Update on intrauterine contraception

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Continuing education material

This continuing education (CE) program presents practical strategies to meet the needs of nurse practitioners (NPs) and other clinicians who manage the contraceptive needs of reproductive-age patients. The program is based on the proceedings of a luncheon symposium developed by the National Association of Nurse Practitioners in Women's Health (NPWH) Education Committee and presented as part of the NPWH 16th Annual *Premier* Women's Healthcare Conference in San Diego, California. The content focuses on the need for top-tier contraception and the ongoing problem of unintended pregnancies and how best to address patient misconceptions and concerns through effective counseling. Available intrauterine contraceptives (IUCs) are reviewed, and potential candidates for each type of IUC are identified using U.S. medical eligibility criteria. Placement techniques are presented to enhance success and avoid complications. Proceedings of the live event may be accessed at **https://npwh.globalclassroom.us/portal/**.

Learning objectives

- Describe each of the three available IUCs and their indications.
- Counsel women on potential side effects.
- Summarize placement techniques for each IUC, as well as the steps to follow to minimize risks of complications with placement.
- Outline management strategies to treat side effects and avoid complications with use.

Accreditation statement

This activity has been evaluated and approved by NPWH's Continuing Education Approval Program and has been approved for 1.0 contact hour of CE credit, including 0.25 contact hour of pharmacology content.

Faculty disclosures

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- Dr. Nelson reports that she has received honoraria for consultation from Actavis, Agile, Bayer, Merck, and Teva. She has received honoraria for participation in speaker bureaus from Bayer, Merck, Teva, and Watson. She has received research grants from Bayer, Merck, Pfizer, and Teva.
- Ms. Rawlins is a consultant to Merck and Mission.

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The rate of unintended pregnancies, estimated at 49%, has remained unchanged since 1994, despite the availability of many effective forms of contraception.[1] This statistic becomes even more troubling when placed into context:

- Approximately 43% of unintended pregnancies are terminated by abortion.[1]
- One-third of all women in the United States will have had an induced abortion by age 45.
- Pregnancy carries its own health risks: The rate of maternal mortality is 14.5 per 100,000 live births. A total of 4,693 deaths were reported from 1998 to 2005.[2]
- Each year, 1 million pregnancies result from incorrect or inconsistent use of oral contraceptives.[3]

Although widely used in other countries (*Figure 1*),[4] intrauterine contraceptives (IUCs) represent an underused birth control option in the U.S. Fortunately, IUC use in this country is increasing: The National Survey of Family Growth reported an overall use of 1% in 1995, compared with 5.6% in 2010.[5] The literature supports the use of IUCs as safe and effective forms of contraception:

- A 2012 ACOG committee opinion encourages the use of IUCs in adolescents.[6]
- CDC medical eligibility criteria note that IUCs are safe and effective for younger women and nulliparous women.[7] Of note, nulliparity has never been a contraindication for the use of any IUC in the U.S.
- The 2005 ACOG Practice Bulletin indicates that IUCs provide safe, effective, long-term contraception and should be considered for all women, including multiparous and nulliparous women at low risk for sexually transmitted diseases (STDs).[8]
- Multiple reports have shown the safety and efficacy of immediate postpartum insertion, as well as insertion postabortion or during elective cesarean section.[9-13]

> Nulliparity has never been a contraindication for the use of any IUC in the U.S.

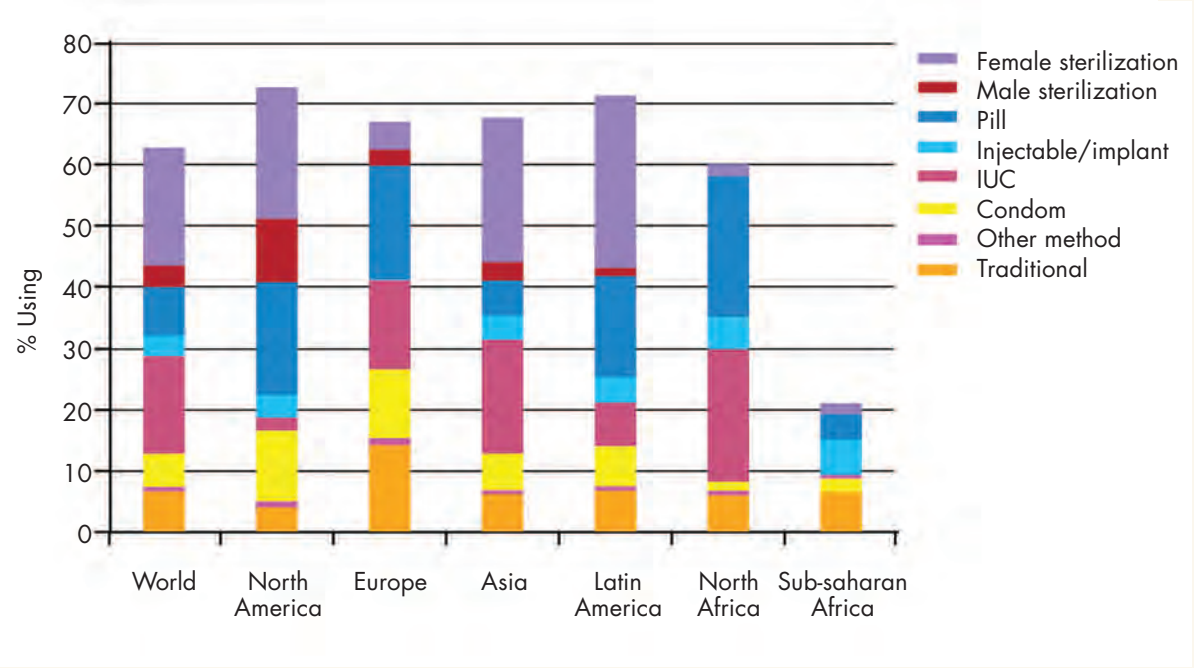
In some special settings, women have distinctly favored long-acting contraceptive agents. The U.S. CHOICE study provided more than 9,000 women with free contraception, counseling, and ability to select the contraceptive option that most appealed to them from among the IUC, an implant, DMPA, the pill, the patch, or the ring.[14-16] Among the enrollees, 75% chose IUDs or implants. The first-year continuation rate with these long-term options was 86% and the pregnancy rate was 0.27%. With the pill, the patch, and the ring, the continuation rate was 55% and the pregnancy rate was 4.55% (almost 20 times higher than the pregnancy rate with IUCs and implants).[14-16]

Available forms of intrauterine contraception

Three forms of intrauterine contraception are available in the United States (*Figure 2*). The **Copper T-380A IUD** (intrauterine device) was approved by the FDA in 1984 and has been available for use in this country since 1988. The copper T-shaped device measures 36 mm vertically and 32 mm horizontally (top of the T) (380 mm^2 of copper). Although this device is approved for up to 10 years' use, data suggest that it may be effective for 20 years.[17] The copper IUD is the only nonhormonal top-tier method of contraception and the most effective method for emergency contraception,[18] with safety and efficacy demonstrated in multiple trials dating from the mid-1990s.[19-21] In terms of mechanism of action, this device interferes with sperm transport from the cervix to the Fallopian tube, inhibits sperm capacitation/survival, and inhibits fertilization. It does not function as an abortifacient.[22]

Recent investigations have demonstrated the utility of placing the copper IUD immediately after elective C-section, vaginal delivery, or uterine aspiration.[9-13,23,24] In addition to the efficacy and safety of same-day placement in women who have just given birth, the copper IUD has been shown to be appropriate for use in nulliparous women.[6,25] Despite these exten-

Figure 1. Contraceptive use in major global regions[4]



Cleland J. *Best Pract Res Clin Obstet Gynecol.* 2009;23:165-176. Reprinted with permission from Elsevier.

sive published data, 30% of healthcare practitioners continue to have misconceptions concerning IUD use in women who have never borne children.[26]

In 2000, the **levonorgestrel (LNG) intrauterine system (LNG IUS20)** was approved by the FDA for 5 years' use. This device features a reservoir containing LNG 52 mg. It initially releases approximately 20 mcg of LNG daily; this level decreases by half after 5 years. The T-shaped device measures 32 mm by 32 mm. The current tubing for placement is 4.75 mm in diameter. Although product labeling notes that the LNG IUS20 is recommended for women who have previously given birth, clinical reports and recommendations from ACOG indicate safety and efficacy for all women, regardless of parity, who are at low risk for STDs.[6] In terms of mechanism of action, the LNG IUS20 prevents pregnancy by thickening the cervical mucus.

In addition to preventing pregnancy, the LNG IUS20 is indicated for the treatment of heavy menstrual bleeding, effectuating a very rapid decline in blood loss.[27] A 2009 meta-analysis compared this IUS with ablation for heavy menstrual bleeding.[28] No apparent difference emerged between rates of treatment failure, nor was there any difference in bleeding reduction. Both methods achieved similar improvements in quality of life. The LNG IUS group had less need for analgesia/anesthesia. Women who have undergone ablation require consistent and correct use of contraception postprocedure.[28] In a randomized comparison with hysterectomy, the LNG IUS provided similar improvements in health-related quality of life for women with menorrhagia at a 5-year follow-up, with significantly lower costs.[29] LNG IUS has been suggested as treatment for a variety of other conditions,[30,31] including endometriosis.[32,33] The device can be placed on the day of the office visit, although a week of back-up contraception is needed (*Table*).[34] It may also be placed postpartum or postabortion.[35,36]

The **LNG IUS 13.5 mg** was recently approved by the FDA. This T-shaped device measures only 28 mm by 30 mm (the placement tubing is only 3.8 mm in diameter) and it contains only 13.5 mg of LNG. This device is approved by the FDA for 3 years' use. The product labeling indicates that this IUS can be used in nulliparous as well as parous women. It features a first-year failure rate of 0.41% and a cumulative 3-year failure rate of 0.9%. Approximately 30% of those pregnancies were ectopic. This new device represents an important option for

nulliparous women or for those who have not had prior vaginal delivery. It is also a potential choice for women who are sensitive to LNG and have experienced breast tenderness or headache with the LNG IUS20. It is appropriate for women who do not tolerate amenorrhea; only 12% of users experience amenorrhea by the end of the third year of use.

Planning for intrauterine contraceptive placement

Regardless of the type of IUC selected, planning for placement includes these elements:

Informed consent—Nurse practitioners must make sure that patients sign the manufacturer's consent form, which indicates that they have read the patient insert material. A copy of this form and the procedure checklist are retained as part of the health record. For the LNG IUS products, the consent form is sealed in the product packaging. These materials are available on the company websites and may be downloaded and copied for use in advance of the procedure. Users of the LNG IUS products must also sign the consent contained in the packaging for their health records.

Examinations needed—For all IUCs, a bimanual examination and cervical inspection are performed.

Requirements for backup contraception—Women in whom a copper IUD has been placed do not require a subsequent backup contraceptive. If more than 7 days have elapsed since their last menstrual period, women in whom an LNG IUS has been placed will need to use a backup contraceptive for the next 7 days.[34]

Timing of placement—Multiple studies have shown that timing of IUC placement has little effect on continuation rates, removal, expulsion, pregnancy, pain, or bleeding. No benefit has been associated with copper IUD placement during menses.[13] Evaluation of midcycle placement of an LNG IUS has shown that, although the quality of cervical mucus changed rapidly, sperm penetration was possible for up to 5 days.[37] Postpartum placement may be done within 10 minutes of vaginal delivery using special instrumentation.[9,36] Expulsion rates at C-section are lower than those associated with vaginal delivery.[9] Suturing an IUC to the intrauterine wall does not reduce the risk for expulsion.[9] Placement with cervical dilation <2 cm lowers the risk for expulsion.[9] Of note, immediate postpartum placement represents a challenge because the cost must be taken out of the global pregnancy fee.[38] In a comparative study, IUC placement during lactation was not associated with pregnancy,[39] but uterine involution must be complete or the risk for perforation increases. One-year continuation rates were 89% with the LNG IUS20 and 91% with the copper IUD.[39]

Pain control during place-

Figure 2. Available forms of IUCs in the U.S.

Copper IUD photo courtesy of TEVA Women's Health, Inc., registered owner of the ParaGard® trademark. For illustration purposes only; image shown is not actual size.
LNG IUS product photos courtesy of Bayer HealthCare Pharmaceuticals, Inc., registered owner of the Skyla™ and Mirena® trademarks.

Table. Starting contraceptive methods: Anytime if not pregnant[34]

Method	Exams/tests needed	Backup needed
Copper IUD	Bimanual exam & cervical inspection	None
LNG IUS	Bimanual exam & cervical inspection	7 days*
Implant	None	7 days†
Injection	None	7 days*
Combined hormonal contraceptives	Blood pressure	7 days†
Progestin-only pills	None	2 days†

*If >7 days since LMP. †If >5 days since LMP.

MMWR Recomm Rep. 2013;62(RR-05):1-60.

ment—Pain levels during IUC placement have been shown to be unaffected by the use of NSAIDs[40] or misoprostol.[41] In fact, use of misoprostol increased complications.[41] Neither nitroprusside[42] nor intrauterine infusion of lidocaine[43] has proved effective in relieving pain during device placement.

Use of antibiotics during placement—Prophylactic use of antibiotics is not necessary.[44-46]

Placement of intrauterine contraceptive

In preparation for IUC placement, the NP needs to examine the position, size, and mobility of the patient's uterus. The physical examination should reconfirm that the patient has no contraindications such as vaginal or cervical discharge, large fibroids, or ovarian cysts. Tests for cervical infection are obtained if indicated.

Many patients who are anxious about the procedure can be calmed by an explanation of the procedure or distracted by conversation during the procedure. Premedication with an anxiolytic may be advisable for worried patients—as long as they have transportation home.

In preparation for IUC placement, the NP needs to examine the position, size, and mobility of the patient's uterus.

The NP uses a speculum, preferably a short-bladed device, to allow maximum dorsal space. The cervix (ecto and endo) is cleansed with antiseptic. The NP evaluates the utility of providing an anesthetic injection at the tenaculum site. The tenaculum is placed on the far cervical lip to stabilize the cervix and straighten the uterine axis. A uterine sound is introduced to the fundus; the depth of the uterus (the distance between the external os and the fundus) is noted.

For the copper IUD, the NP loads the device into the tubing with the arms tucked down inside the tubing. To place the device, the NP advances it to the fundus and releases the arms by withdrawing the tube one-half inch while holding the solid rod stationary. The tube is then advanced back over the stationary rod one-half inch to seat the opened arms of the IUD at the fundus. The stationary rod is then removed, followed by the tubing.

For the LNG IUS, the inserter allows easy placement with one hand. The introducers for each LNG IUS differ, but they share the practices that follow from the fact that the arms of the LNG IUS fold upward into the tubing. This means that the tubing is introduced to 2 cm below the fundus and the arms are opened. Only after the arms open is the device advanced to the fundus. The process for loading the LNG IUS20 differs from that of the LNG IUS 13.5 mg.

The NP documents the procedure, noting (1) its duration, (2) completion of the manufacturer's consent form by the patient; (3) uterine size and position; (4) sounding data; (5) the specific device placed following the manufacturer's instructions; (6) length of the tail strings at trim; (7) the method by which bleeding control was performed at the tenaculum site; (8) complications; and (9) a detailed list of postprocedure instructions provided to the patient.

Preplacement checklist

- Obtain health history and social history
- Perform speculum examination to assess for cervical infection
- Screen for *Neisseria gonococcus* and *Chlamydia*, when appropriate
- Perform bimanual pelvic examination
- Review consent process
- Discuss pain control options
- Do not institute antibiotic prophylaxis

Challenging intrauterine contraceptive placements

In obese patients, an NP having difficulty assessing the uterus by bimanual examination can do so with a rectal exam. Uterine strictures may also make IUC placement challenging. A stenotic os may be overcome by using a pulsating technique for sounding at the os or by using cervical os finders. The NP may want to perform a paracervical block or possibly use misoprostol to minimize discomfort. As an alternative, rescheduling the procedure to coincide with menses may be helpful. If the passage is obstructed by fibroids, the NP may need to use ultrasonographic (USG) guidance with or without saline infusion USG to evaluate the structures and determine whether space is sufficient for the device arms to extend. Large submucosal fibroids may be a contraindication to IUC use.

For women with an extremely verted uterus, the tenaculum becomes important. The sound can be bent in the direction of the flexion, as can the introducer. If the cervix is behind the symphysis, the patient is asked to push down firmly over her bladder (for an anteverted uterus). The NP may find it useful to flip over the LNG IUS introducer if the patient's uterus is retroverted.

Complications

Various complications are possible during or shortly following IUC placement.

Vasovagal reactions—The potential for vasovagal reactions may be assessed preprocedure based on prior history, hypoglycemia, and anxiety. The potential may be reduced by encouraging the patient to eat and hydrate prior to the procedure.[47] A paracervical block may be considered for women with prior vasovagal episodes. Some patients may find it helpful to prophylactically perform lower extremity skeletal muscle tensing.[48] Also, the patient can be positioned to prevent peripheral vessel pooling. If an episode occurs, the NP should not use ammonia salts or alcohol wipes, which are classified as poisons by OSHA. The NP needs to stop the stimulus, elevate the patient's legs, and administer oxygen.

Seizure—If a patient experiences a seizure during the placement procedure, the NP needs to stop the procedure immediately, call for a crash cart and team, protect the patient's tongue (in the case of a grand mal seizure), assess ABCs, and record vitals. The NP then proceeds as usual with resuscitation and administers an anticonvulsant if needed.

Perforation—In a study of LNG IUS use over more than 20 years, 701 cases of uterine perforation were reported; only 8.5% of these cases were detected at the time of placement.[49] For the remainder, abdominal pain or changes in bleeding patterns provided clues. Perforation may also be detected at subsequent routine checkups. Acute perforation may be indicated by a finding that uterine depth on sounding exceeds the estimate from the bimanual exam, a sudden loss of resistance, and/or patient report of pain.

Vaginal bleeding—This complication is unlikely with uterine perforation. In the case of acute injury, removal of the instrument is attempted and evidence of bowel injury assessed, along with pain and blood pressure. If the patient is unstable, if the instrument cannot be removed, or if internal organ damage is suspected, the patient is transported to an emergency department. Otherwise, monitoring should continue. If the patient is stable for 30 to 60 minutes, she may be able to be discharged to home with another contraceptive method.

Preparation for placement

- Confirm via the patient's health record that she has no contraindications and update recent conditions
- Answer the patient's questions
- Obtain informed consent
- Have all instruments available
- Consult instructions/ videotape as necessary

Postplacement patient counseling

After IUC placement, the NP

needs to remind the patient about likely changes to bleeding patterns and the need to check the device strings on a monthly basis. The patient can use a menstrual calendar to track bleeding over the next few months. She is informed that cramping, if it occurs, can be managed by the use of NSAIDs. The NP needs to review the signs and symptoms of pregnancy, infection, and expulsion. The patient is counseled that if any symptom occurs, she should return for evaluation. In the absence of such symptoms, routine follow-up visits are unnecessary.[34]

Postinsertion problems

Problems associated with IUC use include heavy or intermittent bleeding, actinomycosis on Pap smear, change in string length, pelvic inflammatory disease (PID), missing strings, and pregnancy. If a patient experiences heavy bleeding, the NP needs to rule out pregnancy, partial expulsion, and anemia. Use of NSAIDs with the start of menses may help. If misplacement is suspected, transvaginal USG can be used to visualize the area.[50] A 3D USG may be even more informative.

Treatments for bleeding problems with the copper IUD have been evaluated.[51] NSAIDs may significantly lessen blood loss or duration; antifibrinolytics may also reduce blood loss. In new users, these treatments may prevent early bleeding. Use of high-dose aspirin is associated with increased blood loss. A longitudinal study showed that, over time, pain, bleeding, and serious menstrual problems decreased, whereas intermenstrual problems did not change.[52]

The current recommendation for an asymptomatic woman whose Pap smear reveals actinomycosis-like organisms is to do nothing except advise her of the results and provide precautions relating to PID. The literature suggests that women who retain their IUCs have better outcomes than do those whose devices are removed.[53]

For most reproductive-aged women, IUCs represent a safe and effective long-term option for contraception.

Malposition on follow-up

Elongated strings indicate that the IUC is not in contact with the fundus. USG localization may be advisable. If the IUC is within the cavity (not the cervix) and the woman is asymptomatic, the device may be left in place. Shorter strings indicate the possibility of perforation, twisting, or expulsion. If strings are missing and the patient is not pregnant, strings—but not the IUC—may be tucked into the canal. The tail strings can be gently straightened. If strings in a nonpregnant woman are not found in the cervical canal, radiography can be used to determine whether the IUC is present in the pelvic region. USG can reveal both the presence and the location of the device. As an alternative, the intrauterine cavity may be explored with alligator forceps or an IUC string removal device (i.e., the Emmett I UC retrieval device or the Retrievette IUCD retrieval device).[54] Adequate analgesia with or without vaginal misoprostol may be needed.[55] If the IUC is within the uterus, it may be removed and replaced. If it is in the peritoneal cavity, it should be removed surgically. If the IUC is expelled, contraception will need to be provided.

In a study of 182 women, none whose IUCs had been identified as malpositioned based on USG and left in place experienced a pregnancy.[56] All pregnancies in the study occurred in women who had IUCs removed or had late expulsions. In a retrospective study, patients who did not have visible strings were evaluated.[57] Among 14,935 IUC users, 750 (5.0%) had missing strings at any follow-up. On USG, 735 (98.0%) of these 750 women had devices in situ. Expulsion had occurred in 9 patients (1.2%) and 5 patients (0.5%)

showed perforation. On follow-up, among women whose IUC was in situ, 24% subsequently experienced expulsion.

Conclusion

For most reproductive-aged women, IUCs represent a safe and effective long-term option for contraception. These devices enable women to make a one-time decision in accord with their goals for childbearing and eliminate the pitfalls leading to unintended pregnancy and possible abortion. Increasing patient awareness of these options and active efforts by NPs to dispel myths and misconceptions will result in increased patient well-being and safety.

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