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AMGA Member Best Practices

*The Strength of Primary
Care Providers to Educate
and Empower Women to
Receive Evidence-Based Care
for Heavy Menstrual Bleeding
(HMB) Associated with Uterine
Fibroids (UFs)*

The Strength of Primary Care Providers to Educate and Empower Women to Receive Evidence-Based Care for Heavy Menstrual Bleeding (HMB) Associated with Uterine Fibroids (UFs)

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Larkin



Valbrun



As-Sanie

Patient at the Center

Tanika Gray Valbrun, founder and CEO of the White Dress Project, started the webinar with her life experience with uterine fibroids (UFs). Her symptoms started at the age of 15 and were exhibited by heavy menstrual bleeding and excruciating pain that resulted in need for multiple blood transfusions. The only treatment offered was a dilation and curettage (D&C). She described a challenging patient journey that taught her the importance of self-advocacy to receive acceptable quality of care. She shared, “As a Black, female, empowered patient, I had to use every strategy and tactic to navigate the healthcare system, to get informed, and receive acceptable quality of care. [I learned] that no one knows my body better than me, and I need to be a partner in my treatment.”

Women May Not Be Getting the Healthcare They Need Overall

Dr. Lisa Larkin, founder and CEO of Ms. Medicine, reviewed barriers to women receiving evidence-based care such as lack of education, lack of focus/awareness, and limitations to our healthcare systems. She stated that often primary care providers are not focused on women’s health issues, women’s health education is limited during medical school, and training during residency is variable. She discussed how healthcare delivery models for primary care negatively impact care of women who have complex health conditions that cannot be addressed during a brief 5–10-minute consultation. The focus of such visits is on doing damage control, and women may not feel empowered to seek

answers to their healthcare questions. Finally, she stated that conditions specific to women (e.g., endometriosis, polycystic ovarian disease, fibroids, menopause, women's sexual health) have been underfunded and under researched, so data are lacking.

Women's Health Focus on UFs: Treatment Gaps and Unmet Needs

Uterine leiomyomas (fibroids) are solid neoplasms composed of smooth muscle cells and fibroblasts.¹ Despite 25% to 50% of women with fibroids being symptomatic, data demonstrate that UFs are often undiagnosed and undertreated due to lack of disease awareness among both patients and providers, societal stigma around menstruation, and the lack of knowledge regarding normal bleeding.² Despite the significant psychological impact of UFs on women, few seek help from mental health professionals.³ On average, women wait 3.6 years to seek treatment, and 41% visited at least 2 healthcare providers before diagnosis.⁴ Limited knowledge of UFs and normal menstruation may lead to women having a distorted view of what is normal and when to seek medical treatment. The most common cited reason for delayed diagnosis was perception that what they were experiencing was normal.⁵

Barriers to Care and Speaking Up

Keeping the patient at the center of care requires women's voices to be heard. As a patient with UFs, Ms. Gray Valbrun reminded participants that "every patient story has value, and if a patient shares their personal story and is explicit about their symptoms having a negative impact on quality of life, the information should be valued and inform treatment options." As the founder of a patient advocacy organization, she asks providers to "listen, serve, educate, and help to marry the science with the patient's experiences by seeking to understand belief systems, education, family history, and access when communicating and caring for the patient."

Disease Burden

U.S. studies demonstrate that about 70% of women will have fibroids before menopause,⁶⁻⁸ and of those women, 25% will experience debilitating symptoms that require treatment.^{6,9} About 70% of women who seek treatment have surgery. In fact, 30% to 50% of all performed hysterectomies are related to fibroids.^{10,11} Further, 30% of hysterectomies are performed in women between 18 to 44 years of age,¹¹ and 29% of gynecologic hospitalizations among patients 15-54 years of age are related to fibroids.¹² Data show that \$4.1-\$9.4 billion is spent annually related to surgery, hospital admissions, outpatient visits, and medications for fibroids.¹³

Risk Factors

Risk factors for UFs include: increased age (until menopause), race (Black/African-American women are 2-3 times at greater risk than white women), nulliparous, and obesity.^{14,15} Data from National Health and Nutrition Examination Survey (NHANES) Reproductive Health Surveys, conducted from 1999 to 2006 in 41,474 U.S. women, indicated the average diagnosed prevalence rate for UFs was 11.9%. Rates increased with age at time of survey completion, and the highest prevalence of UFs was among women aged 50-54 (24.9%). Prevalence of UFs was higher in Black/African-Americans (18.9%) than in whites.¹⁶

Symptoms of UFs

Heavy menstrual bleeding (HMB) is the most common and burdensome symptom of UFs.¹⁸ In fact, one-third of women with UFs will suffer from HMB.¹⁸ HMB is quantitatively defined as menstrual blood loss (MBL) >80 mL per cycle in both research and clinical settings,^{18,19} and may also be defined as excessive MBL that interferes with a woman's emotional, physical, and social quality of life.^{2,20} HMB is manifested by flooding (defined as a change of pad or tampon more frequently than hourly) and/

or prolonged menses.²¹ Although HMB is the most common symptom of UFs, menstrual patterns are not commonly discussed during primary care visits. In efforts to maintain patient focus and overcome any stigmas around menstrual bleeding, Dr. Larkin advocates to proactively ask women about their menstrual cycles and probe to learn if their bleeding keeps them up at night, how often, and if bleeding through their tampon or pad when in bed. Patients may also present with fatigue and/or severe iron deficiency anemia, which is often directly tied to the HMB. Pain is the second most common symptom for women with UFs,⁷ and the experience of pain in women with UFs is individual and spans a range of pain symptoms, with dysmenorrhea and pelvic pain frequently encountered. Pain can significantly impact a woman's quality of life (QoL) and impairs daily activities.²² The chronicity of UFs symptoms can have a significant negative impact on overall QoL.³

Patient Evaluation

A thorough patient history and assessment of menstruation is critical to the patient evaluation process. Dr. As-Sanie advocates to incorporate a series of questions into the routine exam, such as:

- What are your periods like?
- Are they heavy?
- Are they regular?
- What is the amount of flow that you have?
- How many days do you bleed?
- How many days is that bleeding heavy?
- Are they constipated?
- Do they have pain and what type?
- Are they fatigued?
- Are they tired?

In the early 2000s, the International Federation of Gynecology and Obstetrics convened a team to develop a classification system for underlying causes of abnormal bleeding in women of reproductive years that are not pregnant (Figure 1).²³ The FIGO

Figure 1: FIGO Uterine Bleeding Differential Diagnosis

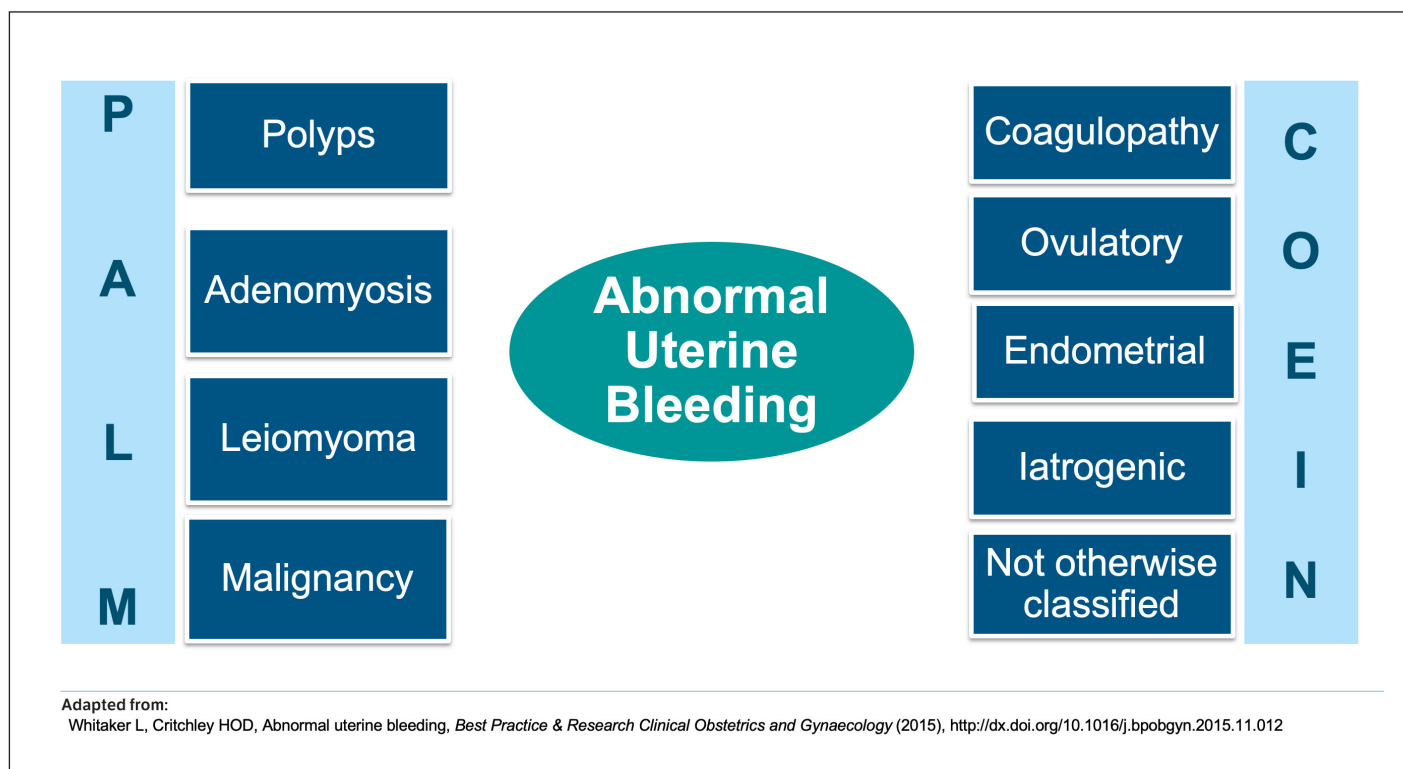
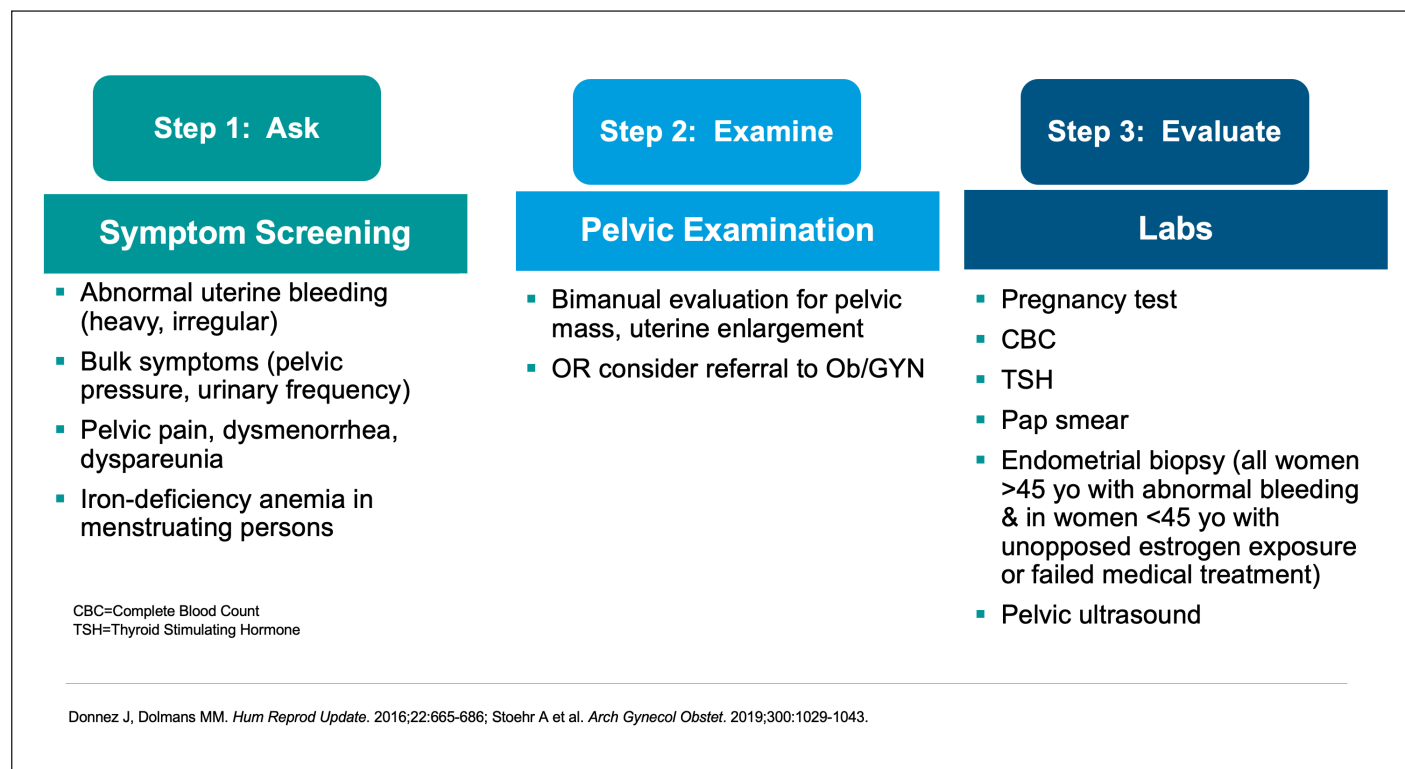


Figure 2: Diagnosis of UFs



classification is important for a differential diagnosis, and Dr. As-Sanie stresses that the patient interview is also a critically important piece.

Dr. An-Sanie also provided context for Figure 2 regarding an approach for eliciting necessary information to diagnose UF.²² **Ask** involves a discussion with the patient about symptoms that they may be experiencing. **Examine** focuses on the importance of a bimanual pelvic examination to assess for uterine enlargement or pelvic mass. Of note, if a pelvic exam is out of scope for the provider, then a gynecology referral is recommended. **Evaluate** involves a laboratory evaluation that includes a pregnancy test to make sure that bleeding is not related to an early pregnancy, a complete blood count to assess for anemia with iron studies as indicated, and a thyroid screening for any patient with abnormal bleeding either in quantity or frequency. A Pap smear is useful to rule out an underlying diagnosis, such as cervical cancer, that can be missed, particularly in patients who have not had regular screening prior

in their life.²² If hyperplasia is noted on a Pap smear, per the American College of Obstetricians and Gynecologists (ACOG), *ACOG Bulletin*, an endometrial biopsy is recommended for:¹

1. All women who are over the age of 45 with abnormal bleeding
2. Women under the age of 45 who either have a history of unopposed estrogen exposure (e.g., hydrogenic estrogen exposure or physiologic unopposed estrogen exposure), such as patients who do not have regular menses (less than three or four menstrual bleeds per year that are not due to hormonal suppression)
3. Patients who have other risk factors for endometrial cancer, such as morbid obesity, or patients who are younger than 45 who have not had improvement in the bleeding despite medical treatment

ACOG further states that pelvic ultrasound is considered the gold standard (90%-99% sensitivity) and is the preferred imaging for patients who have any

type of abnormal bleeding to identify most uterine fibroids as well as other pathologies (e.g., adenoma, meiosis, and ovarian masses). If further assessment is needed, referral to a gynecologist is recommended. Imaging is critical because the size, location, and number of fibroids informs the types of treatment that is most likely to result in a positive response for a given patient. It is important to recognize that fibroids can occur anywhere within the uterus.²²

Treatment Strategies

Figure 3 describes the ACOG 2021 Practice Bulletin Management of Symptomatic Uterine Leiomyomas.¹ Selection of therapy depends on severity of symptoms, patient age (pre- or peri-menopausal), desire to preserve uterus and/or fertility, and fibroid location, size, and most important, the individual patient’s treatment goals. Critical questions include whether the symptoms are related to abnormal

bleeding, pelvic pressure, bowel dysfunction, or a combination. Figure 4 provides an overview of the current treatment landscape.

Expectant management of uterine leiomyomas can be considered for patients who are asymptomatic or for those who do not desire intervention. Patients should be counseled to return for follow up if symptoms become bothersome or if active management or pregnancy is desired. Expectant management may be particularly appropriate in patients who do not have bothersome symptoms or are experiencing perimenopausal symptoms.


Medical treatment options for uterine leiomyomas include: agents that address only bleeding symptoms such as gonadotropin releasing hormone [GnRH] antagonists, levonorgestrel releasing intrauterine devices [LNG-IUDs], combination contraceptives, and tranexamic acid. Medications

Figure 3: Management of Symptomatic Uterine Leiomyomas


American College of Obstetricians and Gynecologists (ACOG) 2021 Practice Bulletin Management of Symptomatic Uterine Leiomyomas

Key to Treatment Selection


- Provide evidence-based recommendations for the management of symptomatic leiomyomas




CLINICAL
SURVEILLANCE



MEDICAL
MANAGEMENT



PROCEDURAL
INTERVENTIONS



SURGICAL
MANAGEMENT

- Acknowledge that comparative evidence is lacking for leiomyoma management options
- Emphasize counseling and a patient-centered shared decision-making approach
- Acknowledge and focus on racial disparities in disease presentation, severity, treatment, outcomes, and quality of life for Black women compared with White women with UF

Adapted from:
ACOG Practice Bulletin Summary, Number 228. *Obstet Gynecol.* Jun 1 2021;137(6):1131-1133.

Figure 4: UFs – Current Treatment Landscape

Treatment Options ¹⁻⁴		
Medical	Procedural Interventions	Surgical
<ul style="list-style-type: none"> • Combined oral contraceptives* • GnRH agonists[†] • GnRH antagonist combination therapy[‡] • NSAIDs* • Progestins: oral, intrauterine system* • Selective progesterone receptor modulators (SPRMs)* • Tranexamic acid* 	<ul style="list-style-type: none"> • Endometrial ablation[§] • Fibroid radio-frequency ablation (RFA)[§] • Focused ultrasound (MRgFUS)[§] • Uterine artery embolization[§] 	<ul style="list-style-type: none"> • Hysterectomy (laparoscopic, vaginal or abdominal)[§] • Myomectomy (laparoscopic, hysteroscopic or abdominal)

Treatment Goals ¹
<ul style="list-style-type: none"> • Relieve signs and symptoms, such as abnormal uterine bleeding, pelvic pressure, bowel dysfunction, etc. • Sustain reduction of the size of fibroids • Maintain fertility (if desired) • Avoid harm

Asymptomatic UFs ⁴
<ul style="list-style-type: none"> • Watchful waiting and clinical surveillance are recommended

*Not FDA approved for UFs or UF-related symptoms
[†]FDA approved for improving hematologic parameters prior to surgery for UFs
[‡]FDA approved for heavy menstrual bleeding associated with UFs
[§]Not fertility-sparing
 GnRH=gonadotropin-releasing hormone; MRgFUS=magnetic resonance-guided focused ultrasound; RF=radiofrequency.

Adapted from:
 Bulletin No. 228. *Obstet Gynecol.* 2021; 137:e100-e109.

that reduce both bleeding and leiomyoma size include GnRH agonists and selective progesterone receptor modulators. Some medical therapies for UFs are indicated for long-term use, whereas others are meant to be a bridge to surgical treatments, interventional procedures, or menopause.

Surgical treatment options for UFs include myomectomy and hysterectomy. Goals of treatment should be defined for each patient, including desire for uterine preservation and future fertility, as well as primary symptomatology, including bleeding and bulk symptoms. The most minimally invasive route is recommended whenever feasible.¹

Dr. As-Sanie presented her evidence-based approach to care, emphasizing that you need to consider the patient’s desire to preserve fertility as well as the patient’s presenting symptoms to optimize care for women with UFs.

Dr. As-Sanie concluded her comments by stating that it is critical to ask, examine, and evaluate when providing evidence-based care for your patients with UFs.

Ms. Valburn concluded with stating, “The physician patient dynamic is often a heart-to-heart language, and the relationship can be strengthened through the acknowledgement of your own implicit bias.... Being a true champion for your patients is a key takeaway that I hope really resonates with you.”

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