the heart.[7] Postmenopausal women are more likely to develop heart failure with a preserved ejection fraction, while men of the same age are more likely to develop heart failure with reduced ejection fraction.[6] Most of our medical therapies are aimed at treating heart failure with reduced ejection fractions, with few options targeted at heart failure with preserved ejection fractions.[6] Awareness of the misrepresentation of women in clinical trials has increased, and understanding of the differences and implications that biological sex has on disease processes and outcomes is improving.[6]

Another growing discipline, pharmacogenetics, holds promise for increasing treatment efficacy and reducing adverse drug reactions by studying the relationship between medications and genetic variability.[8] Pharmacogenetics will help tailor CVD treatment in women by providing personalized medicine: "the right

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drug to the right patient at the right time and dosage.'"[9] The purpose of this article is to provide a review of factors that influence the therapeutic benefit of drugs and risks for toxic effects with a focus on pharmacogenetics, as one of these factors. Examples highlight the role of pharmacogenetics in choosing and monitoring the use of three common medications for treatment of CVD. The implications of pharmacogenetics in all therapeutic areas, including those related specifically to women's health, are expanding as we learn how to use information on genetic variations effectively.

CVD Risk and Recommended Screening

Well-established CVD risk factors include obesity, hypertension, diabetes, smoking, kidney disease, lipid abnormalities, and family history.[1,10] Other risk factors include chronic inflammatory diseases, such as rheumatoid arthritis, lupus, or HIV/acquired immunodeficiency syndrome, and chronically elevated inflammatory markers.[1,2,10] Female-specific CVD risk factors related to pregnancy history and reproductive health have been identified. Pregnancy-related conditions such as gestational diabetes, gestational hypertension or preeclampsia, premature delivery, stillbirth, and giving birth to an infant that is small or large for gestational age have been associated with a higher risk for CVD.[3,11–13] Other female-specific CVD risk factors include early menarche before the age of 10 or 11 and early onset of menopause before the age of 50.[3,11–13] Breastfeeding has been identified as providing protection against CVD.[3] These female-specific factors have been linked to increasing or decreasing cardiovascular risk and are included in the risk calculators for purposes of early detection. Unfortunately, with the addition of pregnancy and reproductive factors, the predictive value of these calculators in determining CVD risk in women has not improved significantly.[1] Women aged 20–75 years should be screened for risk of CVD.[10] The Framingham Heart Study recommends using the American College of Cardiology (ACC)/American Heart Association (AHA) Atherosclerotic Cardiovascular Disease (ASCVD) Risk Estimator[A] to predict 10-year CVD risk.[14] Younger women between 20 and 39 years of age should be screened for traditional risk factors (ie, high blood pressure, high low-density lipoprotein cholesterol, obesity, diabetes, smoking, too much alcohol use, stress/depression, physical inactivity, and unhealthy diet) every 4–6 years.[10] At 40 years of age, routine screening for 10-year CVD risk is recommended; however, risk calculators may overestimate or underestimate risk, may not accurately represent every ethnicity or gender, and may not consider strong familial history or other social demographics.[1,10,15] For example, in the Multi-Ethnic Atherosclerosis Study, 32% of women considered "low-risk" based on the Framingham ASCVD risk assessment were found to have coronary artery calcium.[15] The presence of coronary artery calcium in those low-risk women was determined to be predictive of future CVD and cardiovascular events.[15] Coronary calcium scores are determined by taking a computed tomography scan of the chest and measuring the amount of calcium deposited in the coronary arteries.[16] Coronary artery calcium is the single most predictive risk marker for CVD in asymptomatic people.[16] Thus, it is necessary to consider the specific patient population being screened to determine the most appropriate predictor scale and treatment to use. In patients with borderline or intermediate 10-year ASCVD risk or with uncertainty of evidence, evaluating the coronary artery calcium score or other clinical factors can help further assess risk and guide treatment.[10]

Factors Influencing Response to Medications

There are many factors that affect how people respond to medications, including genetics, sex, age, weight, diet, herbal supplements, environmental factors, gastrointestinal microbiome, drug–drug interactions, kidney function, and liver size and function.[17,18] Women have a higher risk of developing adverse drug reactions than men.[18] This could be for many reasons, including clinical trials without adequate female participants leading to drug safety, efficacy, and dosing protocols based on male-dominated findings.[19] In addition, adverse reactions may be attributed to biological differences in pharmacodynamics and pharmacokinetics (eg, differences in absorption, distribution, metabolism, and excretion), smaller body size and higher body fat, and biological processes involving hormonal changes, including the menstrual cycle, pregnancy, and menopause.[17–19] There are known genetic variations among ethnicities; however, there is a lack of representation of non-Hispanic Black and Hispanic women in pharmacogenetic research, placing these populations at even higher risk for adverse events.[18] Older adults usually have decreased or altered drug metabolism. Commonly known drug–herb and drug–food interactions include grapefruit and statins, vitamin K and warfarin, and St. John's wort and oral contraceptives. For example, grapefruit juice inhibits the enzymes that metabolize statins, increasing plasma statin concentration.[20]

Pharmacogenetics

Pharmacogenetics is an advancing area of pharmacology that studies the impact of genetics on drug responses.[4] A list of defined terms commonly associated with pharmacogenetics is provided in the Table. Pharmacogenetics emerged after a study completed in 1958 attributed notable differences in systemic blood concentrations of the antibiotic isoniazid among European and East Asian patients to genetic variations in the metabolism of the antibiotic.[8]

Its clinical use has increased over the last decade and is applicable to many areas of medicine, including oncology,

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Table. Terminology Associated With Pharmacogenetics[17]

TERM	DEFINITION
Pharmacogenetics	The study of genetic factors and how they influence the pharmacodynamics and pharmacokinetics of a drug
Pharmacodynamics	The effects that drugs have on the body, including how the drug interacts with its biological receptor (eg, binding affinity, agonism, and antagonism) to elicit a biological effect; pharmacodynamics play a role in determining what drug to use to treat a disease or symptom
Pharmacokinetics	The effects that the body has on drugs, including absorption, distribution, and elimination; pharmacokinetics play a role in determining dosage and administration of a drug
Allele	One of two or more forms of a gene found at the same genetic locus
Allele variations	Different forms of a gene that can result in varied phenotypic expression of that gene; for example, the extent to which the CYP2D6 enzyme functions is a result of which CYP2D6 variant alleles a person has in their genotype
Genotype	The genetic makeup of an organism, including what allelic variations for a specific gene the organism has
Phenotype	The expression of an organism's genotype
Phenotype variant	One of two or more possible expressions of a gene
Metabolizer phenotype	Determines the extent to which an enzyme will transform a drug; metabolizer phenotypes include poor metabolizers, intermediate metabolizers, rapid metabolizers, and ultra-rapid metabolizers
Inherited genetic variants	Genes inherited from parent to child that may affect the pharmacologic relationship between a drug and a human; for example, certain inherited variations in the HLA genes gene can predispose a person to drug-induced hypersensitivity reactions, such as Stevens–Johnson syndrome
CYP450 enzymes	Enzyme family responsible for the majority of drug metabolic reactions; enzymes that can metabolize a drug from an inactive to an active form or vice versa; over 50 CYP450 enzyme genes identified; each enzyme gene's name reflects family designation, subfamily, and individual enzyme within subfamily, for example, CYP2C19
Prodrug	Drugs that must be metabolized to become pharmacologically active; developed to improve stability, increase absorption, or prolong duration of drug activity; for example, valacyclovir used in the treatment of herpes genitalis is not effective, but its active metabolite acyclovir is

Abbreviations: CYP450, cytochrome P450; HLA, human leukocyte antigen.

cardiology, neurology, psychiatry, gastroenterology, and infectious diseases.[8] Inherited genetic variations influence the expressions and functions of proteins, which in turn alter an individual's response to drug metabolization.[8] These genetic variants can cause an increase, decrease, or inactive function of the proteins that metabolize, transport, and bind drugs, producing an alternate or unintended response.[8,9] For example, the cytochrome P450 (CYP450) enzymes are responsible for most drug metabolism in the liver. Over 50 CYP450 enzyme genes have been identified. Genetic variants result in ultra-rapid, rapid, normal, intermediate, and poor metabolizers for enzymatic drug metabolism.[4,8] Normal metabolization is the population average. Intermediate and poor metabolizers metabolize drugs poorly, increasing the risk of drug toxicity, while rapid and ultra-rapid metabolizers metabolize drugs rapidly, increasing the risk of insufficient drug efficacy.[8] However, whether the patient experiences increased toxicity or decreased efficacy from a drug ultimately is dependent on whether the drug is activated or deactivated by metabolism.[8]

Most of the population possess at least one clinically significant pharmacogenetic variant.[8] Pharmacogenetic testing helps predict drug responses and can be completed preemptively to help guide and direct drug dosing and selection to optimize therapy and improve outcomes.[4] Preemptive pharmacogenetic testing is a one-time test that can be used throughout the life of the patient to guide prescribing decisions, as opposed to reactive pharmacogenetic testing, which refers to genotyping performed following the use of a drug to explain the response to the drug and which may only include a specific gene–drug association.[8] The pharmacogenetic test can be ordered once by the primary care provider and shared with the

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entire health care team for future reference as it gives information about drugs from all specialties and eliminates the need for additional testing.

Some barriers, misconceptions, and concerns may influence the implementation of pharmacogenetics in clinical practice, including lack of education, knowledge, and understanding of how to interpret results; insurance reimbursement; cost; privacy and confidentiality; and accuracy of results. The Clinical Pharmacogenetics Implementation Consortium (CPIC), the U.S. Food and Drug Administration (FDA), and the AHA/ACC are leading organizations in the field of pharmacogenetics and cardiovascular treatment. The CPIC[B] publishes clinical practice guidelines and recommendations that provide useful information for clinicians who wish to incorporate the use of pharmacogenetic testing into their practice.[8] The CPIC was founded by the National Institutes of Health and PharmGKB (Pharmacogenomics Knowledge Base) and consists of a group of international pharmacogenetic experts who evaluate the current research and publish detailed practice guidelines and recommendations for gene–drug interactions based on the strength of evidence.[8] Gene–drug associations classified as levels A and B have the strongest level of evidence to support clinical action and should guide the choice of therapy, while levels C and D signify a weak level of evidence that should not direct clinical action.[8] The pharmacogenetic information released by the FDA and the AHA/ACC does not endure the same austerity in the evaluation process as CPIC guidelines and can be incongruent or outdated at times.[8] However, they do serve as a valuable secondary resource and hold a necessary role in the progress of pharmacogenetics. The AHA and ACC are leaders in establishing and presenting up-to-date recommendations to guide cardiovascular treatment, while the FDA regulates drug labeling and direct-to-consumer testing to ensure quality and safety. The FDA drug labels include pertinent pharmacogenomic information, with some drugs having boxed warnings for clinically significant genetic variations and drug efficacy.[8] As insurance reimbursement for pharmacogenetic testing increases, out-of-pocket costs are declining, so more individuals may seek specific FDA-approved direct-to-consumer pharmacogenetic testing. Thus, providers should be able to provide counseling on genetics or have resources for patients on where they can access genetic counseling because patients will need assistance in understanding and interpreting their results. Cost will vary depending on insurance coverage; Medicare will often completely cover the cost of testing for medications demonstrated to have clinically actionable pharmacogenetics. The Genetic Information Nondiscrimination Act (GINA) prevents most health insurance and employment discrimination based on test results. However, GINA protections do not extend to certain life, long-term care, or disability insurance types.[8] Finally, there is the risk of inaccurate genotyping, which could affect health outcomes. For example, lowering or stopping statin therapy based on inaccurate genotyping can increase CVD risk.[21] Monitoring lipid levels to evaluate treatment efficacy and switching to an alternate statin as necessary may help reduce the risk of CVD in the event of an error in allele genotyping.[21]

Utilizing pharmacogenetics to tailor treatment in CVD provides individualized person-centered care that can improve treatment efficacy, decrease adverse reactions, and reduce costs in women.[4,8] Pharmacogenetic testing can be completed preemptively to help guide and direct drug dosing and selection to optimize therapy and improve outcomes.[4] To expand on the application of pharmacogenetics for the treatment of women with CVD, the authors present three cardiovascular drug classes with the highest level of evidence supporting their recommendations, including clopidogrel, statins, and warfarin.[22]

Clinical Guidelines and Recommendations

Clopidogrel is a platelet inhibitor used for prevention of blood clots in the treatment of acute coronary syndrome, including percutaneous intervention and stent placement.[22] It is a prodrug metabolized to its active form by the CYP2C19 enzyme.[8] A prodrug is an inactive drug that must be metabolized by the body to its active form to become effective. Clopidogrel has a boxed warning because poor or intermediate metabolizers have a decreased ability to activate this drug, rendering it less effective and placing those individuals at an increased risk for adverse cardiovascular events.[8,22] These patients should avoid taking clopidogrel and instead should use a different P2Y12 inhibitor, such as ticagrelor or prasugrel.[8]

HMG-CoA (3-hydroxy-3-methylglutaryl) reductase inhibitors, known as "statins," are a class of lipid-lowering medications used in the treatment of hypercholesterolemia and CVD.[20] They inhibit the enzyme HMG-CoA reductase, which is responsible for cholesterol synthesis in the liver.[20] Pharmacogenetics can be used in the selection and dosing of statins to decrease the risk of statin-associated musculoskeletal symptoms (SAMS), which include myalgia, myopathy, and rhabdomyolysis.[8,21] SAMS are one of the driving factors negatively impacting long-term compliance and effectiveness of the lipid-lowering agents.[8,21] Genetic variations in the SLCO1B1, ABCG2, and CYP2C9 genotypes are associated with increased systemic drug exposure and are relevant to consider for the risk of SAMS.[21]

SLCO1B1 is a protein transporter that promotes statin uptake in the liver.[21] When this transporter has reduced or poor function, the body is exposed to a higher drug concentration.[21] In a patient with poor or decreased function of the SLCO1B1 protein, the CPIC guidelines provide an algorithm to substitute the high SAMS risk statins with low SAMS risk statins to provide effective lipid-lowering

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treatment.[21] For example, a patient may have an indication for atorvastatin 80 mg, yet is at risk for SAMS due to decreased SLCO1B1 function. The provider may substitute for rosuvastatin 20 mg to reduce the risk.[21] The provider should consistently monitor lipids to evaluate for effective treatment. This algorithm can be found in the 2022 CPIC Statin Guidelines for further reference.[21]

The ABCG2 phenotype variant is associated with increased plasma concentration of rosuvastatin.[21] Therefore, it is recommended to initiate rosuvastatin at a 20-mg dose or less for patients with poor ABCG2 function. If additional lipid-lowering effects are needed, the clinician should consider switching statins or adding combination therapy with a statin and ezetimibe.[21]

The CYP2C9 enzyme is important in metabolizing many drugs, including statins.[15] The intermediate and poor metabolizer phenotypes are associated with increased systemic fluvastatin concentration.[21] Thus, it is recommended to prescribe 40 mg or less for intermediate metabolizers and 20 mg or less for poor metabolizers.[21]

While pharmacogenetics helps guide statin therapy to reduce SAMS risk, it is paramount to ensure patients receive statin therapy regardless of genotype results to reduce their risk for cardiovascular events.[21–23] Statin selection will be based on which statin intensity and dose the patient needs, considering their metabolizer phenotype.

Warfarin is an anticoagulant utilized in the prevention and treatment of blood clots in people with disorders such as atrial fibrillation, venous thromboembolism, or prosthetic heart valve replacement.[24] It decreases thromboembolism by inhibiting epoxide reductase from activating vitamin K, which activates clotting factors.[22] It has a narrow therapeutic index, making appropriate dosing critical, and can be heavily influenced by dietary intake. Genotype-guided warfarin therapy considers how the allele variations in the CYP2C9 and VKORC1 enzyme genotypes influence dose requirements.[8] People with variants in VKORC1 that cause increased sensitivity to warfarin require decreased doses of the drug. Allele variations in CYP2C9 decrease warfarin metabolism, thus increasing drug concentration and placing the patient at risk for hemorrhage and adverse events.[22] These allele variations typically decrease dose requirements and should be considered when dosing warfarin, especially in patients of African descent.[23]

Implications for Women's Health Care Providers

Pharmacogenetics is a developing field with promising advances and implications for future CVD treatment as well as pharmacologic interventions for other health indications. Most of the population has at least one clinically actionable pharmacogenetic variant predisposing them to toxicity or subtherapeutic drug effects.[8] At the forefront of precision medicine, pharmacogenetic testing can be used to guide selections for individualized drug regimens. One very practical potential benefit of having genetic testing to inform treatment plans is having information to support requests for prior authorization from insurance companies. Being able to use pharmacogenetic testing to demonstrate how one drug may not be an appropriate choice even though it may be the preferred first-line treatment by the payer could decrease medication costs for patients. Avoiding the trial-and-error process with drugs decreases the risk of adverse side effects.

This article provides an illustration of incorporating pharmacogenetics to tailor therapy with clopidogrel, statins, and warfarin, which can help improve CVD outcomes and reduce adverse events. Women's health care providers can draw implications for practice from the information provided in at least two aspects. First, CVD is the leading cause of morbidity and mortality for women in the United States and worldwide. Prevalence increases with age, but 11% of women have some form of CVD before the age of 60. While the women's health care provider might not prescribe the medications described, they will see women who are taking these medications as they collaborate with cardiovascular specialists in their care, so they will want to be knowledgeable about factors that can influence efficacy and drug toxicity. Second, the application of pharmacogenetics is growing. Drugs related to the treatment of specific women's health conditions will be identified as having efficacy and drug toxicity affected by genetic variants. Utilizing pharmacogenetics allows clinicians to make predictions of how patients will respond to medications based on their genotype, thereby creating individualized treatment plans that maximize effectiveness and minimize adverse reactions. As evidence accumulates, clinical utility and integration into care planning will evolve. Precision medicine will undoubtedly improve cardiovascular health outcomes for women.

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Web Resources

A. https://tools.acc.org/ascvd-risk-estimator-plus/#!/calculate/estimate
B. https://cpicpgx.org

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The authors received no specific grant or financial support for the research, authorship, and/or publication of this article.

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https://doi.org/10.1891/CJNPWH-2404

A Holistic Approach to Female Infertility

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Fertility issues are common, and potential causes of female infertility can be multifactorial. A thorough history and physical examination and laboratory and imaging tests can provide information regarding ovarian reserve, structural abnormalities, and ovarian and hormonal dysfunctions that can be factors. A holistic approach to infertility treatment is one that is person-centered and considers the individual's overall health rather than focusing only on the disease. This approach can help women improve their fertility before or in tandem with assisted reproductive technologies. This article provides the nurse practitioner with an overview of holistic lifestyle choices that can potentially improve fertility.

Keywords: female infertility, holistic fertility, female infertility treatment

Birth rates for women over 35 have increased steadily from 1972 to the present as women choose delayed childbearing to seek higher education, participate in the workforce, and consider financial and relationship issues and societal values.[1] This has also resulted in higher rates of infertility as women try for their first pregnancy later in life.[1] It is estimated that 8.5%, or 2.4 million, of women aged 15–49 years were infertile in the United States from 2015 to 2019.[2] Approximately 12% of all women aged 15–49 years sought infertility services during this period.[2]

Infertility is defined as the inability to conceive after 12 months of unprotected intercourse.[3] For women over age 35, the period shortens to 6 months.[3] Most patients experiencing infertility are referred to fertility specialists for consideration of assisted reproductive technologies (ART). Before referral, visiting a women's health nurse practitioner in a primary health care setting has benefits. Using a holistic approach, the nurse practitioner can provide an initial assessment that includes looking at behavior and lifestyle factors. In this article, the author describes a holistic approach to care for women with infertility issues before and in tandem with referrals to fertility specialty care. Current evidence for behavior and lifestyle changes that may influence infertility is provided.

Female Infertility Causes and Initial Evaluation

There are several potential causes of infertility in couples. This article focuses on female infertility while recognizing that male factors account for approximately 20%–30% of infertility cases and contribute to 50% of all cases.[4] Physical impediments include blocked fallopian tubes due to scarring, surgical removal of fallopian tubes, or uterine anomalies such as fibroids or uterine malformations.[3] Hormonal impediments include anovulation due to thyroid disease, polycystic ovary syndrome (PCOS), diminished ovarian reserve, hyperprolactinemia, or other hormonal abnormalities.[3] Estrogen-dominant conditions like endometriosis and elevated cortisol due to stress can affect menstrual cycles and ovulation.[3] Endocrine and metabolic diseases, including pituitary disease, adrenal disease, eating disorders, diabetes, and autoimmune disorders, also contribute to infertility.[3] Other studied potential factors for infertility are the genital tract microbiome, endometrial receptivity, obesity, and genetic disorders.[3,5–7]

After a thorough history and physical examination, laboratory and imaging tests can provide information regarding ovarian reserve, structural abnormalities, and ovulatory and hormonal function.[8] Laboratory tests may include measurement of anti-Müllerian hormone, follicle-stimulating hormone (FSH), estradiol, progesterone, prolactin, and thyroid hormone levels. Testosterone levels and glucose tolerance testing may be considered when PCOS is suspected. Imaging tests, such as hysterosalpingogram, transvaginal ultrasound, or sonohysterography, may be necessary to investigate any uterine or tubal anomalies. Ultrasound can also be done to measure antral follicle count when evaluating ovarian reserve.[3,8]

Holistic Approach

A holistic approach to infertility treatment is person-centered and considers the individual's overall health rather than focusing only on the disease. Behavior and lifestyle are essential to consider, including attention to nutrition, avoidance of toxins and pollutants, physical activity, sleep hygiene, stress management, and sexual health.

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https://doi.org/10.1891/CJNPWH-2402

Education about fertility is another essential component of holistic care for the individual experiencing infertility. Studies show that women's understanding of the fertile time window is low, fertility awareness practices need to be utilized sufficiently, and women want more information to understand their fertility.[9] Fertility awareness methods can improve conception rates by using cervical mucus observation, basal body temperature charting, calendar observations, and ovulatory predictor kits to measure increase in luteinizing hormone (LH).[9] Period tracker applications are being used to determine fertility windows and are now Food and Drug Administration-approved for contraception.[10] More research is needed on the use of period tracker applications for fertility.[10,11]

The nurse practitioner needs to understand the evidence behind using behavior and lifestyle changes to improve fertility. Person-centered care with a holistic approach requires sharing this information with women and couples so they can make informed decisions and feel supported.

Diet and Fertility

There is a growing interest in investigating specific diets and any association with fertility. Among the diets that are receiving attention are the Mediterranean diet (MeD), the typical Western-style diet, and more specific diets for individuals seeking ART. The MeD has been well-researched concerning mental and physical health.[12] The MeD, which includes whole grains, legumes, low-fat dairy, poultry, fish, olive oil, vegetables, fruits, and red wine, with avoidance of red meat and sugars, has been shown in multiple studies to reduce insulin resistance and obesity.[12,13] A systematic review with a meta-analysis of 11 cohort studies evaluated infertile men and women following a diet that contained all of the main food groups of the MeD compared with those with low adherence to the MeD. Clinical pregnancy was analyzed in five studies, with a greater chance of becoming pregnant found with moderate and high adherence to the MeD. The meta-analysis did not confirm that high adherence to the MeD increased the chance of live births, corroborating the results of other studies.[12]

In contrast to the MeD, the Western-style diet includes simple refined carbohydrates, processed foods, and decreased intake of fruits and vegetables.[12] In one cohort study of 5,628 women at their first pregnancy visit, a retrospective look at diet found modest increases in time to pregnancy and infertility for participants with lower intakes of fruit and higher intakes of fast food.[14] More direct studies on fast food, lower fruit intake, high glycemic foods, and high fat in the Western-style diet are needed to understand the association with infertility and delayed time in achieving pregnancy.

A profertility diet that included supplemental folic acid, vitamin B_{12} vitamin D, low-pesticide fruits and vegetables, whole grains, seafood, dairy, and soy foods was shown in one observational study to result in higher pregnancy rates for women undergoing ART.[15] However, there are no randomized controlled studies confirming this association.[12]

Micronutrients

Micronutrients are essential to cellular function, and studies show relationships with fertility. Fertility may be affected by folic acid, vitamin B_{12} and vitamin B_6 in relation to homocysteine metabolism.[12] Vitamin B_{12} and B_6 deficiencies cause a buildup of homocysteine.[12] Hyperhomocysteinemia affects the vascularity of the chorion, decreases gonadotropin levels, increases endothelial inflammation via cytokine release, and increases oxidative stress, thereby decreasing fertility.[12]

Vitamin D has a key role in reproductive hormonal function, with vitamin D receptors found in multiple organs including the ovaries, endometrium, placenta, pituitary gland, and hypothalamus.[12] There needs to be more clarity on the impact of vitamin D on healthy individuals and their fertility.[12] Vitamin D deficiency disrupts calcium balance, escalates proinflammatory cytokines, stimulates insulin levels, and affects glucose metabolism.[12] Vitamin D deficiency has been associated with PCOS and endometriosis, both affecting fertility outcomes.[16,17]

A common finding in PCOS is an elevated LH/FSH level that results in anovulation. In a study that examined the effects of vitamin D on the endocrine and metabolic parameters of PCOS, participants with PCOS who received vitamin D supplementation had improvements in FSH level, LH to FSH ratio, and glucose levels.[16] The researchers noted that given the high prevalence of vitamin D deficiency in women with PCOS and the significant decrease in fertility, further investigation with large randomized controlled studies including women with and without PCOS is needed.[16]

Vitamin D receptors are known for immune modulation, and their presence in reproductive tissues is potentially associated with endometriosis.[12,17] Animal studies show that vitamin D can reduce endometriosis development, but clinical studies have been inconsistent and more needs to be done to understand this relationship.[12]

Minerals may play a role in fertility as deficiencies in calcium, iodine, iron, selenium, and magnesium can affect oocyte quality, embryo fertilization, maturation, and implantation.[12] There are no studies to elucidate the influence of calcium on fertility or pregnancy complications. Iron, iodine, and selenium impact thyroid function, and their deficiencies are linked to fertility and pregnancy delay.[12] Magnesium is vital to glucose metabolism and is probably associated with insulin sensitivity, impacting hormonal balance.[12] Usually, a balanced diet is sufficient to maintain adequate mineral requirements of the body. Still, supplementation may be necessary, and further research is needed on minerals and their connection to fertility.

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Antioxidants

The role of antioxidants in fertility continues to be explored in studies. Free radicals damage DNA in the sperm and oocyte through lipid peroxidation in the membranes.[13] Free radicals are related to epigenetic factors such as a highly processed diet, alcohol use, obesity, smoking, stress and anxiety, radiation, endocrine-disrupting toxins, infections, and inflammatory conditions.[13] Free radicals increase insulin resistance and inflammation and exacerbate conditions such as PCOS and endometriosis associated with infertility.[13]

Antioxidants neutralize free radicals, potentially increasing blood circulation, impacting sex hormone levels, and increasing insulin sensitivity, thereby improving fertility.[12,13] A diet rich in antioxidants is not enough to boost fertility and supplementation may be necessary.[13] Studies on antioxidants show L-carnitine, N-acetylcysteine, and alpha-lipoic acid heightened pregnancy probabilities in the over-35 age group.[13] L-carnitine is beneficial to women with PCOS, endometriosis, and amenorrhea by balancing hormones, decreasing inflammatory cytokines, and combating oxidative stress.[12,18]

Vitamins A, C, and E are potent antioxidants. Women with endometriosis and PCOS often have lower levels of these vitamins, and supplementation can reduce oxidative stress.[12,19]

Probiotics and the Reproductive Microbiome

Extensive research on the gastrointestinal microbiome shows that probiotics positively affect multiple body systems while causing minimal side effects.[20] The positive effects and minimal side effects create an appeal for these products.[20]

Lactobacilli, the predominant microbial species in the vagina, are recognized as a critical player in a healthy reproductive microbiome.[20] Lactobacilli prevent the overgrowth of pathogens, improving the endometrial lining and implantation and subsequent pregnancy rates.[20,21] Pathogens such as *Chlamydia trachomatis*, *Gardnerella vaginalis*, *Ureaplasma* species, and Gram-negative microorganisms in coexistence with a lack of *Lactobacillus* may affect fertility.[21] Vaginal and oral probiotics have been used in treating and preventing the recurrence of bacterial vaginosis (BV).[20] There is speculation that BV could contribute to subfertility.[20] Randomized controlled trials on the direct relationship between the reproductive microbiome, probiotics, fertility, and ART outcomes are needed.[20,21]

Role of Toxins in Fertility

Alcohol and tobacco have been associated with fertility issues and poor pregnancy outcomes.[12,22] Heavy alcohol consumption impacts fertility with the development of disordered menstrual cycles.[12] It is hypothesized that alcohol directly affects hormones, ovulation, egg maturation, blastocyst development, and implantation.[12,22] Tobacco diminishes ovarian reserves, causing delays in conception, increased spontaneous miscarriage, and decreased successful ART outcomes.[22] Research has shown a relationship between high caffeine use, a delay in achieving pregnancy, and an increased risk of spontaneous miscarriage.[12,23] Caffeine is found in coffee, tea, soda, and cocoa.[12]

Environmental Pollutants

Over 80,000 registered chemicals in the United States contaminate air, soil, water, consumer products, food, and household dust.[24] Nearly 100% of pregnant women have evidence of toxins such as phthalates and pesticides in their system.[24] Extensive exposure to toxins can potentially affect conception and cause harm to the embryo and fetus during pregnancy and beyond.[24] Endocrine-disrupting chemicals (EDCs), plasticizers, pesticides, and heavy metals such as mercury, lead, and cadmium are prevalent, with adverse effects on reproductive health.[24]

Mercury accumulates in fish after being released into the environment from incineration, coal burning, and industrial release.[24–26] Consuming large fish such as shark, tuna, and swordfish can lead to mercury exposure, affecting estrogen levels and fertility.[24,25] Lead exposure can lead to multiple adverse outcomes, including congenital disabilities and miscarriage, but there are no data on fertility.[24,26] Cadmium is a heavy metal found in rechargeable batteries, sewage, plastics, and paint. It affects the placenta, causes oxidative stress, and acts as an endocrine disruptor.[24,26] Exposure to pesticides can lead to poor reproductive outcomes.[24,26] EDCs, including bisphenol A, phthalates, and polybrominated diethyl ethers, mimic or block hormones, affecting fertility.[24,26] It is recommended that women reduce exposure to EDCs found in foods, household and personal products, cosmetics, cans, and plastics.[24] Air pollution has been associated with miscarriage, and studies show couples who live near major highways have decreased fertility.[24,27]

Physical Activity

A systematic review found inconclusive results on the association between physical activity, sedentary behavior, and female fertility.[28] High levels of physical activity could be a stressor to the body, affecting LH and FSH release and thereby affecting estrogen and progesterone levels necessary for ovulation.[28] Alternatively, moderate exercise could be significant in maintaining hormonal balance and improving the ovulatory cycle, especially in specific populations such as women with PCOS or obesity.[28]

Sleep

Humans will spend a third of their lives asleep, and many complain about poor sleep quality and insomnia.[29] With

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linkages between sleep and chronic, metabolic, and mental health diseases, it is relevant to consider the relationship between sleep and fertility.[29] A recent systematic review contributes to our knowledge about the potential impacts of sleep on reproductive function.[29] Circadian rhythms and short sleep affect reproductive hormones and menstrual cycles and influence ovarian function and natural fertility. Those who work evening and night shifts show longer times to conception than daytime workers. Short sleep has also been linked to sexual dysfunction, menstrual irregularities, and metabolic disease, impacting fertility. Chronotypes classify the type of sleeper, those who sleep early, sleep late, or intermediate types, and are related to melatonin levels. Melatonin is a hormone that captures free radicals, protects the ovaries from oxidative stress, and impacts fertility.

Stress and Mental Health

The results of studies on how stress can affect fertility are mixed.[30,31] Stress can lead to high cortisol levels, which can have an immunosuppressant effect.[30] Chronic stress can also lead to low cortisol levels and cause changes in the hypothalamic–pituitary–adrenal axis.[31] Hypercortisolism contributes to inflammatory conditions such as rheumatoid arthritis, chronic fatigue syndrome, metabolic disorders, and mental health issues.[31] How cortisol interfaces with the reproductive hormones is complex and not completely understood. Cortisol does interfere with the release of gonadotropin-releasing hormone, which guides the menstrual cycle and ovulation.[30] High cortisol levels inhibit the normal release of LH and FSH, crucial to ovulation. Some women may be more resilient than others to the effects of cortisol on ovulation. Aging may also affect the relationship between cortisol and reproductive hormones.[30]

A holistic approach to stress can address the emotional, mental, psychosocial, and spiritual needs of infertile women and reduce infertility-related stress, anxiety, and depression.[32] Potential strategies include cognitive behavioral therapy, mind–body interventions, stress management skills, and educational interventions.[32,33] In a meta-analysis, psychosocial interventions that improve mental health and stress are positively associated with pregnancy rates.[34]

Sexual Function

Sexual dysfunction can contribute to infertility or can be an outcome of psychological stress on the couple experiencing infertility.[35] Issues with sexual function affect 40%–45% of adult women and 10%–60% of infertile couples.[35] Women experiencing infertility face physical and psychological changes during infertility treatment, the burden of costly treatments, and social stigma, which can contribute to sexual dysfunction.[35] Approximately 5% of infertility cases are affected by preexisting conditions such as vaginismus, dyspareunia, and hypoactive sexual desire disorder.[35] Addressing female responses to the sexual phases of arousal, desire, orgasm, and resolution can help elucidate areas of concern regarding sexual function.[35] It is recommended that patients are referred to sex therapy or sexual health clinicians.[35]

Implications for Practice

A holistic approach to care that is evidence-based is essential for women facing infertility before and in tandem with referrals for ART. Women's health nurse practitioners in primary care settings can perform a comprehensive medical history and physical examination, order laboratory markers, and interpret initial findings. They can assess understanding of menstrual cycles, fertile windows, and fertility awareness methods, and provide education in these areas.

The nurse practitioner can thoroughly assess behaviors and lifestyle factors that can affect fertility and provide appropriate education, counseling, and referrals. Lifestyle interventions can include dietary changes, nutrient and probiotic supplementation, exercise, toxin and substance use avoidance, mindfulness and mental health practices, stress reduction, and attention to sexual health. Referrals to specialists, including dietitians, physical trainers, pelvic floor therapists, sexual and mental health therapists, and others, can optimize health. Helping women make informed choices regarding their health and fertility can improve outcomes. Nurse practitioners can create an environment within the clinical setting to communicate and deliver care that offers personalization, sensitivity, and continuity.[36]

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Disclosure

The author has no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The author received no specific grant or financial support for the research, authorship, and/or publication of this article.

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https://doi.org/10.1891/CJNPWH-2402

Heavy Menstrual Bleeding: One Patient's Complex Journey

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Heavy menstrual bleeding affects millions of women annually. There are several evidence-based approaches to managing this condition. Nurse practitioners (NPs) providing care for patients with heavy menstrual bleeding should be knowledgeable about all options so they can discuss them with their patients, utilizing a shared decision-making process for management. While many of these options have good safety profiles, NPs must be mindful of the side effects and regularly assess their patients' response to care. This case presentation provides the reader with a scenario that required the NP and the patient to consider and try several treatments with variable efficacy in reducing menstrual bleeding and with some unexpected adverse events.

Keywords: heavy menstrual bleeding, side effects, norethindrone acetate

LK, a 42-year-old female, presents to the office for follow-up with the nurse practitioner (NP) due to continued prolonged menstrual bleeding since her endometrial ablation 6 months ago. She describes her bleeding as irregular in quantity and duration, having a cycle at least once per month, and occasionally over the past 6 months she has had two cycles per month. She notes the bleeding lasts at least 10 days at a time, although the overall amount is less than before the ablation. LK tells the NP that her workday and social life are impacted as she is unable to predict when her bleeding will occur, how much it will be, and whether her pain will be tolerable. She does report that her pain has been relieved with 800 mg of ibuprofen taken with food up to three times per day at the onset of bleeding, as previously advised by the NP. LK notes great frustration with continuing to bleed as she was hopeful for amenorrhea with the endometrial ablation. The ablation with dilation and curettage was performed because she had heavy menstrual bleeding that persisted over 1 year, and there was no pathologic etiology to explain the bleeding pattern, although she was suspected to be in the perimenopausal period. Endometrial sampling at that time returned benign.

Abnormal Uterine Bleeding Overview

Abnormal uterine bleeding (AUB) includes heavy menstrual bleeding, prolonged menstrual bleeding, frequent menstrual bleeding, and irregular menstrual or nonmenstrual bleeding. In 2011, the International Federation of Gynecology and Obstetrics (FIGO) standardized the AUB terminology based on four parameters of normal bleeding and definitions for bleeding that fall outside of these parameters.[1] A review of the AUB terminology is included in Table 1. Older terms, including *menorrhagia*, *metrorrhagia*, and *dysfunctional uterine bleeding*, are considered obsolete.[2]

FIGO also created a system called PALM-COEIN to classify and separate the causes of AUB into structural and nonstructural etiologies. The acronym PALM describes common structural causes of AUB (polyp, adenomyosis, leiomyoma, and malignancy and hyperplasia) and COEIN describes nonstructural causes (coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, and not yet classified).[4] FIGO's standardized AUB terminology and the PALM-COEIN classification system have been endorsed by the American College of Obstetricians and Gynecologists (ACOG), allowing clinicians to use universal language when describing factors associated with AUB.[5]

Heavy menstrual bleeding, defined as menstrual blood loss that impacts quality of life irrespective of the amount of blood loss, affects between 20% and 50% of women of reproductive age.[1,6] Heavy menstrual bleeding should be addressed in any patient presenting with challenges related to menstrual flow impacting their life. To assist women in determining if they are having heavy menstrual bleeding that requires medical attention, ACOG

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https://doi.org/10.1891/CJNPWH-2420

Table 1. Overview of AUB Terminology[1,3]

CRITERIA	DEFINITION/EXPLANATION
Regularity	Irregular menstrual bleeding with age-dependent variations
Frequency	Varies from amenorrhea (no bleeding) to infrequent bleeding with more than 38 days between cycles to frequent bleeding with 24 days or less between cycles
Duration	Prolonged bleeding >8 days
Volume	Patient-determined Menstrual blood loss that interferes with the patient's quality of life
Irregular nonmenstrual bleeding	Irregular bleeding occurring between regular menstrual cycles that may be light and short or prolonged and heavy, or a combination Includes bleeding with intercourse

Abbreviation: AUB, abnormal uterine bleeding.

offers consideration of bleeding that meets any of the following parameters:

- lasts longer than 7 days,
- saturates one or more pads or tampons several hours in a row,
- requires wearing multiple pads at a time,
- requires changing pads or tampons overnight, and
- contains blood clots at least the size of a quarter.[7]

Anemia is a common finding among women with prolonged or heavy menstrual bleeding, and clinical suspicion should be high when evaluating patients for this concern. The prevalence of anemia in women of childbearing age is approximately 30% and continues to represent a global public health concern.[8]

Assessment and Diagnosis

LK's medications include vitamin D 2,000 IU daily and a women's multivitamin. She is up to date with her cervical cancer screening and cotesting and has received three doses of the human papillomavirus vaccine. There is no history of or concern for sexually transmitted infections. Her medical history is negative for uterine fibroids, polycystic ovary syndrome, endometriosis, or obesity. Her surgical history includes a tubal ligation 12 years ago and endometrial ablation with dilation and curettage 6 months before this appointment. Physical examination reveals a weight of 108 lb, body mass index of 18.5, and blood pressure (BP) of 118/72. Recent hemoglobin and hematocrit levels were 12.1 g/L and 36.1%. Her thyroid-stimulating hormone level was 0.98 mU/L. Her lipid panel and recent hemoglobin A1c were within normal limits based on a review of records from her primary care provider. A pelvic examination at this visit is negative for external or internal lesions. There is scant white discharge without odor and no cervical motion tenderness. The uterus is anteverted, midline, smooth, mobile, and nontender. There are no adnexal masses or tenderness.

The diagnosis of AUB remains the same as it was before LK had her endometrial ablation. A Cochrane review reveals that endometrial ablation reduces menstrual blood loss with low to moderate evidence. Bleeding can persist after endometrial ablation, and reinterventions may be necessary within 2 years of the procedure, affecting patient satisfaction.[9]

Treatment Options

Treatment recommendations for managing heavy menstrual bleeding are variable and require an individualized approach designed to manage patient expectations, minimize side effects, and consider expectations for pregnancy if desired in the future. Options may include hormonal or nonhormonal medical interventions or surgical options. Tables 2 and 3 identify the common treatment options to consider in the management of chronic heavy menstrual bleeding. Chronic heavy menstrual bleeding is generally defined as having been present for the majority of the last 6 months.[4] However, treatment should begin whenever a woman determines that the change in bleeding is significant. Management of acute heavy menstrual bleeding is not discussed in this article.

A recent Cochrane review and network meta-analysis summarized treatment options and ranked them based on two primary measured outcomes of menstrual bleeding reduction and patient satisfaction at 1-year follow-up. The review categorized treatments as either first line or second line. First-line treatments included all medical treatments, hormonal and nonhormonal. Second-line treatments included surgical interventions.[6]

Based on the two primary measured outcomes among first-line treatments, the levonorgestrel intrauterine system was rated as the best treatment, antifibrinolytics second best, followed by long-cycle progestogens.[6] Among the second-line treatment options, evidence suggested that hysterectomy was the best option, with increased patient satisfaction, followed by endometrial ablation (resectoscopic endometrial ablation and microwave nonresectoscopic endometrial ablation, in that order).[6]

Treatment and Education

LK tells the NP her primary goal is to achieve amenorrhea. While the manufacturer does not explicitly preclude placement of a levonorgestrel intrauterine system following endometrial ablation, it advises against placement if a condition changes the shape of the uterine cavity.[10] Because of the scar tissue resulting from an endometrial

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Table 2. Hormonal Treatment Options for Heavy Menstrual Bleeding[6,10–13]

TREATMENT OPTIONS	CONSIDERATIONS	PRIORITY LEVEL
COCs	May be used continuously; multiple options; contraindicated in patients with history of, current, or increased risk of thrombosis; see U.S. MEC for Contraceptive Use for other possible contraindications	First line
Levonorgestrel-releasing intrauterine system	Irregular bleeding can still occur; effective suppression of heavy menstrual bleeding may last less time than duration of device efficacy; current or history of thrombotic or thromboembolic disorders is not a contraindication; See MEC for Contraceptive Use for possible contraindications	First line
Norethindrone acetate	Oral medication approved for treatment of secondary amenorrhea, endometriosis, and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology; taken daily; not a contraceptive; contraindicated in patients with current or history of thrombotic or thromboembolic disorders	First line
Progestin-only contraceptive methods (oral, injection, implant)	Greater safety profile than COCs; can cause irregular bleeding; see U.S. MEC for Contraceptive Use for possible contraindications	First line
Relugolix, estradiol, and norethindrone acetate combined	Oral medication approved for heavy menstrual bleeding related to uterine fibroids and moderate to severe pain related to endometriosis; contraindicated if current or history of thrombotic or thromboembolic disorders and those at increased risk for these events, including women greater than age 35 who smoke or with uncontrolled high blood pressure; more expensive than other hormonal treatment options	First line

Abbreviations: COCs, combined oral contraceptives; MEC, Medical Eligibility Criteria.

Table 3. Nonhormonal Treatment Options for Heavy Menstrual Bleeding[6,14]

TREATMENT OPTIONS	CONSIDERATIONS	PRIORITY LEVEL
Nonsteroidal anti-inflammatory drugs	Associated with gastrointestinal disturbances if not taken with food; used only while bleeding; contraindicated in patients with severe asthma, gastrointestinal ulceration, or kidney disease	First line
Tranexamic acid (antifibrinolytic)	Oral medication approved for treatment of cyclic heavy menstrual bleeding; contraindicated in patients with increased risk of thrombosis; should not be used in combination with estrogen-containing contraception; used only while bleeding for a maximum of 5 days	First line
Endometrial ablation	Amenorrhea not guaranteed; may require repeat to address bleeding if done before age 40; consider only if fertility preservation is not desired	Second line
Myomectomy and uterine artery embolism	Treatment if fibroids are causative factor	Second line
Polypectomy	Treatment if endometrial polyps are causative factor	Second line
Hysterectomy	Definitive; not an option for those who desire to maintain fertility	Second line

ablation, this option was deemed unviable after shared decision-making. LK does not desire to use any treatment that would expose her to estrogen as a personal preference.

Her assessment indicates that she does not have any history of or known risk for thrombotic or thromboembolic disorders. She is a nonsmoker, does not have obesity, and has always had a normal BP. She elects a trial of tranexamic acid 650 mg three times per day for up to 5 days. The NP instructed LK to start this medication with the next onset of vaginal bleeding, and a follow-up appointment in 3 months was scheduled to evaluate treatment response. After three doses of the tranexamic acid, LK experienced progressively worsening hives, so the medication was discontinued. The next intervention chosen by LK is norethindrone acetate 5

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mg daily. She is advised to return in a few months to evaluate treatment response.

An Unanticipated Event

LK returns for a follow-up visit 3 months later. She describes a return of spotting with norethindrone acetate following approximately 6–8 weeks of amenorrhea. She states she has taken the medication as directed with no missed doses and has not started any new medications or herbal treatments. An unanticipated clinical finding at this visit is severely elevated BP and a 5-lb weight gain from her baseline. The patient tells the NP that she had BP readings of 150–160 systolic and 90–100 diastolic on multiple occasions at home, in the absence of any headaches, vision changes, or nausea/vomiting. She explains she questioned the accuracy of her electronic BP cuff and thus did not report these readings to the clinician. At this office visit, her BP is 169/99, with a repeat reading of 162/100.

Given the lack of efficacy of this treatment for this patient and her significantly elevated BP, LK is discontinued from norethindrone acetate and later elected surgical intervention with hysterectomy as a definitive option. Notably, the hysterectomy rate is as high as 21% after endometrial ablation.[9] Her BP returned to normal after 1 week of discontinuing norethindrone acetate. Hypertension is not included as a specific contraindication or an adverse reaction in the U.S. Food and Drug Administration's labeling for norethindrone acetate. While not listed under common side effects, high BP and fluid retention are listed under other side effects in the patient information section of the norethindrone acetate package labeling.[11]

Conclusion

Management of heavy menstrual bleeding can be complex and may require the NP to provide ongoing reassurance to the patient that they can try several different treatments to meet their goals. Multiple sources provide clinical guidance on defining AUB, warranting clinicians to examine the literature to determine evidence-based inclusion criteria. As patients approach the perimenopausal period, where menstrual irregularities are common, management of this condition can be even more challenging. There is a myriad of medication options to be explored for symptom management. Patient preference, treatment goals, current or future desire for pregnancy, and safety should be paramount in selecting options. A medical history and physical examination based on knowledge of the parameters of normal menstrual bleeding and the PALM-COEIN classification system are essential. It is also important to remember that heavy menstrual bleeding is not simply the quantity of blood flow for patients but also the duration of the menstrual flow and its subsequent impact on quality of life. Laboratory testing, including evaluating for pregnancy and anemia, and imaging studies to assess anatomy when symptom resolution does not improve or is not achieved, are part of the assessment.

Each treatment option and each patient requires the NP to consider the benefits and risks, including common and less common side effects associated with therapies. Some of the hormonal and nonhormonal medications indicated for the treatment of heavy menstrual bleeding can place patients at risk for thrombotic and thromboembolic events. As cardiovascular disease rates continue to rise disproportionately among women, it is important not to increase the patient's risk for harmful cardiovascular sequelae inadvertently. Patient education about potential adverse medication reactions and what symptoms require prompt medical attention is relevant to preventing harm.

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Disclosure

The author has no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The author received no specific grant or financial support for the research, authorship, and/or publication of this article.

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https://doi.org/10.1891/CJNPWH-2420

Managing Pain and Anxiety With Intrauterine Device Placement: A Client-Centered Approach

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Long-acting reversible contraceptives, including transdermal implants and intrauterine devices (IUDs)/systems, are the most effective nonpermanent contraceptive methods available in the United States. Barriers to the use of IUDs include fear and anxiety related to anticipated and actual pain with placement of these products. Mass news media and social media have illuminated actual patient experiences with anxiety and pain during IUD placement in the past several years. Researchers at Duke University reviewed the top 100 videos shared on TikTok in 2022 describing pain with IUD placement and the growing concerns among young women about the lack of pain control options. The purpose of this article is to address the management of pain and anxiety with IUD placement. Client-centered strategies aimed at mitigating pain as well as reducing anxiety are emphasized.

Keywords: contraception, intrauterine device, IUD, IUD placement, pain with IUD placement

Unintended pregnancy has been related to lack of access to or inconsistent use of contraception. Intrauterine devices (IUDs) are long-acting, safe, highly effective, and reversible contraceptive methods. Although the expansion of health plans like the Affordable Care Act, the Title X Family Planning Program, and Medicaid has improved access to IUDs, media, especially social media campaigns that began in 2022, have highlighted women's experiences of heightened anxiety, pain, and discomfort with IUD placement.[1]

It is important that clinicians do not underestimate a client's level of actual or anticipated pain with IUD placement. The client's experience can be affected by one or a combination of factors.[2,3] The table lists the physical, physiologic, procedural, psychological, and sociocultural factors that have been associated with an increased potential for pain during IUD placement. Identifying such factors can facilitate discussions between the clinician and the client about nonpharmacologic and pharmacologic interventions to decrease anxiety and pain. Strategies for clinicians to improve client-centered care and informed consent, as well as to decrease negative experiences related to pain, are critical to increasing options for highly effective contraception.

Client-Centered Approaches

A client-centered approach to sexual and reproductive health care, in general, is respectful of the individual's dignity and autonomy and is provided in a supportive and nonjudgmental environment where the client feels understood and valued. The clinician's role is to actively listen, review, and reflect on the client's feelings and facilitate the client's exploration and identification of solutions. When discussing a client's interest in an IUD, it is essential that the clinician understands the client's reproductive objectives and identifies risk factors that may increase pain. When explaining the procedure and potential complications, it is imperative to use honest, compassionate, culturally responsive, and linguistically appropriate language. The clinician can, for instance, relay that most women describe the discomfort associated with IUD placement as mild or moderate and less than expected but that it varies from none to severe in research studies.[3] Using neutral language such as "placement" instead of "insertion," or "procedure" and "removing" instead of "pulling," may be perceived as less harsh

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Table. Factors Associated With Increased Potential for Pain With IUD Placement[a]

PHYSICAL AND PHYSIOLOGIC FACTORS	PROCEDURAL FACTORS	PSYCHOLOGICAL AND SOCIOCULTURAL FACTORS
Length of uterine cavity	Presence of cervical resistance and pain	Age (adolescence)
Low parity	Difficulty or pain when using uterine sounding	History of sexual trauma
>13 months between last birth and placement	Size of inserter	Previous negative experience with vaginal examination
Nonbreastfeeding at the time of placement		Pain with a previous placement
Cesarean deliveries		Heard or read about potential for pain
History of dysmenorrhea		Anticipation or expectation of pain
Menstruating at the time of placement (nulligravida)		Mood disorders

Abbreviation: IUD, intrauterine device.

[a]Data adapted from Gemzell-Danielsson et al. (2019).[3]

and mechanical. Asking the client about specific concerns to provide more direct anticipatory guidance and tailor nonpharmacologic and pharmacologic options to the individual is also recommended. Ensuring the client knows they can ask questions or stop the process at any point helps alleviate anxiety. Asking the client what they have done in the past to decrease anxiety and pain is a strength-based technique that may help empower them to be proactive in managing their pain.

In a literature review that looked at nonpharmaceutical interventions aimed at reducing anxiety in clients undergoing procedures, clients reported using deep breathing techniques, meditation, lavender and other essential oils, heating pad, listening to music, and playing video games on mobile devices for distraction and relaxation.[4] Clinicians can encourage the client to use anxiety-relieving strategies they have previously found helpful. Examination rooms should be clean and uncluttered, comfortable, and private.[2] Once in the examination room, the clinician should ensure the client is comfortable. The instrument and product tray should be prepared ahead of time to ensure a smooth, efficient, and uninterrupted process for placement. It is appropriate to cover the prepared tray and only show the client specific items on the tray if they request it. Clients only have to remove clothing to expose the genital/vaginal area.[4]

Pharmacologic Strategies for Pain Reduction During IUD Placement

Because IUD placement can be uncomfortable, it is critical for clinicians to discuss what options are available before, during, and after the procedure to help reduce discomfort. To date, no specific pharmacologic intervention has been conclusively demonstrated to reduce pain with IUD placement. The challenge is that studies have used a variety of IUD types and placement techniques, as well as variable participant characteristics, comparators, manners of administering therapeutic agents, and evaluation of pain.[3,5]

A 2015 Cochrane review of randomized controlled trials of interventions for reducing IUD placement-related pain provides the most comprehensive look at studies.[6] The 2023 Faculty of Sexual and Reproductive Healthcare guidelines for intrauterine contraception from the United Kingdom provide similar findings, referencing the same studies with a few additions.[5] Clinicians can use the findings from studies, knowledge about how specific strategies might work and any potential adverse reactions, their own and others' clinical experience, and discussion with clients for shared decision-making.

Prior to IUD placement, over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs) may be considered for decreasing cramping during and after placement.[6] Naproxen sodium 550 mg taken 1 hour before the procedure was the only NSAID in the 2015 Cochrane review that demonstrated effectiveness in reducing pain with IUD placement for parous women only.[6] Ibuprofen has been demonstrated effective in reducing pain post-IUD placement but not during placement.[6] These common over-the-counter medications can be continued, according to manufacturers' instructions, to control pain from uterine cramping and bleeding after the procedure. They should be taken with food, and the manufacturers' maximum daily recommended doses are 1,100 mg for naproxen and 2,400 mg for ibuprofen.

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Nitrous oxide is an easy-to-use inhaled gas that is inexpensive and relatively easy to acquire and maintain. The gas is administered through a nasal mask using a combination of nitrous oxide and oxygen. This gas can be delivered throughout the placement process. Studies indicate that the use of nitrous oxide for light sedation during labor and in-office hysteroscopic sterilization decreases pain and is easy to administer.[7,8] Limited research is available on its use with IUD placement.[9,10,11] However, preliminary data show a reduction in pain and anxiety, along with improved client satisfaction, with a 70:30 nitrous oxide to oxygen ratio.[11] It is the most commonly used inhalation anesthetic in dentistry and has few side effects. In rooms where nitrous oxide is used, monitoring for proper ventilation and waste gas scavenging is necessary.[8,12]

Medications that require a prescription may be considered to provide additional anxiety and pain relief. Tramadol (Schedule IV of the Controlled Substances Act) decreased pain during insertion in parous women, but only slightly more than naproxen did.[6] Although evidence is limited, there is some support for cervical anesthesia as a pain relief method for IUD placement.[6] A variety of lidocaine formulations and administration routes have been studied. Three randomized controlled studies reported that a 10% lidocaine spray applied to the surface of the cervix and external os 3 minutes prior to the IUD placement procedure offered clinically significant reductions in pain.[3] Application of lidocaine gel did not have a significant pain reduction effect.[3,6]

A paracervical lidocaine block may be used just before the IUD is placed. This local anesthetic is injected into areas around the cervix, targeting the uterosacral ligaments containing cervical and uterine nerves. An amount of 20 mL of buffered lidocaine (18 mL of 1% lidocaine and 2 mL of 8.4% sodium bicarbonate) without epinephrine is injected in two to six separate locations on and around the cervix. The injection takes effect within 1–2 minutes.[13] A 2015 Cochrane review noted that pain at the tenaculum site and with placement of IUD was lower with administration of a paracervical block compared with no intervention.[6] The effectiveness of paracervical blocks is further supported by a randomized, single-anonymized, placebo-controlled study with 64 participants. Women who received a paracervical block had less pain during IUD placement compared with women who received no block. Pain was also substantially less for the paracervical block group for uterine sounding and overall pain perception.[13]

Finally, while misoprostol has been used during IUD placement, research has not shown that it is effective in reducing pain. In fact, it may increase uncomfortable side effects like abdominal cramping. A systematic review with meta-analysis of 14 studies looking at misoprostol use during IUD placement concluded that misoprostol premedication may reduce insertion failure rates in women who had experienced previous placement failure, but that pain scores with IUD placement increased with both sublingual and buccal use of misoprostol.[14]

Nonpharmacologic Strategies for Anxiety and Pain Reduction During IUD Placement

To promote a successful client visit, standard nonpharmacologic strategies should be utilized to minimize the anxiety surrounding IUD placement. Clinicians are encouraged to go at a slow pace during IUD placement to eliminate any time-related pressure that may increase the client's anxiety. Support staff should be well-trained to enhance a professional, unhurried, and smooth experience for the client.[2] Clinicians are also encouraged to use interpersonal techniques to minimize anxiety and the perception of pain by creating a calm and supportive environment for the client.

Distraction therapy, otherwise known as "verbicaine" or "vocal local," can be implemented by clinicians and support staff using soothing words to help manage any anxiety that the client may be experiencing, allowing for an easier process for both parties.[15] Aside from providing reassurance, adding other distractions has proven helpful. For instance, the client can watch television, listen to music, or hold a heating pad/hot water bottle on the lower abdomen.[16,17]

Another strategy to minimize anxiety is the use of lavender. One study of 106 women found that aromatherapy with lavender inhalation had a positive effect on minimizing anxiety during IUD placement when compared with placebo.[18] Some randomized controlled studies of the general population have shown lavender aromatherapy to have a beneficial anxiolytic effect. Lavender inhalation (one to two drops of oil on a cloth inhaled a few minutes before a procedure) can be used as a complementary treatment in addition to other techniques.[19]

IUD Placement Technique to Reduce Pain

The efficient and effective use of instruments and appropriate technique is integral to minimizing discomfort, pain, and complications such as perforation during IUD placement. Steps during placement that have been found to provoke moderate to severe pain include placement of the tenaculum on the cervix, uterine manipulation for stabilization, sounding for uterine depth, placement of the device inserter, and deployment of the device.[2] A speculum that is wider but not longer should be selected. Excessive speculum length can partially immobilize the cervix and hinder movement when used. Warm metal speculums before use and only keep the speculum inside the vagina for the briefest duration needed. An alternative to the single-tooth tenaculum for cervical traction is an investigational tenaculum, which enables atraumatic traction of the cervix using a semicircular suction pad designed to conform to the anatomical shape of the

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external cervical os. A small pilot study showed that the device could be used to manipulate the cervix safely and effectively for IUD insertion.[20]

It is essential to proceed with caution and deliberation. Gently navigate instruments and the device through the internal os, avoiding forceful actions. After successfully passing through the internal os, take a moment to pause before moving forward. Then, with careful intent, continue toward the fundus, making certain to avoid unnecessary force. It is crucial not to exert pressure beyond the fundal resistance, even if the flange on the IUD inserter has not reached the external os. Aim to contact the fundus with the uterine sound and the device only once, as repeated tapping can increase client discomfort.

Conclusion

Creating a supportive and empathetic environment fosters trust and communication between the clinician and the client, improving client satisfaction with contraceptive methods in general. Counseling and education provide opportunities for building the client–clinician relationship and for the clinician to assess for anxiety and address concerns about the IUD placement process. During IUD placement, it is important for the clinician to communicate with the client about any discomfort or pain they are experiencing. This communication helps the clinician adjust their technique and provide additional verbal support to the client. The successful placement of an IUD depends not only on clinical and technical proficiency but also on employing clinically proven and evidence-informed strategies to mitigate pain and anxiety. By implementing shared decision-making in nonpharmacologic interventions like client education and distraction and pharmacologic choices like NSAIDs or other medications, clinicians can significantly enhance the client's overall experience and ensure the success of IUD placement. Blending multiple strategies based on clinical experience and client preferences is more likely to produce improved outcomes, and a combination of evidence-based pharmacologic and nonpharmacologic strategies is more likely to produce superior results. For instance, clinicians might offer premedication with naproxen 550 mg approximately 60 minutes prior to the procedure, heat therapy in the form of reusable heating pads or chemical heat, and the opportunity to listen to music during the procedure. By promoting the implementation of all or even some of these strategies, we move closer to achieving the goal of enhancing the client's health care experience and promoting positive reproductive health outcomes.

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within the article.

Kristin Metcalf-Wilson, DNP, WHNP-BC serves on the advisory board for Afaxys Pharmaceuticals and is a Nexplanon trainer for Organon. She has relevant financial relationships with ineligible companies, and they have been mitigated.

Funding

This publication was partially supported by the Office of Population Affairs of the U.S. Department of Health and Human Services (HHS) as part of financial assistance award #FPTPA006031-03-00. The contents are those of the author(s) and do not represent the official views of, nor an endorsement, by the Office of Population Affairs/OASH/HHS, or the U.S. Government.

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https://doi.org/10.1891/CJNPWH-2440

Health and Healthcare for Midlife Women

The National Association of Nurse Practitioners in Women's Health (NPWH) asserts that women's health nurse practitioners (WHNPs) and other advanced practice registered nurses (APRNs) who provide women's health care have a critical role in providing evidence-based care, education, and anticipatory guidance that promotes wellness and quality of life throughout the midlife years and beyond. Midlife is often defined as comprising a specific age range (eg, 35–65 years) or specific reproductive aging parameters (eg, perimenopause, menopause, postmenopause). The Table highlights the criteria established for these reproductive aging parameters.[1] In this position statement, the term *menopause* is used to encompass the menopause transition and postmenopause.

NPWH is committed to raising public and health care provider awareness about menopause and its effect on women and their health. Expected changes and health considerations related to menopause are often not discussed within families and communities or addressed by health care providers. When women do not have access to accurate, culturally responsive, and linguistically appropriate information, they are left to navigate this transition with inadequate or incorrect information and are not aware of effective and safe treatment options to manage their symptoms, prevent osteoporosis, and potentially preserve cardiovascular function.[2] In fact, inadequate or incorrect information can leave women vulnerable to financial and health harm.[3,4] NPWH promotes a person-centered approach to the care of women at midlife and beyond. This approach to care should be based on current evidence and recognized guidelines on hormone therapy and nonhormonal therapies, with shared decision-making about the best strategies for individualized symptom management, health promotion, disease prevention, and quality of life. Cultural background, socioeconomic status, health literacy, history of trauma, and overall health must be considered as these factors influence the menopause experience. NPWH is dedicated to providing resources that WHNPs and other APRNs can use to provide evidence-based, person-centered care for midlife women.

NPWH affirms that WHNPs, as leaders in women's health care, are supported in their academic and clinical education to obtain the knowledge and competencies needed to provide common and complex menopause health care. NPWH's *Women's Health Nurse Practitioner: Guidelines for Practice and Education* specifies curriculum content for WHNPs to prepare them with the competencies to provide advanced assessment, diagnosis, and management, with attention to the influence that an individual's menopausal health has on overall well-being and the potential effect that other health conditions can have on menopausal health (Box 1).[5] WHNPs bring expertise to health care teams to successfully advocate for patient-centered care that addresses all components of midlife women's health. Social determinants of health (SDOH)-mediated inequities in menopausal care must be addressed through changes in health care systems, health professional education, and public health measures. Persons from minority ethnic and racial populations, sexual minority women, transgender and gender-diverse individuals, persons with disabilities, persons with comorbidities, and other underrepresented and marginalized groups must be fully represented in research about menopause, the findings of which constitute the basis for guidelines on best health care and best health outcomes.

Background

In the United States, 1.2 million women experience menopause yearly.[6] Worldwide, 70%–85% of women experience menopausal symptoms.[7] The symptom profile is vast and varied, and can arise within nearly all body systems as female hormones play an important role within and beyond the reproductive system. The most common symptoms include hot flashes, night sweats, sleep disruption, muscle and joint pain, and changes in genitourinary and sexual function, as well as mood changes such as irritability, anxiety, and depression.[1] The type, timing, and severity of symptoms are variable, as are the perspectives of individuals on the significance of these symptoms in their daily lives.

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Table. Reproductive Aging Terminology: STRAW Criteria and Characteristics[1]

TERMINOLOGY	DURATION	MENSTRUAL CYCLES	VMS
Menopause transition (MT): time before FMP when menstrual cycles become variable and other menopause-related symptoms begin	Early MT variable Late MT 1–3 years	Early MT variable length persistent >7-day difference in length of cycles Late MT intervals of amenorrhea >60 days	Early MT not likely Late MT likely
Menopause: permanent cessation of menses	Early postmenopause within 8 years of FMP Late postmenopause remaining lifespan	Absent	Most likely in the first 2 years after FMP and often extends beyond this time
Perimenopause	Encompasses early and late menopause transition and early postmenopause		

Abbreviations: FMP, final menstrual period; STRAW, Stages of Reproductive Aging Workshop; VMS, vasomotor symptoms.

Box 1. WHNP: Guidelines for practice and education examples of menopause/midlife-related content.[5]

- Advanced menopause transition physiology, endocrinology, and body changes
- Menopause transition and postmenopausal health care
- Social/structural determinants and inequities that affect health
- Comprehensive and age-appropriate health risk assessment
- Age- and risk-based health screening recommendations
- Gynecologic, sexual, reproductive, and menopausal health care for women who have sex with women or who identify as lesbian or bisexual
- Gynecologic, sexual, reproductive, and menopausal health care for transgender and gender nonconforming individuals
- Nongynecologic conditions that may affect or be affected by gynecologic, sexual, reproductive, and menopausal health
- Psychological factors and conditions that may affect or be affected by gynecologic, sexual, reproductive, and menopausal health
- Abnormal uterine bleeding
- Breast and gynecologic cancers
- Pelvic floor disorders
- Urinary and fecal incontinence
- Vulvovaginal disorders

Abbreviation: WHNP, women health nurse practitioner.

Women who receive education about menopause and its associated symptoms have more positive attitudes about the transition and report less severe symptoms.[3,8] Anticipatory guidance, that is, the education provided before an event, can reduce anxiety and be reassuring and validating when symptoms do occur.[9] However, anticipatory guidance is rarely provided by health care providers, and menopause-related symptoms continue to be seen as unimportant, something to be endured, or completely ignored.[3,10,11] Women's knowledge about menopause is often limited, with much information being unreliable, negative, and difficult to navigate.[3,8,11]

Many health care providers have misconceptions and knowledge gaps related to menopause.[4,12] Nationally, obstetrics and gynecology, internal medicine, and family medicine residency programs lack adequate menopause curricula.[13,14] Without this education, health care providers are more likely to misunderstand, misdiagnose, or dismiss menopausal symptoms, with resulting implications for health and quality of life.[4] Improved menopause-specific curriculum for all health care providers who see women in midlife can prepare them to provide anticipatory guidance and individualized, evidence-based symptom management.[4,12]

Midlife and aging-related body changes also occur and often become evident during the menopause transition. Weight gain, body composition changes, especially an increase in abdominal visceral fat, increased vascular dysfunction, and dyslipidemia are changes that occur in midlife, all of which can significantly increase the risk of metabolic and cardiovascular disease (CVD).[15,16] Beyond physical health, changes in weight and increased abdominal girth can be psychologically distressing for some women.[7] Bone loss is most marked during the menopause transition and can lead to postmenopausal osteoporosis and potentially life-altering fracture events.[1] Opportunities exist before, during, and after the midlife years to reduce the risk of CVD and osteoporosis-related fractures and to promote overall long-term health. The Women's Preventive Services Initiative provides age- and risk-related recommendations for screening, counseling, and anticipatory guidance that can be used at well

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Box 2. WPSI wellness visit components for women aged 40–64 years.[17]

- Alcohol use screening and counseling
- Anxiety screening
- Blood pressure screening
- Contraceptive counseling (when indicated)
- Depression screening
- Intimate partner violence screening
- Lipid screening
- Obesity screening and counseling
- Substance use screening and counseling
- Tobacco screening and counseling
- Urinary incontinence screening
- Hepatitis C screening (at least once in adult years)
- HIV risk assessment
- HIV screening (at least once in adult years)
- Immunizations (use ACIP recommendations)
- Breast cancer screening (use current age- and risk-related recommendations)
- Cervical cancer screening (use current age- and risk-related recommendations)
- Risk assessment for *BRCA1/2* testing

Abbreviations: ACIP, Advisory Committee on Immunization Practices; *BRCA*, breast cancer susceptibility gene; HIV, human immunodeficiency virus; WPSI, Women's Preventive Services Initiative.

visits.[17] Recommendations that correlate with the midlife years of ages 40–64 are noted in Box 2. Other guidelines are available for health care providers to use in mitigating risk factors and treating specific conditions that are identified (eg, dyslipidemia, hypertension, osteoporosis, urinary incontinence, depression, and anxiety).

Studies examining how SDOH affects the menopause experience indicate that attitudes toward menopause are influenced both positively and negatively by cultural and ethnic factors and that lower education level and socioeconomic status are associated with more severe menopausal symptoms.[18,19] Studies of the menopause experience have revealed disparities between Black and White women. Black women are more likely to experience earlier menopause, have more severe and longer lasting vasomotor symptoms, and are less likely to receive treatment for symptoms.[20,21] More research is needed to understand the factors that drive recognized inequities in menopause, including racism, discrimination, and lack of access to health care.[22,23]

The effects of menopause extend to a reduction in workforce productivity. In the United States, it is estimated that $1.8 billion is lost annually due to lost days of work related to menopausal symptoms. This does not account for unpaid work done by women or the costs associated with reduced work hours, switching to lower paying jobs, not taking a promotion, or retiring early. Black and Hispanic women report worse work-related outcomes due to their menopausal symptoms.[23,24] The EMPACT Menopause (Employee Perspectives and Challenges Concerning the Transition of Menopause) study found that one in three women experiencing menopausal symptoms considered reducing or reduced their workload. As well, two out of five women considered finding a new job, over one-third of respondents experienced presenteeism or working while feeling unwell, and less than half felt comfortable talking about their symptoms and experience of menopause at work.[25]

Implications for Practice

WHNPs and other APRNs who provide women's health care are well-positioned to support a paradigm shift that promotes wellness during midlife and menopause as more than the absence of disease.[26] They play a key role in improving the quality of health care and health outcomes for women during midlife, menopause, and beyond. Anticipatory guidance is relevant for all life transitions, including menopause and midlife. Promoting health behaviors such as nutrition, physical activity, weight management, stress management, and avoiding substance misuse before and during menopause can potentially lessen symptom severity and have positive long-term health effects.[1,27]

Person-centered, evidence-based care and shared decision-making are essential to managing menopausal symptoms effectively and promoting current and future health. A collaborative, team-based approach with other primary care providers, social workers, mental and behavioral health professionals, other specialists, and health care administrators is critical to overcoming SDOH-mediated inequities in menopause and midlife health. Within this team-based approach, WHNPs and other APRNs have an important leadership role in the development, implementation, and outcome evaluation of initiatives for improving the quality of menopause and midlife care.

NPWH Leadership

NPWH will provide leadership to ensure the following:

- Continuing education programs and resources are available to support WHNPs and other APRNs who provide women's health care in evidence-based, person-centered menopause and midlife care.
- WHNP educational programs have access to evidence-based information on person-centered menopause and midlife health care that can be incorporated into curricula.
- Collaborative engagement takes place with other organizations that support campaigns to increase public awareness about menopause and midlife health.
- Advocacy for health policies addresses SDOH influencing women's experience of menopause and their health at midlife and beyond.

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- Menopause research and quality improvement initiatives progress and include attention to diversity, equity, and inclusion.

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https://doi.org/10.1891/CJNPWH-2449

NPWH gratefully acknowledges Genevieve Hofmann, DNP, WHNP, MSCP (lead writer); Mary Fischer, PhD, WHNP-BC, MSCP; Danielle D. Grimm, MPH, MS, CNP, WHNP-BC, MSCP; Beth Kelsey, EdD, APRN, WHNP-BC; Christine A. Hart Kress, DNP, APRN, WHNP-BC, MSCP; Jennie Mastroianni, DNP, WHNP-BC, MSCP; Jaclyn Piasta, MSN, WHNP-BC, MSCP; and Heather Quaile, DNP, WHNP-BC, for their contributions as writing group members of this position statement.

Approved by the NPWH Board of Directors:
August 30, 2023

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https://doi.org/10.1891/CJNPWH-2449

Nursing-Led Volunteer Doula Program at a Large Academic Medical Center

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Doulas are nonmedical professionals who provide physical and emotional support to birthing patients.[1,2] Doulas can help with positioning, movement, and encouragement for patient autonomy during labor.[1] The cost of doula care is often prohibitive for patients. Yet research has consistently shown that doulas reduce labor time, decrease cesarean rates, improve birth outcomes, and contribute to overall patient satisfaction.[2] Of note, doulas have been shown to improve birth outcomes for patients of color.[1,2] With racial disparities in maternal mortality and cesarean rates within the United States, it is vital for doula support to be an equitable intervention for all birthing patients.

Keywords: Doulas, birth outcomes, racial disparities

Nashville Volunteer Doula Program

The Nashville Volunteer Doula Program (NVDP) was designed in 2015 by the Vanderbilt University School of Nursing's (VUSN) Midwifery Program Director at the time and a midwifery student. The program was created in partnership with Vanderbilt University Medical Center's (VUMC) Volunteer Services and VUSN's Midwifery Program to offer free labor support to patients at the VUMC and the Vanderbilt Birth Center (VBC).[3] Before COVID-19, there were almost 100 volunteers, including nursing students and community doulas. The program was suspended from 2020 to 2022 due to the pandemic and concern for increasing infection rates. However, in March 2022, the NVDP was one of the first volunteer programs allowed back in the hospital. Currently, nursing students are allowed to volunteer in the hospital in accordance with the post-pandemic guidelines instituted by the VUMC. Over the last 2 years, the program has grown to almost 40 student volunteers.

NVDP Mission

The Centers for Disease Control and Prevention define health equity as the circumstances in which each person can reach the highest health potential. Health disparities occur when at-risk populations suffer from preventable diseases due to social determinants of health.[4] Historically, maternal health and health care have been rife with disparities.

Nashville is plentiful in doula organizations; however, many come at a cost for prenatal, intrapartum, and postpartum care. The NVDP mission is to serve the Nashville community by providing equitable doula services to birthing patients. We strongly support the benefits of doula care and believe this should be available to all patients. The NVDP actively addresses health equity and disparities by offering all volunteers training and professional development opportunities. Our program also benefits nursing students by providing them with training and education on doula support. Our midwifery students find this volunteer experience particularly advantageous prior to starting their intrapartum clinical rotations. However, we have students of all specialties who volunteer because they are passionate about improving birthing outcomes and want more experience working with patients in the intrapartum setting.

Program Operations

The NVDP is led by two faculty members at the VUSN who also practice in a women's health care setting. The faculty coordinator is the program's design, evolution, and growth leader. Their primary duty is to serve as a liaison between the VUSN, VUMC, and VBC. The assistant faculty coordinator helps plan and organize continuing education events. They also play a vital role in maintaining and creating relationships with community partners. Student leadership comprised a student coordinator, continuing education coordinator, research and membership

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https://doi.org/10.1891/CJNPWH-2450

coordinator, communications coordinator, and social media coordinator. The student coordinators have a pivotal role in completing and implementing the many administrative tasks it takes to manage the program. A labor and delivery coordinator position has recently been added to the leadership team. A VUMC labor and delivery nurse filled this role to improve communication and relations between the obstetrical care team members and the volunteer doulas.

Current requirements to be a member of the NVDP are set forth by the VUMC volunteer services. Volunteers must have completed a background check by the volunteer services, be current on vaccines, and complete the safety modules that are required of all VUMC volunteers. Volunteers must be enrolled at the VUSN and attend training after being cleared by the volunteer services. This training session is a 1-day in-person session led by a local doula organization. Volunteers attend a didactic session on the phases and stages of labor and rotate through several small groups that focus on breastfeeding, labor support, and comfort measures during labor. Volunteers are also strongly encouraged to attend monthly continuing education sessions to improve their comfort level and skills in caring for laboring patients.

We recommend that volunteers sign up for at least one 8-hour shift per month. Shift coverage is offered 24/7 for the VUMC labor and delivery unit and the VBC. There is an average of 5,000 births each year in these settings. Volunteers are asked to be on the unit for the first 2 hours of their shift and to check in with the charge nurse. Given that the labor and delivery unit and the VBC are located on different ends of the Vanderbilt campus and that the labor and delivery unit has a higher volume of deliveries, volunteers are instructed to contact the VBC during their shift for any doula needs.

Volunteers are educated on their scope of practice during training and must sign a volunteer doula expectations form. Volunteers cannot perform nursing student duties or tasks while volunteering for the NVDP. Breach of scope would result in removal from the NVDP program.

As previously mentioned, the assistant faculty coordinator has worked to establish and maintain affiliations with community doulas who donate their time and expertise. Workshops are scheduled monthly and offered during the typical VUSN school day, allowing for increased attendance. Thus far, some topics covered in these workshops include peanut ball use in the second stage of labor, bereavement care, aromatherapy, movement in the first and second stages of labor, and communication techniques.

Student Volunteer Perspectives

The NVDP appeals to students when they choose a nursing program. Most of the volunteers are midwifery students who want more hands-on experience outside clinical hours. Some of the student volunteers have previous doula experience, while others do not. Many students have reported that this experience has been educational and helped them feel more confident working in the intrapartum setting. A current student volunteer stated this about the program:

> It's been such an amazing opportunity to gain doula experience and work with diverse patients. The doula role is different from the nursing student role, and I feel like the labor and delivery staff are so welcoming to me as a volunteer doula. I feel much more confident comforting moms during labor now than before I started volunteering.

Achievements

In the fall of 2021, an undergraduate Vanderbilt University anthropology student contacted the NVDP about completing an honors thesis on the impact of doula care. Over the academic year, the student worked closely with the NVDP leadership team on doula training and membership retention and even designed the leadership model that is still used today. The student's honors thesis focused on bridging the gap between Western medicine birthing practices and marginalized communities. In the spring of 2022, the student was awarded the Vanderbilt Anthropology student of the year award.

In the fall of 2022, the NVDP partnered with a faculty member from a community college in Baton Rouge, Louisiana, to start a local doula program. The NVDP assisted the program with mentorship, guidance, and support to start a volunteer doula organization that was individualized to the community. From this partnership, a nonprofit organization called Mary's Hands was created to offer free doula training for volunteers and labor support for patients.

Generous community donors have provided funding for the NVDP over the last 2 years. All donations received by the program have been used to cover training expenses or doula supplies. Annual training is the biggest expense for the program, so volunteers are charged a small fee to help pay for the cost. Supplemental funds are used to purchase helpful equipment such as peanut or birthing balls.

Future of the NVDP

The NVDP hopes to continue recruiting nursing students as volunteer doulas. This has been an invaluable experience for our students pursuing careers in midwifery or other areas of women's health. Within the last year, our volunteers have spent almost 450 hours at the bedside supporting laboring patients. We would also like to see the volunteer pool expand to community

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doulas, as they were included prior to the pandemic. Increasing the number of volunteers would result in increased doula availability and support for birthing patients. We also hope our organization can serve as an example for other nursing schools or organizations looking to improve birth outcomes within their community.

The NVDP believes that doulas provide valuable patient support that improves birth outcomes. Doula programs should be offered at more birthing institutions and have a place in nursing academia. We hope that doula support continues to grow nationwide and improve US birthing outcome trends.

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The authors received no specific grant or financial support for the research, authorship, and/or publication of this article.

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https://doi.org/10.1891/CJNPWH-2450

Effects of Sex Education on Sexual Function and Sexual Assertiveness in South Asian Women

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The purpose of the quality improvement project was to create orgasm awareness through sex education interventions. The secondary aims included improving female sexual function and sexual assertiveness in women of reproductive, premenopausal, and menopausal age.

Keywords: sex education, Kegel's exercises, orgasm awareness, orgasm satisfaction, sexual assertiveness

Orgasm is a significant indicator of fulfillment or is the centerpiece of sex. Sexual well-being and orgasms are also linked to a longer lifespan, a strengthened immune system, lower depression and anxiety, and improved relationships; the short-term effects include muscular relaxation, restful sleep, and pain reduction.[1] Even though women are physiologically capable of experiencing multiple orgasms due to having no refractory period, research has repeatedly shown that, in heterosexual sexual interactions, men experience orgasms more frequently than women. In many cultures, the talk of sex, orgasms, masturbation, self-exploration, or sexual pleasure is still outlawed or frowned upon. Additionally, a significant social stigma may exist among women, preventing open dialogue about sexual health between them and their health care providers.[2] As one illustration in a survey of patients at an outpatient clinic in New Delhi, India, showed, 82% of patients revealed that they did not report sexual issues to their gynecologists even though such issues were frequent, while 64% of women reported not discussing sexual issues with their spouses.[3] Furthermore, findings from a recent literature review identified an ongoing gendered orgasm gap that may result from societal preferences for penile-vaginal intercourse over more clitorally focused sexual practices.[4] Sexual pleasure and satisfaction are inherent component of the human sexual experience. Nevertheless, these fundamental aspects of sexuality are rarely highlighted in sexual education programs. Consequently, sexual dysfunction and sexual health are not addressed in clinical, educational, social, cultural, or personal settings.

Project Purpose

The purpose of the quality improvement (QI) project was to create orgasm awareness through sex education interventions. The secondary aims included improving female sexual function and sexual assertiveness in women of reproductive, premenopausal, and menopausal age. The Johns Hopkins Evidence-Based Practice Model for Nursing and Healthcare Professionals was used to determine the need, provide structure, and aid in putting the evidence into practice for this project at a South Asian women's organization in Southern California.[5] A pretest–posttest design was used to measure the project's impact on meeting its purpose and aims.

Description of Setting/Population

A South Asian women's organization with over 1,500 members was the distinctive population for this QI project. The members communicated virtually through social media forums like Facebook and WhatsApp groups and in person through monthly meetings, which mainly consisted of educational and fun activities. The population, primarily composed of women of reproductive, premenopausal, and menopausal ages, presented a unique project context and group at high risk for lack of sex talk and orgasms due to their conservative cultural background, which generally promotes modesty.

Participants were recruited through flyers advertising the educational event on the group's Facebook and multiple WhatsApp groups. Group members registered to participate in the project using a link or quick response code on the flyer.

Description of Intervention

The design of the intervention was based on a review of literature that included 14 studies revealing that sexual health education and Kegel exercises could be utilized as two cost- and time-effective, nonpharmacologic methods to improve

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https://doi.org/10.1891/CJNPWH-2430

women's sexual satisfaction and assertiveness. The project leader-conducted intervention comprised three integral components: (a) a single, in-person, 2-hour sex education session; (b) an informative infographic flyer (Figure 1) designed by the project leader for the attendees of the sex education session to review in the comfort of their homes; and (c) a follow-up phone call by the project leader during week 2 meant to answer queries and reinforce teaching. The organization's leadership helped find a safe and secure location for the 2-hour session during one of the monthly



Figure 1. Informative infographic flyer (created by the project leader).

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meetings. The education topics were developed based on the literature reviewed and included the following:

- Icebreaker activity: draw and label the vulva
- Sexual anatomy
- Orgasm gap
- Sexual activity
- Sexual response cycle
- Changing sexual script to promote female orgasm
- Skills and ideas to empower women to orgasm, including masturbation
- Kegel's exercise
- Mindfulness
- Variety of realistic genital appearances
- Body shaming
- Views, values, and feelings about sexual issues
- Genital hygiene/care
- Sexual communication
- Group activities/discussions: sexual communication scenarios

In response to participants' requests and the first session's popularity, the intervention was scheduled for a second date as a 2-hour live video conference, which included the advertisement of the event, registration, and all three interventions as mentioned above components for the participant's friends, female family members, and other organization members.

Methods to Evaluate Outcomes

The project was reviewed and deemed a QI project by the institutional review board criteria; therefore, full approval was not required. Participant confidentiality was maintained throughout the project using the secure Research Electronic Data Capture web-based survey system. Personal information was separated from all other survey information and used only for follow-up phone calls, and $5 gift cards were sent as a token of appreciation to participants who completed all surveys.

The outcomes for the project were measured by the Female Sexual Function Index-Modified (FSFI-Modified) scale and the Sexual Assertiveness Questionnaire (SAQ) over 4 and 8 weeks, following a single sex education session with Kegel exercise training. The FSFI, comprising 19 questions measuring desire, arousal, lubrication, orgasm, satisfaction, and pain, was the primary outcome measurement tool among six studies in the literature review. However, FSFI-Modified, comprising 12 questions measuring all six domains, with good internal consistency (α value >0.70) for the desire, arousal, and dyspareunia, and moderate internal consistency (α value = 0.60) for the lubrication and orgasm subscales and discriminant validity, was selected for this project to avoid survey fatigue and comply with organizational leadership requests for shorter surveys.[6] Sexual assertiveness is an essential component of feeling entitled to and promoting one's orgasm in sexual relationships. Four of the studies reviewed utilized the SAQ, which has good reliability comprising communication regarding sexual initiation and satisfaction (α = 0.79), refusal to unwanted sex (α = 0.78), and sexual history (α = 0.81), with no validity indicated.[7] Permission for use was received from the authors of both scales.

The presurvey developed by the project leader for demographic data, the FSFI-Modified, and the SAQ were collected before the start of the session on the day of the intervention. A postsurvey (including the FSFI-Modified and the SAQ) was emailed in 4 and 8 weeks. Paired *t* tests were used to analyze the FSFI-Modified and the SAQ means from the pre- and postsurveys.

Outcomes

Of the 33 in-person intervention participants, 28 completed the presurvey, 27 completed the postsurvey at 4 weeks, and 26 completed the postsurvey at 8 weeks. Out of 36 participants in the live video conference intervention, 26 completed the presurvey, 22 completed the postsurvey at 4 weeks, and 21 completed the postsurvey at 8 weeks. The mean age of the participants was 48.5 years (range, 37–60 years). Most participants reported heterosexual preferences (n = 52), while one participant reported a homosexual preference and one participant reported being bisexual. Majority had no preexisting diseases (n = 24) and no preexisting medications (n = 25; see the Table for demographic details).

After 8 weeks, the mean for sexual assertiveness, as measured by the SAQ, increased from 86.68 to 93.92 (P = .002) in the in-person intervention group, and 79.19 to 86.52 (P = .005) in the video conference intervention group (see Figure 2). After 8 weeks, the FSFI-Modified score improved from 40.6 to 43.28 (P = .09) for the in-person intervention group. In the video conference intervention group, the overall FSFI-Modified score at 8 weeks improved significantly from 33.29 to 38.24 (P = .05; see Figure 3). Also, Kegel exercises improved from "no Kegel exercises" to being mostly performed "1–3 times per week or whenever possible" in both groups.

During follow-up phone calls, the participants reported that education was much needed and was delivered in a culturally sensitive manner. They reported feeling anxious and hesitant prior to the presentation but felt very relaxed as soon as the icebreaker activity was done. Postintervention, the participants reported the following in the written posteducation survey and verbal comments:

> "Now, I feel more in control and feel less shame in seeking orgasm from my partner."
>
> "I wish I had learned about all this 20 years ago!"
>
> "It is my right to prioritize myself and my pleasure."
>
> "Thank you for doing this and being so courageous in talking about women's orgasms!"

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Table. Demographics

CHARACTERISTICS	IN-PERSON AND LIVE VIDEO CONFERENCE INTERVENTION GROUPS (N = 54)
Age, mean (range)	48.5 (37–60)
Marital status, *n*	
Married	48
Divorced	3
Separated	1
Widowed	1
Single	1
Education, *n*	
Bachelor's degree	28
Master's degree or above	23
Diploma	1
Occupation, *n*	
Full-time	37
Homemakers	6
Self-employed	5
Part-time	4
Total children, *n*	
2	36
1	8
3	6
None	1
Births, *n*	
Vaginal births	49
Cesarean section	43
Sexual preferences, *n*	
Heterosexual	52
Homosexual	1
Bisexual	1
Preexisting diseases, *n*	
None	24
Thyroid disease	14
Type 2 diabetes	12
Hypertension	6

(*continued*)

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Table. Demographics (*continued*)

CHARACTERISTICS	IN-PERSON AND LIVE VIDEO CONFERENCE INTERVENTION GROUPS (N = 54)
Anxiety	5
Allergies	2
Breast cancer	1
Depression	1
Connective tissue disorder	1
Preexisting medications, *n*	
None	25
Thyroid medications	14
Diabetes medications	11
Antihypertensives	6
Antiallergy	3
Antidepressants	2
Heart medications	1
Painkillers	1
Antianxiety	1
Cholesterol-lowering medications	1

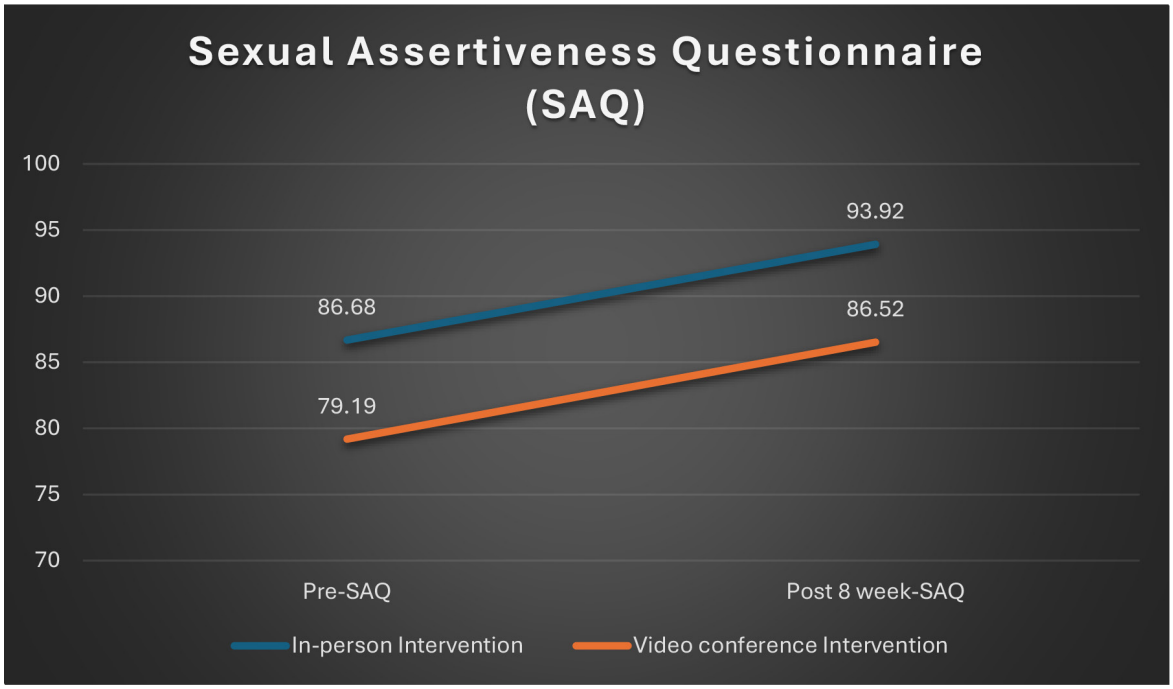

Figure 2. Sexual Assertiveness Questionnaire (SAQ) results.

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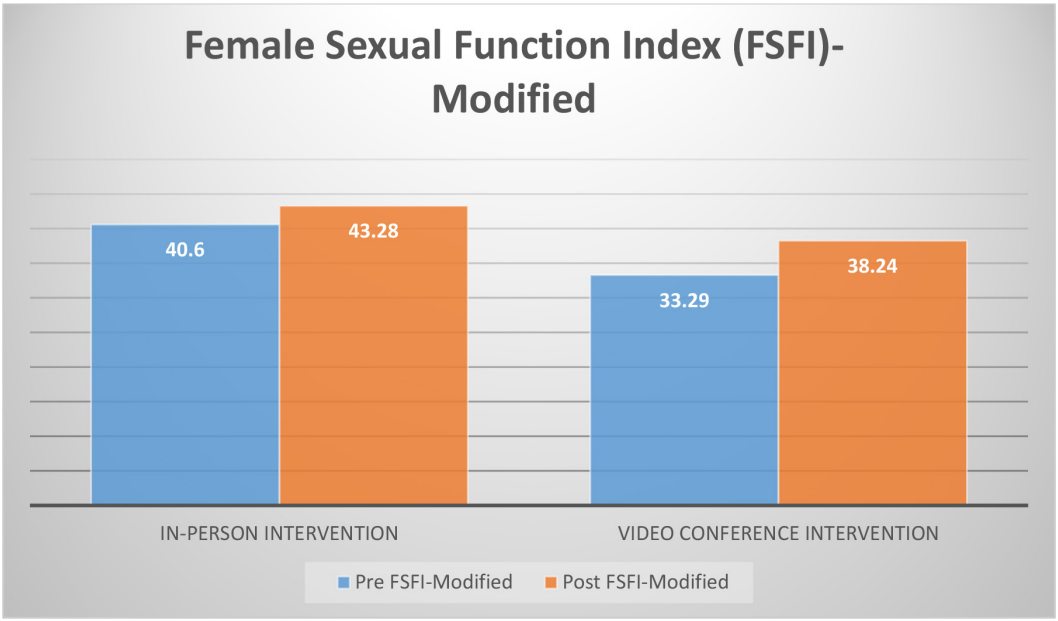

Figure 3. Female Sexual Function Index (FSFI)-Modified results.

The participants expressed relief to talk about orgasm and sexual difficulties finally in a safe setting. During follow-up phone calls (n = 38 accepted the call), most participants reported feeling more assertive about their sexual needs and that they felt more equipped to discuss their orgasms, script changes, and techniques to promote their orgasms with their spouses. Additionally, some of the participants were excited to buy vibrators or vibrating dildos to try masturbation or use it during partnered sex and reported finally experiencing an orgasm. Some reported discussing with other friends and female family members. Some participants reported sharing the educational pamphlet with their spouses. Finally, some of the participants reported having discussions about women's sexual health among their family members.

Discussion

Among the multiple factors involved in sexual dysfunction, in addition to sex education about female orgasms and strengthening the pelvic floor, teaching women about exploring self, feeling empowered, and feeling positively assertive appears to have an essential influence on improving female sexual function and assertiveness as per the literature. In one study, almost all sexual functioning measures improved among female students of undergraduate human sexuality courses from pretest to posttest as compared with participants who were not enrolled in the course.[8] Furthermore, sexual health education has been noted as a favored strategy for boosting sexual assertiveness and satisfaction in newly married women as it does not require complex counseling skills like cognitive-behavioral therapy requires.[9]

Thus, despite this project being a QI, pre- and posttest project with no control group and held with a population of South Asian women aged 37–60 years, sexual assertiveness improved significantly, as measured by the SAQ. This remarkable increase in sexual assertiveness may encourage participants to seek clitoral stimulation during sexual activity and feel equipped to discuss strategies to enable orgasm with their partners. According to a recent literature review, equal assertiveness between partners increases the likelihood that their personal sexual desires will be sufficiently expressed and fulfilled.[10] Moreover, group education is cost- and time-effective, allowing interested providers to incorporate it within their patient population.

Due to the topic's popularity and sustainability, the project leader was invited to the organization's International Women's Day event to give a 30-minute summarized version of the same presentation without group discussions and elaborate Kegel exercise training to a different set of members, with significant effect assessed from audience comments and responses. Thus, this project and sustainability intervention demonstrated that specific elements of sexual function in reproductive, premenopausal, and menopausal women could be improved through direct, culturally sensitive teaching methods that are easy to apply, require minimal resources, and potentially take only 30 minutes. Consequently, there is an ongoing assessment of the feasibility of annual sex education classes via in-person or video conference for sustainability in this organization.

Family and women's health care providers are encouraged to become aware of the orgasm gap and the role of cultural upbringing in sexual assertiveness, learn more

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about addressing sexual issues throughout the lifespan of their female patients, and encourage dialogue about sexual function. Providers must recognize that holistic and patient-centered education on sexual health can positively affect their patients' and families' lives.

Conclusions

The limitations of this project included the data collection time of only 8 weeks, which may not have been enough time for participants with multiple work and family responsibilities to engage in regular sexual activities. During the time of data collection after the in-person intervention, popular South Asian religious activities may have taken precedence over sexual activity. Additionally, some participants reported no sexual activity due to being away from their spouses because of work, travel, or life events. Another limitation included the inability to objectively assess commitment level to Kegel exercises; the participant's state of mind, relationship, or feelings toward their partner; feeling overwhelmed due to multiple responsibilities; and time crunches while taking the survey. A further notable limitation brought to light by the participants was the absence of a sex education program for their sexual partners.

Despite the limitations, in this population of South Asian women with a conservative cultural background that generally promotes modesty, the education session enhanced sexual assertiveness, orgasm satisfaction, and orgasm awareness, thus positively impacting their lives and opening conversations within their families. Finally, improvements in this critical aspect of a woman's well-being can improve their quality of life and extend to other areas, including their family. This project aligned with the organization's mission of women empowerment and therefore was well-positioned to stimulate change.

Acknowledgments

Special thanks to Dr Angela Jun, DNP, FNP-BC, ACHPN (team member and participating investigator), Dr Seema Choudhary, PhD (site mentor), Namrata Singh, MS (site mentor), Franny Shah, MEd (site champion), Dr Sanghyuk Shin, PhD (statistician), and Steve Clancy, M.L.S. (research librarian).

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Disclosure

The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding

The authors received no specific grant or financial support for the research, authorship, and/or publication of this article.

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