

Your teenage patient and contraception: Think “long-acting” first

➡ Although use of long-acting reversible contraception is increasing slowly in the United States, there is plenty of room for improvement, particularly among young women. Here, 2 experts address the nuances of choosing a method for a teenage patient.

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CASE Teen patient asks to switch contraceptive methods

A 17-year-old nulliparous woman comes to your clinic for an annual examination. She has no significant health problems, and her examination is normal. She notes that she was started on oral contraceptives (OCs) the year before because of heavy menstrual flow and a desire for birth control but has trouble remembering to take them—though she does usually use condoms. She asks your advice about switching to a different method but indicates that she has lost her health insurance coverage.

What can you offer her as an effective, low-cost contraceptive?



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Long-acting reversible contraception (LARC) methods are especially suited for adolescent and young adult women, for whom daily compliance with a shorter-acting contraceptive may be problematic. Five LARC methods are available in the United States, including a new levonorgestrel-releasing intrauterine system (LNG-IUS; Liletta), which received approval from the US Food and Drug Administration (FDA) this year. Like Mirena, Liletta contains 52 mg of levonorgestrel that is released over time. Liletta was introduced by the nonprofit organization Medicines360 and its commercial partner Actavis Pharma in response to evidence that poor women continue to lack access to LARC because of cost or problems with insurance coverage.¹

For providers who practice in settings eligible for 340B pricing, Liletta costs \$50, a fraction of the cost of alternative intrauterine devices (IUDs). The cost is slightly higher for non-340B providers but is still significantly lower than the cost of other IUDs. For health care practices, the reduced price of Liletta may make it feasible for them to offer LARC to more patients. The reduced pricing also makes Liletta an attractive option for women who choose to pay for the device directly rather than use insurance, such as the patient described above.

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Patient experience with Liletta also is key. Not surprisingly, Liletta’s clinical trial found patient satisfaction to be similar to that of Mirena users.² The failure rate is less than 1%, again comparable to Mirena. The rate of pelvic infection with Liletta use was 0.5%, also comparable to previously published data.³

One difference between Liletta and Mirena is that Liletta carries FDA approval for 3 years of contraceptive efficacy, compared with 5 years for Mirena. In order to make Liletta available to US patients now, Medicines360 decided to apply for 3-year contraceptive labeling while 5- and 7-year efficacy data are being collected. Like Mirena, Liletta is expected to provide excellent contraception for at least 5 years.

Skyla is another LARC option for women seeking an LNG-IUS for contraception. It provides highly effective contraception for at least 3 years through the release of 13.5 mg of levonorgestrel over time. Skyla’s reduced levonorgestrel content, as compared with Mirena and Liletta, means that fewer users will experience amenorrhea (13% vs 25%).

Paragard is a nonhormonal IUD that uses copper for contraceptive efficacy. The device contains a total of 380 mm of copper. Possible mechanisms of action include interference with sperm migration in the uterus and damage to or destruction of ova. It is FDA-approved for at least 10 years of use. The lack of any hormone in

Paragard IUDs may make them attractive to women who do not wish to experience amenorrhea.

Nexplanon is a subdermal implant containing 68 mg of etonogestrel; it is approved for at least 3 years of use. It is the only LARC method that does not require a pelvic examination. Providers are required to complete a training course offered by the manufacturer to ensure proper placement and removal technique.

LARC should be a first-line birth control option

The primary indication for LARC is pregnancy prevention. Because LARC methods are the most effective reversible means to prevent pregnancy—apart from complete abstinence from sexual intercourse—they should be offered as first-line birth control options to patients who do not wish to conceive. The ability to discontinue LARC methods is an attractive option for women who may want to become pregnant in the future, such as the patient in the opening vignette.

Efficacy rates are high

Because LARC methods do not require users to take action daily or prior to intercourse, they carry a risk of pregnancy of less than 1% (TABLE 1)⁴⁻⁷—equal to or better than rates seen with tubal sterilization. In comparison, the OC pill has a typical use contraceptive failure rate of about 8%.



LARC methods carry a risk of pregnancy of less than 1%

TABLE 1 A comparative look at 5 LARC methods⁴⁻⁷

LARC method	Content	FDA-approved duration of use	Pregnancy rate	Discontinuation rate*
Copper IUD (Paragard)	copper 380 mm	10 years	0.2%	9.7%
Implant (Nexplanon)	etonogestrel 68 mg	3 years	0.1%	11.3%
LNG-releasing intrauterine systems				
Mirena	LNG 52 mg	5 years	0.3%	1.3%
Skyla	LNG 13.5 mg	3 years	0.9%	9.1%
Liletta	LNG 52 mg	3 years	0.6%	1.5%

Abbreviations: IUD, intrauterine device; LNG, levonorgestrel.

* Due to bleeding and/or pain.

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National organization identifies barriers to LARC

In 2014, the National Committee for Quality Assurance (NCQA), with support from Bayer Healthcare, organized a meeting of key opinion leaders to discuss ways to eliminate barriers to the most effective contraceptive methods, better known as long-acting reversible contraception (LARC). The resultant issue brief, *Women's Health: Approaches to improving unintended pregnancy rates in the United States*, identified a number of key barriers:

- **Financial and logistical obstacles.** The consensus attendees agreed that LARC methods should be offered to all women not planning a pregnancy in the next 2 years, but acknowledged that operational or administrative process issues sometimes interfere with this goal. One of the most prominent of these issues was the lack of opportunity for same-day insertion of LARC. Other issues included the cost to stock LARC methods, a lack of understanding of billing and reimbursement for LARC, reimbursement policies that prohibit billing for the visit and placement on the same day, and an overabundance of paperwork.
- **Timing of the contraceptive counseling session.** Many women fail to return for the 6-week postpartum visit—the visit typically set aside for counseling about contraception.
- **Lack of a quality measure** that would “motivate change in clinical practice.”¹ One option: Treat family planning as a “vital sign” that needs to be addressed during the annual visit. “This would lead to stronger evidence for effecting change,” the report notes.¹
- **Lack of adequate communication**

skills by the provider. According to the NCQA report, “There are strong positive relationships between a health care team member’s communication skills and a patient’s willingness to follow through with medical recommendations.”¹ The establishment of a “current counseling approach” that emphasizes the efficiency and effectiveness of LARC methods as well as the tremendous impact an unintended pregnancy would have on a woman’s whole life course would help improve provider-patient communication and increase the likelihood of LARC methods being utilized.¹

- **Lack of receptivity among some patients.** For some women, the person delivering the message is as important as the message itself, depending on social and cultural norms. Sensitivity of health care providers to these nuances of communication can help enhance patient receptivity to the key message. As the NCQA report notes, “Physicians and the health care system are not always the most trusted source of information, and understanding disparities in contraception care will be important in changing patient behavior.”¹
- **Basic issues such as cost and access to care.**¹ Not all women are covered by insurance, particularly in states that opted against expanding access to Medicaid. For these women, the cost of LARC methods and insertion may be prohibitive.

Reference

1. Women’s health: Approaches to improving unintended pregnancy rates in the United States. National Committee for Quality Assurance. Issue Brief. 2014. <http://www.ncqa.org/HEDISQualityMeasurement/Research/WomensHealth.aspx>. Accessed August 18, 2015.

LARC still has a low utilization rate

It is unfortunate that barriers to LARC methods remain in the United States (see, for example, “National organization identifies barriers to LARC,” above). As recently as 2011 to 2013, only 7.2% of US women aged 15 to 44 years used a LARC method.⁸ Provider inexperience and patient fears surrounding LARC use remain major barriers. In the past, nulliparity and young

age were thought to be contraindications to IUD use. Research and experience have demonstrated, however, that IUDs and contraceptive implants are safe for use in young women and those who have not had children.

Cost barriers also have significantly limited the use of LARC methods. Over time, however, these contraceptives have become less costly to patients, and most



IUDs and contraceptive implants are safe for use in young women and nulliparous patients

TABLE 2 When LARC may be contraindicated⁹

Condition	LARC method	CDC medical eligibility criteria
Current breast cancer	Implant	Category 4 – Unacceptable health risk
	LNG-IUS	
Previous breast cancer (no disease for ≥5 years)	Implant	Category 3 – Theoretical or proven risk outweighs the advantages
	LNG-IUS	
Cirrhosis (severe–decompensated)	Implant	
	LNG-IUS	
Distorted uterine cavity	Copper IUD	Category 4
	LNG-IUS	
GTN with decreasing or undetectable beta-hCG levels	Copper IUD	Category 3
	LNG-IUS	
GTN with persistently elevated beta-hCG levels or malignant disease	Copper IUD	Category 4
	LNG-IUS	
Untreated cervical cancer (initiation of device)	Copper IUD	
	LNG-IUS	

Abbreviations: GTN, gestational trophoblastic neoplasia; hCG, human chorionic gonadotropin; IUD, intrauterine device; LNG-IUS, levonorgestrel-releasing intrauterine system.



IUD users have a reduced risk of endometrial cancer

insurance providers routinely cover LARC devices and insertion fees. The contraceptive mandate of the Affordable Care Act ensures coverage of contraception, including LARC, for interested women. These trends suggest continued improvement in women’s access to LARC.

Noncontraceptive benefits include reduced bleeding

The 3 LNG-IUS methods and the subdermal implant offer several benefits beyond contraception. Because of their progestin content, these methods reduce or even eliminate menses. This benefit can be very helpful for women who experience heavy menstrual periods and the consequent risk of anemia. Because of reduced menstrual flow, users of hormonal LARC methods also commonly experience less cramping associated with menses.

Women with endometriosis often benefit from hormonal LARC methods, as the disease is suppressed by the progestin component. Users of IUDs also have a reduced risk of endometrial cancer.

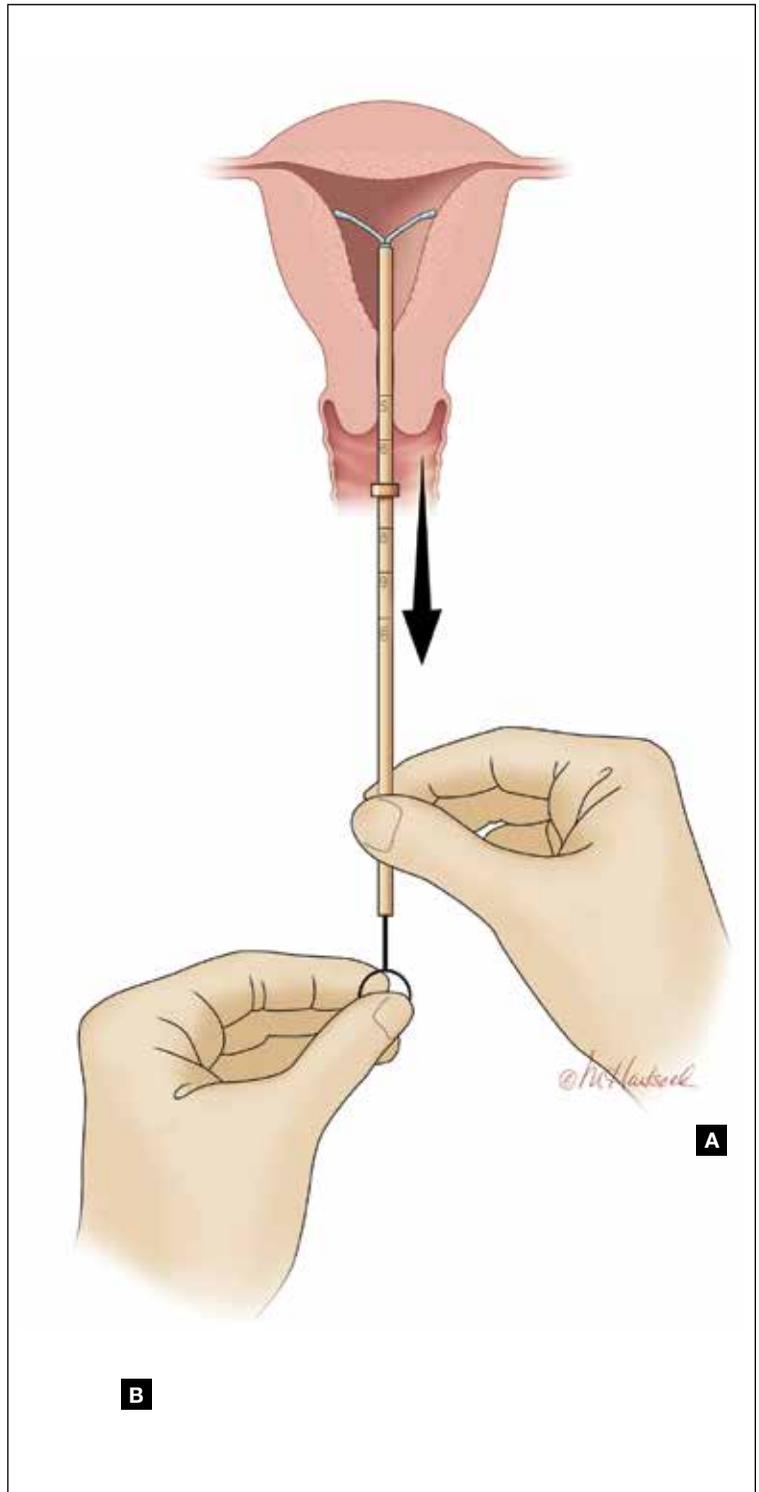
Contraindications to LARC

There are few contraindications to LARC methods, making them an appropriate choice for most women. The *US Medical Eligibility Criteria for Contraceptive Use, 2010*, published by the Centers for Disease Control and Prevention (CDC), contain guidelines that are based on the best available evidence.⁹ Contraceptive methods that are labeled as Category 1 or 2 are not contraindicated for most women. Methods that fall into Category 3 (theoretical or proven risks outweigh the advantages) or Category 4 (unacceptable health risk) are contraindicated (TABLE 2).⁹

IUDs once were thought to expose women to an increased risk of pelvic inflammatory disease, but this fear has long been disproven. Screening for chlamydia can be performed at the time of placement, as recommended annually for women younger than 25 years. Unless there is concern for active cervical or uterine infection, there is no need to delay insertion of an IUD while awaiting test results. In most cases, women found to have positive cultures after

How to insert Liletta

1. With the intrauterine system (IUS) loaded at the top of the insertion tube, firmly pinch the proximal end of the insertion tube to keep the IUS in the correct position. Applying gentle traction on the tenaculum, align the cervical canal and uterine cavity.
2. While still pinching the insertion tube, slide the tube through the cervical canal until the upper edge of the flange is approximately 1.5 to 2 cm from the cervix. Do not force the inserter. If necessary, dilate the cervical canal. Release your hold on the tenaculum.
3. Hold the insertion tube with the fingers of one hand (Hand A) and the rod with the fingers of the other hand (Hand B).
4. Holding the rod in place (Hand B), relax your pinch on the tube and pull the insertion tube back with Hand A to the edge of the second indent of the rod. This will allow the IUS arms to unfold in the lower uterine segment (FIGURE). Wait 10 to 15 seconds for the arms of the IUS to open fully.
5. Apply gentle traction with the tenaculum before advancing the IUS. With Hand A still holding the proximal end of the tube, advance both the insertion tube and rod simultaneously up to the uterine fundus. You will feel slight resistance when the IUS is at the fundus. Make sure the flange is touching the cervix when the IUS reaches the uterine fundus. Fundal positioning is important to prevent expulsion.
6. Hold the rod still (Hand B) while pulling the insertion tube back with Hand A to the ring of the rod. While holding the inserter tube with Hand A, withdraw the rod from the insertion tube all of the way out to prevent the rod from catching on the knot at the lower end of the IUS. Completely remove the insertion tube.
7. Using blunt-tipped sharp scissors, cut the IUS threads perpendicular to the thread length, leaving about 3 cm outside of the cervix. Do not apply tension or pull on the threads when cutting to prevent displacing the IUS. Insertion is now complete.



insertion can be treated successfully without IUD removal.

Main adverse effect is altered bleeding patterns

Adverse effects vary depending on the method being used. All LARC methods may affect menstrual patterns. For example, clinical trials involving the copper IUD indicate that abnormal heavy bleeding may lead to discontinuation in up to 10% of users.^{5,10} Amenorrhea or oligomenorrhea is uncommon with this method and rarely leads to discontinuation. For example, in one trial involving more than 900 women using a copper IUD for up to 5 years, there were no discontinuations due to amenorrhea. Dysmenorrhea may arise, but data from clinical trials indicate that its frequency decreases over time. In one trial, the frequency of any menstrual pain decreased from about 9% of users to 5% after 8 months or more of use.

The LNG-IUS also can be associated with abnormal uterine bleeding. In contrast to the copper IUD, LNG devices tend to reduce menstrual bleeding and can be unpredictable. Clinical trials involving the 5-year 52-mg LNG-IUS indicate that bleeding decreases over time, with as many as 70% of users developing amenorrhea or oligomenorrhea.^{5,11} However, some women using an LNG-IUS experience heavy bleeding—although the frequency of such bleeding tends to be substantially less than that experienced by copper IUD users.⁷

A lack of comparative trials makes it unclear whether the newer 3-year LNG-IUS devices are associated with a significantly altered bleeding pattern. Noncomparative data from the package insert for Skyla suggest that women using it may have a higher frequency of heavy menstrual bleeding and less amenorrhea than users of the 5-year device.⁶

Data from a 3-year clinical trial of the newest 52-mg LNG-IUS (Liletta) indicate that bleeding and dysmenorrhea led to discontinuation 1% to 2% of the time.²

Although the concentration of progestin circulating systemically is low with the

various LNG-IUS devices, some women may experience symptoms such as mood swings, headaches, acne, and breast tenderness.

Expulsions during the first year of use of the copper IUD and the 3 LNG-IUS devices range from 2% to 10%, with the higher rates associated with immediate postpartum insertion.⁵

Uterine perforation has been reported in about 1 of every 1,000 insertions. Other adverse events are uncommon.

Clinical trials indicate that about 11% of implant users will discontinue the method due to bleeding abnormalities.¹² About 25% to 30% of users will experience heavy or prolonged bleeding, while up to 33% will experience infrequent bleeding or amenorrhea. About 50% of implant users will experience improved bleeding patterns over time.

Other reasons for discontinuation of implant use in a very small percentage of users include emotional lability, weight gain, acne, and headaches.⁴ Complications due to insertion and removal are rare and include pain, bleeding, and hematoma formation.

Public health impact of LARC methods

An important question in regard to LARC use is: How do we best provide safe and effective contraception for teens and young adult women? There is increasing evidence that, with appropriate counseling and the removal of cost barriers, LARC methods can have a significant public health impact in this population.

The Contraceptive CHOICE Project, a cohort study in a teenage population of women in the St. Louis, Missouri, area, achieved increased utilization of LARC methods and significantly lower rates of pregnancy, birth, and abortion.¹³ Investigators proactively counseled young women about the advantages of LARC methods and offered them free of charge. As a result, 72% of women in the study chose an IUD or implant as their method of contraception. Pregnancy, birth, and abortion rates among participants were 34.0, 19.4, and



As many as 70% of Mirena users develop amenorrhea or oligomenorrhea

9.7 per 1,000 teens, respectively. By comparison, national statistics during the same time frame for pregnancy, birth, and abortion were 158.5, 94.0, and 41.5 per 1,000 US teens, respectively.¹³

A similar project in Colorado received \$23.6 million in 2009 from an outside donor to make LARC methods more affordable to patients in family planning clinics in the state.¹⁴ Between 2009 and 2014, 30,000 contraceptive implants or IUDs were made available at low or no cost to low-income women attending 68 family planning clinics statewide. The use of these methods at participating clinics quadrupled. Further, the teen birth rate declined by 40% between 2009 and 2013—from 37 to 22 births per 1,000 teens.¹⁴ Seventy-five percent of this decline was attributable to increased use of these methods. The teen abortion rate declined by 35% in the same time frame.

In 2014, the Colorado governor's office indicated that the state had saved \$42.5 million in health care expenditures associated with teen births. It was estimated that, for every dollar spent on contraceptives, the

state saved \$5.68 in Medicaid costs. However, a bipartisan bill to continue funding the project has failed so far in 2015 due to concerns among some legislators that these methods—particularly the IUDs—are abortifacients. The reduced cost of the 3-year LNG-IUS (Liletta) and recent guidance from the US Department of Health and Human Services mandating that at least 1 form of contraception in each of the FDA-approved categories must be covered by insurers may help to overcome this barrier.

CASE Resolved

You counsel the patient about the value of each LARC method, letting her know that they are all highly effective in the prevention of pregnancy. You also let her know how each method would affect her menstrual cycle and acknowledge that she may have a preference for whether the contraceptive is placed in her uterus or under the skin of her arm. She chooses the contraceptive implant, which you insert during the same visit. At a follow-up visit 6 weeks later, she reports satisfaction with the method. ☺



In Colorado, the teen birth rate declined 40% between 2009 and 2013 after LARC methods were provided at reduced cost

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