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Current options in contraception
Help your patient choose wisely for satisfaction and adherence

Patient counseling to meet individual needs throughout a woman's reproductive life

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Physicians and advanced practice clinicians who provide health care for women

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- **Ms Wysocki** reports that she serves on speakers' bureaus for Berlex, Duramed, Organon, Ortho-McNeil, and Wyeth.

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CME/CE OBJECTIVES

After completing this educational activity, participants should be able to

- Discuss both reversible and permanent options in contraception
- Counsel patients to identify the most appropriate form of contraception for individual patients
- Identify contraceptive options that will improve patient adherence
- Explain the need for contraception during the perimenopausal years

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In this roundtable discussion, 2 obstetrician/gynecologists, a family physician, and a nurse practitioner in women's health review contraceptive options available to women in the United States. This dialogue is intended to help clinicians develop and implement counseling strategies to enable their patients to select the most appropriate option. Today, 30.6% of contracepting reproductive-age women use oral contraceptives (OCs); 5.3% use injectable contraceptives and 17.9% use condoms or other temporary methods. Of the 36.2% of contraceptive users who have permanent contraception, 27% have had tubal sterilization (laparoscopic or hysteroscopic) and 9.2% have partners who have had vasectomies.[1]

Discussion with every female patient

Dr Connor: A patient's contraceptive needs (and her choice of the most appropriate method) may vary according to her life stage (eg, before she has had children, while she is child-bearing, or after she has completed child-bearing). Clearly, counseling patients about contraception is important. Do you discuss contraception with every reproductive-age patient?

Dr Creinin: Yes, as an obstetrician/gynecologist, I regard counseling about contraception to be as important as performing a Pap [Papanicolaou] smear, given the prevalence of unplanned pregnancies. About 500,000 women per year will be diagnosed with low-grade or high-grade lesions with routine screening;[2] about 3 million women per year will have an unintended pregnancy. Roughly half of all pregnancies in the United States are unintended;[3] the rate among teenagers is higher than that of many other developed countries.[4]

For these reasons, I counsel my patients about all forms of contraception at each visit: barrier methods, the pill, the patch, the ring, injectable methods, intrauterine devices (IUDs), and, when applicable, sterilization. (I refer to laparoscopic tubal ligation for reference only; I believe that hysteroscopic sterilization is a preferable option for women who desire permanent sterility.) I also discuss emergency contraception and provide an advance prescription. I inform a patient about contraceptive options that not only meet her needs today, but that may be appropriate in 5 or 10 years.

Dr Apgar: As a family practitioner (FP), I focus on the whole patient. Contraception is one element of the overall discussion during an office visit. Patients are very curious about their options. I initiate the discussion, perhaps by saying: "Are you happy with your current contraceptive method or would you like to hear about the new options?" or "You're approaching menopause, but you still may need contraception: let's talk about it." We discuss options in terms of risks and benefits applicable to her age or comorbidities such as diabetes or hypertension. For example, a woman with a family history of ovarian cancer may want to know that OCs are linked with lower risk of ovarian cancer.[5]

Ms Wysocki: If a woman does not want to become pregnant, I review all options. I also focus on the noncontraceptive benefits associated with specific agents. Even if her main interest is effective permanent contraception, there may be other reasons she would choose another method over sterilization. For example, if she experiences heavy bleeding, the levonorgestrel intrauterine system (IUS) would provide her with both effective contraception and help with her bleeding.

Identification of patient goals

Dr Connor: How do you identify patient goals?

Dr Apgar: We ask patients to complete a questionnaire about current contraceptive practices. We assess cultural, religious, psychological, and medical issues that may affect contraceptive choices. If a patient has menstruation-related concerns, we discuss specific agents that may offer her benefits.

We also ask her if she would choose her current method again. Does she want to continue it? If she says "No" and she does not want to become pregnant, we need to identify an alternative. Has she heard about another option (and how did she learn about it)? Many women learn about an option from the media and want to discuss that method, providing an opportunity to correct misconceptions and discuss equally valid options with which the patient may be unfamiliar.

Dr Creinin: I take the questioning further to be sure I interpret my patient's comments correctly. When a

patient says she is satisfied, she may mean: "I'm satisfied with my birth control pill, but it is hard to remember to take it every day." According to 1 study, 50% of women miss 3 or more pills per month![6]

Dr Apgar: We provide patient education materials in the patient's primary language in case she cannot make an immediate decision. For these patients, we schedule another appointment to ensure that her contraceptive needs are addressed and that she is happy with her decision.

Dr Creinin: I also guide patients to good Internet sites, such as www.arhp.org. This site features valuable patient contraception and selection tools.

Determining the best reversible option for an individual patient

Dr Connor: You raise a good point about "interpreting" a patient's comments. It's important to not make assumptions about patients and their understanding of the subject: We can't assume that even a very organized and responsible patient will adhere to a daily schedule of use. Regarding reversible forms of contraception, how do you counsel patients about OCs?

OCs: Adherence, risks, and benefits

Ms Wysocki: In use for more than 40 years, OCs are the most popular reversible method and are highly effective. I always mention this option. Women often don't know about the benefits of OCs. During perimenopause, for example, OCs alleviate menstrual irregularity and may reduce menorrhagia. They also provide benefits in terms of bone strength and relief of vasomotor symptoms.[7-17]

OCs are not appropriate for women who smoke and are over 35, have uncontrolled hypertension, diabetes with vascular complications, migraines with aura, vascular disease, breast cancer, history of thromboembolism, coronary artery or cerebrovascular disease, acute or chronic hepatocellular disease with abnormal liver function tests, or cholestatic jaundice with prior pregnancy or contraceptive use.[18] If OCs are contraindicated, so are combination hormonal patches and the contraceptive vaginal ring. I always discuss the reasons why they are a poor choice for these patients.

Dr Creinin: OCs are a great option for many healthy women. For perimenopausal women, I perform a risk assessment to evaluate the evidence for or against hormonal contraception. This ensures that the patient is provided with the safest form of birth control.

Ms Wysocki: It's also important to assess risk in younger women; they may have medical problems for which OCs are contraindicated.

Dr Creinin: We also have alternatives to standard combination OCs. Progestin-only products may be appropriate for some women who are not candidates for estrogen-containing OCs.

In a study of women scheduled for abortions, detailed contraceptive histories revealed that 14% of patients had been put at higher risk because of inappropriate counseling by their health care providers.[19]

Reversible options: Longer duration of use

Dr Connor: What about options that offer longer duration of action? The patch offers efficacy comparable to that of OCs, although failure rates may increase in women who weigh 90 kg or more. Fewer than 4.7% of patches detach, and, although application site reactions may occur, these are unusual.[20-23] Side effects are similar to those of OCs (eg, headaches, breast tenderness and nausea). The once-weekly regimen may improve adherence compared with a regimen of 1 pill daily. We need to keep in mind, however, that patients for whom OCs are contraindicated also should not use the patch. The risk for venous thromboembolism (VTE) is similar among OC and patch users. In a recent study, the overall incidence of VTE was 52.8 per 100,000 women-years among patch users and 41.8 per 100,000 women-years among OC users.[24]

The ring provides consistent serum hormone concentrations with low hormonal exposure. Spontaneous expulsion occurs, although infrequently. Overall, the monthly bleed is slightly reduced, and patients have a favorable view of this option.

We've heard about the black box warnings associated with depo-medroxyprogesterone acetate (DMPA). How do you counsel patients regarding this option?

Dr Apgar: The bone effects are reversible. No study

Special Issues: Gynecologic conditions and recommendations for patients

Dr Connor: We've discussed, to some extent, how various agents affect menstrual flow. How do gynecologic health issues, such as menorrhagia, affect your counseling? When do you consider endometrial ablation for menorrhagia? How do you counsel patients who are candidates for endometrial ablation, particularly in terms of its contraindication for subsequent pregnancy?

Dr Creinin: My first goal is to determine the cause of menorrhagia. If a patient has a submucosal fibroid, simple resection may resolve the problem.

Dr Apgar: Intrauterine devices are not approved by the US Food and Drug Administration for treatment of menorrhagia; however, they often are effective. In 1 study of women who had an intrauterine device placed as a bridge to the hysterectomy, 64% canceled the procedure within the next 6 months.[1]

Dr Connor: Endometrial ablation should be offered only to women who no longer desire childbearing since pregnancy after an ablation is associated with a high probability of adverse outcomes. In most endometrial ablation procedures, hysteroscopic sterilization can be accomplished during the same session. This provides a level of comfort to both the health care provider and the patient, although back-up contraception will be required for 3 months until the hysterosalpingogram confirms proper bilateral micro-insert placement and tubal occlusion.

Dr Creinin: Most insurers in my area cover hysteroscopic sterilization.

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has shown that women who take DMPA have an increased rate of fractures. Obviously, DMPA would be a poor choice for a hypoestrogenic, anorexic young woman, but this agent may be an appropriate option for a woman who may have adherence problems with OCs.

Ms Wysocki: I agree. DMPA also may appeal to a patient because of the cessation of menses associated with this agent. But this also will be achieved with the levonorgestrel-releasing IUS or with specific schedules of OC administration that offer quarterly withdrawal bleeds or reduced bleeding. Patients must understand that amenorrhea or less frequent bleeding is normal in the context of use of hormonal contraceptives.

Dr Apgar: Patients also need to know that DMPA has a slower return to fertility, a potential issue for a woman in her mid-30s who decides to have children.

Dr Creinin: Health care providers need additional education about DMPA, as well: I have heard reports of young reproductive-age women on DMPA regimens being placed on bisphosphonate or teriparatide therapy. These products are contraindicated for this population.

Dr Connor: What about the copper IUD or levonorgestrel-releasing IUS?

Ms Wysocki: Women want to learn about these methods. Some women are concerned about a foreign object inserted into the uterus.

Dr Creinin: My patients are very interested in the levonorgestrel-releasing IUS because it reduces menstrual flow and often results in amenorrhea.[25]

Ms Wysocki: I also find that women are very interested in this option, but health care providers often are reluctant to discuss it. I think part of the problem is that many of them received their training after the problems associated with the Dalkon Shield were reported.[26] At that time, IUD use in the United States virtually ceased, and individuals trained in the 1980s and 1990s have little or no experience with IUDs. Clinicians need to know that the incidence of pelvic inflammatory disease (PID) associated with IUDs is similar to that within the general population; the risk is increased slightly only during the first month after insertion.[27-30]

Dr Creinin: I agree: From 1995-2002, the use of IUDs in the United States has tripled. Nevertheless, only 1.5% of women using contraception have an

Hysteroscopic Sterilization: An overview of the procedure

The system consists of a micro-insert, a disposable delivery system, and a disposable introducer. The delivery system comprises a delivery wire, a release catheter, a delivery catheter, and an ergonomic handle that allows for one-handed placement and deployment of the device. It also retracts the outer delivery catheter and allows withdrawal of the inner release catheter, which fully deploys the micro-insert. Steps are as follows:

- The uterus is distended with warm saline.
- Diagnostic hysteroscopy is performed.
- Both tubal ostia are identified and assessed hysteroscopically.
- The delivery catheter with micro-insert is inserted hysteroscopically into the proximal section of the tubal lumen.
- When the device is correctly placed, the outer delivery catheter is withdrawn to expose the device.
- When the release catheter is activated via the ergonomic handle, the micro-insert expands.
- The delivery wire is withdrawn from the micro-insert.
- Once in place, polyethylene terephthalate fibers in the micro-insert induce a benign tissue growth around and into the micro-insert, thus blocking the fallopian tube.
- Three months postprocedure, a hysterosalpingogram confirms blockage of the tubes and proper bilateral micro-insert placement. Until this is confirmed, a back-up contraceptive method is essential.

IUD,[30] although it is widely used in other countries.

Dr Apgar: Some practitioners believe IUDs are abortifacients; they are not. Ovulation is rarely suppressed, even in the absence of bleeding associated with the hormonal IUS. While spotting or increased bleeding may occur in the first 3 to 6 months, 14% to 20% of women progress to amenorrhea.[25] I agree that most clinicians have insufficient knowledge about IUDs and patients generally do not bring up this option.

The levonorgestrel-releasing IUS is approved for 5 years' use. It improves menorrhagia, dysmenorrhea, and anemia. It decreases menstrual symptoms in women with uterine fibroids or adenomyosis and may decrease the risk of PID and ectopic pregnancy as well as benign endometrial polyps in tamoxifen-treated breast cancer patients.[31-33] This option is often appropriate for women who are not candidates for or prefer not to use other reversible contraception, those who are contemplating sterilization but are unsure about making an irrevocable decision, and those whose menstrual symptoms, especially menorrhagia may improve with use of a hormonal IUS.

The copper IUD does not reduce bleeding but is approved for 10 years of use, increasing its cost-effectiveness for patients who wish to have contraception for a long duration.

Ms Wysocki: Many women and their clinicians mistakenly believe that IUD-use is contraindicated in a woman who has not been pregnant. Additionally, the package insert was changed recently: A history of PID or ectopic pregnancy is no longer a contraindication of the copper IUD.

Patients who wish never to become pregnant or who have completed childbearing

Dr Connor: How do you counsel patients who do not intend to become pregnant? Under what conditions would you recommend reversible vs permanent contraception? We routinely address sterilization postpartum for candidates who express an interest. What about in other settings?

Dr Creinin: Many health care providers use patient age as a criterion and do not offer sterilization to young women. I do not believe chronological age should be an issue. Our patients' lives often differ significantly from our own.

Certainly, we need to discuss the possibility of regret with our patients, perhaps asking such questions as: If your child dies, are you certain you won't regret sterilization? If your child has a major illness and the only way to help that child is to have another, what would you want to do?

CPT Coding for Permanent Sterilization

In 2006, The Centers for Medicare and Medicaid Services (CMS) approved a national physician payment of $2,194.64 for office-based hysteroscopic sterilization and $459.31 for hospital-based procedures.

Hospital outpatient amounts are as follows: Current procedural terminology (CPT) code 58565 for hysteroscopic sterilization was assigned to ambulatory payment classification (APC) 202 with a 2006 payment level of $2,453.75. CPT code 58600 for tubal ligation is assigned to APC 195, which pays an average of $1,594.73.

If a patient wants sterilization, my job is to be certain that she understands her options, not to decide for her what options are reasonable in her life; I don't know her life better than she does. Regret is expressed at some point over the 14 years following sterilization by 40% of women aged 18 to 24 years and 16% of women aged 25 to 30 years. However, the majority do not express regret.[34]

Ms Wysocki: It is important to know what kind of sterilization procedures are available in your area, so you can counsel appropriately. Hysteroscopic sterilization might not be available in rural settings. Additionally, I would not talk to a woman about her permanent sterilization without talking about her male partner's options for vasectomy.

Dr Creinin: I discussed tubal ligation, vasectomy, and hysteroscopic sterilization with all patients interested in permanent methods of contraception. However, my experience has shown that hysteroscopic sterilization has greater efficacy than either. In a phase II trial of hysteroscopic sterilization, 98% of the women who used the device over a 2-year period reported it to be very good to excellent. No pregnancies were reported over 1894 women-months of effectiveness.[35] It offers a return to normal activities for almost all women within about 1 day. Use of a hysteroscopic procedure to access the fallopian tubes results in negligible risk of visceral injury or conversion to a laparotomy. Infection, such as endometritis, is extremely rare. General anesthesia is not required, so associated risks are avoided.[18] Additionally, it is well known that the "down time" from a hysteroscopic procedure is significantly shorter than with a laparoscopic procedure, as is the level of postoperative pain. Based on these improved clinical outcomes, in our institution approximately 90% of interval sterilization procedures are performed hysteroscopically.

When I counsel women about sterilization options, I mention laparoscopic sterilization as the way we used to perform sterilization, with instruments in the abdomen and risks of internal injuries: 0.9% of patients are converted to laparotomy and 5% experience wound infection or complications.[36,37] Most women returned to normal activities in about a week.[38]

Ms Wysocki: What about insurance coverage for hysteroscopic sterilization?

Dr Creinin: Insurance coverage for all contraceptive options varies widely. Most public and private insurers in my area cover hysteroscopic sterilization. We provide all of the procedures in the operating room, although this is not necessary. I do give patients the option of local anesthesia, which many choose in the operating room.

Informed consent and hysteroscopic sterilization

Dr Connor: How do you counsel a patient who may be interested in permanent sterilization?

Dr Apgar: As an FP, I see male and female patients; I discuss sterilization options for men and women in general terms to make sure patients understand that that these procedures are permanent. I review the data regarding failure rates and potential adverse effects.

Dr Connor: Patients are often misinformed about tubal ligation. They believe that the tubes are actually tied and do not realize that implants, clips, or plastic rings are placed. They also may be concerned about the nickel metal alloy used in hysteroscopic sterilization micro-inserts. Very few patients have a true nickel allergy.

Health care providers may not realize that hysteroscopic sterilization can be performed on nulliparous patients. Hysteroscopic sterilization, while relatively new, has excellent 5-year safety and effectiveness data.[39-41] Currently, there is only 1 FDA-approved device for hysteroscopic sterilization; however, clinical trials to evaluate 2 other devices are underway.

Dr Creinin: Clinicians need to understand that patients may have misconceptions about many forms

of contraception. They should be patient and persistent in exploring such issues. For example, it is important that patients understand that hysteroscopic sterilization is a truly permanent procedure. With laparoscopic sterilization, a patient is typically aware that there may be a small chance of reversal even though we stress the permanence of the procedure.

Regarding ability to perform hysteroscopic sterilization, my experience mirrors that of others who have performed this procedure after the clinical trials.[42] I cannot place the coils in both tubes in about 2% of patients. This is an important counseling point and leads to a discussion of what the patient will want to do if I can't place both coils, that is, a laparoscopic tubal ligation or an IUD.

Dr Connor: I do discuss the laparoscopic procedure with patients prior to scheduling a hysteroscopic sterilization. Generally patients tell me that if the micro-inserts cannot be placed, they are not interested in tubal ligation because of the need for general anesthesia, surgical incision, and longer recovery time. What about timing? How do you schedule this procedure?

Dr Creinin: If the patient is on a DMPA regimen, it can be scheduled at any time. Otherwise, I have found the most ideal time to be within 1 or 2 days after cessation of menses. If scheduled later in the cycle, endometrial build up may obscure the ostia and make placement difficult.

Dr Connor: In summary then, it is clear that a number of safe and effective contraceptive options are available to our patients. Our role as health care providers is to provide the patient education and effective counseling necessary to help women understand these options. Only then will these patients be able to select the contraceptive strategy that will best meet their needs. ■

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CME/CE POSTTEST AND EVALUATION

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1. In 1 study of women using oral contraceptives (OCs)
- a) 25% missed taking 1 pill each month
- b) 50% missed taking 3 pills each month
- c) 50% missed taking 1 pill each month
- d) 25% missed taking 3 pills each month

2. The noncontraceptive beneficial effects of OCs include
- a) Alleviation of menstrual irregularity
- b) Improvement in menorrhagia
- c) Improvements in bone strength
- d) All of the above

3. Bone effects associated with depo-medroxyprogesterone acetate are reversible.
- a) True
- b) False

4. Hormonal intrauterine devices
- a) Improve menorrhagia and dysmenorrhea
- b) Reduce symptoms in women with uterine fibroids
- c) May decrease risk of pelvic inflammatory disease
- d) All of the above

5. Pregnancy is contraindicated after endometrial ablation.
- a) True
- b) False

6. Of women who have permanent contraception, what proportion express regret over the next 14 years?
- a) 25% aged 18 to 24
- b) 54% aged 18 to 24
- c) 16% aged 25 to 30
- d) 40% aged 25 to 30

7. Hysteroscopic sterilization can be done in an office setting.
- a) True
- b) False

8. Most insurers cover hysteroscopic sterilization.
- a) True
- b) False

9. In a phase II trial of hysteroscopic sterilization, what percentage of patients rated the procedure as very good or excellent at 24 months?
- a) 99%
- b) 98%
- c) 95%
- d) 90%

10. Until hysterosalpingogram confirms blockage of the tubes at 3 months post-procedure, a back-up contraceptive method should be used.
- a) True
- b) False

PROGRAM EVALUATION (PLEASE PRINT)

Please circle the letter that best reflects your agreement with the statements below, using the following scale:

A. Strongly disagree **B.** Disagree **C.** Agree **D.** Strongly agree **E.** Does not apply

1. The program objectives were fully met	A	B	C	D	E
2. The quality of the educational process (presentation and information) was satisfactory and appropriate.	A	B	C	D	E
3. The educational activity has enhanced my professional effectiveness and improved my ability to:					
a. Treat/manage patients	A	B	C	D	E
b. Communicate with patients	A	B	C	D	E
c. Manage my medical practice	A	B	C	D	E
4. The information presented was without promotional or commercial bias.	A	B	C	D	E
5. The program level was appropriate.	A	B	C	D	E
6. I intend to change my clinical practice as a result of the information presented in this CME program.	A	B	C	D	E
7. Suggestions regarding this material, or recommendations for future presentations:	A	B	C	D	E

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