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Enhanced Client Counseling Can Promote Reversible Long-Acting Contraceptive Methods

When clients express that they do not want to get pregnant at any time in the near future, it is important for staff to view this as an opportunity to provide valuable information that can improve clients' reproductive health and assist them in achieving their family planning goals. Remember, education and counseling will help clients achieve two public health goals: 1) pregnancies are intended and planned for; and 2) assist in creating healthy families according to their personal family planning goals.

The Family PACT Program includes reimbursable education and counseling visits that can be used to conduct comprehensive method counseling. Read on to learn more about reversible, long-acting methods and how they can help reduce unplanned pregnancy.

UNDERUTILIZATION OF IRREVERSIBLE AND REVERSIBLE LONG-ACTING CONTRACEPTION

Patty Cason, NP and Andria Hancock-Crear, MPH

Approximately 43 million American women, or roughly 70% of women in their childbearing years, are sexually active but are not currently intending to conceive^{1,2}. Although 90% of these women use contraception, approximately half of all pregnancies in a given year are unplanned^{3,4}. These contraceptive failures can be attributed to a combination of factors: the inherent unreliability of the method used (which varies widely between different approaches)⁵; the increased failure rate seen in short-term methods because of frequent switching between methods^{6,7}; and the challenges facing couples to use their method properly. It follows, therefore, that the high failure rate of typical contraceptive attempts could be greatly improved by an increased usage of more reliable methods that don't involve repeated motivational acts by either participant—i.e., by using long-term, rather than short-term, methods.

Currently, there are three general approaches to meeting this contraceptive need for highly effective methods: sterilization, intrauterine contraception (IUC), and implants. All of these methods have a less than 1% failure rate⁵, which is significantly better than that of shorter-term contraceptive methods like combined hormonal contraceptives (OC, rings, patches), progestin-only shot, barrier methods, or Natural Family Planning/rhythm methods⁵. Just as importantly, these methods do not rely upon the active and consistent efforts of either participant, and are thus far less susceptible to user error. Where these methods differ is in the length of time they can be used, reversibility, cost, and potential side effects. None of these long-term methods contain latex or estrogen,⁸ and all of them are covered by Family PACT. On the other hand, each long-term method requires an insertion or surgical procedure,

which necessitates skill on the part of the healthcare provider. In addition, these methods do not protect against Sexually Transmitted Infections or HIV⁸.

Sterilization is currently a widely chosen approach to contraception. Over 10 million women, or roughly 27% of all sexually active women of reproductive age, have had a tubal ligation.² Another 3.5 million, or 9%, are with partners who have had a vasectomy.² These methods are almost entirely reliable, and obviously require no ongoing action by either participant. It is important to note, however, that sterilization is more expensive and entails procedures that are more invasive than reversible long-term methods (implants including Implanon, Mirena, and ParaGard, described below). A comprehensive review of tubal ligation, vasectomy and tubal occlusion is beyond the scope of this article, but a recent review in the Green Journal (Obstetrics & Gynecology) is referenced below⁹.

The issue of reversibility is not a trivial matter: ten (or more) years after their tubal ligation, up to 21% of women express regret about their sterilization¹⁰. To mitigate this regret, providers can offer alternatives to sterilization in the form of highly effective reversible long-acting contraceptive methods. However, reversible long-acting contraceptive methods are among the least frequently chosen by American women of reproductive age: currently only 1% choose implants, and only 2% choose IUCs².

As a Family PACT provider, you can help promote long-acting reversible methods with clients who want to prevent pregnancy. Among these methods, the newest long-acting method is a highly effective progestin (etonogestrel) implant called Implanon™. (Norplant, previously the only progestin implant available in the US, is no longer available.)

Although women using Implanon are likely to have the same or fewer menstrual “bleeding” days than Norplant, the bleeding episodes are unpredictable and usually there are more “spotting” days. Even over time, no predictable bleeding patterns emerge⁸. However, experience with Norplant particularly suggests that the quality of counseling before insertion can improve a patient’s satisfaction with the implant and reduce the likelihood she will discontinue it because of side effects.⁵ Implanon is marketed with a duration of action of 3 years.⁵

Sexuality benefit of some long-term methods:

Since these methods (ParaGard, bilateral tubal ligation, and vasectomy), contain no hormones, the pattern of menstrual cycling will be unaffected. Women relying upon them will ovulate normally. Some women appreciate the cyclic changes in their libido that this allows.

The two IUCs currently available in the US are the Copper T 380A (ParaGard) and the levonorgestrel intrauterine system (Mirena). ParaGard contains no hormones, so it is a superior choice for women who prefer no hormones, cannot tolerate hormones, or for whom hormones are contraindicated. There are data supporting off-label use of ParaGard as an emergency contraceptive¹⁰. The approved duration of use for ParaGard is ten years, although data indicate high effectiveness as long as 12 years.⁵

Mirena is a highly-effective progestin-(levonorgestrel) containing intrauterine contraceptive device with valuable off-label non-contraceptive benefits (see side bar on Mirena). With Mirena, levonorgestrel is time-released directly into the uterus. The approved duration of use for Mirena is five years, although protection may last 7 years⁵. Keep in mind, the Family PACT

Mirena non-contraceptive benefits/treatments: (off-label)

- Reduced blood loss for patients with menorrhagia^{12, 13}
- Provides progestin protection to endometrium for peri or post menopausal patients on estrogen therapy^{14, 13}
- Symptom control/reduced blood loss for patients with uterine fibroids^{14, 15}
- Symptom control/reduced pain for patients with dometriosis or adenomyosis¹⁶
- Alleviate pain for patients with dysmenorrhea¹²

program covers both IUCs for contraceptive use only.

IUCs at one time received negative press due to complications associated with previous generations of devices (e.g. Dalkon Shield) so it could be beneficial to clearly discuss the benefits of the modern devices. Current IUCs are highly effective, protective against etopic pregnancy and some cancers, convenient and long-lasting, cost-effective, safer than previously thought and well-liked by users. Users exhibit high compliance and high continuation rates (about 85% to 90% at one year) compared to combined oral contraceptives.⁵ This translates into superior protection against unintended pregnancy.

Reversible long-term contraception may not meet the needs of all sexually active couples. However, if more of them were aware of the strikingly superior reliability of these methods, along with their other benefits, many undoubtedly would consider them.

This fact underscores the importance of the role of clinicians and counselors in presenting the benefits of reversible long-acting methods to clients. Since many clients are first introduced to new methods by their health care provider, promotion of these methods to clients that desire very effective methods of contraception will help to reduce the rate of unplanned pregnancy among Family PACT clients.

Table 1 and Table 2 on the following pages provide a concise summary of Reversible and Irreversible Long-Term Contraceptives, respectively.

Footnotes:

- 1 Wylie, K. Global Sex Survey 2005. Durex web site. Available at:<http://www.durex.com/us/gss2005Content.asp?intQid=778&intMenuOpen=>
- 2 Mosher WD, Martinez GM, Chandra A, Abma JC, Willson SJ. Use of contraception and use of family planning services in the United States: 1982–2002. *Advance Data from Vital and Health Statistics*. 2004; 350.
- 3 Chandra A, Martinez GM, Mosher WD, Abma JC, Jones J. Fertility, family planning, and reproductive health of U.S. women: Data from the 2002 National Survey of Family Growth. *National Center for Health Statistics. Vital Health Stat.* 2005;23(25).
- 4 Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States. *Perspectives on Sexual and Reproductive Health*. 2006;38(2):90–96.
- 5 Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive efficacy. Contraceptive Technology: Nineteenth Revised Edition*. New York NY: Ardent Media, 2007.
- 6 Grady WR, Billy JOG, Klepinger DH. Contraceptive Method Switching in the United States. *Perspectives on Sexual and Reproductive Health*. May/June 2002;34(3):135-145.
- 7 Nelson AL, Westhoff C, Schnare SM. Real-World Patterns of Prescription Refills for Branded Hormonal Contraceptives. A Reflection of Contraceptive Discontinuation. *Obstetrics and Gynecology*. October 2008; 112(4):782-787
- 8 From products' respective package inserts
- 9 Peterson HB. Sterilization. *Obstetrics & Gynecology*. Jan 2008;111(1):189-203.
- 10 Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol*. 1999;93:889–95.
- 11 Cheng L, Gulmezoglu AM, Piaggio G, Ezcurra E, Van Look PF. Interventions for emergency contraception. *Cochrane Database of Systematic Reviews*. 2008;(2):CD001324.
- 12 Luukkainen T. The levonorgestrel intrauterine system: therapeutic aspects. *Steroids*. 2000; 65: 699–702.
- 13 Kriplani A, Singh BM, Lal S, Agarwal N. Efficacy, acceptability and side effects of the levonorgestrel intrauterine system for menorrhagia. *International Journal of Gynaecology & Obstetrics*. Jun 07;97(3):190-4.
- 14 Chrisman C, Ribeiro P, Dalton VK. The levonorgestrel-releasing intrauterine system: an updated review of the contraceptive and noncontraceptive uses. *Clinical Obstetrics & Gynecology*. Dec 2007;50(4):886-97.
- 15 American College of Obstetricians and Gynecologists Committee on Gynecologic Practice. ACOG committee opinion. No. 337: Noncontraceptive uses of the levonorgestrel intrauterine system. *Obstetrics & Gynecology*. Jun 2006;107(6):1479-82.
- 16 Lockhat FB, Emembolu JO, Konje JC. The evaluation of the effectiveness of an intrauterine-administered progestogen (levonorgestrel) in the symptomatic treatment of endometriosis and in the staging of the disease. *Human Reproduction*. Jan 2004;19(1):179-84.

Table 1: Reversible Long-Term Contraceptive Summary

Method	Implanon™	Mirena®	ParaGard® T 380A
Consent Form Included in Package for Device	yes	upon request	yes
Pearl Index ^{5,6}	0.05-0.4	0.6-0.8	0.1-0.2
Training Provided by Manufacturer	yes	video only	video only
Length of Use ⁶	3 years	<ul style="list-style-type: none"> Up to 5 years per package insert Effective up to 7 years by WHO study^{1,2} 	<ul style="list-style-type: none"> Up to 10 years per package insert Effective up to 12 years by WHO study^{2,3}
Mechanism of Action ⁶	<ul style="list-style-type: none"> Suppression of ovulation Thickened cervical mucus Alterations in the endometrium 	<p>Local effects of LNG in the uterine cavity</p> <ul style="list-style-type: none"> Primary mechanism is prevention of fertilization <ul style="list-style-type: none"> Thickening of the cervical mucus Inhibition of sperm motility and function inside the uterine cavity and fallopian tubes, preventing fertilization Prevention of endometrial growth 	<p>Copper continuously released into the uterine cavity and present in the cervical mucous, uterus and fallopian tubes</p> <ul style="list-style-type: none"> Primary mechanism is prevention of fertilization <ul style="list-style-type: none"> Reduce motility and viability of sperm ovacidal effect of copper ⁴ * Inhibition of implantation is secondary mechanism
Hormone Content	Progestin (etonogestrel)	Progestin (levonogestrel)	none
Most Common Side Effects	<ul style="list-style-type: none"> Unpredictable menstrual bleeding pattern and all bleeding/spotting is unscheduled. Possible progestogenic effects. 	<ul style="list-style-type: none"> Spotting during the first 3-6 months Mild progestogenic effects (rare) 	Heavier, longer and/or more painful periods
Description	A single off-white nonbiodegradable, nonradio opaque, etonogestrel containing rod 4cm long x 2 mm in diameter. Implanon is implanted just below the surface of the skin (subdermally) in the surface of the upper arm. The mean peak serum concentrations of etonogestrel range between 781 and 894 pg/mL within a few weeks after insertion to 156-177 pg/mL at 36 months.	T-Shaped radiopaque polyethylene device 32 mm x 32mm with a reservoir around the vertical stem, which contains levonogestrel (LNG) and silicone. The reservoir releases 20ug/day of levonogestrel into the uterine cavity. Two brown nonofilament strings attached to the bottom of the device are used for detection and removal.	T-shaped radiopaque polyethylene device 32mm X 36mm. Approximately 176 mg of copper wire coiled along the vertical stem and a 68.7 mg copper collar on each side of the horizontal arm allow a total exposed copper surface area of 380 ± 23 mm ² . Two white monofilament strings attached to the bottom of the device are used for detection and removal.

Footnotes:
 1 UN Development Program, UN Popular Fund, WHO, World Bank, Special Programme of Research, Development and Research Training in Human Reproduction. Long Term Reversible Contraception: Twelve Years of Experience with the TCu380A and TCu220C. Contraception. 1997;56:341-352.
 2 Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNG 20) and the Copper T380 Ag IUDs. Contraception. Nov 1991;44(5):473-80.
 3 Diaz J, Faundes A, Diaz M, Marchi N. Evaluation of the clinical performance of a levonorgestrel-releasing IUD, up to seven years of use, in Campinas, Brazil. Contraception. Feb 1993;47(2):169-75.
 4 Alvarez F, Vrache V, Fernandez E, et al. New insights on the mode of action of intrauterine contraceptive devices in women. Fertility and Sterility. 1988;49(5):768-772.
 5 Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive efficacy. Contraceptive Technology: Nineteenth Revised Edition. New York NY: Ardent Media, 2007.
 6 From products' respective package inserts

Table 2: Irreversible Long-Term Contraceptive Summary

Method	Essure®	Bilateral Tubal Ligation ¹	Vasectomy ¹
Consent Form Included in Package for Device	yes	see below ¹	see below ¹
Pearl Index ^{2,3}	.2	.05-0.7	0.15-.07
Training Provided by Manufacturer	yes	not applicable	not applicable
Length of Use ³	Permanent, lifelong to be considered irreversible	Permanent, lifelong to be considered irreversible	Permanent, lifelong to be considered irreversible
Mechanism of Action ³	The fiber mesh and the micro-insert act as scaffolding into which tissue grows. This tissue in-growth into the micro-insert permanently anchors the device and occludes the fallopian tube, resulting in sterilization.	Coagulation, clips, bands or salpingectomy to ligate and or occlude the fallopian tube resulting in sterilization. Gametes can not pass through the fallopian tube to meet.	Occludes the vas deferens with nonabsorbable suture, cautery, clips or some combination after cutting. When complete, sperm can no longer exit the body through the penis.
Hormone Content	none	none	none
Most Common Side Effects	Complications from surgical procedure or anesthesia	Complications from surgical procedure or anesthesia	Complications from surgical procedure or anesthesia
Description	Micro-insert consists of a stainless steel inner coil, a nitinol, super-elastic outer coil, and polyethylene (PET) fibers. The PET fibers are wound in and around the inner coil. The micro-insert is 3.85 cm X 0.8 mm in its wound down configuration. When released, the outer coil expands to 1.5 to 2.0 mm to anchor the micro-insert in the varied diameters and contours of the fallopian tube. One Essure micro-insert is placed in the proximal section of each fallopian tube lumen. The micro-insert expands upon release, acutely anchoring itself in the fallopian tube. ³	Performed by laparotomy, laparoscopy, or hysteroscopy through a variety of methods utilizing cutting, absorbable sutures, coagulation, spring clips, titanium clips, silicone bands or inserts (see Essure).	Typically performed as an outpatient procedure under local anesthesia by incisional or “no-scalpel vasectomy”. Vas occlusion achieved by ligation utilizing nonabsorbable suture, cautery, clips, or some combination.

Footnotes:

- 1 Peterson HB. Sterilization. *Obstetrics & Gynecology*. Jan 2008;111(1):189-203.
- 2 Grady WR, Billy JOG, Klepinger DH. Contraceptive Method Switching in the United States. *Perspectives on Sexual and Reproductive Health*. May/June 2002;34(3):135-145.
- 3 From products' respective package inserts

HELPFUL RESOURCES AND LINKS:

Review article on sterilization in the Green Journal: Peterson HB. Sterilization. Obstetrics & Gynecology. Jan 2008;111(1):189-203

WHO Medical eligibility criteria. WHO website where each contraceptive method has a recommendation 1-4 when being considered for use in specific patient populations or for patients with particular disease states:

From FPACT website: http://reproductiveaccess.org/contraception/downloads/WHO_Chart.pdf

From WHO website: <http://www.who.int/reproductive-health/publications/mec/mec.pdf>

Mirena website: <http://www.mirena-us.com/physician/patients.html#PPI>

Implanon website:

<http://www.implanon-usa.com/hcp/aboutimplanon/components/index.asp?C=54361397842956481481&svarqvp2=0>

Essure website and training:

<http://www.essuremd.com/Home/bYourEssurePracticeb/bGetTrainingb/tabid/233/Default.aspx>

ParaGard website: www.paragard.com/

Contraceptive Technology Summary table of contraceptive efficacy

<http://www.contraceptivetechnology.com/table.html>



Calendar of Events

(See familypact.org or call 1-877-FAMPACT for more information about these events)

Provider Orientations:	8:30 am - 4:30 pm
March 5, 2009	Provider Orientation & Update Session - Lancaster
Regional Provider Forums:	9:00 am - 1:00 pm
Pregnancy Test Options Counseling in Family PACT	
February 24, 2009	Regional Forum - Ontario
Special Interest Trainings:	9:00 am - 3:30 pm
February 11, 2009	IUC Insertion Training - Berkeley