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DIALOGUES IN CONTRACEPTION®

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In This Issue

Philip D. Darney, MD, MSc
Professor and Chief
Obstetrics, Gynecology and Reproductive Sciences
San Francisco General Hospital
University of California, San Francisco
San Francisco, California

Grant/Research Support: Organon Inc., Population Council. *Consultant:* Organon Inc. *Speakers Bureau:* Bayer Laboratories, Organon Inc.

Carolyn L. Westhoff, MD, MSc
Director, Division of Family Planning and Preventive Services
Professor of Obstetrics and Gynecology
Professor of Epidemiology and Population and Family Health
Columbia University Medical Center
New York, New York

Grant/Research Support: Barr Laboratories, Organon Inc. *Consultant:* Bayer Laboratories, Duramed Pharmaceuticals, Organon Inc., Schering-Plough Corporation.

Kathryn M. Andolsek, MD, MPH
Professor, Community and Family Medicine
Duke University School of Medicine
Durham, North Carolina

No financial arrangement or affiliation to report.

Ronald T. Burkman, MD
Department of Obstetrics and Gynecology
Baystate Medical Center
Springfield, Massachusetts
Professor of Obstetrics and Gynecology
Tufts University of Medicine
Boston, Massachusetts

Consultant: Ortho-McNeil Pharmaceutical, Inc.
Speakers Bureau: Ortho-McNeil Pharmaceutical, Inc.

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Advances in Sterilization

Philip D. Darney, MD, MSc, and Carolyn L. Westhoff, MD, MSc

Educational Objectives:

The health care provider should be able to:

- **describe available techniques and efficacies of female and male sterilization**
- **identify central issues (eg, consent, regret, reversibility) to be considered in sterilization decisions compared with the advantages/disadvantages of reversible methods of contraception**
- **utilize an evidence-based approach to dispel myths and misperceptions about long-term health effects of sterilization**

Illustrative Case Study

Rose H: *A 28-year-old woman with 3 children is about to lose her health insurance coverage because her husband will soon be laid off from work. She has been using combination oral contraceptives (COCs) successfully and satisfactorily since her third child was born 3 years ago. Because the couple does not want to have more children, she is concerned about the ongoing cost of contraception and, therefore, is considering sterilization while she is still insured.*

Female and male sterilization combined are the most common form of birth control in the United States. The 2002 National Survey of Family Growth reported that, among reproductive-age (15-44) women using contraception, female sterilization was used by 10.3 million (27%) and male sterilization by 3.5 million (9.2%), compared with 11.7 million (30.6%) using oral contraceptives (OCs).[1] The percentage of contraceptors choosing sterilization increases with age; female sterilization is the leading method among contraceptors aged 35 and older (35-39: 41.2%; 40-44: 50.3%), followed by male sterilization (35-39: 14.2%; 40-44: 18.4%).[1]

About half of the estimated nearly 700,000 annual sterilizations among women in the United States are performed within 48 hours postpartum (approximately 338,000), with sterilization immediately following nearly 10% of all births (58% following vaginal, 42% following cesarean).[2,3] Approximately 345,000 female sterilizations annually are interval procedures, unrelated in time to a pregnancy, and most are performed on an ambulatory or outpatient basis by laparoscopy.[3]

Techniques of Female Sterilization

Surgical sterilization. Tubal sterilization is achieved through occlusion of the fallopian tubes. Intra-abdominal access for surgical sterilization can be provided through laparoscopy (primarily used for interval tubal sterilization) or minilaparotomy (used for both postpartum and interval sterilization).[4] Sedation and/or local or regional anesthesia are sometimes used, but general anesthesia is most common.[5] Methods of tubal occlusion include electrosurgical methods (with partial resection or transection by unipolar electrosurgery or bipolar electrocoagulation)[6], mechanical methods (eg, Hulka-Clemens spring clip, Filshie hinged clip, Falope or Yoon Silastic ring/band), and ligation techniques (eg, Pomeroy, Pritchard [Parkland], or—less commonly—Irving, Uchida).[7]

Major morbidity is a rare outcome following either laparoscopy or minilaparotomy. A meta-analysis of data from studies comparing the 2 methods found no difference in major

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Dear Colleague:

Dialogues in Contraception® continues to bring you the latest information from experts in the field of women's health and contraception. Their insights and analyses serve as resources for improving comprehensive contraceptive management. At the suggestion of some of your fellow readers, this issue covers the topics of advances in sterilization, the economics of contraception, and extended combination hormonal contraceptive regimens and menstrual suppression.

Included in this issue is the annual ***Dialogues in Contraception*** Reader Survey. We are requesting your feedback and opinions on this newsletter series, including topics you would like to read about in future issues. If you have not done so already, please take a few moments to complete and return this survey.

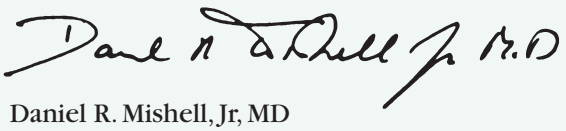
This survey is also available at: http://www.formdesk.com/general_/DICsurvey.

Your responses are extremely valuable and help us continue to produce an effective educational tool that can help you in your daily practice.

If you would like to share additional thoughts with me and the rest of the Editorial Board, please contact Chelsea Eaton, Associate Publications Manager at Health Learning Systems, by phone (973-352-2205) or by e-mail (ceaton@commonhealth.com).

We look forward to hearing from you and learning your thoughts about ***Dialogues in Contraception!***

Sincerely,



Daniel R. Mishell, Jr, MD
The Lyle G. McNeile Professor
Department of Obstetrics and Gynecology
Keck School of Medicine
University of Southern California
Los Angeles, California

Executive Editor
Dialogues in Contraception

morbidity; minor morbidity was significantly less with laparoscopy (Peto odds ratio [OR] 1.89, confidence interval [CI] 1.38, 2.59).[8] The risk of complications is increased in women whose body mass index is 30 kg/m^2 or more (OR, 1.7, CI 1.2-2.6).[9]

Transcervical (hysteroscopic) occlusion. A nonincisional method of interval tubal sterilization was approved by the US Food and Drug Administration (FDA) in November 2002.[10] Under local or general anesthesia, a metal/fiber microinsert is placed hysteroscopically into the interstitial portion of each fallopian tube. The insert expands and stimulates tissue ingrowth over several weeks to occlude the tubes.[11] Backup contraception is necessary for 3 months after microinsert placement, when performance of a hysterosalpingogram (HSG) is required to demonstrate both satisfactory location of the microinserts and bilateral tubal occlusion.[12]

In 2 clinical trials, correct bilateral placement of the microinsert during the first insertion procedure was achieved in only 642 (86%) of the 745 women in whom placement was attempted.[12] Bilateral insert placement was accomplished in 22 women during a second procedure but in 2% of women occlusion was still not complete after the second attempt.[12-14] No pregnancies have been reported during

4 years of follow-up in women in whom bilateral placement and occlusion was demonstrated by HSG.[15] Transcervical occlusion is not surgically reversible.

Techniques of Male Sterilization

Vasectomy is surgery to occlude the vas deferens to prevent sperm passage into the ejaculate; it is almost always performed under local anesthesia.[7] Male sterilization is safer and less invasive than female surgical sterilization.[16] The no-scalpel technique of reaching the vas is widely preferred to conventional scalpel incision.[6,7,17] Occlusion of the vas is achieved through ligation, excision, clips, clamps, sutures, or a combination of these techniques, or through cautery; addition of fascial interposition appears to increase effectiveness.[18-20]

Vasectomy is not immediately effective for contraception. Additional contraception is required until the ejaculate is sperm-free, a period that can last for 12 weeks or more.[18,21] Evidence suggests that 60% to 80% of vasectomized men are azoospermic after 12 weeks and after 20 ejaculations, although study results vary.[21,22] The time to azoospermia can be highly variable and may depend upon the type of occlusion used as well as on the age of the individual.[19-22] Repeat sperm testing may be required until azoospermia is achieved. Recanalization is possible both early and years after vasectomy.[23-25]

Efficacy

Female sterilization. The contraceptive efficacy of surgical tubal sterilization is high overall, but varies by occlusion method as well as a woman's age, race, and ethnicity.[26] A community study of tubal sterilization usage (US Collaborative Review of Sterilization [CREST]) that followed 10,685 women who had undergone tubal sterilization for up to 8 to 14 years showed that unintended pregnancies occurred more frequently and continued to occur later than originally believed.[26] The cumulative 10-year probability of pregnancy following tubal sterilization was found to be 18.5 per 1000 procedures (CI 15.1-21.8). The annual risk of pregnancy following sterilization is about as high in the 10th year as in the first year. The cumulative probability of unintended pregnancy was highest following laparoscopic Hulka-Clemens spring clip sterilization (36.5/1000 procedures; this study predated use of the Filshie hinged clip) and lowest following laparoscopic unipolar coagulation and postpartum partial salpingectomy (each, 7.5/1000 procedures). For all methods other than interval partial salpingectomy, the probability of pregnancy was found to be greater for women sterilized at age 28 or younger than for women sterilized at age 34 or older. Relative differences in effectiveness among sterilization methods diminish with increasing age at time of sterilization. Because there are no similar long-term US community usage data regarding sterilization with Filshie hinged clips, the rate of unintended pregnancy several years after occlusion by this method is unknown.

Similarly, no US community usage data and few other data exist regarding unintended pregnancy following sterilization with the hysteroscopic transcervical microinsert. In 2 US clinical trials, no pregnancies have occurred in more than 600 women with bilateral occlusion who have used the microinsert for 4 years.[12,15] No longer-term data are yet available. As noted above, though successful placement and/or occlusion initially failed in 14% of women, correct bilateral placement was achieved in most of them after a second procedure.

Vasectomy. CREST data indicate that the cumulative probability of pregnancy per 1000 vasectomy procedures was 7.4 (CI 0.2-14.6) during the first year after the procedure and 11.3 (CI 2.3-20.3) after 2, 3, and 5 years.[27]

Overall, the high contraceptive efficacy of female and male sterilization methods is comparable to that of copper and levonorgestrel-releasing intrauterine devices (IUDs) over 10 or more years.[28-30] Moreover, placement of an IUD is a simpler procedure than female or male sterilization, with no anesthesia required. Unlike sterilization, which should be considered permanent contraception, the contraceptive action of IUDs is rapidly reversible if desired. The copper IUD is approved by the FDA for 10 years of use before replacement. In one study, there were no pregnancies 10 to 15 years after copper IUD insertion among 1886 woman-years of follow-up.[31] In another study, no pregnancies occurred in 154 women who used the same copper IUD device for 20 years postinsertion.[28] One investigator suggested that a single copper IUD placed in a woman aged 35 or older can be used effectively without pregnancy until menopause.[28] The levonorgestrel-releasing IUD is approved for 5 years of use but efficacy has been demonstrated for more than 7 years.[32] One study reported that no pregnancies occurred when a second device was inserted for an additional 5 years of use.[33,34]

Risks and Complications

Although ectopic pregnancies occur less frequently following female surgical sterilization than in women using no contraception, sterilization is associated with an increased risk of ectopic pregnancy if pregnancy occurs.[35] Data from the CREST study indicate that the 10-year probability of ectopic pregnancy for all tubal sterilization methods studied was 7.3 per 1000 procedures (CI 5.0-9.6), about one-third of all post-tubal sterilization pregnancies. Risk of ectopic pregnancy varied by occlusion method (10-year probability highest with bipolar coagulation) and by age at time of sterilization, with age under 30 associated with a higher risk. Postoperative complications of tubal sterilization procedures are rare and generally minor; they include infection (1%), minor or major bleeding (0.6% to 1%), uterine perforation (0.6%), injury to adjacent organs (0.6%), and anesthesia-related effects (1% to 2%).[36] These risks are substantially higher in obese women.[9] There is some controversy regarding whether or not surgical tubal sterilization increases risk of subsequent hysterectomy. The CREST study found that the 5-year cumulative probability of hysterectomy following all surgical sterilization procedures studied was 8.4% (CI 2.4-9.0) compared with 1.8% among nonsterilized women (ie, with vasectomized husbands).[37] In this study, risk of hysterectomy was most common among women sterilized before age 30. Other cohort studies have found no overall increase in risk of hysterectomy.[2] One group of investigators concluded that any increased risk of hysterectomy among sterilized women is not a physiologic consequence of the sterilization, rather that women who choose tubal sterilization for contraception may also be more likely to select a surgical solution (eg, hysterectomy) for menstrual disorders.[38]

In addition to the risk of unsuccessful bilateral placement, the transcervical microinsert is associated with such complications as risk of microinsert expulsion (15/682; 2.2%), perforation (11/682; 1.5%), pelvic cramping on the day of the procedure (161/544 procedures; 29.6%), and back pain/low back pain in the first year of microinsert use (43/476 women; 9.0%).[12] No major complications are associated with vasectomy.[36] Minor complications include infection (1%-6%), bleeding (1.6%-4.6%), granuloma (1%-40%), and epididymitis (0.4%-6%).[25,36]

Counseling for Sterilization

Because special consent forms, documenting informed consent, are often required for sterilization procedures, individuals considering such procedures must be thoroughly counseled regarding a variety of crucial

issues *(Table)*. In all states, special consent forms are required for women undergoing publicly funded sterilization. In a few states (eg, New York, California), special consent is required from all women seeking sterilization. For Medicaid-funded sterilizations, a 30-day waiting period is required from the signing of the consent form to the time of sterilization. Exceptions are cases of premature delivery when sterilization was scheduled for the expected delivery date, and emergency abdominal surgery with informed consent signed 30 days or more prior to intended date of sterilization.[5,39] Women aged under 21 cannot have federally funded sterilizations in most states.[5] There are no such restrictions for male sterilization. Clinicians must be familiar with all applicable state and local government guidelines.

Table. Key Sterilization Counseling Issues

Women and men considering sterilization procedures should be fully informed that:

- Sterilization is intended to permanently prevent pregnancy, so those considering such procedures should be certain they do not wish to have more children.
- Unintended pregnancy can still occur even many years after the procedure.
- Surgical tubal sterilization usually requires anesthesia in an operating room and several days of recovery time.
- Many women and men later regret having been sterilized and request reversal procedures.
- Surgical reversal of sterilization operations is costly and not always possible or successful; transcervical microinsert sterilization cannot be reversed.
- The only other means of achieving pregnancy following sterilization is through in vitro fertilization, which also is costly and not always successful, particularly in women aged 35 or older.
- Surgical sterilization procedures do not have adverse health effects.
- Long-term reversible contraceptives, such as IUDs, should be considered as alternatives to sterilization. Both types of IUDs available in the United States can prevent pregnancy as effectively as sterilization for many years, do not require anesthesia or recovery time, and are easily and rapidly reversible if pregnancy is ever desired.

IUDs=intrauterine contraceptives.

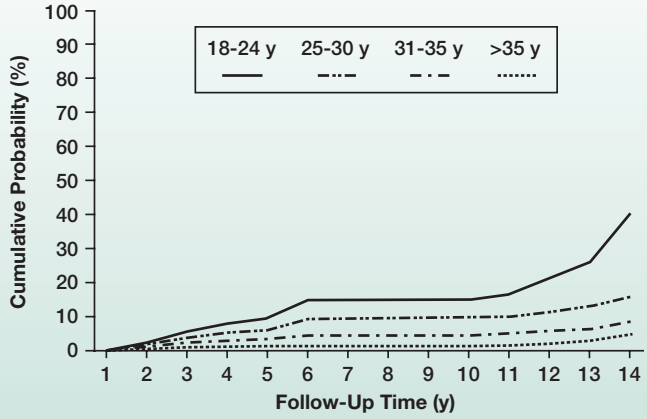
Permanence. Sterilization is intended to be permanent. Nevertheless, permanent protection against pregnancy is not guaranteed, and unintended pregnancy can occur even many years after the operation.[30] Long-acting reversible contraceptive methods, especially IUDs, are highly effective alternatives to sterilization. Counseling about these methods and their advantages may help to reduce the number of women and men undergoing sterilization procedures and of those who might later regret having done so.[40,41] Each couple considering permanent contraception should be encouraged to assess the advantages and disadvantages of female versus male sterilization and IUD insertion in their individual circumstances. As sterilization does not provide protection against sexually transmitted infections (STIs), individuals considering sterilization should also assess the long-term costs and likelihood of consistently using STI protection, if warranted.[30]

Possibility of future regret. A considerable number of individuals who undergo or whose partners undergo sterilization later regret having had this procedure and want to have more children.[42-48] The CREST study found that the cumulative probability of expressing regret within 14 years after tubal sterilization was 12.7% (CI 11.2-14.3).[42] Young age at time of sterilization is the strongest predictor of regret, regardless of parity or marital status.[42,45-47] Women aged 30 or younger at the time of sterilization were twice as likely (adjusted rate ratio 1.9; CI 1.6-2.3) as women older than 30 to report regretting having the procedure performed.[42] Five years after sterilization, regret was higher among women sterilized postpartum than among women receiving interval sterilization.[45] At 14 years of follow-up, the cumulative probability of regret was higher among women whose sterilizations were performed within 1 year of the birth of their youngest child (17.6%) or during the postpartum period (16.1%-17.8%) than later interval sterilization procedures.[42] Divorce and/or remarriage subsequent to sterilization are also risk factors for regret: 23.9% of women aged 30 or younger at time of sterilization and 8.0% of women aged over 30 at time of sterilization cited these reasons for regret during the 14 years of CREST follow-up.[42] CREST data also indicate that the 5-year probability of women regretting their partners' vasectomies (6.1%; CI 3.6-8.6) is similar to that of women regretting their own tubal sterilizations (7%; CI 5.8-8.1).[43]

Requests for sterilization reversal. Requests for information about reversal are also an indication of regret. CREST data indicate that the 14-year cumulative probability of requesting female sterilization reversal information after the procedure was 14.3% (CI 12.4-16.3).[49] The cumulative probability of women sterilized at a very young age (18-24) requesting reversal is 40.4% (CI 31.6-49.2), nearly 4 times as likely as women aged 30 or older at time of sterilization (adjusted rate ratio 3.5; CI 2.8-4.4) *(Figure)*.[49] In a study of women in a military population, women who requested sterilization reversal were twice as likely to have been aged 25 or younger at the time of sterilization than sterilized women not seeking reversal (63%, 33%, respectively).[48]

Within 5 years of vasectomy, 1.4% of US men and 2.0% of their wives request reversal, but less than 1% of men actually obtain reversal.[43]

Figure. Cumulative probability (per 100 surgical tubal sterilization procedures) of requesting reversal information by age at sterilization and year of follow-up.[49]



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Dispel myths. Despite lingering beliefs that surgical sterilization procedures may adversely affect long-term health, substantial evidence exists to refute such misperceptions. Clinicians should inform women and men considering sterilization that there are no long-term adverse health effects as a result of these procedures. No information is yet available regarding long-term health effects of transcervical microinserts.

Female surgical tubal sterilization is not directly related to any detrimental effects on sexuality.[50] Follow-up data from the CREST study found that 2 to 3 years after interval tubal sterilization, 80% or more of 4576 women reported no change in either sexual interest or sexual pleasure from presterilization; among the women who reported change, increases in interest and pleasure were reported more than 10 and 15 times more often, respectively, than decreases.[50]

(continued on page 9)

Assessing Costs and Improving Access to Contraception

Kathryn M. Andolsek, MD, MPH, and Ronald T. Burkman, MD

Educational Objectives:

The health care provider should be able to:

- **describe impediments, including costs, that often limit women's access to contraception**
- **identify factors limiting clinicians' ability to enhance successful contraceptive use**
- **assess status of contraceptive equity legislation in the United States**
- **utilize a variety of strategies to expand the availability of contraceptives**

Illustrative Case Study

Karen F: *A 25-year-old combination oral contraceptive (COC) user is leaving in 3 days to travel in Europe for 2 months with her husband. Her pharmacy has refused to refill her monthly COC prescription because her insurance mandates that only 1 month's supply may be dispensed every 30 days, and her prescription refill is not due for another 8 days. She calls her clinician to explain that she needs a refill now so that she can continue her contraceptive protection while she is abroad.*

According to the 2002 National Survey of Family Growth, 49% of US pregnancies in 2001 were unintended.[1] Contraception was not used during the month of conception for 52% of the unintended pregnancies.[1] For many sexually active women, financial factors and structural/procedural impediments limit access to consistent, continued use of effective contraception.[2-10] Clinicians also face a number of challenges when facilitating women's ability to obtain appropriate contraception.

Economic Impediments to Access

The costs involved in obtaining contraception for consistent use, whether by prescription or over the counter, can be impediments for many women *(Table)*.[10-16] Women without health insurance or prescription drug plans as well as those with such coverage may be hampered by their inability to afford out-of-pocket costs for contraceptives, ie, full costs for the former and co-pays for the latter. Recently introduced and/or long-acting contraceptive methods with high upfront costs are less frequently available and may require greater out-of-pocket costs than other methods.

Nearly 1 in 5 women in the United States is uninsured, and two-thirds of women obtain health insurance from their own or their spouses' employers.[17] The remainder are covered by privately purchased health insurance or publicly funded programs such as Medicaid. Nearly 17% of individuals employed by others become uninsured.[18] Underfunded and/or limited numbers of public family planning services may further limit uninsured women's ability to obtain contraceptives.[8,9,19]

Access to contraception may also be affected by age. Sexually active adolescents are at high risk for unintended pregnancy, but various factors often impede their access to reproductive health services. Such factors may include[20]:

Table. Contraceptive Cost Ranges: 1 Month's Supply[10-16]

Contraceptive by Class	Average Wholesale Cost Range per Month's Supply
Combination OCs (28-day pack)	$27.49-$59.06[11]
Progestin-only OCs	$36.92[11]
Transdermal patch	$54.27[11]
Vaginal ring	$47.82[11]
Injectable DMPA	$17.69-$22.02 ($53.07-$66.06 amortized over 3-month length of effectiveness)[11] (plus quarterly injection fee: $35-$73)
IUDs	$3.78-$8.24 ($453.60-$494.40 amortized over 5- and 10-year approved length of use)[11] (plus insertion fee $117-$261)
Implant	$17.42 ($634.32 amortized over 3-year approved length of use)[11] (plus insertion fee $168-$377)
Diaphragm	$3.47[11] ($85 amortized over 2-year estimated length of use; plus exam/fitting fee $50-$200)[10]
Female condom	$2.50 (one-time use)[12]
Cervical cap	$5.63 ($70 amortized over 1-year estimated length of use; plus exam/fitting $50-$200)[13]
Vaginal spermicides (OTC)	$0.22-$1.01 (price per use)[11]
Condoms (OTC)	$0.26-$0.96 (price per use)[11]
Surgical tubal sterilization	$1,500-$6,000[14]
Transcervical insert sterilization	$2,314[15]
Vasectomy	$350-$1,000[16]
Emergency contraception	$33.36 (1 dose)[11]

OCs=oral contraceptives; DMPA=depot medroxyprogesterone acetate; IUDs=intrauterine devices; OTC=over the counter.

- financial issues (eg, inability to pay directly for services, lack of private or public health insurance coverage, limited availability of free or low-cost family planning programs)
- structural obstacles (eg, exclusion from confidentiality and consent rights in some states, lack of adolescent-friendly environments, difficulty with transport to available community services)

One recent effect of the Deficit Reduction Act of 2006 is a loss of discounts on the prices of steroid contraceptives purchased by university and college health services.[21] College students are now faced with higher costs for steroid contraceptives and/or the necessity to switch to less expensive and less effective birth control methods.

Some health insurance plans provided through employment (eg, some small employers, some employer self-insurance) do not cover contraception.[22] Employers selecting one or more health plans to offer to their employees generally choose what benefits will be included. (See below discussions of contraceptive equity mandates.) Even when several contraceptive methods are covered by a woman's health insurance, the

particular method or formulation best suited to her individual needs may not be included in the plan's formulary. Alternatively, if the method is covered under a cost-sharing tiered system, it may require a higher co-pay than a less-appropriate method or a greater proportion of total cost than that required for noncontraceptive drugs.[8,23] Co-payments for nonpreferred drugs (those of all types not included on a formulary or preferred drug list) more than doubled from an average of $17 in 2000 to $38 in 2006; co-payments for preferred drugs (those included on a formulary or preferred drug list, eg, drugs without generic substitutes) increased by 84%, from an average of $13 in 2000 to $24 in 2006.[24]

A 2003 study found that women who received fewer than 13 cycles of oral contraceptive (OC) supplies at a time were more likely to have pregnancy tests than women who received 13 cycles, suggesting a greater perceived risk of pregnancy due to gaps in cost coverage.[25] Prescription plans vary widely, but some plans and/or pharmacies limit dispensing of steroid contraceptives to 1 to 3 months' supply at a time; such limitations can complicate women's consistent use and may lead to method discontinuation.[5,8,25] Although state policies vary, no more than a 100-day supply of any drug at any one time is allowed by Medicaid.[25]

Impediments to Clinician Provision

Economic and structural factors also pose challenges to clinicians who wish to facilitate a woman's consistent use of contraception. For example, clinicians must contend with the myriad difficulties and costs of acquiring and maintaining contraceptive supplies for contraceptive initiation. In addition to institutional rules governing these procedures, the limited shelf life of products that must be stocked for clinician administration (eg, intrauterine devices [IUDs], implants) complicates supply and increases costs. Due to these concerns, many clinicians no longer stock IUDs or implants in their offices, creating the need for additional visits. In such settings, if an IUD or implant is inadvertently contaminated during insertion, an additional device is not available in the office.

Some health insurance plans may cover steroid contraceptives only if they are prescribed for a noncontraceptive indication, such as treatment of menstrual irregularities. Clinicians are thus faced not only with the need to be familiar with the requirements and limitations of many varying plans but also with ethical quandaries.

Formulary issues often make it difficult for clinicians to prescribe the least expensive and most individually appropriate contraceptive method or regimen for each woman.[23,26] Formulary differences among multiple insurance plans, tiered pharmacy benefits, and recurrent intraplan formulary changes are further complicated by the frequency with which women change or are switched to different insurance plans.

As new contraceptive methods are developed, clinicians in some practice settings may have difficulty in finding training for using them. Paradoxically, training techniques are often less available for methods used less often, but lack of training limits the number of clinicians who can increase use of such methods by their patients.

Insurance Coverage of Contraception

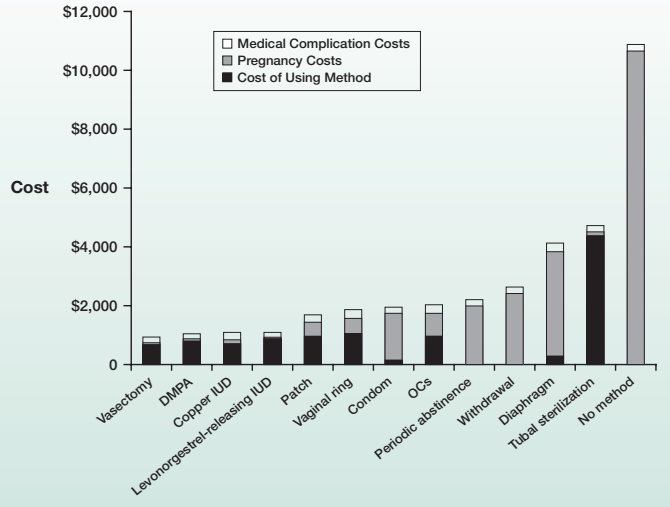
Without comprehensive insurance coverage of contraception, many women do not use contraception at all if it is not covered by their insurance plans; alternatively, they may opt for the methods best covered by the health plan rather than paying out of pocket for a method they may find more appropriate or effective.[27] The most recent employer-based studies (2003) indicate that only 72% of employer health plans cover all methods of prescription contraception approved by the US Food and Drug Administration (FDA).[28] Because many uninsured women are dependent on public family planning services, more public funding is crucial to the ability of all clinics to provide the full range of contraceptive options.[8,19] In 2003, fewer than 1% of publicly funded agencies offered all the FDA-approved contraceptive methods then available, with 57% of agencies reporting that they did not stock certain methods (eg, IUDs, patch, ring) because of cost.[29] While almost all publicly funded clinics offered OCs and the injectable, only 58% offered IUDs; 75% offered the transdermal patch and 40% offered the vaginal ring (both relatively new methods at the time).[29,30]

Contraceptive Equity Legislation: Current Status

The federal Equity in Prescription Insurance and Contraceptive Coverage Act was introduced in Congress in 1997, reintroduced in 1999, 2001, 2003, and 2005, and reintroduced in 2007 as part of the Prevention First Act.[28,31] This bill has not yet passed in either house of Congress; hearings are pending in various committees. It would require that insurers/plans (including health care organizations, hospitals, health maintenance organizations) that cover other prescription drugs and/or outpatient services must also cover FDA-approved prescription contraceptives and related contraceptive services in a manner comparable with other covered prescription drugs, devices, and outpatient services.[28] Despite lack of federal legislation, about half of the 50 states currently provide some form of contraceptive equity mandate, but many state mandates have exclusion criteria or are limited to certain types of insurers.[32]

The social, economic, and individual advantages of comprehensive contraceptive coverage have been well established. Insurers and public health agencies generally pay the direct medical costs of unintended pregnancies, including: ectopic pregnancy; spontaneous abortion and, frequently, induced abortion; prenatal care; term pregnancy; newborn care; and associated maternal morbidity and mortality.[33,34] Several studies have demonstrated that contraceptive use is cost-effective compared with no contraceptive use and have estimated the substantial potential cost-savings to employers, insurers, and public funders by comprehensively covering contraception *(Figure[35])*.[27,35-38] Furthermore, while there may be a large initial up-front cost to payers for providing women with some long-term contraceptive methods (eg, IUDs, implant, sterilization), this cost amortized over several years is still less than the costs of

Figure. Components of costs associated with contraceptive method use versus no method use over 2 years.[35]*



*Adjusted to 2002 dollars.
DMPA=depot medroxyprogesterone acetate; IUD=intrauterine device; OCs=oral contraceptives.
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unintended pregnancy and may be lower to payers over time than the total costs of shorter-term contraceptive methods used for the same time period.[39,40]

Clinician Strategies to Enhance Access

Clinicians can implement steps that may improve an individual woman's access to her most appropriate and effective contraceptive method.

Separate contraceptive prescription from health screening procedures. Some well-intended clinician actions may discourage or delay women from seeking or obtaining contraception. A number of medical examinations are important for women's health—such as periodic pap tests, pelvic examinations, breast examinations, and sexually transmitted infection screening—and should be performed periodically. Nevertheless, these measures are unrelated to the use of hormonal contraception, are unnecessary for assessment of hormonal contraceptive candidates, and may increase delay, fear, and embarrassment for women seeking contraception if they are associated with contraceptive initiation or continuation.[3,4,6,9,41-44] Results of such tests should not be prerequisites for or allowed to delay contraceptive prescription.[4,6] Women, particularly adolescents, may be deterred from using highly effective contraceptive methods if these examinations are required prior to initiation. Studies have found that prescribing contraception without first imposing these measures does not compromise women's health. In an 18-month project, 73% of adult women who were able to obtain hormonal contraception without a pelvic examination subsequently followed up on referrals for additional medical care, and 83% of women referred for pap tests or pelvic exams kept these appointments.[43]

Thorough medical history-taking, particularly a family history of blood clots, and blood pressure measurement are the most useful approaches to detect any contraindications to hormonal contraceptive use, and are the only measures required for contraceptive prescription if no preexisting medical problems are present or suspected.[4,6,45]

Prescription of generic COCs. Generic COCs are less costly to insurers and pharmacies than branded COCs with the same hormonal formulation; that is why generic COCs are more likely than branded ones to be available on pharmacy plans with lower or no co-pays.[26] When prescribing COCs, clinicians need to familiarize themselves with the formulary status of the various agents to improve access.

Because several generic versions of a particular COC formulation may exist, a plan's formulary may frequently switch from one to another to reduce costs, often confusing and disturbing women who worry that their prescription refill COCs appear different from previous refills. Women should be informed that class efficacy and safety labeling applies to all COC formulations, and that formulations with the same estrogen dose and progestin dose and type are pharmacologically equivalent, have equally high effectiveness, and exhibit similar side-effect profiles even when the tablets themselves and their packages differ in appearance.[26,45-47] Although additional counseling time may be required to present this information to patients, it is likely to enhance consistent, continued contraceptive use.

Maximum contraceptive refill prescription. Many health plans limit prescribing and/or pharmacy dispensing of COCs, transdermal patches, and vaginal rings to 3 cycles or fewer. Whenever possible, clinicians should prescribe contraceptives for the maximum refill period—ideally 1 year (13 28-day cycles)—to facilitate convenience, eliminate the need to schedule and pay for additional clinician visits, avert missed doses, and help prevent unintended lack of continuation.[25]

Clinicians can also encourage women to avail themselves of whatever conveniences and advantages their plans allow, such as mail, fax, and Internet options for obtaining timely—and possibly less expensive—multiple-month refills. Similarly, women whose insurance coverage is provided through their own or a family member's employment should know that beneficial plan changes can sometimes be made by informing the employer's Human Resources department about the existence of procedural obstacles to correct medication usage.

Clinicians should also be aware that although emergency contraception (EC) is now available without a prescription for most women, some insurance plans will not cover the cost of EC unless it has been prescribed. Therefore, if a woman is in a plan that covers EC, the clinician should provide an EC prescription in addition to prescribing regular contraception so that the woman can obtain EC quickly at lower cost if and when she needs to use it.

Simplified renewal process. If a visit to the clinician is not medically necessary because of a concomitant medical condition, ongoing side effects, or other problems, clinicians can save themselves and their patients time, inconvenience, and costs by facilitating contraceptive prescription renewals through telephone, mail, or e-mail requests. Similarly, in the absence of side effects or other problems during contraceptive use, there is no reason to require clinician appointments for more-frequent renewal of contraceptive prescriptions than 1 year.[7,25]

Participate in resolving insurance/pharmacy issues. Clinicians often need to play a key role in overcoming coverage obstacles to continued contraceptive use. While a refused contraceptive refill is sometimes the result of pharmacy misunderstanding rather than of insurance plan restrictions, the clinician's office staff usually knows whom to contact at the plan office to determine applicable rules. At times, pharmacies may have to be reminded that they have the ability to "over-ride" the limited-time prescription for common exigencies, such as prolonged travel, lost prescriptions, etc. Clinicians and staff members are also likely to be able to alter coverage more easily and effectively than the woman herself. Performing such liaison functions to pharmacies and plan offices not only helps prevent frustration and delay that can lead to contraceptive discontinuation but also broadens clinician/staff familiarity with individual health plans, to assist other women.

Support increased community-based contraceptive access. Clinicians can help to expand adolescents' access to contraception by supporting and participating in community-based solutions, such as school-based clinics, Planned Parenthood facilities, and other innovative outreach programs. Such programs can make it easier for sexually active teenagers to avoid unintended pregnancy despite lack of money or insurance and concerns about confidentiality. Clinicians should be familiar with and inform appropriate women about available community resources that offer contraceptive services at lower cost, often on an income-based sliding scale, than an individual clinician can provide.

Inform low-income women about assistance programs. Free or low-cost contraceptives may be available by prescription to women who meet low-income guidelines and have no private or public prescription coverage. Because the costs of some contraceptive methods, such as IUDs and implants, are high, contraceptive manufacturer Patient Assistance Programs (PAPs) and state Medical Assistance Programs may enable women who could otherwise not afford these methods to use them. The manufacturers of IUDs also offer monthly installment payment plans to help women who can't afford the full cost upfront to pay for these devices over time.[48,49] PAPs are available for both IUDs (see the Needy Meds Web site, at www.needymeds.com). Some state Medical Assistance Programs, as well as many Planned Parenthood sites, provide IUDs and/or implants in this manner. In many states, Medicaid may also provide IUDs and implants. Clinicians should become familiar with and recommend such programs to women who could take advantage of them.

(continued on page 10)

Extended Combination Hormonal Contraceptive Regimens and Menstrual Suppression

Sharon M. Schnare, RN, FNP, CNM, MSN, FAANP
Clinical Instructor
Department of Family and Child Nursing
University of Washington Seattle School of Nursing
Seattle, Washington

Daniel R. Mishell, Jr, MD
The Lyle G. McNeile Professor
Department of Obstetrics and Gynecology
Keck School of Medicine
University of Southern California
Los Angeles, California

Scheduled cyclic withdrawal bleeding during use of hormonal contraception is not biologically necessary, and no adverse health effects accrue if such bleeding does not occur.[1-3] When combination oral contraceptives (COCs) were first developed, each 1-week hormone-free interval with withdrawal bleeding was intended to reassure women that pregnancy had not occurred.[3,4] Subsequently, studies were performed with extended use of COCs by increasing the standard 21-day duration of active-hormone tablets between hormone-free intervals.[5] Other hormonal contraceptive formulations have recently been introduced, with some increasing the duration between scheduled bleeding episodes and one eliminating the hormone-free interval entirely. The amenorrhea resulting from continued steroid contraceptive use has been found to be acceptable and desirable by many women and clinicians worldwide.[1,2,6-11]

Rationale for Extended or Continuous Use

Extended- or continuous-use regimens can increase lifestyle convenience by allowing women to eliminate or decrease the frequency of withdrawal bleeding or to schedule it when and if desired. Many women are interested in learning about the potential advantages of prolonging the duration of the administration of contraceptive hormones to avoid bleeding during certain times of work, leisure activities, sexual activity, vacations, and travel.[12] In particular, adolescents,[13,14] athletes,[11,12] female military personnel,[4,11] and perimenopausal women[11] may desire reduced or absent scheduled bleeding episodes.

Although unscheduled bleeding and/or spotting episodes may occur frequently during early use of extended and continuous combination hormonal contraceptive regimens, these effects usually decrease with continued use.[15-23] With extended-use formulations, the total number of bleeding days is generally decreased from baseline, although days with spotting episodes may occur with some frequency.

Women with menorrhagia and/or dysmenorrhea may especially obtain benefit from reduction or elimination of scheduled bleeding.[24,25] Menstrual-cycle-related symptoms (eg, mood symptoms, including those occurring with premenstrual syndrome and premenstrual dysphoric disorder, such as irritability, bloating, breast tenderness, and headaches) are often exacerbated by a hormone-free interval during hormonal contraceptive use; these symptoms may be reduced or eliminated when fewer or no scheduled bleeding episodes occur.[8,11,24,26-32]

Because extended- and continuous-use regimens provide less opportunity for unintended extension of hormone-free intervals than occurs with a 21/7 interval,[33,34] successful regimen adherence and therefore the typical-use contraceptive effectiveness of combination hormonal contraceptives should be increased.[33,35,36]

Regimens

Three COC formulations, in 2 regimen lengths, have been approved by the US Food and Drug Administration (FDA) for extended or continuous use.[37,38] Two COCs are formulated to be used for a 3-month period with 4 scheduled bleeding episodes per year: active tablets (150 mcg levonorgestrel [LNG]/30 mcg ethinyl estradiol [EE]) are taken for 84 consecutive days, followed by 7 days of either placebo tablets or 10 mcg EE.[17,22,39,40] In 1-year clinical trials, the number of unscheduled bleeding/spotting days was similar with use of both regimens in the first 91-day cycle (median 11-12 days) but declined in subsequent cycles (median 4 days).[17,39] However, nearly 60% of users of the placebo-containing regimen still had some unscheduled bleeding/spotting days (median 4 days) in Cycle 4.[17] Although the percentage of users with unscheduled bleeding was not reported for the non—placebo-containing regimen, there was a mean of 7.6 days of unscheduled bleeding or spotting in Cycle 4.[39] In a 2-year open-label extension trial of the placebo-containing regimen, the median number of unscheduled bleeding and/or spotting days in Cycle 8 was 2.[22]

A continuous-use (365 days) COC containing 90 mcg LNG/20 mcg EE (provided in packs of 28 active tablets) has no scheduled hormone-free interval and thus no scheduled bleeding episodes.[23,41] No data are yet available regarding use for more than 1 year. In a North American clinical trial, 58.7% of women who used this COC for 1 year reported amenorrhea (defined as neither bleeding nor spotting) and 79% reported no episodes of bleeding (with or without spotting) during pill-pack 13.[23] The percentage of users with only spotting episodes increased from 3.7% during the first pill-pack to a high of 26.7% during the 6th pill-pack before decreasing to 20.2% during the 13th pill-pack.[23] During use of pill-pack 2, 67% of users experienced 4 or more days of bleeding or spotting and 54% experienced 7 or more days of bleeding and/or spotting; during the 13th pill-pack, these percentages were 31% and 20%, respectively.[41]

Off-label extended regimens using other COC formulations have been studied and/or reported in various extended cycle lengths (eg, 49, 126, 168 days).[12,15,16,21,28,32,42] It is biologically plausible that any COC formulation could be used in an extended regimen. Although triphasic COCs have been used in extended regimens,[43] most published studies have utilized monophasic formulations. Concerns about a potential greater incidence of unscheduled bleeding episodes caused by the hormonal fluctuations of triphasic COCs suggest that use of monophasic COCs in extended regimens may be more appropriate for most women. However, except for the 3 formulations mentioned earlier, extended use of other formulations is an off-label use.

A randomized trial compared off-label extended use of the transdermal contraceptive patch (12 consecutive weekly patch applications: 84 days active hormones, 7 hormone-free days) with the cyclic regimen of 3 weekly patch applications with 1 patch-free week.[19] Overall, the extended-regimen group had fewer total bleeding days but more spotting days than the cyclic-regimen group.

Studies of off-label extended regimens of the vaginal ring also have been conducted.[18,35] A randomized trial compared consecutive ring use for 42 days, 84 days, or 357 days with the approved regimen of

21 days (each of these regimens was followed by 7 ring-free days).[18] The 42/7 regimen showed a reduction in total bleeding/spotting days (mean percentage, 15.5%) compared with the 21/7 cycle (mean percentage 17.6%); the other 2 extended regimens had an increase in total bleeding/spotting days of a mean 3.5% and mean 7.1%, respectively, compared with the 21/7 regimen.

A few studies indicate that women using extended hormonal regimens who experience problematic unscheduled bleeding/spotting may benefit from taking a 3-day hormone-free break, starting when bleeding occurs, before resuming active hormones.[42,44] To maintain contraceptive efficacy, the first hormone-free break should not be taken until active hormones have been used consecutively for at least 1 month and breaks should be repeated no more frequently than every 3 weeks.

Summary

During use of hormonal contraceptives, cyclic withdrawal bleeding is not biologically necessary. Extended or continuous use of combination hormonal contraceptives is safe and effective. Benefits may include fewer bleeding days, less dysmenorrhea, and reduction of several premenstrual symptoms including breast pain, bloating, headaches, and irritability. Women selecting extended combination hormonal regimens can control whether and when they experience hormone-withdrawal bleeding, although unscheduled spotting may persist.

References are available online at www.usc.edu/cme

Advances in Sterilization (continued from page 4)

Women who have undergone surgical tubal sterilization are no more likely to experience menstrual abnormalities than nonsterilized women; in fact, sterilized women were found to be more likely than nonsterilized women to have a decreased amount and number of days of menstrual bleeding from baseline, as well as decreased menstrual pain.[51] No significant changes have been found in ovarian stromal blood supply or in luteal phase hormone levels from preoperative levels or compared with nonsterilized women.[52-54] Similarly, hormonal levels in sterilized perimenopausal women are comparable to those in nonsterilized perimenopausal women.[55]

Surgical tubal sterilization is associated with an important noncontraceptive health benefit, a decreased risk of ovarian cancer. The Nurses' Health Study prospective cohort found a 67% reduction in risk of epithelial ovarian cancer in sterilized compared with nonsterilized women (relative risk 0.33; CI 0.16-0.64).[56] The protection appears to persist for at least 15 to 20 years after sterilization.[57-60]

Evidence refutes a number of misperceptions about health effects of male sterilization. Vasectomy is not associated with adverse effects on male libido, erectile function, or sexual satisfaction.[61] Risks of testicular and prostate cancer are not increased among vasectomized compared with nonvasectomized men.[62-68] Vasectomy also has no effect on the risk of cardiovascular disease, even 20 years following sterilization.[64,65,69]

Sterilization Reversal Techniques

Transcervical microinsert tubal sterilization cannot be surgically reversed. Women who have undergone this procedure and subsequently wish to become pregnant may attempt to do so through the use of in vitro fertilization (IVF). Women who have undergone surgical tubal sterilization can have tubal reanastomosis or IVF. Surgical reversal, if effective in restoring tubal patency as determined by a hysterosalpingogram 3 months later, is usually permanent. IVF provides an opportunity to obtain pregnancy in only 1 cycle.

Reported success rates for surgical reversal of tubal surgical sterilization are highly variable, ranging from 25% to 82% and higher.[2,70-72] Rates of intrauterine pregnancy and/or live births following surgical reversal of tubal sterilization (reported range: 34% to 87%[47,71]) are also highly variable (depending on the woman's age and the length and portion of remaining undamaged fallopian tube[4]), but are generally higher than those following tubal reconstruction after tubal disease, which have been reported to range from only 11% to 41%.[72]

The success of surgical vasectomy reversal depends on the type of vasovasostomy or epididymovasostomy procedure implemented (reversal of microsurgical procedures are more successful than macrosurgical procedures), shorter interval from vasectomy to reversal (pregnancy rates are less than 50% when reversal is performed more than 9 to 10 years after vasectomy), longer postvasectomy length and location of vas deferens segments, and lower age of female partner.[7,16,36,73-76] Approximately 60% of men develop circulating antisperm antibodies, which also decrease the likelihood of pregnancy following vasectomy reversal.[73] For these reasons, widely varying pregnancy rates following vasectomy reversal have been reported, ranging from 7% to 89.7%.[7,73-75,77]

Conclusions

Illustrative Case Study Resolution

Rose H: *The clinician explained to Rose that sterilization must be considered permanent birth control but that substantial numbers of sterilized women, particularly those aged 30 or younger at the time of the procedure, later regret their inability to have children. Reminding Rose that sterilization involves anesthesia and several days of recovery before resumption of normal activities, she suggested that Rose also consider the copper IUD as an alternative long-term contraceptive method. She explained that this IUD is highly effective (as effective as sterilization) and provides this level of effectiveness for 10 years or longer as well as being rapidly reversible. She stated that this IUD could be placed during an office visit while the full cost of at least 10 years' worth of contraception would be covered up front by her insurance. Informed that she could schedule the sterilization procedure if she still wanted it, Rose decided instead to have a copper IUD inserted the next day.*

Sterilization is a popular contraceptive choice for many men and women. Surgical tubal sterilization and vasectomy are safe and highly effective. Interval tubal sterilization with a transcervically induced microinsert appears equally effective when correctly placed and does not require incisional surgery, but it has not yet been studied for more than 4 years after the procedure. Women and men contemplating sterilization are informed that it is intended to be permanent, yet substantial numbers of sterilized women and men later regret having had their operations. Both operative reversal of surgical sterilization and IVF are costly, and transcervical tubal sterilization cannot be surgically reversed. Women considering tubal sterilization, particularly those aged 30 and younger wishing interval tubal occlusion, should be encouraged to consider equally effective reversible alternatives, such as IUDs. Placement of an IUD does not require use of an operating room, general anesthesia, or delayed recovery time. In addition, IUDs are rapidly and easily reversible, with return to full fecundity after removal.

References are available online at www.usc.edu/cme

Assessing Costs and Improving Access to Contraception (continued from page 7)

Conclusions

Illustrative Case Study Resolution

Karen F: *In this case, as in many other insurance and/or pharmacy controversies, Karen's clinician took the lead to resolve the COC refill problem. The clinician telephoned Karen's health plan and explained her travel schedule to a supervisor. Learning that the plan allows a vacation exception for early refill of contraceptive prescriptions, he asked the supervisor to authorize the pharmacy to provide Karen with a 3-month supply of COCs. The pharmacy may have already had this ability prearranged with the insurance company, since travel is a frequent condition for which insurance plans allow the local pharmacist to "over-ride" the rule. Willingness to become involved, and familiarity with insurance plan procedures, enabled the clinician to support Karen in avoiding risk of unintended pregnancy.*

Of the 6.1 million pregnancies that occurred in the United States in 2001, 49% (about 3 million) pregnancies were unintended, and 52% of these unintended pregnancies (about 1.5 million pregnancies) occurred in women who were not using contraception during the month of conception. Economic and structural obstacles to contraceptive access account for a large proportion of contraceptive nonuse and inconsistent use. Federal actions to enhance contraceptive equity and to increase public funding for reproductive health care would greatly improve women's access to contraception. Nevertheless, clinicians can make an immediate positive difference by implementing strategies to expand women's ability to obtain and successfully use effective contraception. In addition, clinicians can support innovative means of helping adolescents and women at risk of unintended pregnancy who are not currently using contraception to do so more easily and affordably.

References are available online at www.usc.edu/cme

Post-Test

The following Post-Test contains 10 multiple-choice questions based on information contained in the *Dialogues in Contraception®,* Volume 11, Number 3, newsletter. It is designed to enable practitioners to assess the knowledge they have gained from the newsletter and to identify areas for further study.

On the Answer Sheet, fill in all identifying information requested. Complete the Answer Sheet by circling the one response that most accurately answers each question.

1. During 2 clinical trials of the transcervical (hysteroscopic) microinsert, in what percentage of women in whom placement was attempted was correct bilateral placement in both fallopian tubes achieved during the initial procedure?
   a. 46%
   b. 66%
   c. 86%
   d. 96%

2. The time to azoospermia in vasectomized men can be highly variable and may depend upon the type of occlusion used as well as on the age of the individual.
   a. True
   b. False

3. According to the US Collaborative Review of Sterilization (CREST) study, the cumulative 10-year probability of pregnancy per 1000 female surgical tubal sterilization procedures was:
   a. 8.5
   b. 18.5
   c. 28.5
   d. 38.5

4. The CREST study found that the cumulative probability of expressing regret within 14 years after female surgical tubal sterilization was higher among women:
   a. aged 30 or younger at time of sterilization compared with older women
   b. sterilized postpartum compared with those undergoing interval procedures
   c. sterilized within 1 year of the birth of their youngest child
   d. all of the above

5. Which of the following describes long-term health effects of surgical sterilization procedures?
   a. detrimental effects on male and/or female sexual interest and pleasure
   b. reduced risk of epithelial ovarian cancer in sterilized women
   c. adverse effects on erectile dysfunction in vasectomized men
   d. increased risk of prostate cancer in vasectomized men

6. Women considering tubal sterilization, particularly those aged 30 and younger, should be encouraged to consider equally effective reversible alternatives, such as intrauterine devices.
   a. True
   b. False

7. Scheduled cyclic withdrawal bleeding during use of hormonal contraception is not biologically necessary, and no adverse health effects accrue if such bleeding does not occur.
   a. True
   b. False

8. In the United States in 2001, 49% of pregnancies were unintended. What percentage of unintended pregnancies occurred in women who were not using contraception during the month of conception?
   a. 32%
   b. 42%
   c. 52%
   d. 62%

9. In the United States, how many women do not have health insurance?
   a. 1 in 5
   b. 1 in 8
   c. 1 in 10
   d. 1 in 20

10. Pelvic and breast examinations are necessary for assessment of candidates for hormonal contraception prior to prescription.
    a. True
    b. False