Best practices for counseling adolescents about the etonogestrel implant

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Abstract

Among young persons, ease of use, high efficacy, and high acceptability makes the etonogestrel (ENG) contraceptive implant an important choice for this age group. Adolescent-friendly, patient-centered counseling considers the patient's cognitive development, the influence of friends and family, as well as their own preferences and values. Age appropriate language, graphics and models are useful to explain contraceptive options and relevant side effects. Effectiveness, reversibility, safety, non-contraceptive benefits, and side effects are important attributes and should be discussed when teens are choosing a contraceptive method. This review describes suggested best practices for counseling adolescents about the ENG implant so they can make informed, prudent decisions about using this contraceptive method.

Introduction

Unintended pregnancies can adversely affect the lives of adolescents, their children, and families. Efforts to ensure equitable access to contraceptive options for young people who desire pregnancy prevention are vitally important. Its ease of use, high efficacy, and high acceptability among young persons makes the etonogestrel (ENG) contraceptive implant an important choice for this age group. This review describes suggested best practices for counseling adolescents about the ENG implant so that they can make informed decisions about using this safe and highly effective contraceptive method.

What is the etonogestrel (ENG) implant?

In 1999, a progestin-only subdermal contraceptive implant (Implanon®) containing ENG 68mg was launched in a number of European countries.[1] The white rod measured 2mm in diameter and 40mm in length with ethylene-vinyl-acetate (EVA), a copolymer, holding crystals of ENG suspended in its core. The core was encased in an EVA membrane allowing sustained release of ENG. The implant was licensed to provide contraception for 3 years when inserted subdermally, typically in the inner aspect of the non-dominant arm. When launched, this implant was not radiopaque,[2] the insertion technique required two hands, and the rod was not 'locked' in the inserter which resulted in non-insertion when health care professionals (HCPs) failed to attend training courses or received poor quality teaching.[3] In the US, a mandatory training program accompanied the 2006 launch of this implant. An active monitoring program found that of more than 20,000 insertions, only 4 non-insertions were reported.[4]

About 10 years ago, an updated version of the ENG implant called Nexplanon® or Implanon NXT was introduced, with a new inserter and a radiopaque implant. The addition of barium sulfate 15mg to the rod had no effect on its size, color, flexibility, contraceptive efficacy or side effect profile. This updated implant system utilized a single-handed inserter, designed with the goals of facilitating correct subdermal insertion while reducing the chances of non-insertion. Additionally, to minimize the

risk of neurovascular injury and implant migration,[5] Merck updated its insertion site guidance related to technique and insertion location on the arm. The most recent recommendations are to insert the ENG implant subdermally over the triceps muscle, 3-5 centimeters away from the biceps/triceps sulcus, and about 8-10 cm from the medial epicondyle of the humerus (Figure 1).[6,7]

Who is using the ENG implant and what is the impact?

In 2019, Merck supplied 8.64 million implants globally. US, France, Australia and the UK are the biggest markets for this long acting reversible contraceptive (personal communication, Hans Rekers, Merck Inc). More than 80% of users, including teenagers, continue to use this method over 12 months, reporting high rates of satisfaction.[8–10] The Contraceptive CHOICE Project, a prospective cohort study based in St. Louis that provided same-day, no-cost contraception found that 51% of 14-19 year olds selected the implant when the barriers of cost and availability were removed.[11] In the UK, teenage pregnancy rates are now at their lowest for 50 years,[12] an accomplishment in part related to attitude changes in young people about becoming parents early in their adult lives and also to increased access to long acting reversible contraceptives (LARCs) with more HCPs in family medicine and the community trained to insert ENG implants.[13] In the US and Australia, demographic trends are similar and studies demonstrate very low pregnancy rates in users of LARC methods, including teens.[11,14,15]

What is the evidence for contraceptive counseling in adolescents?

Importance of HCP

Counseling by HCPs plays an important role in improving adolescents' contraceptive knowledge, acceptability, initiation and continuation but published evidence specific to this group is scarce. Although adolescent contraceptive decision-making is influenced by friends, family and social media/internet, teens consistently report that they value HCPs providing accurate information.[16,17] Adolescents feel that confidentiality in sexual and reproductive healthcare is of great importance and they appreciate relationships/encounters with providers that are friendly, informal, and nonjudgmental.[18]

Influences on contraceptive decision making

Contraceptive counseling continues to focus on shared decision making models in which the HCP contributes medical knowledge and the patient provides expertise on their own priorities, values and preferences.[19] These preferences are influenced by multiple factors including personal contraceptive experiences and experiences of

their friends and family.[16,20,21] Many teens report effectiveness as a priority; however, this does not always translate into choosing the most effective method.[22] Other non-contraceptive priorities include the desire for regular monthly, lighter or no bleeding, improvement of acne, avoidance of a foreign body, or ability to stop their method independently.[23]

Adolescents' fears play a role in decision-making and should be addressed. Common concerns include impact on fertility, safety of amenorrhea, and the absence of autonomy in LARC removal.[24–27] HCPs should be prepared to help teens have access to removal if and when they desire discontinuation. Teens value HCP discussion and may specifically ask for decision support but also value autonomy in decision making.[18] HCPs must be aware of their own agenda in adolescent counseling and avoid undue pressure or influence.

Awareness of adolescent development and learning needs

It is important that HCPs have an awareness of an adolescent's developmental stage. Younger adolescents rely more on concrete thinking and as teens age they are increasingly capable of abstract thinking. Comfort in initiating sensitive discussions or asking questions, and ability to understand and process information can differ by age and developmental stage. Frequent checks for understanding ("teach back") and encouragement of questions is important. Adolescents' preferences around parental involvement in contraception decision making are also influenced by their cognitive and psychosocial development. HCPs should discuss possible side effects in plain language regardless of whether these are nuisance side-effects or possible health risks, then share a plan for managing these (i.e. contact HCP, follow up in clinic, treatment options).[28]

Adolescents may have poor knowledge about their bodies and contraception. Models and visual aids can clarify their views on anatomy, physiology (reasons for amenorrhea), insertion (IUD, implant, ring) and help dispel fears about devices (size, rigidity, movement in the body).[17,18] Models can be obtained from a variety of sources. Planned Parenthood League of Massachusetts offers a comprehensive teaching kit with models.[29] Youth friendly visual aids and educational materials are available from Bedsider/Power to Decide.[30] Despite concerns that teens may have difficulty with complex decision making, they are capable of weighing risks and benefits of methods and choosing one they feel is most appropriate for them.[18,31] Table 1 summarizes recommendations for contraception counseling with adolescents.

Which features of the ENG implant are most important to discuss?

Effectiveness, reversibility, safety, non-contraceptive benefits and side effects are important attributes and should be discussed when teens are choosing a contraceptive method.[22,32,33] It is also important to inform young persons that the implant doesn't prevent sexually transmitted infections and to recommend the use of condoms with sexual intercourse.

Effectiveness

The ENG implant is highly effective for pregnancy prevention.[34] The 3-year cumulative pregnancy rate of the implant is 0.4 per 100 women/year [95% CI 0.1–1.4].[35] No pregnancies were reported in a publication summarizing 11 clinical trials of almost 1000 ENG users.[36] Post marketing surveillance of over 20,000 insertions reported only 6 confirmed contraceptive failures during a 6.4 year period (0.03% with a 95% CI 0.01-0.05%).[4]

Reversibility

An essential feature of any LARC is its immediate reversibility and no effect on future fertility.[7,8] A comprehensive review of pregnancy rates after contraceptive implant discontinuation found the one-year pregnancy rate following cessation ranged between 76.5% and 85.6% after exclusion of one study with unusually low pregnancy rates.[37] A more recent systematic review and meta-analysis had similar findings.[38] This range overlaps with pregnancy rates reported following discontinuation of oral contraceptives or use of no contraceptive method. [39,40]

Safety

The ENG implant has few contraindications, with current breast cancer and pregnancy being absolute contraindications.[41] It does not cause clinical changes in blood pressure, carbohydrate metabolism, and lipid profile[42–44] and as it is estrogen-free, it does not affect the risk of arterial and venous thromboembolism.[44] For this reason, it can be used in a variety of women with comorbid conditions.[41]

Non-contraceptive benefits

In persons with dysmenorrhea, 83% note improvement with ENG implant use (77% resolution, 6% decrease in severity).[45] ENG implant also reduces non cyclic chronic pelvic pain and dysmenorrhea associated with endometriosis-associated pelvic pain.[46,47] As the ENG implant suppresses ovulation, it likely has the ability to help in any cycle-related disorders.

What changes in vaginal bleeding do ENG implant users experience?

Changes in vaginal bleeding are common while using the ENG implant. In clinical trials with users 18 to 40 years of age, participants experienced a range of bleeding patterns. Figure 2 depicts bleeding during the first year of ENG implant use. Of importance, when evaluating bleeding patterns during any 90-day interval, a person's pattern in one interval may be different in future intervals. Overall, 60% of participants' bleeding in the first 90-day reference period was characterized as favorable (i.e. amenorrhea, infrequent bleeding, and normal frequency bleeding), and participants with favorable bleeding were highly likely to continue with favorable bleeding through at least 2 years.[48] For those whose vaginal bleeding during the first reference period was characterized as unfavorable (i.e. frequent bleeding and/or any prolonged bleeding), future bleeding patterns were less predictable with 40-50% reporting a more favorable pattern in the next 2 out of 3 reference periods. Not surprisingly, users with unfavorable bleeding were more likely to discontinue ENG implant,[48] and 11.3% of the overall participants discontinued ENG implant use due to bleeding irregularities,[45] citing 'frequent, irregular bleeding' or 'prolonged menstrual flow' in most cases.

During the first 2 years of use, the mean prevalence of amenorrhea during any 90-day reference period was 22.2%, infrequent bleeding (less than 3 bleeding or spotting episodes per 90 days) 33.6%, normal frequency bleeding (3 to 5 bleeding or spotting episodes per 90 days) 37.5%, frequent bleeding (more than 5 bleeding or spotting episodes per 90 days) 6.7%, and prolonged bleeding or spotting (more than 14 days uninterrupted per 90 days) 17.7%.[45] Unfavorable bleeding patterns, such as frequent and/or prolonged bleeding, decreased during the first 2 years of use (from 38% to 18%).[45] Mean bleeding and spotting days per 90 day reference period was 17.7, and mean bleeding days was 7.2.[45]

Contraception-induced vaginal bleeding changes are frequently cited as reasons for non-use, discontinuation and dissatisfaction[49] Changes in bleeding are a leading cause for early ENG implant discontinuation in adults and adolescents.[49–53] Therefore, these changes should be addressed during counseling.

Box 1. How do you counsel adolescents about changes in their bleeding?

It is important to be clear about changes in bleeding but avoid categorizing them as "good" or "bad" as patients have different subjective experiences. It is also important to stress that, regardless of the changes, the majority of users experience light bleeding.

You are likely to experience a change in your bleeding on this method. -or-

Your bleeding will be unpredictable on this method, but most of the bleeding tends to be light. -or-

Irregular bleeding on the implant is normal and not dangerous but may be bothersome to you. -and-

I want you to let me know if you are concerned or unhappy with your bleeding on the implant. We may want to check if there is anything other than the implant that could be causing your bleeding, such as an infection. Some of my patients just want reassurance that there is nothing else wrong with them and that the bleeding is not dangerous and is an expected side effect in some implant users. If your bleeding is bothersome, we have medicines that could help the bleeding, or we can remove the implant and try something else.

What other side effects are associated with use of ENG implant?

Few studies have specifically examined side effects in adolescent users.

Weight gain

Studies on weight gain in ENG implant users have suffered from methodologic flaws and have often been contradictory. [54–57] In clinical trials which excluded women over 130% their ideal body weight, US participants reported gaining a mean of 2.8 pounds within the first year and 3.7 pounds over two years of ENG implant use; 2.3% reported weight gain as the reason for implant removal.[6] A recently published study of adolescents found no difference in weight changes between ENG implant users and non-users (which included oral contraceptive users) at 2 years follow up.[57] The highest quality studies investigating weight gain and ENG implant, after controlling for relevant confounders, found little or no weight changes; any changes observed were less than the average weight gain for non-users over the same period of time.[58,59]

Mood changes

In clinical trials, 6.4% of participants reported emotional lability and 5.5% report depression, with 3.3% of participants citing these as the reason for discontinuation.[2,6] Mood changes have been described in observational studies of ENG implant use and are an infrequent reason for discontinuation.[50,53,54,60] No studies have assessed mood changes and ENG implant using validated instruments.[61]

Acne

Acne is reported as a side effect of ENG implant use. Etonogestrel is a third-generation progestin and is weakly androgenic. Thirteen percent of clinical trial participants reported acne as an adverse event and 1.3% discontinued due to acne.[2,6] Acne was assessed in approximately two thirds of the participants: 15% had improvement in acne, 14% had worsening acne, and 71% had no change.[2] It is possible that the acne experienced by some implant users was due to discontinuing an estrogen-containing hormonal contraceptive (which improves acne) rather than starting a progestin-only implant.

Bone density

In contrast with the injectable depot medroxyprogesterone acetate, which suppresses ovarian estradiol production, estradiol levels remain physiologic in ENG implant users.[62,63] Accordingly, loss of bone mineral density would not be anticipated in users. Few high-quality studies have assessed ENG implant-associated changes in BMD and none have examined adolescents, whose use of hormonal contraceptives during peak bone mineral density accrual has attracted attention. Studies of forearm trabecular bone BMD at 18 months and 36 months found no difference compared to baseline for users of ENG implant.[64,65] Prospective studies found no change in BMD among ENG implant users compared to copper IUD-using women at lumbar spine and femoral neck at 12 and 24 months, the sites where BMD is most predictive of fracture risk.[56,66]

Ovarian cysts

Because the ENG implant effectively inhibits ovulatory activity, users may experience painless and transient enlargement of ovarian follicles or cysts.[67,68] In published series, no intervention was necessary, and changes resolved within 7 to 72 days.[67,68]

Box 2. How do you counsel adolescents about side effects?

As with any medication, it's possible to experience side effects with use of the implant. Changes in bleeding patterns are the most common. It doesn't look like the implant normally causes weight gain problems or mood changes, but everyone responds differently and if you have any concerns, I want you to get in touch with me.

What are potential challenges with inserting and removing ENG implant?

Less than 10% of users experience insertion site reactions (i.e. erythema, hematoma, bruising, pain, and swelling).[6] Although uncommon, deep insertions have been associated with paresthesia due to neural injury and implant migration due to insertion into the muscle or fascia.[4,69] Vascular migration of ENG implants is extremely rare. There were 107 reported cases of implant migration to the pulmonary artery or chest between August 1998 and September 2019.[7] Non-palpable implants should be localized and then removed by a procedural specialist with appropriate expertise.[70,71]

Box 3. How do you counsel adolescents about post-placement wound care?

You may experience some tenderness and bruising at the site. I recommend that you keep the site clean and dry for the next couple of days. You should remove the

pressure bandage in 24 hours and keep the adhesive dressing on the site for the following 3-4 days. If you notice that the site is very tender, red, swollen, or has greenish-yellow draining, please contact the office, as these could be signs of an infection.

Box 4. How do you counsel adolescents about risks of serious adverse events?

This is one of the safest birth control methods available. Although there are reports of deep insertions and movement of the implant to other parts of the body, these are very rare. In fact, because it doesn't contain estrogen, using the implant is safer than using birth control pills. It is important that you can always feel the implant. If you ever notice you can't feel it, please let me know. If that happens, we will do some tests to locate the implant and it should be removed. We can always place another one if you'd like.

Conclusion

The ENG implant is an excellent contraceptive option for adolescents. Adolescent-friendly, patient-centered counseling considers the patient's cognitive development, the influence of friends and family, as well as their own preferences and values. Age appropriate language, graphics and models are useful to explain contraceptive options and relevant side effects. Patients who choose the contraceptive implant should understand that changes in menstrual bleeding patterns are expected and are not harmful. Concerns should be thoroughly addressed, and reassurance given that the implant can be removed at any time.

Conflicts of Interest

Dr. Berlan is a Merck Nexplanon Clinical Trainer and Consultant to Merck, Bayer, and Ohio Chapter, American Academy of Pediatrics. Reviewer for UptoDate (royalties received).

Dr. Richards is a Merck Nexplanon Clinical Trainer and Consultant to Merck.

Dr. Sales Vieira serves on Medical Advisory Boards and gives lectures for Bayer and Merck.

Dr. Kaunitz is a Consultant for Merck and Mithra. Author for UpToDate (royalties received). His institution receives research monies from Abbvie, Merck and Mithra. Receives travel reimbursement from American College of Obstetricians and Gynecologists and the Centers for Disease Control and Prevention for preparation of guidance regarding contraception and menopause.

Dr. Fraser has no conflicts of interest to report.

Dr. Edelman is a consultant for Gynuity Health Projects, FHI360; Nexplanon trainer for Merck (No monies accepted since 2016). Author for UptoDate (royalties received). Her institution receives research monies from Merck, HRA Pharma, and NIH on projects where she is principal investigator. These potential conflicts have been reviewed and managed by OHSU. She is the Chair of the ACOG ACOG Practice Bulletins for Gynecologycommittee and has received travel and honorarium from ACOG. She is an expert technical consultant for the CDC and the WHO on reproductive health issues and has received travel reimbursement.

Dr. Creinin serves on an Advisory Board for Merck & Co. and TherapeuticsMD and is a consultant for Danco, Estetra Mayne, Medicines360, and Merck & Co. The Department of Obstetrics and Gynecology, University of California, Davis, receives research funding for contraceptive research from Daré, HRA Pharma, Medicines360, Merck & Co. and Sebela.

Dr Mansour has served on an advisory board for Merck & Co. manufacturers of the etonogestrel implant and has received financial support to attend pharmaceutical advisory board meetings, undertake research studies, speak at educational meetings, webinars, conferences, along with travel grants from Bayer, Consilient Healthcare, Gedeon , Merck & Co, Mithra, Mylan, Pfizer and Vifor Pharma.

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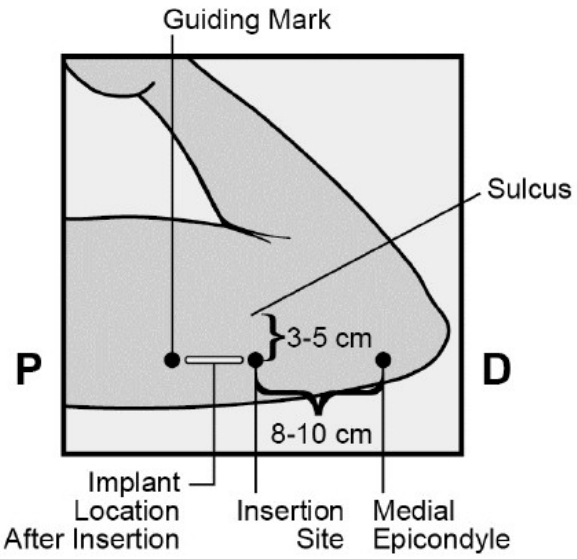
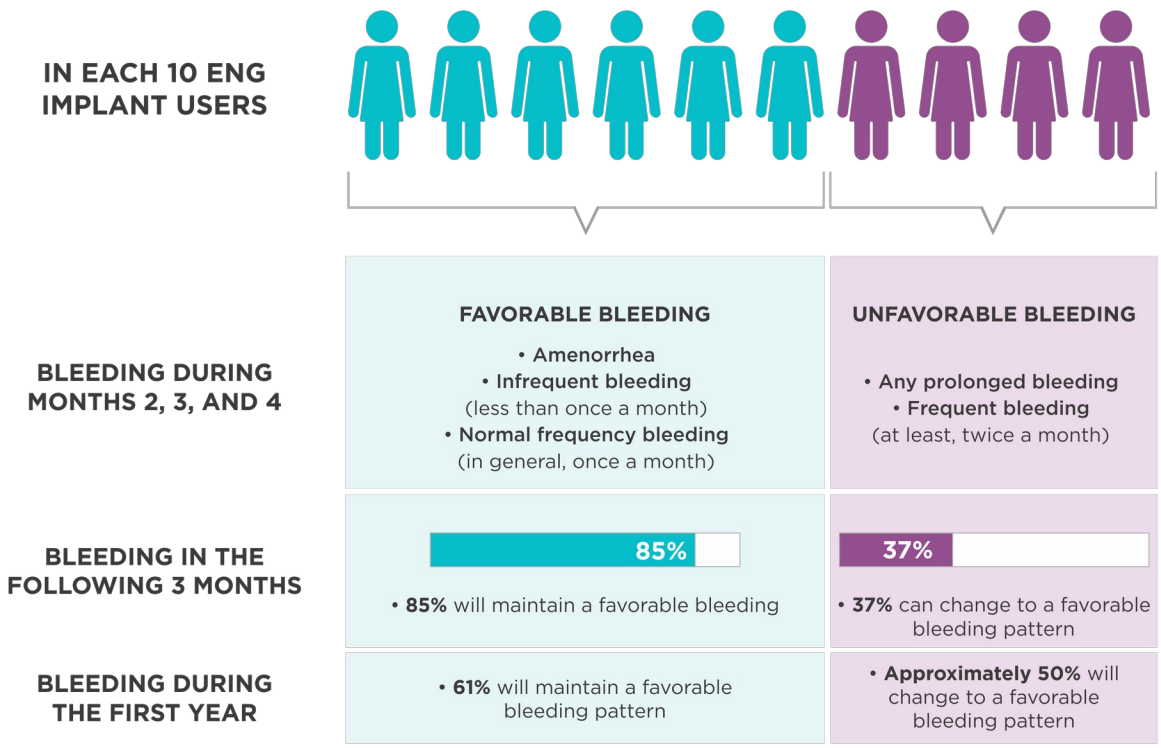


P – proximal (toward the shoulder), D – distal (toward the elbow)

Figure 1.

Etonogestrel implant insertion site[6] *(used with permission)*



Adapted from Mansour et al (2019)[48]

Figure 2.

Vaginal bleeding during first year of etonogestrel implant use

Table 1.

*Recommendations for contraception counseling with adolescents**

Recommendation	**Sample language**
Speak to all adolescents one on one	*I am happy to see you with your friend/mother but will also chat with you by yourself as well.*
Discuss confidentiality and limits of confidentiality-	*Everything you say to me will be kept confidential/ private unless I have concerns about your safety or the safety of those around you. If I feel a possible need to break confidentiality, I will discuss this with you first.*
Ask about contraceptive priorities and preferences (e.g. effectiveness, convenience, medical indications, lack of side effects)	*Is there a contraceptive method that interests you? What is important to you about your contraceptive method? Do you want to have a monthly bleed? What do you think about having less frequent bleeds or even no bleeds?*
Ask about personal contraceptive experiences	*What have you used in the past? What did you like about it? What was not so good about it?*
Ask about experiences of friends and/or family members on contraception	*What are your friends or family using? What have they said about the method?*
Address fears and concerns about contraceptive methods	*Is there anything that concerns you about birth control methods? Is there anything you have heard about birth control methods that scares or worries you?*
Consider dispelling common myths/misconceptions	*Some of my patients worry that not having a period is not healthy. It is important to know that not having a period on birth control is normal and healthy for your body. There is no back up of blood or risk to your fertility. Your period should come back normally after stopping birth control.* *Patients have told me they worry about their ability to get pregnant after using birth control. No birth control method causes infertility. In fact, with many methods you can get pregnant within days or weeks of stopping them.*
Assure teens they are not “committed” to use of a method for a certain period of time and assure autonomy in removal of LARC methods.	*Although some of these methods last for years, you do not need to use them for that long. The method can work for “up to” that number of years. You have flexibility. If you decide the method doesn’t work for you or if you want to get*

	pregnant, you can always have it removed.
Discuss possible side effects and plan for managing them	*Everyone responds differently to birth control. If you have any concerns or unwanted side effects, please call us or make a follow up appointment. We may have ways to help with the side effects or we can discuss stopping your method.*

*Models or pictures of the pelvis/uterus as well as models of different contraceptive methods (pill pack, ring, implant, IUD) are helpful to have available when counseling.