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FAMILY PLANNING (A BURKE, SECTION EDITOR)

# The Contraceptive Implant: An Updated Review of the Evidence

**Jennifer Amico · Bhavik Kumar · Hilary Rosenstein · Marji Gold**

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**Abstract** The etonogestrel implant is a form of highly effective and long-acting reversible contraception, available in the U.S. as Nexplanon® (Merck and Co, Inc., Kenilworth, NJ, U.S.). It is placed under the skin of the upper arm by health care providers and is approved for use up to 3 years. It is more effective than any other method, including the intrauterine devices (IUDs) and permanent sterilization methods. It has few contraindications, and has high rates of satisfaction and continuation. While irregular bleeding is the most common side effect and reason for discontinuation of the method, most women experience reduced bleeding overall, and it can be used to improve dysmenorrhea, menorrhagia, and endometriosis. Complications related to use, insertion, and removal are rare. While the implant has many advantages, it is important for providers of family planning to use a patient-centered approach to counseling about all contraceptives, including highly effective reversible methods, and to support women's reproductive autonomy.

**Keywords** Contraceptive implant · Etonogestrel · Highly effective reversible contraception · HERC · Long-acting reversible contraception · LARC · Family planning

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J. Amico (✉) · B. Kumar · H. Rosenstein · M. Gold
Department of Family and Social Medicine, Albert Einstein College of Medicine, Montefiore Medical Center,
3544 Jerome Ave, Bronx, NY 10467, USA
e-mail: jamico@montefiore.org

B. Kumar
e-mail: bkumar@montefiore.org

H. Rosenstein
e-mail: hirosens@montefiore.org

M. Gold
e-mail: Marji.Gold@einstein.yu.edu

## Introduction

The contraceptive implant is a form of long-acting reversible contraception (LARC, also sometimes referred to as highly effective reversible contraception, or HERC). The U.S. Food and Drug Administration (FDA)-approved single subdermal progestin rod can be used for up to 3 years and is marketed in the United States as Nexplanon®. The rod is made of a semi-rigid plastic called ethylene vinyl acetate copolymer and contains 68 mg of etonogestrel, the active metabolite of desogestrel [1]. The implant measures 40 mm by 2 mm, roughly the size of a matchstick. Etonogestrel is slowly released over at least 3 years, peaking initially at 60–70 mcg per day and decreasing to 25–30 mcg per day at the end of 3 years [2].

The implant was first approved by the FDA in 2006, and was marketed as Implanon®. The manufacturer, Merck, modified the insertion device and added radiopaque barium sulfate before releasing the current version, Nexplanon®, in 2011 [3•, 4•]. These modifications reduce the chance of failed and deep insertions and allow for x-ray detection of non-palpable implants [4•].

The implant is a safe option for most women and has very few contraindications [5]. Although it is the most effective form of contraception readily available in the United States, less than 1 % of women use the contraceptive implant [6]. A recent study that removed access barriers, such as cost, demonstrated a higher rate of selection of the implant and also high rates of continued use and satisfaction over time [7].

Two levonorgestrel implants have been approved in the U.S., but are not currently available. The Norplant® was made up of six rods containing 216 mg of levonorgestrel, and was available in the U.S. from 1990 to 2002. While the product was discontinued due to lack of materials per the manufacturer, litigation secondary to difficult removals may have contributed to the discontinuation [8]. Jadelle® is a two-rod implant

containing 75 mg of levonorgestrel in each rod, and was produced by the same manufacturer as the Norplant®. Jadelle® was approved by the FDA in 1996 for use up to 3 years, and re-approved in 2002 for use up to 5 years. While it is used in many other countries, it was never marketed in the U.S., perhaps as the result of the manufacturer's experience with the Norplant®. As the Nexplanon® is the only implant currently available in the U.S., it is the focus of this review.

## Mechanism of Action

The etonogestrel implant works primarily by altering the hypothalamic-pituitary-ovarian axis to suppress ovulation [1, 9, 10]. Additional contraceptive benefits are achieved by thickened cervical mucus, which prevents sperm from penetrating, and changes in the endometrial lining, including thinning of the lining and inactivation of the endometrial tissue [1, 9].

## Effectiveness

The etonogestrel implant is one of the most effective methods of contraception, with effectiveness comparable to the copper intrauterine device (IUD), the levonorgestrel IUD, and both male and female sterilization (Fig. 1) [11, 12]. The pregnancy rate is reported to be 0.001–0.05 % in first year, compared to 8 % for typical use of combined hormonal contraceptives [13, 14•]. While all of the many prospective and retrospective studies of the implant have reported no pregnancies [15, 4•, 12, 16–18], there have been rare cases of pregnancies with the etonogestrel implant reported to the manufacturer; most of these pregnancies were not the result of actual method failures, but instead occurred because the device was inadvertently not inserted, or the woman conceived prior to the insertion or shortly after the insertion of the device [16, 19].

Although there is evidence that serum etonogestrel levels are lower in obese women than in normal weight women [20, 21], there is no evidence of increased risk of ovulation or pregnancy in obese women using the implant [22, 21, 16, 23•]. In 2012, a prospective cohort study of 5,368 women using an etonogestrel contraceptive implant or an IUD found no difference of failure rates among obese, overweight, and normal weight women [23•].

While the etonogestrel implant has been primarily studied for use up to 3 years in duration and is FDA-approved for only 3 years, serum etonogestrel levels remain relatively stable over the 3 years [24], which suggests that it may be used for at least 4 years and perhaps longer. Small studies in Thailand, China, and Indonesia that extended use to 4 years did not result in any unintended pregnancies [15, 25, 26].

## Continuation and Satisfaction

Along with being one of the most effective methods, the implant has high continuation and satisfaction rates. Recent studies show continuation rates ranging from 72 to 87 % at 12 months, 53 to 74 % at 24 months, and 25 to 66 % at 36 months [27, 28•, 29–31], which are higher than the continuation of shorter acting methods and comparable to continuation of the copper and hormonal IUDs [28•, 27, 30, 32, 33]. Continuation rates are also high when implants are used by

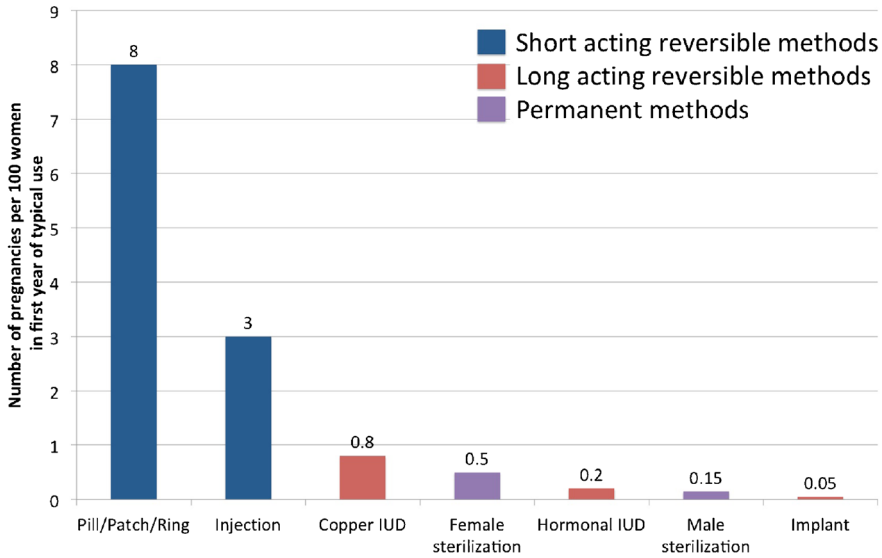


**Fig. 1** Effectiveness of short acting, long acting and permanent methods: number of pregnancies tper 100 women in first year of typical use

Adapted from Centers for Disease Control and Prevention. *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition.* Morbidity and Mortality Weekly Reports. 2010.

adolescents [32, 31], when inserted immediately postpartum [34, 31], and when inserted immediately post-abortion [35, 36].

Satisfaction with the implant is also higher than for shorter-acting methods and comparable to satisfaction with the copper and hormonal IUDs, with recent studies demonstrating that 80–90 % of users reported satisfaction with the method [7, 37, 30, 33]. One study reported that while most women reported no change or decrease in cramping, bleeding volume, and bleeding frequency, those who reported worsening in menstrual symptoms were less likely to be satisfied with the method [37].

## Eligibility

The implant is safe and effective for the majority of women [5]. In fact, given that the implant is highly effective and has high continuation and satisfaction rates, it should be included as a first-line option, along with IUDs, for adult women and adolescents [38, 39•], rather than as a method to consider only if other ones are unsatisfactory or fail. There are no restrictions of implant use based on age, weight, body mass index (BMI), parity, or postpartum/post-abortion status.

Per the Centers for Disease Control and Prevention U.S. Medical Eligibility Criteria (MEC 2010), there are few contraindications to using the progestin implant (Table 1). The only absolute contraindication (MEC Category 4) to use of the implant is current breast cancer [5]. Other medical conditions that may be contraindications to etonogestrel implant use are described in Table 1.

Other than ruling out pregnancy [24], no testing or exam is needed to verify eligibility before use of the implant [40]. Of note, while it is recommended that pregnancy is excluded prior to implant insertion, there is no evidence that the etonogestrel implant or any other hormonal contraceptive (other than the hormonal IUD) has any effect on an established pregnancy [41].

## Providing the Method

In order to provide the method in the United States, the FDA has mandated that clinicians participate in a 3-hour training by the manufacturer, which reviews insertion, removal, and complication management [24]. While the training requirements are more burdensome than those for comparable methods (e.g., IUDs), they are likely meant to prevent some of the issues related to deep insertion and difficult removal that occurred with the previously available multi-rod implant.

Insertion and removal are technically simple procedures, with studies demonstrating an average insertion time of less than 1 minute and removal time of 2–4 minutes [25, 17, 42, 4•]. These techniques are easily learned by a range of providers, including obstetrician-gynecologists, family physicians, pediatricians, internists, and advanced practice clinicians. Unlike the

**Table 1** Contraindications to the contraceptive implant: conditions categorized as Category 3 or 4 in the CDC Medical Eligibility Criteria (MEC) for Contraceptive Use*

| Relative contraindications (MEC Category 3) | Absolute contraindications (MEC Category 4) |
|---|---|
| Past breast cancer, no evidence of disease>5 yrs | Current breast cancer |
| Cirrhosis, severe, decompensated | |
| Ischemic heart disease† | |
| Stroke† | |
| Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies | |
| Migraine with aura† | |
| Vaginal bleeding suspicious for serious condition, prior to evaluation | |
| Liver tumors (hepatocellular adenoma and malignant hepatoma) | |

*Categories of classification:

3: The theoretical or proven risks generally outweigh the advantages

4: Unacceptable health risk if the contraceptive is used

† Method is a Category 3 for continuation of the implant if condition occurs during use of the implant

Adapted from Centers for Disease Control and Prevention. *U.S. Medical Eligibility Criteria for Contraceptive Use,* 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition. Morbidity and Mortality Weekly Reports, 2010;59:1-84.

IUDs, comfort and experience with uterine procedures is not necessary for provision of the implant.

Prior to providing the method, clinicians should provide patient-centered counseling about the advantages and disadvantages of the implant, as well as other contraceptive methods that are not contraindicated. A sample list of advantages and disadvantages of the implant is provided in Table 2.

The implant can be inserted anytime during a woman's menstrual cycle if pregnancy can be reasonably excluded [24]. While many providers require a pregnancy test, pregnancy can be reasonably excluded if a woman has no signs or symptoms of pregnancy and meets any of the following criteria [40]:

- Last normal menses≤7 days ago
- No vaginal intercourse since last menses
- Using reliable contraception consistently and correctly
- Spontaneous or induced abortion≤7 days ago
- Postpartum≤4 weeks

**Table 2** Advantages and disadvantages of the contraceptive implant

| Advantages | Disadvantages |
|---|---|
| ***Easy to use***<br>To use the method, you don't have to remember to do anything on a regular basis. | ***Can't start on your own***<br>Your health care provider has to insert it in order for you to start using it. |
| ***Completely reversible***<br>Once the implant is removed, you can become pregnant right away. | ***Can't stop on your own***<br>Your health care provider has to remove it in order for you to stop using it. |
| ***It's discreet***<br>You can't see the implant, though most women can feel it under the skin. | ***Rare complications with insertion and removal***<br>Since it is inserted under the skin, your provider has to use a needle to insert it, and has to make a small cut in the skin to remove it. Temporary soreness is common, but other complications such as infection, nerve damage, or difficulty locating or removing the device are rare. |
| ***Lightens menstrual bleeding***<br>Most women using the implant experience lighter periods, and it helps reduce symptoms in women who have very heavy or crampy periods, or who have endometriosis. Some women stop getting a period all together. | ***Irregular bleeding***<br>While the bleeding is commonly lighter with the implant, it is often irregular, which can be inconvenient. |
| ***Highly effective***<br>It is more effective than the birth control pill, patch, ring, injection, IUD, or even male or female sterilization! | ***Possible weight gain***<br>Implant users may cause a small amount of weight gain, but it is unknown if this is actually because of the implant. |
| ***High satisfaction and continuation***<br>Women report higher satisfaction with the implant than with the pill, patch, ring, or the injection, and tend to want to continue it for longer than women using other methods. | ***Possible decreased bone density***<br>While the implant may decrease bone density, there is no evidence that it causes osteoporosis or bone fractures. |
| ***No estrogen***<br>Since the implant does not contain estrogen, it can be used by women who cannot use estrogen due to their migraines, high blood pressure, diabetes, or history of clots, for example. | ***Other possible side effects***<br>Women using the implant have reported headache, mood swings, depression, acne, gastrointestinal upset, breast pain, and vaginal discharge. It is unknown if these side effects are actually from the implant. |
| ***No monthly cost***<br>While the implant and insertion can be costly, these costs are generally covered by insurance, and using the implant eliminates the monthly copay that many women encounter with other contraceptives. | ***No protection from sexually transmitted infections (STIs)***<br>Unlike condoms, the implant does not protect against sexually transmitted infections. |

Adapted from the following sources:

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Centers for Disease Control and Prevention. *U.S. Medical Eligibility Criteria for Contraceptive Use,*

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- Fully or almost fully breastfeeding, amenorrheic, *and*< 6 months postpartum

### Patient Information after Insertion or Removal

Patients should be advised that soreness in the arm may last a few days, and swelling and bruising can persist for up to 1–2 weeks. After insertion, patients should use backup contraception for 7 days unless the implant is inserted within 5 days of the last menstrual period [40]. After removal, fertility can resume immediately, so patients should use a method of contraception if trying to avoid pregnancy.

Although follow-up is not required after either procedure, providers should advise patients to return at any time to discuss side effects or other concerns, if they want to change to a different contraceptive, or when it is time to remove or replace the implant [40]. While symptoms may be managed with medication or reassurance, patients should also be advised that the implant may be removed at any time if desired.

## Non-Contraceptive Benefits

### Menstrual-Related Symptoms

In addition to preventing pregnancy, the contraceptive implant provides non-contraceptive benefits [43]. While frequent or prolonged bleeding is a common side effect and the most common reason for dissatisfaction with the implant [44, 45], most implant users actually experience bleeding that is similar or decreased compared to their regular periods [37, 44]. The implant is an effective treatment for dysmenorrhea—one study found that the implant resolved dysmenorrhea in more than three quarters of patients [44]. Because most women experience decreased bleeding or amenorrhea with the implant, it may be an effective treatment for women with menorrhagia. The implant has been shown to reduce pain due to endometriosis [46, 47], as well as pain due to pelvic congestion syndrome [48].

### Cancer Risk

The relationship between the etonogestrel implant and cancer risk is unknown. However, given that other progestin methods have been shown to decrease endometrial cancer risk, it is possible that the implant also reduces this risk [43]. Also, given that combined hormonal contraceptives have been shown to decrease ovarian cancer risk, presumably from their anovulatory effect, it is plausible that the implant may reduce this risk as well [43].

## Side Effects and Complications

### Effect on Bleeding

While most women experience the same or decreased bleeding with the contraceptive implant [37, 44, 15, 49], bleeding changes are the most commonly reported side effect and the most common reason for follow-up or implant discontinuation [44, 45, 50]. While 20–40 % of implant users report frequent or prolonged bleeding, the implant can also cause amenorrhea (10–30 %) or infrequent bleeding (30–50 %); about 40–60 % of women report lighter bleeding volume and 10–15 % report heavier bleeding volume [44, 37, 15]. Bleeding in the first 3 months after insertion is predictive of future bleeding with the implant: most women with favorable bleeding patterns continue to have favorable bleeding patterns, and only half of women with unfavorable bleeding who continue the implant experience an improvement [44]. Obese women are more likely than overweight or normal weight women to have the implant removed for bleeding [51].

Despite the prevalence of bleeding concerns in etonogestrel implant users, there is minimal data to support the use of treatment for these symptoms. A pragmatic approach to irregular bleeding in implant users starts with combined hormonal contraceptives, such as taking a 30 mcg ethinyl estradiol pill for 21 days followed by a 7-day break, for up to 3 months [52]. This regimen has only limited evidence, but anecdotally appears to help. Some providers offer patients the option to continue the combined hormonal contraceptive for the duration of the use of the implant.

A Cochrane review from 2013 reported on a few medication regimens that show promise in decreasing or regulating bleeding [53]. One study demonstrated that a combination of mifepristone with doxycycline or ethinyl estradiol was more effective at temporarily improving bleeding than placebo, but had no long-term effect; another study demonstrated that mifepristone once monthly was effective to reduce bleeding in levonorgestrel implant users, but not etonogestrel implant users. Nonsteroidal anti-inflammatory drugs (NSAIDs) also show variable results, with some effectiveness in small studies. The authors conclude that the data do not support routine use of any medication for bleeding with progestin methods. A more recent study demonstrated that women receiving reassurance and doxycycline for bleeding with the implant were less likely to remove the implant than those who received reassurance alone [54].

While there are no data to support that pre-insertion counseling improves acceptance and continuation of the etonogestrel implant, it is good practice to realistically

inform women of the bleeding patterns they might expect [55].

### Effect on Weight

The effect of the etonogestrel implant on weight gain is not yet fully known. A systematic review published in 2013 investigated the effect of progestin-only contraceptives on weight, but did not find any published studies evaluating the etonogestrel implant [56]. One more recent study demonstrated weight gain in implant users compared to non-hormonal contraceptive users (2.1 kg vs. 0.2 kg) at 12 months; however, this difference was not present after controlling for confounders, specifically age and race [57]. Yet, another analysis of the same data demonstrated that implant users were more likely to perceive weight gain than non-hormonal IUD users, and that perception of weight gain correlated well with actual weight gain [58]. Therefore, the existing data about the effect on weight from the etonogestrel implant are limited and inconclusive.

### Effect on Mood

Mood changes are commonly reported by implant users, and 1–10 % of women report discontinuing the implant for this reason [33, 17, 32, 30]. A recent animal study investigated the effect of etonogestrel and depot medroxyprogesterone acetate (DMPA) on serotonin and gaba-aminobutyric acid (GABA) receptors, finding that while DMPA appears to decrease serotonin receptors, etonogestrel does not affect either serotonin or GABA receptors [59]. As current data are limited, more research is needed to examine the effect of the etonogestrel implant on mood.

### Effect on Breastfeeding

Women can breastfeed successfully with the implant, even when it is inserted immediately post-partum. There is a theoretical concern, based on older animal studies, about the implant adversely impacting breastfeeding success and infant growth. This concern was addressed in 2010, when a systematic review on contraception and breastfeeding found no negative effect on breastfeeding initiation, continuation, or infant health; however, only two of the studies included the etonogestrel implant [60]. Two later studies found no differences in breastfeeding or infant growth for women starting the implant 6 weeks postpartum compared to other methods [61], and no difference in breastfeeding outcomes in women starting the implant immediately postpartum (1–3 days) compared to 4–8 weeks postpartum [62].As a result, the MEC 2010 considers use of the implant while breastfeeding a Category 2 (advantages generally outweigh the risks) if it is less than 1 month postpartum, and a Category 1 (no restrictions) if it is at least 1 month postpartum [5].

### Effect on Bone Density

Although there is a theoretical concern about the effect of the implant on bone mineral density (BMD), implants and other progestin contraceptives have never been associated with increased fracture risk. Of the progestin methods, DMPA has been shown in numerous studies to reversibly decrease BMD [63], but studies of the etonogestrel implant have been inconsistent. A few studies did demonstrate a decrease of BMD at the forearm, but not other areas such as the hip or spine, and these decreases were small, less than one standard deviation from the mean [64–66]. As a Cochrane review pointed out, no trials of contraceptives and bone effects included fracture as an outcome, so there is no evidence to support that decreased BMD increases fracture risk in progestin contraceptive users [63].

### Cardiovascular and Metabolic Effects

The CDC US MEC considers use of progestin-only contraceptives as a Category 1 (no restriction) or Category 2 (advantages generally outweigh the risk) for conditions which increase a woman's risk of a cardiovascular event, with additional restrictions for DMPA [5]. While combined hormonal contraceptives do show a clear small increased risk of cardiovascular disease, particularly venous thromboembolism (VTE), stroke, or myocardial infarction, studies of progestin-only contraceptives have been inconsistent, and have not included implant users [67–69].

However, a recent study of etonogestrel implant users found that when inserted immediately postpartum, the implant did not have any negative effect on coagulation factors when compared to postpartum controls [70]. Even though this study did not seek to capture changes in cardiovascular outcomes, a lack of change in the coagulation system, particularly in postpartum women, is reassuring.

Studies of the etonogestrel and levonorgestrel implants do not demonstrate adverse metabolic effects including carbohydrate metabolism, lipids, blood pressure, liver function, or thyroid function [71–75]. One recent study suggested improvements in fasting glucose and lipids among etonogestrel implant users when compared to baseline [76].

When providing contraception to women at increased risk for cardiovascular disease, it is important to balance the potential risks of VTE from hormonal contraception with the large increased risk of VTE with pregnancy that could result from the lack of an acceptable contraceptive method [5].

### Other Side Effects

Other commonly reported side effects of the etonogestrel implant include acne, gastrointestinal upset, headache, breast pain, and vaginitis [17]. However, data is limited regarding these side effects, and more research is needed to ascertain if they are related to the use of the implant.

### Complications

Serious complications following implant insertion and removal are very rare, occurring in less than 1 % of procedures [42, 4•, 77]. While studies of the levonorgestrel implants report infection rates of<1 %, the majority of studies of the etonogestrel implant report zero infections [77], and few cases of device expulsions associated with infection have been reported [19]. A small number of cases of nerve damage have been reported secondary to incorrect placement of devices adjacent to nerves [78, 79]. Fracture of the device is also very rare [80, 18], although the manufacturer recommends that when removing devices, they be measured to ensure the entire device has been removed.

It is rare for the implant removal to be difficult, with studies reporting difficulty rates ranging from<1–3 % [81, 26]. Most often the difficulty resulted from deep insertion of the previous version of the device, not the one that is now exclusively used in this country. Deep migration of an appropriately placed device has not been reported [82]. Prior to removal, the clinician should palpate the device at the site of insertion, and not attempt removal of a non-palpable device without further examinations to confirm the device is present. High-frequency ultrasound or magnetic resonance imaging (MRI) may be used to localize non-palpable Implanon® devices [83], while barium-containing Nexplanon® devices should be localized by X-ray or computed tomography (CT) [24]. In the rare cases where the implant cannot be localized, the manufacturer suggests that providers call for further instructions.

## Public Health Implications

The family planning and public health communities are committed to increasing the use of the implant and the IUDs (together referred to as LARC, or long-acting reversible contraception). Despite its high efficacy and many other benefits, implants are used by less than 1 % of women in the U.S. [6], a result of multiple barriers, including cost, lack of trained providers, and lack of patient knowledge about the implant [84–86, 38, 87–89]. Because LARC methods are also more cost-effective than other contraceptives when used for greater than 12–18 months [90], it has been posited that increasing use of LARC would decrease total health care expenditures [91–94]. Multiple efforts have investigated ways to increase the use of LARC in multiple settings, including increasing providers trained in LARC and increasing women's interest in the methods [95, 38, 96].

However, while there are many benefits to implants and IUDs, it is important for providers to keep in mind that these methods are not acceptable to all women. As was pointed out in a recent commentary, socioeconomic disparities cannot be solved solely by increased access to these highly effective and easy-to-use methods [97•]. It is important to recognize that these are clinician-dependent methods, and may undermine women's reproductive autonomy. Historically, sterilization and earlier implant programs have disproportionately targeted women of color and of low socioeconomic status [8]. Recent data demonstrates that providers' recommendations about intrauterine contraception are affected by their perception of a woman's race/ethnicity and socioeconomic status [98], and that some women seeking to discontinue their contraceptive implants encountered resistance from their providers [99•].

While LARC methods have many advantages, clinicians must use a patient-centered approach to counseling about all safe and effective contraceptive options, and support women's reproductive autonomy. Empowering women to make choices about their bodies and their lives is an integral part of providing contraceptive care, and ultimately the best birth control is the one that a woman selects for herself.

## Conclusions

The implant is a contraceptive option that provides women with a highly effective method that is easy to use, is well liked by users, and has a favorable safety profile compared to other hormonal methods. While the implant is underutilized compared to other methods, it is growing in popularity as family planning programs seek to decrease barriers to LARC methods. While these efforts are improving women's access to highly effective contraception, providers must respect women's decisions to use, not use, or discontinue these methods.

#### Compliance with Ethics Guidelines

**Conflict of Interest** Jennifer Amico, Bhavik Kumar, Hilary Rosenstein, and Marji Gold declare that they have no conflict of interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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