

Heavy Menstrual Bleeding: Update on Best Practices and New Options

■ Patricia J. Sulak, MD

Test your diagnostic and patient management skills with this educational activity.

Heavy menstrual bleeding (HMB) affects one-third of all women at some point in their lives.^{1,2} In western countries, approximately 5% of reproductive-aged women seek treatment for HMB each year.¹ Women who experience this condition are significantly more likely to use health care than are women who experience normal flow.¹ The economic impact of lost time from work associated with HMB has been estimated at \$1,692 per woman; in addition, women who experience excessive menstrual flow are more likely to be unemployed.³

HMB has a major impact on a woman's quality of life.⁴ Effects may include fear, anxiety, or worry about the possibility of bleeding through clothing during menstruation.⁵ Sexual activity is often diminished during menstruation, with potential negative effects on relationships.⁶

Although HMB may be clinically defined by specific measures of blood loss, it may be best assessed by evaluating the degree to which bleeding affects the individual patient.^{7,8}

Clinical questions asked of the patient may most appropriately include:

- Does the duration or amount of bleeding interfere with daily activities?
- Does the bleeding pattern impact the patient's quality of life?

Significantly, more than half of women who experience HMB curtail social activities because of this condition.⁹ Millions of American women experience monthly periods heavy enough to sap energy, cause anemia, and interfere with many daily activities.^{10,11}

Cyclic heavy menstrual bleeding: Reproductive hormones and hemostasis

The menstrual cycle is characterized by fluctuations of estrogen and progesterone (Figure 1). It is also regulated by hemostatic factors. In the normal menstrual cycle, vasoconstriction (caused by prostaglandin F_{2α}) and platelet aggregation (caused by thromboxane) are balanced by vasodilation (caused by prostaglandin E₂) and platelet inhibition (caused by prostacyclin).

HMB often results from an imbalance of vasoconstrictors and vasodilators (Figure 2), among other etiologies. Levels of vasoconstrictors decrease; levels of vasodilators increase. The overall result is increased fibrinolytic activity and increased blood loss. Research has confirmed increased uterine fibrinolytic activity in women who have HMB.¹²

Factors that lead to abnormal hemostatic function may be inherited (e.g., von Willebrand disease, hemophilias), result

CE INFORMATION

■ FACULTY

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■ INTENDED AUDIENCE

This continuing education (CE) activity has been designed to meet the educational needs of nurse practitioners (NPs) involved in women's health.

- CE Approval Period: October 1, 2011 through September 30, 2012
- Estimated Time to Complete This Activity: 0.5 hour

■ PROGRAM DESCRIPTION/IDENTIFICATION OF NEED

This program was developed to address educational needs identified by survey and feedback during the 2010 NPWH annual meeting.

■ EDUCATIONAL OBJECTIVES

At the conclusion of this activity, clinicians will be better able to:

- Identify patients who experience heavy menstrual bleeding
- Provide effective management for patients
- Evaluate the utility of available pharmacologic agents and procedures
- Assess the risk/benefit profile of available agents and procedures

■ ACCREDITATION STATEMENT

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), and each activity has been approved for 0.5 contact hour of CE credit, including 0.5 contact hour of pharmacology content.

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- Dr Sulak reports that she receives consulting fees from Teva Pharmaceuticals and has received fees for promotional services from Bayer HealthCare Pharmaceuticals and Merck and for contracted research from Bayer.

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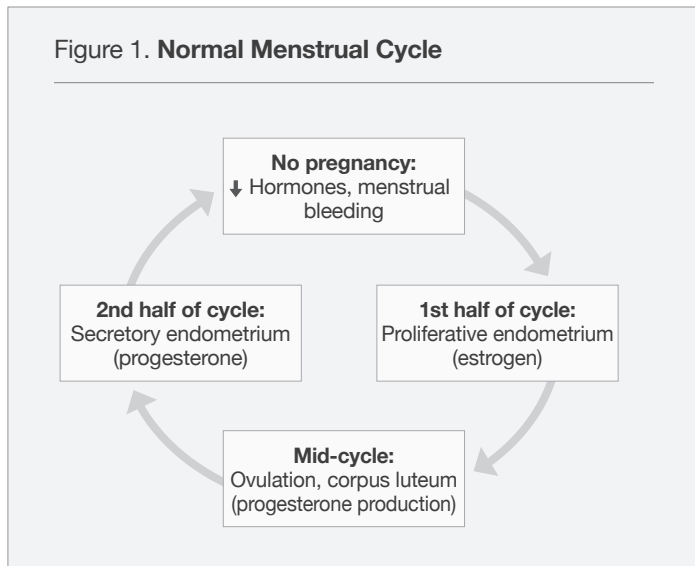
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■ SUCCESSFUL COMPLETION OF THE ACTIVITY

Successful completion of this activity requires the participant to: (a) read the learning objectives, disclosures, and disclaimers; (b) study the material in the learning activity; (c) during the approval period: 1. log on to the NPWH web site (<http://www.npwh.org>), 2. click on CE Activities in the Professional Education dropdown at the top of the page, 3. open the *Heavy Menstrual Bleeding: Update on Best Practices and New Options* post test and evaluation, 4. print out the evaluation and post test, 5. complete and return the activity evaluation and post-test answers only to the address or fax number on the post-test/evaluation form, (d) to receive CE credit, a score of 70% or better on the post test is required.

■ COMMERCIAL SUPPORT

This program is made possible by an educational grant provided by Ferring Pharmaceuticals.



from pathologies, or be associated with the use of anticoagulants, aspirin, or other agents.

Patient assessment

Patient evaluation for HMB should include the questions listed in **Table 1**, along with patient history, vital signs, abdominal exam, and pelvic exam. See **Table 2** for recommended laboratory and other tests.

Management of HMB

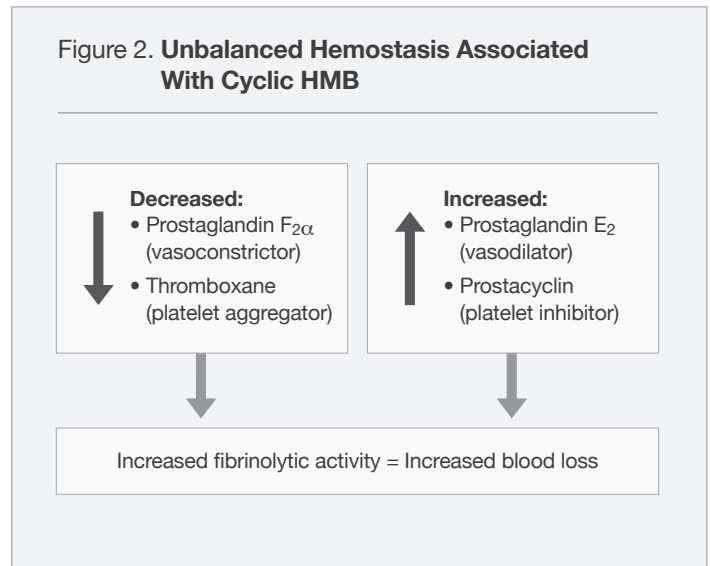
A variety of medical and surgical treatments is available for the management of HMB. See **Table 3** for common HMB treatments and potential unwanted outcomes.

Nonsteroidal anti-inflammatory drugs (NSAIDs) decrease bleeding when given immediately before or on the first day of menses for up to 5 days. However, the majority of patients do not experience sufficient symptom relief.¹³

Hormonal agents

Options include oral contraceptives (OCs), progestins, and the levonorgestrel (LNG) intrauterine device.

Oral contraceptives are often used off-label to manage HMB, despite limited data.¹⁴⁻¹⁶ Studies suggest that continuous OCs may be more effective than OCs with a hormone-free interval. Numerous clinical trials have shown that continuous OC regimens induce amenorrhea in 80% to 100% of women



by 10 to 12 months of use. For women who do not wish to become pregnant, a continuous OC regimen should be an available option.¹⁴

Regimens with extended or shortened hormone-free intervals have also demonstrated efficacy. A 2002 publication assessed patient acceptance and use of OCs with extended active-pill administration beyond 21 days and/or a shortened hormone-free interval to reduce the frequency and severity of hormone withdrawal symptoms.¹⁵ Of the 318 participants, 21% reported symptoms of dysmenorrhea, and 19% reported symptoms of hypermenorrhea. A total of 267 patients initiated an extended regimen. Of that total, 57 discontinued OCs, 38 returned to a standard regimen, and 172 continued use of an extended regimen. At 5 years, 46% ± 5% (mean ± standard error) continued a regimen of 12 ± 12 (mean ± standard deviation) weeks of active pills (median of 9 weeks and range to 104 weeks) with a pill-free interval of 6 ± 2 days (median of 5 days and range of 0-7 days).

Bleeding patterns associated with an extended OC regimen were further evaluated in a single-center prospective analysis.¹⁶ Patients (n = 111) self-rated menstrual flow during a 21/7-day versus a 168-day extended regimen of one OC (3 mg of drospirenone and 30 µg of ethinyl estradiol). A 21/7-day pre-extension cycle evaluated pre-study flow levels. A total of 102 patients (92%) completed the 168-day regimen. Participants who experienced a heavier daily flow rating during the pre-study cycle had greater daily flow ratings (*P* < .001) and tended to have earlier occurrence of breakthrough bleeding (*P* = .07) than did participants with a lighter pre-study flow. Patients

who experienced breakthrough bleeding or breakthrough spotting for 7 consecutive days or more were randomized to 2 arms: (1) a 3-day hormone-free interval, or (2) continuous active pills. Patients who had a 3-day hormone-free interval were less likely to continue to experience breakthrough bleeding/spotting than were patients who continued to use active pills ($P < .0001$). The likelihood of breakthrough spotting/bleeding was similar among patients with heavier pre-study daily flow ratings and those with lighter flow ratings ($P = .53$). The authors concluded that bleeding was effectively managed with the use of a 3-day hormone-free interval.

A 2005 Cochrane review of continuous or extended-cycle combination OCs versus those used in the traditional pattern evaluated 6 randomized, controlled trials. Bleeding patterns associated with continuous dosing were equivalent or improved in 5 of the 6 trials considered, compared with the 21/7-day regimen.¹⁷ Increased breakthrough bleeding and spotting, however, can be a drawback to extended- and continuous-cycle combination OC use.¹⁸

Bleeding patterns may differ among agents. In one study, over the course of 180 days, 139 subjects received a pill containing one of the following:

- 100 µg LNG/20 µg ethinyl estradiol (E₂)
- 100 µg LNG/30 µg E₂
- 1000 µg norethindrone acetate (NETA)/20 µg E₂
- 1000 µg NETA/30 µg E₂

During continuous dosing, the use of OCs containing 1000 µg NETA resulted in more days of amenorrhea and fewer days of spotting than preparations containing 100 µg LNG.¹⁹

Most recently, a study compared E₂ valerate/dienogest with placebo. The active treatment arm showed an approximate 70% reduction in mean blood loss, compared with a 19% reduction in the placebo group.²⁰

Progestins. Depot medroxyprogesterone acetate inhibits ovarian function, typically resulting in amenorrhea within 1 year in 60% of patients and within 2 years in 80% of patients. Oral progestins have also been studied. Medroxyprogesterone (10 mg daily for 10 days, beginning on cycle day 16) has been shown to reduce blood loss by 21.5% at 6 months.²¹ NETA (5 mg three times daily on cycle days 5-26) reduced bleeding by 87% after 3 cycles. However, only 22% of participants wished to continue treatment.²² Ovulatory bleeding typically requires treatment with higher doses/longer intervals than does anovulatory bleeding, making this treatment option impractical for long-term management of HMB.

Intrauterine devices. The LNG intrauterine system (LNG-IUS) provides an effective treatment method to reduce HMB.²²⁻²⁵ The device releases LNG, a progestin used in many combination OC products, at a rate of 20 µg/d for at least 5 years. A study enrolling women with menstrual blood loss of more

Table 1. Evaluation of Heavy Menstrual Bleeding History

- Is heavy bleeding cyclic?
- Is heavy bleeding chronic?
- Does the duration/amount of bleeding impact daily life?
- What contraceptive method does the patient use?
- What are plans for childbearing?
- Does the patient have a history of bleeding disorders?
- Does the patient experience bleeding with surgery or dental procedures?

Table 2. Recommended Laboratory Tests and Other Investigations

- Complete blood cell and platelet counts
- Coagulation studies may be advised if the patient history includes:
 - Heavy menstrual bleeding since menarche
 - Bleeding postpartum, during surgery or dental procedures; nosebleeds, gum bleeding, or bruising
 - Family history of bleeding
- Thyroid function
- Pap test, if the patient is due for one; if not, obtain result of last Pap Test
- Endometrial biopsy, if the patient is at risk for hyperplasia
- Transvaginal sonography, if the pelvic exam produces inadequate or abnormal results

than 80 mL per cycle found that the LNG-IUS was associated with a progressive decrease in blood loss over time: 78.7% by 6 months, 83.8% by 12 months, and 97.7% by 24 months. The reduction in blood loss was associated with a significant increase in hemoglobin and serum ferritin levels.²⁶ Another study reported an 80% reduction after 3 cycles and 85% after 6 cycles, with an 85% rate of treatment success (blood loss <80 mL and a 50% decrease in blood loss from baseline). Irregular bleeding was common in the first 3 to 6 months after insertion.²¹ A 5-year study of 236 women compared those treated with the LNG-IUS with those who had had a hysterectomy. Quality-of-life benefits and satisfaction with treatment were equal in both groups; costs were lower in the LNG-IUS group.²⁷

Heavy Menstrual Bleeding: Update on Best Practices and New Options

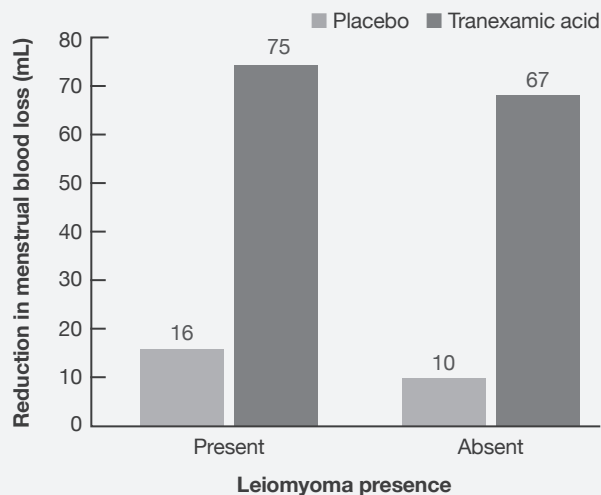
Table 3. Common Treatments for Heavy Menstrual Bleeding and Potential Unwanted Outcomes

TREATMENT	POTENTIAL UNWANTED OUTCOMES EXPERIENCED BY SOME WOMEN ^a
Nonsteroidal anti-inflammatory drugs	Common: Indigestion; diarrhea Rare: Worsening of asthma in sensitive individuals; peptic ulcers, with possible bleeding and peritonitis
Levonorgestrel-releasing intrauterine system	Common: Irregular bleeding that may last longer than 6 months; hormone-related problems such as breast tenderness, acne, or headaches, which are generally minor and transient Less common: Amenorrhea Rare: Uterine perforation at the time of insertion
Tranexamic acid	Less common: Indigestion; diarrhea; headaches
Combined oral contraceptives	Common: Mood changes; headaches; nausea; fluid retention; breast tenderness Very rare: Deep vein thrombosis; stroke; heart attack
Oral progestogen (norethindrone)	Common: Weight gain; bloating; breast tenderness; headaches; acne (but all are usually minor and transient) Rare: Depression
Injected progestogen	Common: Weight gain; irregular bleeding; amenorrhea; premenstrual-like syndrome (including bloating, fluid retention, breast tenderness) Less common: Small loss of bone mineral density, largely recovered when treatment is discontinued
Gonadotropin-releasing hormone analogue	Common: Menopausal-like symptoms (such as hot flashes, increased sweating, vaginal dryness) Less common: Osteoporosis, particularly affecting the trabecular bone, with longer than 6 months' use
Endometrial ablation	Common: Vaginal discharge; increased menstrual pain or cramping (even if no further bleeding); need for additional surgery Less common: Infection Rare: Perforation (but very rare with second-generation techniques)
Uterine artery embolization	Common: Persistent vaginal discharge; postembolization syndrome (pain, nausea, vomiting, and fever not involving hospitalization) Less common: Need for additional surgery; premature ovarian failure, particularly in women over 45 years old; hematoma Rare: Hemorrhage; non-target embolization causing tissue necrosis; infection causing septicemia
Myomectomy	Less common: Adhesions (which may lead to pain and/or impaired fertility); need for additional surgery; recurrence of fibroids; perforation (hysteroscopic route); infection Rare: Hemorrhage
Hysterectomy	Common: Infection Less common: Intraoperative hemorrhage; damage to other abdominal organs, such as the urinary tract or bowel; urinary dysfunction (frequent passing of urine and incontinence) Rare: Thrombosis (deep vein thrombosis and clot on the lung) Very rare: Death (Complications are more likely when hysterectomy is performed in the presence of fibroids.)
Oophorectomy at time of hysterectomy	Common: Menopausal-like symptoms

^a Common = 1 in 100 chance; less common = 1 in 1000 chance; rare = 1 in 10,000 chance; very rare = 1 in 100,000 chance.

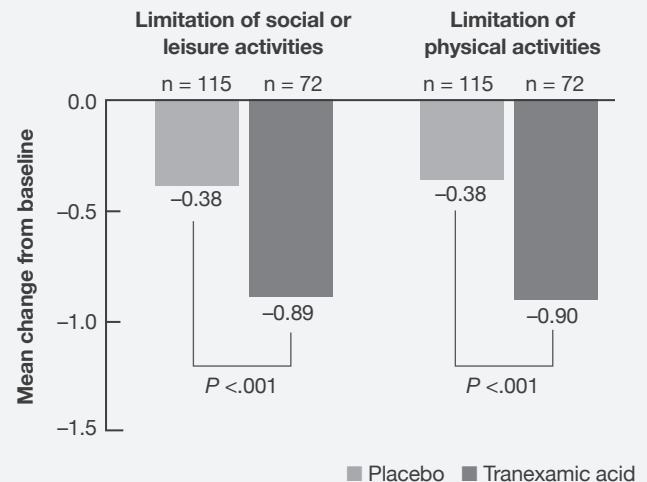
Source: Adapted from National Institute for Health and Clinical Excellence. CG44. *Heavy menstrual bleeding*. London, UK: NICE; 2007. <http://www.nice.org.uk/guidance/CG44>. Accessed September 12, 2011. Reproduced with permission.

Figure 3. Reduction in Blood Loss: Leiomyomas Present or Absent



Lukes AS, et al. Tranexamic acid treatment for heavy menstrual bleeding. *Obstet Gynecol.* 2010;116:865-875. Reprinted with permission.

Figure 4. Improvements in Quality of Life



Lukes AS, et al. Tranexamic acid treatment for heavy menstrual bleeding. *Obstet Gynecol.* 2010;116:865-875. Reprinted with permission.

Nonhormonal management option

Fibrinolysis plays an important role in endometrial hemostasis; thus, antifibrinolytics have been evaluated as a treatment for HMB. Tranexamic acid, a synthetic derivative of the amino acid lysine, has long been used to prevent bleeding. It was first approved by the US Food and Drug Administration (FDA) in 1986 as an injectable drug to reduce or prevent bleeding during and after tooth extraction in patients with hemophilia. Already in use in many countries as a treatment for HMB, it was approved by the FDA in 2009 as the first nonhormonal product to treat menorrhagia. As an antifibrinolytic agent, tranexamic acid inhibits activation of plasminogen and reduces conversion of plasminogen to plasmin (fibrinolysin), an enzyme that degrades fibrin clots, fibrinogen, and other plasma proteins, including the procoagulant factors V and VIII.

In clinical trials, tranexamic acid reduced menstrual blood loss by 45% to 54%.²³ Recent trials, including a retrospective study in a large cohort of women at increased risk for thromboembolic disease, have not shown an association between administration of tranexamic acid and thromboembolic events.^{23,28}

A recent trial (3 and 6 cycles in length) demonstrated efficacy in patients (18 to 49 years old) of various ethnicities (70% white, 25% African American, 5% Asian) with and without

fibroids (40% had fibroids, based on transvaginal ultrasound). The study population included women who were smokers (38%), alcohol users (54%), and those who were overweight. After 2 pretreatment menstrual cycles, women were randomized to receive tranexamic acid 3.9 g/d or placebo for up to 5 days per menstrual cycle through 6 cycles.²⁹

In the 3-cycle phase of the study (n = 115), tranexamic acid reduced menstrual blood loss by 39%, versus 5% with placebo. After 6 cycles, tranexamic acid reduced menstrual blood loss by 38%, versus 12% with placebo. Both sets of results were statistically significant. Significant improvements were noted in women with and without leiomyomas (Figure 3).

Compared with women receiving placebo, women treated with tranexamic acid reported significant improvements in limitations in social or leisure and physical activities (Figure 4), work inside and outside the home, and self-perceived menstrual blood loss ($P < .01$).

In this investigation, few adverse events were reported. No deep vein thromboses were reported in the active treatment group; one incident was reported in the placebo group. Side effects were rated as mild to moderate, primarily menstrual discomfort and headache. The incidence of gastrointestinal adverse events was comparable with placebo.²⁹

Minimally invasive and other surgical options for management of HMB

FDA-approved endometrial ablation procedures have also been shown to be effective for reducing or eliminating menstrual bleeding in women who have completed childbearing or who do not wish to become pregnant. Procedures may be performed in the office setting (with a paracervical block and conscious sedation) or on an outpatient basis. Patient satisfaction rates with various procedures have ranged from 86% to 99%, with rates of amenorrhea ranging from 22% to 55.3% and rates of reduction in dysmenorrhea from 63% to 89%.³⁰⁻³⁴ Devices may use heat, hot water, cold, or microwave technology to ablate the uterine lining down to the basal layer, thus providing improvements in bleeding. Pregnancy after endometrial ablation is contraindicated; patients should have concomitant sterilization performed or understand the importance of using contraception. Long-term results demonstrate that hysterectomy is avoided in 86% of women who have endometrial ablation.³⁵

Hysterectomy is often performed to reduce HMB. Various hysterectomy techniques are available; the vaginal route is associated with less morbidity than other methods.³⁶

In addition to these treatments, there are other surgical options for the treatment of uterine fibroids that may cause heavy bleeding. They include myomectomy and uterine fibroid embolization.

Conclusion

Recent data support the use of both traditional hormonal and antifibrinolytic agents to manage HMB. Thus, clinicians have more opportunities to effectively manage their patients, tailoring the recommended HMB treatment to meet the needs of each patient. ■

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1. In the menstrual cycle, what hemostatic factors do not exert influence?
 - a. Prostaglandin F₂
 - b. Thromboxane
 - c. Prostaglandin E₂
 - d. Prostacyclin
 - e. C-reactive protein

2. Use of anticoagulants can be associated with HMB.
 - a. Yes
 - b. No

3. Continuous OC regimens induce amenorrhea in what percentage of women within 12 months of use.
 - a. 40% to 50%
 - b. 50% 70%
 - c. 70% to 90%
 - d. 80% to 100%

4. Bleeding patterns associated with extended-OC administration may differ based on progestogen used.
 - a. Yes
 - b. No

5. Tranexamic acid reduces HMB by reducing the conversion of hemostatic factors that degrade:
 - a. Fibrin clots and fibrinogen
 - b. Procoagulant factors V and procoagulant factor VIII
 - c. All of the above

6. Tranexamic acid has shown efficacy in reducing menstrual blood loss in which of the following populations:
 - a. Patients who smoke, use alcohol, are overweight, and have fibroids.
 - b. Patients who are at risk for thromboembolic events and have fibroids
 - c. Patients with genetic bleeding disorders who are overweight

7. Long-term results demonstrate that hysterectomy is avoided in what percentage of women who have endometrial ablation:
 - a. 56%
 - b. 66%
 - c. 76%
 - d. 86%

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■ Evaluation (Check all that apply)

1. **Faculty was knowledgeable and effective.** (Please use the "additional comments" field to provide further information)
 Strongly Agree Agree No Opinion Disagree Strongly Disagree
2. **The format was appropriate for the subject matter and I was able to access all components of the activity without difficulty.** (Please use the "additional comments" field to provide further information)
 Strongly Agree Agree No Opinion Disagree Strongly Disagree
3. **This activity will assist in the improvement of my:**
 Competence Performance Patient Outcomes
4. **I plan to make the following changes to my practice:**
 Modify treatment plans
 Change my screening/prevention practice
 Incorporate different diagnostic strategies into patient evaluation
 Use alternative communication methodologies with patients and families
 Other (Please explain in the "additional comments" field below)
 None; the activity validated current practice
5. **What is your level of commitment to making the changes stated above?**
 Very committed Somewhat committed Not very committed Do not expect to change practice
6. **What are the barriers you face in your current practice setting that may impact patient outcomes?**
 Lack of evidence-based guidelines
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9. **The content learned from this activity will impact my practice.**
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10. **The activity was presented objectively and was free of commercial bias.**
 (Please use the "additional comments" field to provide further information)
 Strongly Agree Agree No Opinion Disagree Strongly Disagree
11. **I would recommend this activity to others.**
 Strongly Agree Agree No Opinion Disagree Strongly Disagree
12. **Additional Comments:**