

CLINICAL PRACTICE ALERT

November 2009

CONTRACEPTIVE STERILIZATION

Worldwide, sterilization (tubal sterilization and vasectomy) is used by more couples than any other method of contraception. In order to offer a full range of contraceptive options, Family Planning, Access, Care, and Treatment (Family PACT) benefits include vasectomy and a variety of tubal occlusion procedures, including laparoscopy, mini-laparotomy, and hysteroscopy techniques. This *Clinical Practice Alert* is intended to review recent innovations in contraceptive sterilization and to facilitate client referral for sterilization procedures, when not available at your practice site.

KEY POINTS

- Rates of contraceptive sterilization have been decreasing, in part because the availability of safe and equally effective long acting reversible contraceptive methods, including intrauterine contraceptives (IUCs) and contraceptive implants.
- Vasectomy is less likely to result in serious complications than tubal sterilization and is at least as effective.
- Newer approaches to female sterilization are performed through a hysteroscope under local anesthesia, with or without conscious sedation, thereby avoiding complications of abdominal surgery and general anesthesia.
- To prevent any possibility of a person being sterilized unknowingly, specific state and federal written consent requirements must be followed, including a 30-day waiting period before the procedure can be performed.

QUESTIONS AND ANSWERS

Who should consider a sterilization procedure?

After education and counseling, men who want to end their ability to cause pregnancy and women who no longer want to be able to become pregnant may be candidates for sterilization procedures. As required by state law, men and women who request sterilization counseling must be told about all permanent and reversible contraceptive alternatives. Before signing the PM 330 sterilization consent form, the State's sterilization information booklet must be provided to and reviewed by the client.

How does the efficacy of sterilization compare with long acting reversible contraceptives?

Vasectomy, tubal sterilization, contraceptive implants, and IUCs all have typical use failure rates less than one percent in the first year of use, and tubal sterilization and vasectomy are much more effective than reversible methods over time.¹ Since tubal sterilization provides better protection against intrauterine pregnancy than ectopic pregnancy, if a client has a positive pregnancy test result after a tubal ligation, ectopic pregnancy should be excluded.

Are there any predictors of regret after receiving a sterilization procedure?

Regret at 10 years after tubal sterilization has been reported by 5-21 percent of women. Most studies report higher rates of regret among women undergoing sterilization at young ages, especially under 30 years old. A low number of living children at the time of sterilization does not appear to be a risk factor for requesting information about reversal.

How is hysteroscopic placement of tubal micro-inserts (Essure[®]) different from abdominal procedures?

The Essure[®] procedure entails the placement of a coiled metal micro-insert into each fallopian tube through a hysteroscope. It is usually done as an office procedure under local anesthesia and takes about 7-15 minutes. When compared to laparoscopy or mini-laparotomy, an advantage of the Essure[®] procedure is that abdominal surgery, and its potential complications, is avoided. Hysteroscopic sterilization is the preferred approach for women with morbid obesity (BMI \geq 45); an abdominal mesh that prevents laparoscopy; a permanent colostomy; multiple previous abdominal/pelvic surgeries (because of concerns about adhesions); the use of anticoagulation medications; and medical problems that contraindicate general anesthesia.

How does Essure[®] work?

The micro-insert expands upon release and anchors itself in the fallopian tube, but does not block it. Over the three months following placement, reaction to the micro-insert causes scarring and occlusion of the fallopian tubes. Essure[®] is considered an irreversible sterilization procedure.

What are the risks of the Essure[®] procedure?

Side effects that can occur during or immediately after the procedure include cramping, pain, vomiting, and dizziness. Rare complications include tubal perforation and expulsion of a micro-insert. In about 10 percent of cases, it is not possible to occlude both tubes and a second procedure becomes necessary. Menstrual patterns do not change as a result of the procedure.

What follow-up is necessary after an Essure[®] procedure?

To ensure complete tubal occlusion, a low pressure hysterosalpingogram (HSG) x-ray must be performed by a radiologist three months after the date of the Essure[®] procedure. If occlusion is not demonstrated, a repeat HSG is done three months later. Another method of contraception must be used until bilateral occlusion is confirmed by HSG. If both tubes are not occluded by six months, the procedure is considered to be a failure.

¹ Peterson HB. Sterilization. *Obstetrics and Gynecology* 2008;111:189-203

CONTRACEPTIVE STERILIZATION (CONT.)

Who can be trained to insert Essure® and how can training be arranged?

In order to be certified by the company that manufactures the Essure® device (Conceptus), the surgeon must be an experienced hysteroscopist who has undergone company-sponsored training and proctoring. Information for physicians regarding training opportunities can be found at <http://www.essuremd.com/>. Certification must be in place in order to purchase the devices.

If no one in my practice performs sterilization procedures, how can we facilitate referrals?

- Maintain a list of referral sites in your area that will perform sterilization procedures for Family PACT clients.
- Provide counseling and informed consent (including completion of Consent Form PM 330) on behalf of the surgeon who will perform the procedure.
- Based upon a written agreement with one (or more) providers, it is acceptable to perform preoperative evaluation and post-operative care in your practice, even if your provider did not perform the procedure.

Does Family PACT cover any preoperative evaluation and management of complications of sterilization procedures?

- Family PACT benefits include a limited number of routine preoperative screening tests before vasectomy or tubal sterilization (see *Policies, Procedures, and Billing Instructions* [PPBI], Benefit Grid). If more complex testing is required because of a client's medical condition, a Treatment Authorization Request (TAR) must be submitted which includes medical justification for the services requested.
- Certain immediate and delayed complications of sterilization procedures may be covered, as specified in the PPBI, if they are a direct consequence of the procedure.

How long can Family PACT services continue after completion of the sterilization procedure?

The postoperative period for vasectomy and tubal sterilization procedures is 90 days, or earlier if the clinician determines a client is no longer at risk of becoming pregnant or causing pregnancy. For hysteroscopic sterilization, the post-operative period is 36 weeks (252 days), or earlier, when the clinician determines by HSG that the client is no longer at risk of pregnancy. Once the post-operative period is complete following a successful sterilization, the client is no longer eligible for the Family PACT Program and the health access program (HAP) card must be de-activated.

APPLICATION OF FAMILY PACT STANDARDS

1. Informed Consent

- Clients shall be advised of the availability of contraceptive services including all conventional techniques of male and female sterilization.
- The consent process shall be provided in a language understood by the client and supplemented with written materials.

2. Confidentiality

- Clients shall be advised that services are confidential and that their identity will not be disclosed without their written permission, except as provided by law.

3. Access to Care

- Contraceptive and sexually transmitted infection (STI) services shall be provided without cost to all Family PACT clients.
- Referral resources for medical and psychosocial services beyond the scope of Family PACT, including domestic violence and substance abuse, shall be made available to clients. Services not listed in the Family PACT PPBI are not reimbursable by the program.

4. Availability of Covered Services

- Family PACT providers must provide access to, or referral for, contraceptives listed in the PPBI and offer timely, basic STI prevention and management onsite.

5. Scope of Clinical and Preventive Services

- Clinicians delivering services are expected to have professional knowledge and skills about medical practice standards pertaining to contraceptive services and STI prevention and management services.
- Documentation shall record clinical findings and justification for services in medical record.

6. Education and Counseling Services

- Clients shall receive education and counseling to clarify personal family planning goals.
- When clients desire no future childbearing, a description of the implications and consequences of sterilization procedures shall be provided.

PROGRAM POLICY

This alert provides an interpretation of the Family PACT Standards regarding care of clients seeking permanent contraception. Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT *Clinical Practice Alerts*, the term "shall" indicates a program requirement; the term "should" is advisory and not required.

RESOURCES FOR INFORMATION ON CONTRACEPTIVE STERILIZATION

- Peterson HB. Sterilization. *Obstetrics and Gynecology* 2008;111:189-203
- Abbott J. Transcervical sterilization. *Curr Opin Obstet Gynecol.* 2008 Apr;20(2):182-3
- Masour D, Copper IUD and LNG IUS compared with tubal occlusion. *Contraception.* 2007 Jun;75(6 Suppl):S144-51
- Cook LA, Van Vliet H, et.al. Vasectomy occlusion techniques for male sterilization *Cochrane Database Syst Rev.* 2007 Apr 18;(2):CD003991
- Sterilization Consent: Tutorial on Completing the PM 330, at http://www.familypact.org/Files/PM330/PM330_Final_11-18-08.pdf