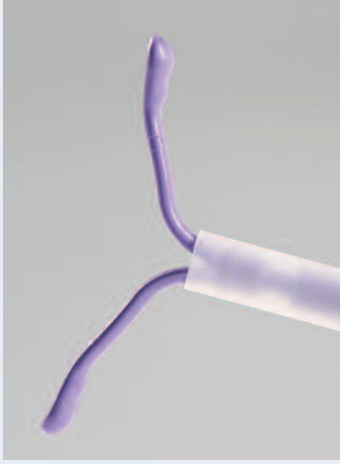
Getting to *yes*:
Interventions to increase LARC acceptance, with a focus on intrauterine contraception



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To participate in this CE program, go to *click here*[A].

Faculty

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Intended audience

This continuing education (CE) activity has been designed to meet the educational needs of women's health nurse practitioners (WHNPs), adult nurse practitioners (NPs), family NPs, certified nurse midwives (CNMs), and other advanced practice clinicians who care for teenagers and women.

CE approval period

Now through August 31, 2017

Estimated time to complete this activity

1 hour

CE approval hours

1.0 contact hour of CE credit (no pharmacology content credit)

Needs assessment

Of the 6.1 million pregnancies in the United States each year, 45% are unintended—either mistimed (27%) or unwanted (18%). Ninety-five percent of unintended pregnancies occur in females who do not use contraceptives (54%) or who use them inconsistently (41%). These unintended pregnancies may end in abortion (42%) or birth (58%), both of which have socioeconomic, fiscal, and health-related consequences. Births resulting from unintended or closely spaced pregnancies can have a variety of adverse maternal and child health outcomes. Furthermore, females who have children before they are ready are less likely to reach their educational, career, financial, and/or family-related goals. Unintended pregnancies can be avoided by correct and consistent use of a birth control method. Among all reversible methods, those that require the least amount of effort by the user have been demonstrated to be the most effective at pregnancy prevention. The authors discuss long-acting reversible contraceptives (LARC), the most effective reversible birth control methods on the market.

Goal statement

Nurse practitioners and other advanced practice clinicians will be fully informed about LARC, recommend them to reproductive-aged females who want the most effective method of reversible birth control available, and know how to create a LARC-friendly practice.

Educational objectives

At the conclusion of this educational activity, participants should be able to:

1. Identify barriers and develop strategies to overcome barriers to intrauterine contraceptive use in clinical practice.
2. Counsel patients about LARC to foster informed decision making.
3. Incorporate data from recent studies into patient counseling about LARC.

Accreditation statement

This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH), and has been approved for 1.0 contact hour of CE credit, (no pharmacology content credit).

Faculty disclosures

NPWH policy requires all faculty to disclose any affiliation or relationship with a commercial interest that may cause a potential, real, or apparent conflict of interest with the content of a CE program. NPWH does not imply that the affiliation or relationship will affect the content of the CE program. Disclosure provides participants with information that may be important to their evaluation of an activity. Faculty are also asked to identify any unlabeled/unapproved uses of drugs or devices made in their presentation.

Colleen McNicholas, DO, MSCI, FACOG, has no financial relationship or other disclosure to make.

Stacy Selbert, MSN, WHNP-BC, has disclosed that she has received consulting fees from Allergan and Medicines360.

Disclosure of unlabeled use

NPWH policy requires authors to disclose to participants when they are presenting information about unlabeled use of a commercial product or device or an investigational use of a drug or device not yet approved for any use.

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uating this information in relation to generally accepted standards in their own communities and integrating the information in this activity with that of established recommendations of other authorities, national guidelines, FDA-approved package inserts, and individual patient characteristics.

Successful completion of this activity

Successful completion of this activity, J-16-03, requires participants to:

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2. Read the learning objectives, disclosures, and disclaimers on the next page.
3. Check "Agree to Terms" on the next page and then click the "Continue" button.
4. Study the material in the learning activity during the approval period (now through August 31, 2017).
5. Complete the posttest and evaluation. You must earn a score of 70% or better on the posttest to receive CE credit.
6. Print out the CE certificate if successfully completed.

Commercial support

This activity is supported by educational grants from Allergan, Plc; Bayer HealthCare, and Teva Pharmaceutical Industries, Ltd.

Before reading the article, ***click here***[A] to take the pretest.

Long-acting reversible contraceptives, or LARC, are growing in popularity because they are highly effective, safe, and well tolerated. In addition, LARC methods require virtually no effort on the part of users besides seeing their healthcare provider (HCP) for insertion and removal. The authors describe their experience in "getting to yes"—that is, in encouraging HCPs to offer LARC methods in a patient-friendly environment and patients to consider using them—so that teens and women have access to all methods, autonomy over their method decision, and decreased risk of unintended pregnancy.

KEY WORDS: **long-acting reversible contraceptives, LARC, intrauterine contraceptive, IUC, IUD, LNG-IUS**

Of the 6.1 million pregnancies in the United States each year, 45% are unintended—either mistimed (27%) or unwanted (18%).[1,2] Ninety-five percent of unintended pregnancies occur in females who do not use contraceptives (54%) or who use them inconsistently (41%).[1] These unintended pregnancies may end in abortion (42%) or birth (58%),[2] both of which have socioeconomic, fiscal, and health-related consequences. Births resulting from unintended or closely spaced pregnancies can have a variety of adverse maternal and child health outcomes.[1] Furthermore, females who have children before they are ready are less likely to reach their educational, career, financial, and/or family-related goals.

Unintended pregnancies can be avoided by correct and consistent use of a birth control method. Among all reversible methods, those that require the least amount of effort by the user have been demonstrated to be the most effective at pregnancy prevention.

Background information on LARC

Long-acting reversible contraceptives, or LARC, include the subdermal implant and intrauterine contraceptives (IUCs).[3] Both implants and IUCs are highly effective in preventing pregnancy and are FDA-approved for 3-10 years of use. In addition, these methods are reversible and do not impair fertility once they are removed; users who wish to become pregnant can have them removed at any time. LARC methods are the most effective forms of reversible birth control available: During the first year, fewer than 1% of implant or IUC users will become pregnant.[4] Failure rates associated with the use of other contraceptives are considerably higher.

Devices

The implant is a single, matchstick-sized, etonogestrel-containing rod that is placed in the subdermal tissue of the inside aspect of the upper non-dominant arm.[5] The implant, which is marketed as Nexplanon®, contains barium, allowing localization with radiography. The implant is FDA-approved for 3 years of use.

Intrauterine contraceptives, either an intrauterine device (IUD) or an intrauterine system (IUS), are T-shaped devices containing copper or levonorgestrel (LNG).[6] Four IUCs are available, the Copper T 380A (ParaGard®) and three LNG-IUS products: Mirena®, Skyla®, and Liletta®. The copper IUD is effective immediately following placement[7] and is FDA approved for 10 years of use.[6] Mirena is FDA approved for 5 years of use, and Skyla and Liletta for 3 years of use.[6] Data collection for Liletta is ongoing; it is expected that the manufacturer will ultimately seek approval for up to 7 years of use. If an LNG-IUS product is placed during the first 7 days of the menstrual cycle or immediately following birth, a miscarriage, or a first-trimester abortion, then back-up contraception is not needed.[6,8] Otherwise, a backup method is recommended for the first 7 days.

All teenagers and women should be considered candidates for LARC use until proven otherwise.

Of note, LARC methods do not protect users against sexually transmitted infections (STIs). Condoms are needed for protection against STIs.

Medical eligibility criteria

All teenagers and women should be considered candidates for LARC use until proven otherwise.[9-11] Readers can access the CDC's Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use[B]. Information from the CDC is also available as a free iPhone or iPad app at the iTunes store or as an eBook available on an eReader app.

Trends in LARC use

LARC methods are gaining in popularity for many reasons, but mainly because of their high efficacy.[12] According to an analysis of National Survey for Family Growth (NSFG) data, the proportion of female U.S. contraceptors using the IUD or implant increased from 2.4% in 2002 to 3.7% in 2007 and to 8.5% in 2009.[13] According to a more recent analysis of the NSFG data, the prevalence of LARC use among contraceptors rose from 8.5% in 2009 to 11.6% in 2012, a significant increase.[14,15] Much of this trend was driven by IUC use, which increased from 7.7% to 10.3%; implant use remained low (1.3%) and did not change significantly between these two time periods.

The Contraceptive CHOICE Project

Although increased use of LARC methods has been encouraging, uptake is still relatively low—especially considering the high rate of unintended pregnancy in this country, the superior efficacy of these methods, and the many non-contraceptive benefits they offer. The next logical question is, What can be done to increase education about and access to LARC methods for reproductive-aged females who wish to prevent pregnancy?

Purpose and methods

The Contraceptive CHOICE Project was undertaken to remove educational, financial, and access barriers to contraception; to promote the most effective methods of birth control; and to reduce unintended pregnancy in the St. Louis, Missouri, area.[16] Objectives of the project were to increase uptake of LARC; to measure/analyze method choice, satisfaction, side effects, and continuation across all reversible contraceptive methods; and to provide enough no-cost contraception to exert a population impact on unintended pregnancies, particularly with respect to teen pregnancy and repeat abortion.

Enrollment began in August 2007 and ended in September 2011. Prospective enrollees ranged in age from 14-45 years, wanted to avoid pregnancy for ≥1 year, and were willing to initiate a new form of reversible contraception.[17,18] Recruitment was done via word of mouth, referral from private and community healthcare providers (HCPs), and from the two abortion facilities in the St. Louis region. Participants underwent standardized evidence-based contraceptive counseling by trained non-clinicians. The counseling was structured on effectiveness tiers, and included the risk and benefits of each method. Tier 1 contraceptives—the most effective methods, which include LARC (IUCs and the implant)—were described first. Next, the counselor described tier 2 methods or refillables: depot medroxyprogesterone acetate (DMPA), and the pill/patch/ring (PPR). Tier 3 methods, including the diaphragm, the condom, the sponge, spermicide, withdrawal, and fertility awareness-based methods, were described last. Participants received their chosen contraceptive free of charge, and they could

switch methods as frequently as they wanted for the duration of their study participation (2-3 years).

Results

Contraceptive choices of the entire cohort and of the teen cohort alone are shown in the *Figure*.[16] Among 9,256 adult and teen participants, 75% chose a LARC method; among teens alone, 71% chose a LARC method.

Continuation rates

Among LARC users, adults and teens had high continuation rates—87% and 82%, respectively—at 12 months.[19,20] Non-LARC users had much lower 12-month continuation rates: 59% for adults and 49% for teens. Among LARC users, continuation rates at 24 months were still high: 78% for adults and 67% for teens.[20] Only 42% of adult non-LARC users and 37% of teen non-LARC users continued using the contraceptive method they chose at baseline for 24 months. At 3 years, continuation rates were 67.2% among LARC users and 31.0% among non-LARC users.[21]

Satisfaction levels

Twelve-month satisfaction levels mirrored continuation rates. A greater proportion of LARC users than non-LARC users reported being very satisfied or somewhat satisfied with their method (81.2% vs. 48.8%).[19] This differential in satisfaction between LARC users and non-LARC users held true for adults (82% vs. 50%) and for teens (75% vs. 42%). Satisfaction was similarly high among users of the subdermal implant, copper IUD, or LNG-IUS (range, 72% for teen users of the copper IUD to 84% for adult users of the LNG-IUS) and similarly low among users of DMPA or PPR (range, 31% for teen users of the ring to 52% for adult users of DMPA or the ring).

Figure. Contraceptive CHOICE Project method selections[16]

Overall cohort	%
LNG-IUS	46.0
Copper IUD	11.9
Implant	16.9
75%	
DMPA	6.9
Pills	9.4
Ring	7.0
Patch	1.8
Other	<1.0

Teen cohort	%
LNG-IUS	32.0
Copper IUD	5.0
Implant	34.0
71%	
DMPA	9.0
Pills	13.0
Ring	7.0
Other	<1.0

DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; LNG-IUS, levonorgestrel intrauterine system.

Unintended pregnancy and abortion rates

Even more important, among 7,486 participants included in this analysis, 334 (4.5%) experienced unintended pregnancies.[4] Failure rates among PPR users were 4.8%, 7.8%, and 9.4% in years 1, 2, and 3, respectively; corresponding rates among LARC users were 0.3%, 0.6%, and 0.9% (P <.001). Failure rates among DMPA users were similar to those of the LARC users. LARC methods were highly effective in preventing pregnancy regardless of a user's age, whereas teen PPR users were twice as likely as adult PPR users to become pregnant.

One of the primary outcomes of interest was the percentage of abortions that were repeat abortions.[18] Using vital statistics data from Missouri's state health department, the investigators found a significant difference in the proportion of repeat abortions between the St. Louis region and Kansas City in 2009 (respective rates, 46% vs. 49%; *P* = .02) and 2010 (respective rates, 44% vs. 51%; *P* <.01). In addition, they detected a significant decline in the proportion of repeat abortions over time in the St. Louis region (*P* = .002). Another analysis revealed that pregnancy, birth, and abortion rates among teens in the CHOICE Project were substantially lower than national rates among sexually experienced teens.[22] Respective annual rates of pregnancy, birth, and abortion were 34.0, 19.4, and 9.7 per 1,000 teen CHOICE Project participants, as compared with 158.5, 94.0, and 41.5 per 1,000 sexually experienced U.S. teens in 2008.

Summary of main findings

LARC methods, as compared with shorter-acting methods, were asso-

ciated with higher continuation rates and user satisfaction levels, regardless of age. In addition, LARC methods were associated with lower rates of unintended pregnancy and, as a consequence, lower rates of birth and abortion. An informative video about the Contraceptive CHOICE Project is available at Pathway to Choice[C]. *Box 1* shows how CHOICE got to yes.

Box 1. CHOICE got to YES by providing....

- Education regarding all birth control methods, especially LARC methods (counselors reframed the conversation to start with the most effective methods).
- Access to clinicians who offer LARC methods, have these methods available for same-day placement, and dispel myths.
- Affordable contraception as per the Institute of Medicine recommendation, the Affordable Care Act, and Medicaid Expansion.

Barriers to IUC use, and how to overcome them

In order for the encouraging results of the CHOICE Project to translate to other populations throughout the country, barriers must be overcome. From this point onward, this article focuses on IUCs.

The National Committee for Quality Assurance has issued a White Paper, *Women's Health: Approaches to Improving Unintended Pregnancy Rates in the United States*, that describes numerous barriers that impede our nation's ability to reduce the rate of unintended pregnancy. To read a summary of these barriers, click here[D]. To read the entire White Paper, click here[E].

Provider barriers

Many HCPs have concerns about prescribing and placing IUCs. Many of these concerns are easily addressed.

Lack of training

If an HCP's training occurred prior to 2001, she or he may not have received instruction in IUC placement. To acquire such training, HCPs can seek out instructors provided by product manufacturers or academic institutions, or they can attend conferences where such training is provided. HCPs need not be certified by the manufacturer to place IUCs; any HCP who feels comfortable with the instructions and the procedure may place them.

Too few patients to gain competency

An HCP such as a primary care provider or a rural health provider may not see enough patients to maintain a comfortable competency in IUC placement. This barrier may or may not be surmountable; each HCP has her or his own threshold for a feeling of competency. One approach is to form a collaborative relationship with a high-volume provider who can offer ongoing support and training. In addition, if HCPs view each patient encounter with a reproductive-aged female as an opportunity to address her goals with respect to pregnancy and/or pregnancy prevention, then they will likely be providing many more contraceptive services than they think.

Fear of litigation

Some HCPs may fear litigation if complications arise; some of the items in the bulleted list in the next section can help dispel this fear.

Concerns based on myths

Each of these myths surrounding IUCs is debunked.

- *Teenagers and nulliparous women are not appropriate candidates for IUCs*. Evidence shows that these females are excellent candidates for IUCs, which are highly effective regardless of age or parity.[10]
- *Young women won't like IUCs because placement is too painful*. Placement comfort varies from patient to patient. Many young women tolerate the placement procedure very well.[23]
- *Most patients cannot afford IUCs*. Many women have coverage for IUCs.[24] More will be able to get them as the Affordable Care Act (ACA) continues to implement the 2011 Institute of Medicine recommendations.
- *Women should have IUC counseling at one visit and return for IUC placement at the next visit*. Two-thirds of women prefer to have the IUC placed on the same day it is prescribed.[25] Adding a second visit places an extra barrier between the patient and her receiving the desired contraceptive, thereby increasing her risk for unintended pregnancy.
- *Patients won't keep their IUCs*. IUCs had the highest continuation rates of any method offered in the CHOICE Project.[26]
- *Patients already know what they want*. When CHOICE Project participants were advised of all

their birth control options and allowed to choose what they wanted, 58% chose an IUC. In the real world, only 10% of U.S. females choose an IUC.[14,15] Many females are unfamiliar with LARC methods or harbor misconceptions about them. They cannot know what they want unless they are fully informed about the options.

- *HCPs don't have time to tell patients about every method*. Trained staff members can inform patients of their options, starting with the most effective methods.[27] In addition, HCPs can provide decision aids that patients can use in the waiting room before their visits.

High upfront cost

The high cost to stock IUCs, with a delay in reimbursement, may keep some HCPs from offering them. The ACA has helped in that the cost of a contraceptive and its placement should be fully covered, with no cost share to the patient. However, barriers do remain: Some health insurance plans exclude contraceptive coverage for religious reasons, small companies need not comply, and some state plans do not cover at 100% or have restrictions on use.

Concern about a prospective IUC user being pregnant

According to the U.S. Selected Practice Recommendations for Contraceptive Use, an HCP can be reasonably certain that a patient is not pregnant if she has no signs or symptoms (S/S) of pregnancy, has a negative urine pregnancy test result, and meets any one of these criteria[8]:

- ≤7 days after the start of her normal menses;
- abstinence since the start of her last normal menses;
- correct and consistent use of contraception;
- ≤7 days after spontaneous or induced abortion;
- within 4 weeks postpartum; or
- fully or nearly fully breastfeeding, amenorrheic, and <6 months postpartum.

Concern about a prospective IUC user having an STI

At-risk patients can be tested for gonorrhea and chlamydia at IUC placement.[10] If a positive result is noted, the device can still remain in place. The HCP can treat the infection, offer expedited partner therapy as per CDC guidelines, inform patients about the warning S/S of pelvic inflammatory disease (PID; e.g., new-onset abdominal or pelvic pain, foul-smelling vaginal discharge, pain during or shortly after sex, fever, abnormal uterine bleeding), and retest in 3 months. However, if an HCP suspects active infection at the time, the device should not be placed. Instead, the patient is tested and treated as needed. No evidence suggests that IUCs increase the risk for developing an STI.

Patient barriers

These barriers include lack of knowledge about IUCs, negative influence of friends or the media, lack of access to HCPs who can provide IUCs, and cost concerns. The CHOICE Project overcame these barriers by having non-clinicians educate participants about all birth control methods. HCPs provided same-day LARC placement as per the U.S. Selected Practice Recommendations for Contraceptive Use guidelines.[8] The birth control methods were provided free of charge. In **Open the Dialogue**[F], CHOICE Project participants describe how they felt when education, access, and cost barriers were removed and they could choose any birth control method they wanted.

VIEW: Open the Dialogue[F]

IUC risks and side effects

One of the main concerns about IUC placement is uterine perforation, which occurs in about 1 in 1,000 placements.[3] Red flags indicating acute uterine perforation include the uterus sounding to a depth greater than that appreciated on bimanual examination, sudden loss of resistance, and patient pain disproportionate to that expected. Vaginal bleeding is unlikely.

Another concern is PID, which develops in fewer than 1% of IUC users, usually during the first 20 days post-placement. Appropriate precaution—screening high-risk women at the time of placement and delaying placement in those with active cervicitis—is the best way to minimize this risk. In very rare cases, pregnancy may occur with the IUC in place; if so, there is a higher chance that it will be an ectopic pregnancy. IUC users with a positive pregnancy test result need to be promptly evaluated to rule out ectopic pregnancy and undergo pregnancy options counseling.

With the copper IUD, menstrual pain and bleeding may increase at first.[3] Intermenstrual bleeding may occur as well. These side effects are common in the first few months of use and tend to subside within a year. The LNG-IUS

may be associated with spotting, irregular bleeding, and menstrual cramping in the first few months of use. Again, these side effects tend to diminish over time. Some users may experience LNG-related effects such as headache, nausea, depression, and breast tenderness.

Creating a LARC-friendly practice

Healthcare providers who wish to create a LARC-friendly practice know that LARC methods are the most effective reversible methods. They know that every patient is a LARC candidate until proven otherwise. They have ensured that all office staffers are knowledgeable about LARC, can follow an effectiveness tier-based counseling approach as per the CDC guidelines, and promote LARC use. After all, support staff members' perceptions can greatly affect patients' decisions. Other tenets of a LARC-friendly practice include the following:

- Every effort is made to help patients obtain the method of their choice.
- Same-day LARC placement is the standard.
- All HCPs have received proper LARC training.
- LARC methods are stocked if possible.

More information about setting up a LARC-friendly practice, including an introductory video, is available at the LARC First website[G]. A message from the authors appears in *Box 2*.

VIEW: LARC First website[G]

Box 2. A message from the authors

As HCPs, we want to avoid adverse events, but every day we withhold LARC methods from our patients is a day that they could get pregnant unintentionally. When we remove barriers to LARC, we are helping women avoid unintended pregnancy in the most effective way possible.

Conclusion

Long-acting reversible contraceptives are the most effective birth control methods on the market. As shown in the CHOICE Project, IUCs and implants are superior to other methods in terms of continuation rates and satisfaction levels. As such, LARC methods should be considered first-line options for all females, including adolescents and nulliparous women. LARC method efficacy does not depend on user compliance. HCPs should provide counseling and reassurance so that patients know what to expect at the time of placement, as well as possible side effects. Same-day IUC placement should be the standard. As providers of healthcare to teenage girls and women, HCPs are privileged to be able to have a dramatic impact on patients' lives with such a simple intervention. ●

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Web resources

A. npwh.org/courses/home/details/707

B. cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf

C. youtube.com/watch?v=cd46pXtMHOo

D. npwomenshealthcare.com/?p=5004

E. ncqa.org/hedis-quality-measurement/research/women-s-health

F. youtube.com/watch?v=VAsdg7f7M7w&index=4&list=PLg4ik20UZ7sVsEyq-K3nc6xNEVqBml8OY

G. larcfirst.com

For readers of the online issue who wishto participate in this CE program, click here[A].