RATIONALE FOR INCREASED USE OF INTRAUTERINE CONTRACEPTION

Nearly half of all unintended pregnancies in the United States happen in women who use contraception. This persistent statistic is largely attributed to inconsistent or incorrect contraceptive use, reflecting the widespread utilization of user-dependent contraceptive methods, among American women.

Methods that require ongoing use, such as oral contraceptive pills (OCPs) or condoms, provide repeated chances for failure, which is why a gap exists between the potential contraceptive efficacy as demonstrated in clinical trials and real-world efficacy as reflected in first-year, typical-use failure rates. In contrast, contraceptive methods that require only a one-time action to prevent pregnancy for extended intervals—even years—provide top-tier efficacy. These top-tier, long-acting reversible contraception methods (sometimes referred to by the acronym LARC) include the subdermal implant and intrauterine devices (IUDs).

Increasing the use (both initiation and continuation) of top-tier contraceptive methods is a critical strategy to reduce unintended pregnancy and induced abortion. Data from the recent US Contraceptive CHOICE Project demonstrate that use of highly effective, long-acting contraception can reduce unintended pregnancy and abortion rates. The objective of the CHOICE study was to evaluate the impact of top-tier contraceptive methods, specifically IUDs and the subdermal implant, on rates of unintended pregnancies. This observational cohort study enrolled 9256 women aged 14 to 45 in St. Louis, MO. Participants were counseled via standardized scripts on all reversible contraceptive methods, then provided with their preferred contraceptive method free of charge, eliminating cost as a determining factor in their decision-making. Follow-up phone interviews were conducted at 3, 6, 12, 18, 24, 30, and 36 months.

Collectively, long-acting, reversible methods—IUDs and the subdermal implant—were chosen by more participants across all ages, and had the highest rates of continuation, satisfaction, and efficacy. Analysis at 12 months showed that among the 4167 eligible participants, 55% chose IUDs, 23% chose a combined hormonal method, 13% chose implants, and 8% chose depot medroxyprogesterone acetate. Twelve-month continuation rates for IUDs and implants were significantly higher (86%) than were the rates for pills, vaginal rings and patches (55%). There were no statistically or clinically significant differences among the IUDs or implants—88% for the levonorgestrel intrauterine system 20 mcg/day (LNG-IUS 20), 84% for the copper intrauterine device (CuT380A), with 83% for implants. Satisfaction ratings at 12 months mirrored continuation rates: 84% of LARC users reported satisfaction with their contraceptive methods, compared with 53% among users of non-LARC methods (RR = 1.59; 95% CI 1.50, 1.68). Efficacy analysis at 12, 24, and 36 months found that among participants using OCPs, the contraceptive patch, or the vaginal ring, risk of pregnancy was 20 times higher than with IUDs or the implant—with risk particularly high in women aged <20 years compared with older women. Among users of IUDs and the implant, unintended pregnancy rates were similarly low across ages.

With the highest rates of efficacy, continuation, and satisfaction, more widespread use of the top-tier contraceptive methods may be expected to expand women’s control over their reproduction and lower the number of unintended pregnancies in the US. This activity focuses on IUD use, reviewing patient eligibility criteria, outlining best practices for IUD placement, and providing tips on managing common challenges associated with IUD placement.

PATIENT ELIGIBILITY FOR IUDs

Although product labels may be more restrictive for manufacturer liability concerns and to meet regulatory requirements, evidence-based eligibility criteria have been developed in contemporary guidelines and are supported by such organizations as the American College of Obstetricians and Gynecologists (ACOG), the US Centers for Disease Control and Prevention (CDC), the Association of Reproductive Health Professionals, and the Society of Family Planning. Despite this strong support, many clinicians remain reluctant to offer or provide IUDs to women who may be reasonable candidates for this contraceptive method.
Current CDC Recommendations on Patient Eligibility for IUD Use

The CDC’s United States Medical Eligibility Criteria for Contraceptive Use (US MEC) provides evidence-based recommendations as to which contraceptive methods are safe to initiate and continue for women in 60 scenarios that include patient age, status (eg, postpartum), and medical conditions.11 The US MEC ranks contraceptive methods on a scale of 1 to 4 according to their risk-to-benefit ratios. (Table 1) A category 1 method is a “green light” with no restrictions, whereas a category 4 method is a “red light,” meaning that the method is unacceptable in terms of the health risk it presents for that particular characteristic or condition.11

The US MEC applies category 4 restrictions for IUDs only to a limited number of patient characteristics or medical conditions, including pregnancy, untreated infection of the cervix or uterus, cervical or endometrial cancer, unexplained abnormal uterine bleeding, or uterine anomalies significant enough to prevent proper placement.11 IUDs are classified as category 2 (advantages generally outweigh risks) methods for1:

- Adolescents (menarche to <20 years)
- Nulliparous women
- Women with a history of pelvic inflammatory disease (PID) without subsequent pregnancy (a history of PID with subsequent pregnancy is rated as category 1)
- Women with any sexually transmitted infection (STI) other than current purulent cervicitis, chlamydial infection, or gonorrhea
- Women at high risk for or with current HIV infection

Youth and nulliparity are not classified as contraindications to any IUD use and have never been. In the past, however, nulliparous women were excluded by the so-called “recommended patient profiles” included in product labeling. Although those profiles have been virtually eliminated and replaced by warnings in the labeling, many clinicians persist in regarding youth and nulliparity as contraindications. Asked about IUD contraindications in a 2013 survey among physicians and nurse practitioners in women’s health, 17% of the 158 respondents named nulliparity and 6%, age <20 years.14 Other contraindications to IUD that were selected by survey respondents included a history of PID (32%), recent history of an STI (68%), and HIV-positive status (29%).14 Yet only current PID, purulent cervicitis, chlamydial infection, and gonorrhea are considered contraindications to IUD initiation by the US MEC.11

A larger survey of clinicians’ knowledge and attitudes concerning IUD use demonstrated a disconnect between knowledge and practice. Among more than 2000 clinicians, 1323 of whom were employed by Title X family-planning clinics, 30% had misperceptions about the safety of IUD use in nulliparous women.16 And among staff members of school-based health centers in New York City, 77% acknowledged the safety of IUDs in adolescents, yet 18% of these noted that they would be unlikely to recommend them to women under the age of 20. And 86% of respondents indicated that IUDs can be used in nulliparous women, but 25% of these would be unlikely to recommend an IUD themselves to a nullipara.13 It should be noted that both these studies included respondents who were either nonclinicians (eg, social workers or health educators employed by the school-based health centers) or clinicians who might not have been prepared to provide IUDs (eg, internists rather than ob-gyns or family physicians). Nevertheless, these individuals were in a position to affect patient decision-making, and the data support the observations that changes in attitudes often lag behind available evidence and changes in behavior are even slower to take place.

Along with the US MEC, clinicians should also consider patient preferences for contraceptive method, the severity of any medical condition that might affect contraceptive decision-making, and the effectiveness, acceptability, and availability of other methods if the preferred method is restricted.17 And always, the risks of the methods should be compared with the woman’s health risks with pregnancy.

ACOG Guidance for IUD Use in Adolescents and Nulliparous Women

ACOG has endorsed the US MEC recommendations17 and issued Committee Opinion statements supporting the use of top-tier, reversible contraceptive methods.9,10 In its 2012 committee opinion on adolescents and LARC methods, ACOG recommends IUDs and the subdermal implant as “the best reversible methods for preventing unintended pregnancy, rapid

TABLE 1. CDC US Medical Eligibility Categories for Contraceptive Use

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No restrictions for use of the contraceptive method</td>
</tr>
<tr>
<td>2</td>
<td>The advantages of using the method generally outweigh the theoretical or proven risks</td>
</tr>
<tr>
<td>3</td>
<td>The theoretical or proven risks of using the method generally outweigh the advantages</td>
</tr>
<tr>
<td>4</td>
<td>Unacceptable health risk with use of the contraceptive method</td>
</tr>
</tbody>
</table>

repeat pregnancy, and abortion in young women.”

ACOG provides the following evidence-based guidance for using IUDs in this population:
• IUDs are safe to use in adolescents. Noting that there is little research specifically on adolescents using the CuT380A and the LNG IUDs, evidence suggests that risk of PID is small, with relative risk elevated only in the first 20 days post-placement. The risk is likely related to bacterial colonization during placement rather than the device itself. The ACOG statement cites evidence suggesting that the levonorgestrel IUD may lower PID risk by thickening cervical mucus and thinning the endometrium.

Evidence on Risk for Complications
A recent retrospective cohort study of nearly 90,500 IUD users compared the rates of complications, method failure, and early discontinuation between teenagers aged 15 to 19 and women aged 25 to 44. Within 12 months of IUD placement, serious complications were uncommon in both groups (<1%), and early discontinuation rates were comparable in teenagers (13%) and in women ≥25 (11%). In contrast, however, in a group of 136 adolescent mothers who chose either a CuT380A or an LNG-IUS 20, the 1-year continuation rate was only 55%, with no device-related differences in the reasons for discontinuation. Study participants were enrolled in a Colorado program that provides prenatal and postpartum care for adolescents up to the age of 22. The IUD failure rate in this group, 4.9%, was higher than anticipated, given that efficacy studies typically report failure at less than 1%. All pregnancies were uterine, and ultrasound examination confirmed that all IUDs were fundally located.

Other points to consider:
• IUDs do not increase the risk of infertility after discontinuation.

Baseline fertility returns rapidly after IUD removal.
• In a retrospective cohort study of IUD placement in women aged 19 years or younger, 77.5% of whom were nulliparous, rates of successful placement were equivalent to those among adult women. More placement difficulties were reported in nulliparous teenagers compared with parous teenagers, but rates were low in both groups, demonstrating that CuT380A and LNG-IUS 20 may successfully be used in younger, nulliparous patients.
• STI screening is not required before IUD placement. If a sexually active woman under age 26 has not already been routinely screened as outlined in the CDC’s Sexually Transmitted Diseases Treatment Guidelines, screening can be performed at the time of IUD placement (“screen and insert”) and unless the woman has evidence of a current infection, placement should not be delayed.
• IUD expulsion is uncommon in adolescents. IUD expulsion risk may be increased somewhat by young age, nulliparity, and prior IUD expulsion, but data are limited. Previous expulsion is not a contraindication for another IUD, but appropriate counseling that the risk of a second expulsion is slightly higher than in the general population should be provided. In a study of the new low-dose levonorgestrel IUD (LNG-IUS 13.5), expulsion rates were lower in nulliparous than in parous women, although risk was low regardless of parity status. There are no data directly comparing expulsion rates with the smaller IUDs against those

Ectopic Pregnancy: A Persistent IUD Misperception
Some clinicians and patients remain wary of IUDs due to an erroneous perception that they are associated with elevated risk of ectopic pregnancy. In fact, risk of ectopic pregnancy is reduced in IUD users compared with sexually active women who use no contraception.

The potential for confusion lies in the fact that while overall pregnancy risk is markedly reduced in IUD users, among the small number of women who do conceive while using an IUD, the proportion of pregnancies that are ectopic is higher than in the general population of pregnant women.

In one study, the incidence of ectopic pregnancies over 1000 woman-years was reported at 0.2 among LNG-IUS 20 users, 0.3 among CuT380A IUD users, and 1.2 to 1.6 among women using no method. Other reports show likewise reassuring results.

of the LNG-IUS or CuT380A.

Immediate postpartum or postabortal IUD placement ensures reliable contraception and significantly reduces the risk of repeat abortion.10,29 The risk of expulsion is higher with immediate postpartum placement, but it is a preferred option if there are barriers to delayed postpartum placement.10

Three FDA-Approved IUDs: Expanding the Options

In January 2013, the FDA approved a LNG-IUS that is smaller in size, delivers a lower daily dose of hormone, and is effective for a shorter duration than the older LNG-IUS 2030 or the CuT380A. The newer LNG-IUS (LNG-IUS 13.5) is indicated for up to 3 years of use; the LNG-IUS 20 up to 5 years; and the CuT380A up to 10 years. Regardless of the duration of efficacy of the device she chooses, a woman can request removal at any point if she no longer wants to use contraception or decides to change contraceptive methods. Choosing to use an IUD with a 5-year duration of efficacy, for example, does not require a commitment to a full 5 years of use.

The characteristics of the LNG-IUS, LNG-IUS 20, and CuT380A are outlined in Table 2.

Although the majority of on-label contraindications to placement apply to all IUDs (eg, IUDs should not be placed in a setting of known or suspected pregnancy, infection, or cancer), some contraindications are device-specific (Table 2). In some cases, on-label contraindications differ from the CDC’s US MEC. Notably, the package inserts for the levonorgestrel IUDs list a history of PID as a contraindication unless there has been a subsequent intrauterine pregnancy, while the US MEC classifies a history of PID without subsequent pregnancy as category 2 (ie, advantages generally outweigh risks) for both the copper and levonorgestrel IUDs. The CDC also classifies current vaginitis as category 2, although the labeling information for both levonorgestrel IUDs lists “untreated cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled” as a contraindication for placement.11,31,32

Regardless of device-specific characteristics, all IUDs prevent fertilization.33 As a foreign body in the uterus, the CuT380A induces an inflammatory response. The copper ions released from the CuT380A alter the metabolism of endometrial cells and contribute increased enzymes, prostaglandins, and macrophages to uterine and tubal fluids, impairing sperm motility and function.

The levonorgestrel released by the LNG-IUS thickens mucus, suppresses endometrial function, and inhibits sperm capacitation and survival.26,34

PROPER IUD PLACEMENT PROCEDURES

Appropriate IUD placement technique, reviewed in this section, can minimize the risk of complications such as perforation; potentially avoid some of the discomfort and pain that can accompany the procedure; and help ensure accurate positioning.

In June 2013, the CDC released the US Selected Practice Recommendations for Contraceptive Use, 2013 (US SPR),25 which offers evidence-based guidance on preliminary steps (eg, testing) before and during initiation of each contraceptive method, as well as guidance regarding subsequent contraceptive management. This document emphasizes the need for a good history, but specifies

| TABLE 2. Selected Characteristics of the 3 FDA-Approved IUDs |
|--------------|-------------|-------------|
| **Dosage** | **CuT380A** | **LNG-IUS 20** | **LNG-IUS 13.5** |
| 176 mg copper wire on vertical stem, 68.7 mg copper collar on each horizontal arm | 52 mg LNG delivered at 20 mcg/d; tapers to about 10 mcg/d after 5 years | 13.5 mg LNG delivered at 14 mcg/d; tapers to 5 mcg/d after 3 years |
| **Dimensions** | Device: 32 mm horizontal, 32 mm vertical | Device: 28 mm horizontal, 30 mm vertical |
| **FDA-Approved Indication(s)** | Pregnancy prevention for up to 10 years | Pregnancy prevention for up to 5 years; treatment of heavy menstrual bleeding for women who choose IUDs |
| **Device-specific Label Contraindications** | Wilson’s disease | Known or suspected carcinoma of the breast or uterine or cervical neoplasia or unresolved, abnormal Pap smear; acute liver disease | Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; acute liver disease or liver tumor (benign or malignant) |

CDC MEC = Centers for Disease Control and Prevention Medical Eligibility Criteria. CuT380A IUD = T 380A copper intrauterine device; LNG-IUS 13.5 = levonorgestrel-releasing intrauterine system 14 mcg/d; LNG-IUS 20 = levonorgestrel-releasing intrauterine system 20 mcg/d; Pap = Papanicolaou; PID = pelvic inflammatory disease.

clearly that in routine IUD candidates, little to no testing is required prior to IUD placement. The only examination elements needed in healthy women being considered for IUD use would be a speculum examination to rule out visible active cervical infection and a careful bimanual examination, both to assess uterine size and position and to detect any signs of anomaly or infection that might make IUD placement inappropriate.25

Apart from determining with reasonable certainty that the patient is not pregnant, the US SPR emphasizes what measures are not required. The US SPR does note that patients generally require no screening for sexually transmitted diseases (STDs) prior to the day of placement.25 It is also not necessary to measure hemoglobin, rule out HIV, obtain a Pap test, conduct a clinical breast examination, or screen for liver disease, hypertension, diabetes, hyperlipidemia, or thrombogenic mutations before placing an IUD. The evidence shows no value to the use of prophylactic antibiotics.25

Some clinicians schedule IUD placement only while a woman is menstruating, although this practice is not evidence-based.26 The US SPR advises that, generally, an IUD may be placed at any time in a woman’s cycle as long as it is reasonably certain that she is not pregnant. To remove access barriers, many are now encouraging one-visit, same-day IUD placement.

There are important differences between the 2 types of IUDs. The copper IUD is an excellent post-coital emergency contraceptive, so recent history of unprotected intercourse is not of concern in deciding if it should be placed. On the other hand, a history of recent (< 5 days) unprotected intercourse may be a reason to delay placement of either LNG-IUS until the woman’s next menses can indicate that she is not pregnant or to use hormonal emergency contraception (ulipristal acetate). Any IUD may be placed immediately postabortion or postpartum. While the risk of expulsion or other complications may be elevated in these situations (although the evidence is mixed), immediate post-pregnancy placement offers both convenience and assurance that the woman is not pregnant.26

Once the IUD has been placed, the question arises: How soon will it be effective? The CuT380A IUD is effective immediately, no matter when in the woman’s cycle it is inserted; if a levonorgestrel IUD is placed more than 7 days after the onset of menstrual bleeding, however, the woman should use a backup contraceptive method or abstain from intercourse for the next 7 days.25

Obtain informed consent before preplacement assessment.35 Ensure that the patient understands the potential risks and benefits associated with the type of IUD she has selected and that she is aware of the possibility of specific changes she should expect in her bleeding pattern.

Consent forms for both LNG-IUSs are included in the IUD box, but outside the sterile package containing the IUD, which should not be opened until the uterus has successfully been sounded. Although it may seem efficient to have all materials ready in advance, if sounding reveals an obstacle to successful placement, an opened IUD will have been wasted. However, the patient must have consented to the procedure before it begins. The consent form for one LNG-IUS box cannot be used for another LNG-IUS, since each LNG-IUS consent form is marked with the expiration date and lot number for that specific IUS unit. One good way to solve this problem is to download a copy of the patient information/consent form from the manufacturer’s website (http://labeling.bayerhealthcare.com/html/products/pi/mirena_patient_insert.pdf). The patient can read and complete the questionnaire and sign a downloaded consent form to indicate informed agreement to attempted placement. She will need to sign the consent form that comes with her LNG-IUS at the end of the procedure.

The CuT380A includes a consent form, but it is not unique to each individual unit. Patient information, in multiple languages, can be downloaded from the manufacturer’s website (http://www.paragard.com/Patient-Brochure.aspx) and provided to the patient.

Conduct preplacement assessment, including sounding the uterus, before opening the sterile package containing the IUD.31,32,35,36

• Perform a bimanual pelvic examination to determine the size, shape, position, and mobility of the uterus. If the bimanual examination does not yield all the information needed to safely place an IUD—specifically uterine size and position—then an ultrasound or a rectovaginal examination can be used to obtain that information.
• Place a bivalve speculum, and open it sufficiently to visualize the cervix and provide space for IUD placement. The smaller Moore-Graves speculum is preferred since it is more comfortable and doesn’t push the cervix farther into the vaginal vault. (See sidebar, Instrumentation Suggestions for Optimizing IUD Placement.)

• Use a tenaculum to straighten the cervico-uterine axis and to bring the cervix closer to the introitus. Some expert clinicians find it helpful to place the tenaculum on the cervical lip that is farther away from the introitus. This placement allows for the cervico-uterine axis to be more effectively straightened when traction is applied.

• Sound the uterus to measure its direction and depth. (The smaller, disposable plastic sounds may be most comfortable.) Note the depth to which the uterus sounded to later record in the procedure note.
Instrumentation Suggestions for Optimizing IUD Placement

Clinical experience suggests that the following instrumentation choices may help make the IUD placement procedure more comfortable for the patient and easier for the clinician:

- When feasible, a bivalve speculum with a shorter blade, such as the Moore-Graves speculum, may be used to obtain closer, better visualization of and access to the cervix, especially if there is an element of pelvic relaxation.
- The Goldstein Grasp™ cervical stabilizer, an instrument developed specifically for sonohysterograms, is a narrow-tipped version of the conventional single-tooth tenaculum, and is preferred because it is associated with minimal pain and bleeding.
- Some clinicians find that semi-rigid plastic graduated sounds are less uncomfortable than metal sounds. An endometrial aspirator may be used in place of a uterine sound.
- Cervical os finders, which progressively dilate the cervix as they are advanced, or slender Hank dilators may be used to dilate the cervix when cervical stenosis or internal os spasm is present.

A recent prospective observational trial of patients at 2 family planning clinics who chose a CuT380A as emergency contraception highlights the importance of preplacement sounding. Although the clinicians had a mean of 14.1 years of IUD-placing experience, 17.6% of attempts to place an IUD in this study were unsuccessful—13.6% in parous women and 19.6% in nulliparous women.37 While the authors noted that the scenario of seeking emergency contraception likely elevated patient anxiety, which could potentially skew results, the most commonly reported reason for failed placement was not sounding the uterus before attempting to place the IUD.37

Perform IUD placement, following the specific technical instructions for each IUD.

It is important to recognize that although some procedural steps for IUD placement apply across the board, technique must be adapted to accommodate device-specific nuances as well as differences in an individual patient’s anatomy and comfort level. Device preparation and placement techniques differ between the CuT380A and LNG IUDs. Follow the step-by-step instructions described in the package labeling, keeping these principles in mind:

- Tuck the tips of the arms of the copper IUD down into the tubing. Move the flange on the inserter tube so that the distance between the top of the flange and the top of the IUD equals the distance that was sounded for uterine depth (from the external os to the fundus).
- When placing the CuT380A, maintain traction on the tenaculum and advance the IUD introducer until the top of the IUD touches the fundus and the flange is at the cervix.
  - Put down the tenaculum and place your index finger into the ring at the base of the IUD stabilizing rod to hold the IUD in place. Then retract the plastic insertion tubing to release the arms of the copper IUD.
  - Once the arms are released, remove the stabilizing rod and then remove the plastic tubing.6 Removing the stabilizing rod and the plastic tube together may dislodge the IUD.
- The arms of the LNG-IUS fit upward into the tubing. When placing the LNG-IUS 13.5 or the LNG-IUS 20, maintain traction on the tenaculum, advance the IUD inserter until the flange, or plastic marker, is 1.5 or 2 cm from the external os, then stop.
- Release the LNG-IUS arms at this position by moving the slider to the mark on the handle. Wait 10–15 seconds to allow the IUD arms to fully open into a horizontal position (“T shape”). The introducer may then be advanced until the opened IUD touches the fundus, indicated by the flange reaching the cervical os.31,32
- This distinction is worth reiterating: Because the arms of the CuT380A are folded down when introduced, direct fundal placement is appropriate. In contrast, the arms of the levonorgestrel IUDs face upward when loaded into the introducer and must be allowed to open into a T shape before the IUS can be advanced to the fundus. Premature advancement to the fundus can result in uterine perforation.
- After the IUD is placed and its introducer has been removed from the uterus, the IUD tailstrings should be cut with curved scissors to create blunt tips rather than sharp barbs. Optimally, the strings should be left long enough to avoid hurting the male partner during intercourse, but not so long that they dangle in the introitus and bother the woman. One recommended technique is to trim the tailstrings long enough to tuck them behind the cervix (posteriorly for an anteverted uterus). The tailstrings length should be measured, using the uterine sound. String
length should also be recorded, for objective assessment if any change in length should later be suspected. For the tucked-away technique, the LNG-IUS strings need an additional 1 cm in length to stay in place compared with the more malleable tailstrings of the copper IUD.

**Documentation in procedure note.** In many clinical settings, an IUD placement procedure requires a “time out” to have a separate staff member confirm right person, right procedure, and right site. Even if that procedural step is not required, a procedure note should be placed into the patient’s record. This note should mention the informed consent; the results of the pelvic exam; the depth to which the uterus sounded; the fact that the manufacturer’s recommended procedures were followed; any anesthesia used; any other steps (e.g., Monsel’s solution used to stop bleeding); length to which the tailstrings were trimmed; the IUD name, lot number and expiration date; as well as any complications the patient may have suffered (or a statement that she tolerated the procedure well).

**Counsel the patient again after placement.**

After IUD placement, remind the patient about anticipated bleeding patterns with her particular IUD. Reinforce her awareness about symptoms of pregnancy and possible IUD complications: infection, heavy bleeding, or expulsion of the IUD. Tell her to report the following signs and symptoms:

- Unusual vaginal discharge or lower abdominal pain (although these are not usually caused by the IUD)
- Change in the length of strings or missing strings
- Heavy bleeding or severe cramping, which may indicate partial or complete expulsion
- Signs or symptoms of pregnancy

**Scheduled follow-up visits**

Recommendations differ as to the necessity of a routine follow-up visit after IUD placement. According to package inserts, follow-up is recommended at intervals that vary by product: at 4 to 6 weeks for the LNG-IUS 13.5; at 4 to 12 weeks for the LNG-IUS 20; and after the first menses or at 12 weeks for the CuT380A. The US SPR, however, indicates that a routine follow-up visit is generally not necessary but may be beneficial in circumstances such as placement in adolescents and women with multiple medical conditions. Other women should be encouraged to return as needed, such as to address side effects, discuss a change in contraceptive methods, or remove or replace the IUD.

Otherwise, at all subsequent routine visits, clinicians should inquire about the woman’s satisfaction with her contraceptive method, assess whether any changes in health status might affect contraceptive choice, and consider checking for the presence of the IUD strings.

Although routine follow-up may not be needed, a scheduled follow-up visit offers an opportunity to check for silent partial expulsion and to review bleeding patterns and other relevant issues with the patient, but it is not prudent to schedule the visit too early. Data have shown that silent partial expulsions are more likely to be detected at 6 to 12 weeks, so a reasonable time for follow-up is at 10 weeks after placement. If the IUD needs to be removed and replaced, patients may still qualify for a free replacement IUD during this time frame. Check with the manufacturer for informal IUD warranty information.

**MANAGING IUD PLACEMENT CHALLENGES**

**Potential Pain with Placement**

For many women, IUD placement is associated with transient discomfort similar to strong menstrual cramps. However, women’s experiences during IUD placement may run along a spectrum ranging from minimal discomfort to severe pain. Most nulliparous women experience at least moderate pain during IUD placement but consider it to be tolerable. A prospective study of IUD placement in nulliparous women found that placement was well tolerated by most, who gave “broadly positive descriptions of the procedure” despite a “reasonable level of pain” at placement. In a study comparing pain associated with IUD placement among nulligravidas, parous women who had delivered only vaginally, and parous women who had at least 1 cesarean delivery, almost all women reported moderate pain. Yet nearly all—70 out of 74 study participants—indicated their willingness to undergo the procedure again when the time came to replace their IUD.

The analysis compared the ease of experimental hormonal IUDs, one that is now available as LNG-IUS13.5 and a second IUD with a higher release rate. The analysis compared the ease of placement from the clinicians’ perspective and of discomfort from the perspective of patients. Study participants were asked to characterize their level of pain during placement of the smaller, experimental IUDs as “none,” “mild,” “moderate,” or “severe.” Among nulliparous women (n=1130), 84.5% char-
acterized the pain as no more than moderate. Nearly all (95.5%) of the cesarean–only parous women (n=357) also rated their pain as no more than moderate.\textsuperscript{28}

Although many clinicians commonly use 1 or more pharmacologic strategies to reduce pain with IUD placement, a recent systematic review concluded that data are insufficient to support the routine use of any of the agents listed below.\textsuperscript{43} These findings are consistent with the latest Cochrane Review on the topic.\textsuperscript{44} Each of the following has been tested and found not to significantly reduce pain scores during IUD placement.

- Nonsteroidal anti-inflammatory agents\textsuperscript{45-47}
- Paracervical block with lignocaine\textsuperscript{51}
- Misoprostol\textsuperscript{52-56}
- Local anesthesia with 2% lignocaine solution\textsuperscript{59}
- Prophylactic use of NSAIDs prior to IUD placement\textsuperscript{50}
- Paracervical block with lignocain\textsuperscript{81}
- Misoprostol\textsuperscript{52-56}
- Nitroprusside gel\textsuperscript{57,58}
- Intrauterine infusion of 2% lidocaine\textsuperscript{59}

Because of the early evidence supporting misoprostol, it is important to emphasize the basis of these newer conclusions. Cervical priming with misoprostol is associated with an increase in known adverse effects, including nausea, cramps, and shivering.\textsuperscript{52-55} In a randomized, controlled trial, nulliparous and multiparous women receiving either a copper or LNG-containing IUD were randomized to 400 mcg of misoprostol or placebo. Results showed no benefit to misoprostol use with regard to the primary end point of failed placement or the secondary end points of complication, pain, or difficulty of the placement procedure. However, adverse effects were more common among the women randomized to misoprostol (P=.05). The authors concluded that preplacement misoprostol showed no benefit and a tendency toward possible harm.\textsuperscript{53,56}

While the evidence offers no support for routine use, each of the following may be useful for selected patients.

- Misoprostol may be appropriate in a patient with a stenotic cervical os or who has had a previous failed placement due to cervical stenosis.\textsuperscript{3} If misoprostol is used for this purpose, co-administration of an NSAID is recommended to manage the adverse effects of misoprostol.\textsuperscript{43}
- Paracervical blocks may be helpful if a vasovagal reaction is anticipated or if cervical pain is encountered.\textsuperscript{31,53,56}
- Prophylactic use of NSAIDs prior to IUD placement may help reduce cramping and pain that follows placement. NSAIDs may be used proactively to relieve pain that develops later.\textsuperscript{43,60}

Nonpharmacologic measures

Higher anxiety levels can contribute to a patient’s experience of pain, exacerbating her discomfort.\textsuperscript{62} There is some evidence to support counseling before IUD placement and attention to patient anxiety as beneficial strategies for pain management during IUD placement.\textsuperscript{61,62} Providing what is sometimes termed “verbal analgesia” about what to expect and providing reassurance throughout the procedure can help to alleviate anxiety, thereby making the patient more calm and relaxed and, ultimately, better able to tolerate discomfort.\textsuperscript{61} Clinical experience suggests that the following tips may help reduce IUD placement discomfort.

- The presence of a companion invited by the patient, and/or a supportive staff person, can be helpful. (In the unusual situation where the clinician finds that the companion interferes with appropriate care, the clinician can ask her or him to step out.)
- Pay attention to your words. IUD “placement” is a less-threatening term than IUD “insertion.”
- Distract the patient with calming, positive images.
- Reassure the patient that any pain she may experience should diminish quickly.
- Use appropriate instrumentation, such as a shorter speculum and a narrow–tipped tenaculum (refer to Instrumentation Suggestions for Optimizing IUD Placement).
- Inform patient about each of the steps and the sensations she may feel.

Ineffective Measures

- Having the patient fill her bladder prior to placement makes no difference in either the ease of placement from the clinicians’ perspective or discomfort from the patients’ perspective.\textsuperscript{63}
- Having the patient cough during tenaculum placement is not advised because it violates fundamental safety principles—sharp instruments should not be applied to moving targets.

Cervical Stenosis

The following strategies may ease IUD placement in patients with a tight or narrow cervix or cervical stenosis:

- Dilate the cervix progressively, being careful not to force, using a cervical os finder. If stenosis is at the external os, a lacrimal probe may be needed.\textsuperscript{35}
- Use a pulsating technique at the internal os. Administer misoprostol or paracervical block, on an individualized basis.\textsuperscript{35}
- Consider pretreatment with vaginal estrogen in breastfeeding women.\textsuperscript{35}

Vasovagal Reaction

Women at risk for a vasovagal reaction during IUD placement are those with a prior history, hypoglycemia,\textsuperscript{64} or extreme anxiety. Some tips for prevention include the following:

- Be sure the patient is well hydrated before the procedure.\textsuperscript{65}
- Provide reassurance to reduce the patient’s anxiety and help her relax.
- Suggest lower–body skeletal muscle tensing to counter peripheral venous pooling.\textsuperscript{66-68}
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• Administer intracervical/paracervical block. If the patient has a vasovagal reaction, stop the procedure, elevate her legs, and lower her head.

PID and STIs
• Prophylactic use of antibiotics before IUD placement to prevent PID is not recommended.25,69,70 Risk of PID after IUD placement is low. A recent retrospective cohort study of more than 57,700 IUD placements showed that women’s overall risk of PID within 90 days of placement was 0.54%, and the risk did not differ between women screened before or on the day of placement.71 A meta-analysis reported that prophylactic use of antibiotics did not decrease the risk of PID nor the rate of discontinuation at 3 months after placement.69 ACOG advocates screening women only if STI risk factors are present, with screening on the same day as IUD placement.70 Most women do not need screening at all. For women who do need routine screening based on their age in accordance with the CDC’s STD Treatment Guidelines, that screening can be done on the day of placement, with no need to delay placement while waiting for test results. (The STD treatment guidelines, including screening recommendations, are available at: http://www.cdc.gov/STD/treatment/2010/STD-Treatment-2010-RR5912.pdf).

IUD initiation is contraindicated in women with purulent cervicitis or known current chlamydial infection or gonorrhea. For women at high risk of STD exposure (eg, with a currently infected partner), IUD placement should be deferred until after appropriate testing and treatment.25

Women diagnosed with cervicitis or PID after IUD placement can be treated without removing the IUD.11,25,71,72 In a systematic review of 3 randomized trials and 1 prospective cohort study, women with PID who retained their IUDs had similar or better outcomes compared with women who had their IUDs removed.72 As with any woman receiving outpatient treatment for PID, the US SPR advises reassessing an IUD user with PID 48 to 72 hours after the initiation of treatment. If no clinical improvement has been noted, antibiotic therapy should be continued with consideration given to removing the IUD or hospitalizing for intravenous therapy.

If a woman with PID requests IUD discontinuation, delay until after antibiotic therapy has begun, to reduce the risk for bacterial spread during removal. If the IUD is removed, another contraceptive method should be offered, and emergency contraception may be appropriate.25

MANAGING IUD COMPLICATIONS AND SIDE EFFECTS

Malpositioned IUD
An IUD should be placed at the uterine fundus, with the “stem,” or vertical portion of the T shape, entirely within the uterine cavity. Whether it takes place during or after placement, malpositioning of an IUD is not an absolute indication for removal, depending on the symptoms present, position of the IUD, and type of IUD. Today, an intrauterine IUD is considered to be malpositioned only if part of it protrudes into the cervical canal or if it is in the lower uterine segment and the patient complains of cramps. A retrospective case-control study comparing malpositioned vs optimally positioned IUDs found that malpositioned IUDs were noted in 10.4% of IUD users who had pelvic ultrasound for any reason.75 (In that study, IUDs were characterized as malpositioned based on radiology reports indicating that an IUD was located in the lower uterine segment or cervix, had rotated, become embedded, was intraperitoneal, or had apparently been expelled.) So although many malpositioned IUDs cause no untoward effects, they can be associated with increased risk for bleeding and pain and greater potential for expulsion and other complications as well as risk of contraceptive failure. Removal of any malpositioned IUD without immediately replacing it with another top-tier contraceptive method is itself associated with increased risk of pregnancy.73

Keep the following suggestions in mind when managing malpositioned IUDs:
• Remove a malpositioned IUD in a patient with symptoms of increased bleeding or pain suggestive of impending expulsion.74,75 These symptoms improve in most women after IUD removal.70
• If an LNG-IUS is noted to be malpositioned as an incidental finding on sonography for another reason, consider retaining it if it is within the uterine cavity in an asymptomatic patient.74 Follow expectant management, offering the patient a replacement if she desires.74 The local effects of LNG most likely provide adequate contraception as long as the LNG-IUS is in the uterine cavity.75
• If a CuT380A IUD is noted to be malpositioned as an incidental finding on sonography for another reason, counsel the patient that she may be at increased risk of pregnancy and offer to remove the IUD, or follow expectant management if that is the patient’s preference.73 The rate of CuT380A malpositioning was significantly higher among women who became pregnant compared with that of nonpregnant controls in a case-control study.77 Whenever possible, offer immediate initiation of another contraceptive method after removal of a malpositioned IUD.73,74 In a recent retrospective case-control study of 182 women with malpositioned IUDs, the only pregnancies that occurred were in women who did not start another form of contra-
Additional Postplacement Management Issues

The focus of this educational activity is on IUD placement and a full discussion of postplacement issues is beyond its scope. Nevertheless, clinicians who place IUDs or who provide care for IUD users should be aware of management issues such as:

- Pregnancy (If the pregnancy is intrauterine rather than ectopic and the woman wishes to continue the pregnancy, remove the IUD, if she is in the first trimester of pregnancy and the tailstrings are in the vagina. If tailstrings are not available, advise her that her risk for preterm delivery is elevated.)
- A finding of actinomycosis-like organisms on cervical cytology (Advise women of results and give reassurance and PID precautions; no other actions are required.)
- PID or other STI (IUDs may remain in place during treatment. Remove IUD only if the patient does not respond to antibiotic treatment.)
- Perforation or expulsion (may be signaled by IUD strings that are missing or have become shorter or longer)


Uterine Perforation

Uterine perforation is a rare event, occurring in 0.4 to 1.3 patients per 1000 users. Risk factors for uterine perforation include breastfeeding, subinvolution of the uterus, fixed or immobile uterus, and clinician inexperience. Only a minority of IUD perforations are noted at the time of placement, but it is likely that all perforations start at that time. It is hypothesized that the others result from placement of a portion of the IUD (eg, arm) into the myometrium; over time the uterine contractions can draw the IUD outside the uterus. There is no evidence that an IUD correctly placed completely into the endometrial cavity will later perforate through the uterine wall, although it may become embedded, especially with long-term use.

If the IUD perforated into another organ (bladder, rectum, or bowel), it must be removed surgically. If the copper IUD is found to be in the peritoneal cavity, removal is generally recommended because of its potential to form sterile abscesses. Laparoscopic removal is generally successful. More controversy exists about an LNG-IUS located intraperitoneally. If the patient wants pregnancy protection, at a minimum, she needs alternative contraception. If she is seeking pregnancy, removal would also be advised. However, in an asymptomatic woman not seeking pregnancy, there is some uncertainty about the necessity for removal.

Fractured IUD

IUDs can become fractured at the time of removal, especially when one portion of the IUD is embedded in the endometrium. With older IUDs that are no longer available (eg, the Lippes Loop), the breakage rate had been reported at 1% to 2% per year, but reports in the literature about current devices are scarce and there are no formal studies on fracture rates with contemporary IUDs. Nonetheless, a recent article shared information on management strategies currently in use, based on 11 case reports solicited from members of the Society of Family Planning. Methods used included in-office removal with an IUD hook; alligator forceps under ultrasound guidance; or manual vacuum aspiration. Office hysteroscopy was employed in 2 cases, and in 5 cases, removal ultimately took place in an operating room. The authors note that it is not clear whether removal of a retained IUD fragment is necessary when the patient is asymptomatic, but they underscore the importance of reporting fractured IUDs to the manufacturer. In general, an IUD hook is not recommended for T-shaped IUDs, but it is helpful for looped IUDs that can be snagged.

Bleeding Irregularities

Unscheduled bleeding and spotting, and sometimes heavy bleeding, can be common side effects of IUDs, particularly in the early months, and a primary reason for method discontinuation. Conversely, after the initial months, LNG-IUS users often experience lighter menstrual periods, with many (estimates range from 20% to 80%) experiencing no menstrual blood flow at 12 months. In fact, the LNG-IUS 20 is indicated to treat heavy menstrual bleeding in women who choose intrauterine contraception. Although many women regard this effect as a boon, others prefer to experience regular monthly bleeding. When counseling adolescents and younger women about contraceptive
**FIGURE 1.** Sagittal and 3-Dimensional IUD Images

Images courtesy of Andrew M. Kaunitz, MD
options, it may be useful to ask if their bleeding is being monitored by someone else. In such cases, absence of a period could be viewed as evidence of pregnancy, or could compel a young woman to disclose information about her contraceptive use. In any scenario, counseling patients before insertion about what to expect concerning bleeding may help to reduce dissatisfaction and discontinuation.

For those bothered by unscheduled or excessive bleeding after placement, effective pharmacologic treatment may be needed. Findings from recent studies illustrate the lack of consensus about optimal approaches to manage irregular bleeding following IUD placement.

- Naproxen 500 mg may reduce the number of bleeding and spotting days during the initial period after LNG-IUS placement.87
- Neither oral tranexamic acid nor mefenamic acid alleviates nuisance bleeding or spotting that typically occurs in the initial period after LNG-IUS placement.88
- NSAIDs may significantly reduce heavy or prolonged bleeding in CuT380A users.89 This confirms findings from an earlier Cochrane Review, which found that NSAIDs effectively reduced bleeding and pain associated with copper IUD use.60
- Tranexamic acid may reduce blood loss in CuT380A users.89
- NSAIDs and antifibrinolytics may prevent bleeding irregularities in new CuT380A users.89

In a patient with heavy bleeding or cramping:
- Rule out pregnancy, partial expulsion, or malpositioning of the IUD.
- Assess for anemia and offer iron supplementation if necessary.
- Recommend that she take an NSAID at the start of menses once expulsion has been excluded.90

IUD Removal

For routine IUD removal, use a ring/uterine dressing forceps to grasp the strings at the level of the external cervical os and exert steady, slow traction without hesitation. If the strings are not apparent, they may have retracted. Twirling a cytobrush in the endocervical canal can help tease out the strings so that they can be grasped.

If the strings have broken off, thread-retrieval devices or an alligator forceps can be used to remove the IUD. Before probing the uterine cavity, rule out pregnancy and infection. Never use an IUD hook to remove a T-shaped IUD from the endometrium because the risk of uterine perforation is higher than with other devices. Be sure to apply a tenaculum to the cervix before introducing any forceps into the uterine cavity.

If the IUD cannot readily be located, ultrasound or other imaging should be used to determine whether the IUD is present. (Figure 1) Note that all IUDs marketed in the US are radiopaque and accordingly are readily imaged with conventional x-rays of the abdomen/pelvis. When an IUD is not imaged in the uterus with ultrasound, a standard kidneys, ureter, and bladder (KUB) or pelvic x-ray is useful in distinguishing between expulsion and perforation.

If the IUD has become embedded deeply into the endometrium, hysteroscopic removal is indicated; if the IUD cannot be found in the uterus, peritoneal cavity, or other structures in the pelvis or abdominal cavity, it can be presumed to have been expelled.

If the patient does not intend to become pregnant and wishes to continue using an IUD as her contraceptive method, a new IUD may be placed immediately. If she is not interested in a replacement IUD and wants to avoid pregnancy, another effective method should be offered at the time of IUD removal to ensure seamless, ongoing contraceptive coverage.

**CONCLUDING REMARKS**

Wider use of IUDs is a crucial tactic in reducing the high rate of unintended pregnancy in this country. Recognizing and responding to evidence-based patient eligibility criteria, attention to
proven method, to be included in the practice guidelines for each of the 3 types of IUDs available in the US, and a greater understanding of how to appropriately manage challenges associated with IUD placement and use can increase the acceptance of this top-tier contraceptive method.

REFERENCES


Toward Optimal Intrauterine Contraception: 
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