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Intrauterine Device

Intrauterine devices (IUDs) offer safe, effective, long-term contraception and should be considered for all women who seek a reliable, reversible contraception that is effective before coitus. Two IUDs currently are available in the United States: 1) the copper T380A, and 2) the levonorgestrel intrauterine system. A growing body of evidence attests to the safety and effectiveness of IUDs and to their potential role in decreasing rates of unintended pregnancy. Only a very small proportion of women in the United States, however, currently use an IUD.

This document presents evidence regarding the safety and efficacy of the copper T380A and the levonorgestrel intrauterine system. To achieve more widespread use of IUDs among women who are appropriate candidates, clinicians should understand the risks, benefits, indications, and contraindications to IUD use.

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Gynecology with the assistance of Eve Espey, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

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Background

Historical Perspective

Intrauterine contraception became popular in the United States in the 1960s and 1970s. Prospective trials demonstrated its safety and efficacy (1). At the height of its popularity, the IUD was used by approximately 11% of women using contraception in the United States (2). In 1970, the Dalkon Shield was first marketed in the United States. Soon after, reports of septic abortion and pelvic infection contributed to class action lawsuits against IUD manufacturers. By 1988, all but 1 IUD had been removed from the U.S. market by manufacturers because of economic considerations, including product liability concerns. Among some providers, concern remains about the safety of IUDs as a result of the Dalkon Shield controversy despite reassuring evidence about modern IUDs and the correction of a design flaw unique to the Dalkon Shield. In 1995, the National Survey of Family Growth reported that fewer than 1% of women who use contraception use an IUD (3). Providers remain concerned about prod-

uct liability and the risk of infection associated with IUDs and, therefore, apply restrictive criteria in selecting candidates for IUD use (4). Worldwide, IUDs are the most common reversible method of contraception and are used by more than 90 million women. The largest number of IUD users resides in China, where 40% of women who use contraception use the IUD. Other countries with high rates of IUD use include Vietnam, Norway, Finland, and Sweden (5, 6).

Overview of Currently Available Intrauterine Devices

The copper T380A is a T-shaped device of polyethylene wrapped with copper wire around the stem and arms. The U.S. Food and Drug Administration (FDA) has approved its use for 10 continuous years, during which it remains highly effective, with a 10-year cumulative pregnancy rate comparable to that of sterilization. Its major advantage over other reversible methods of contraception is that it requires only a single act of motivation for long-term use. Typical-use pregnancy rates (0.1–0.8% for levonorgestrel intrauterine system and copper T380A) are lower than with oral contraceptives, and continuation rates are higher (78–81%) (7). The copper IUD also may be used for postcoital contraception. It has a failure rate of less than 1% when inserted within 5 days after unprotected intercourse (8). The IUD may then be retained for use as long-term contraception (9).

The levonorgestrel intrauterine system also is T-shaped and contains a polydimethylsiloxane sleeve containing 52 mg of levonorgestrel on the stem. The IUD releases 20 μg of levonorgestrel daily. This small amount of steroid confers minimal systemic side effects, although some women may experience hormone-related effects, such as headache, nausea, breast tenderness, and depression. Most women ovulate normally but experience diminished menstrual bleeding because of the local effect of levonorgestrel on the endometrium. In an economic analysis, the levonorgestrel intrauterine system was shown to be the most cost-effective reversible method of contraception after 5 years of continuous use (10). As with the copper T380A, return to fertility is rapid after removal of the device (11). Table 1 compares the copper IUD and the levonorgestrel intrauterine system.

Table 1. Comparison of Levonorgestrel Intrauterine System and Copper Intrauterine Device

Characteristic	Termination Rates at 7 Years per 100 Women	
	Levonorgestrel Intrauterine System	Copper Intrauterine Device
Pregnancy	0.2	0.3
Expulsion	2.9	1.8
Pelvic inflammatory disease	0.7	0.7
Amenorrhea	4.4	0.1
Other menstrual problems	1.5	2.9
Pain	1.4	1.5
Ectopic pregnancy	0	0
Perforation	0.1	0
Continuation	22.8	27.2

Reprinted from Fertility & Sterility, Vol 61, Sivin I, Stern J. Health during prolonged use of levonorgestrel 20 micrograms/d and the copper TCu 380Ag intrauterine contraceptive devise: a multicenter study, 70–7, copyright 1994, with permission from The American Society for Reproductive Medicine.

Mechanism of Action

A number of different mechanisms of action have been proposed for copper-containing IUDs. These include inhibition of sperm migration and viability, change in transport speed of the ovum, and damage to or destruction of the ovum. The evidence suggests these prefertilization effects constitute the primary mechanism of action for pregnancy prevention in the copper IUD (12). Postfertilization effects, including damage to or destruction of the fertilized ovum, also may occur (13). In addition to these effects, the levonorgestrel intrauterine system causes endometrial suppression and changes the amount and viscosity of cervical mucus. All effects, both prefertilization and postfertilization, occur before implantation.

Intrauterine Device Candidate Selection

Candidates for IUD use and contraindications to IUD use are shown in the boxes. Women considering an IUD should be counseled about its advantages and side effects as well as other family planning methods. They should understand when to return for follow-up evaluation and should be instructed in checking for the strings of the IUD. Generally, women should be reevaluated 1–4 weeks after IUD placement. For women who use the copper T380A, a missed period should prompt a pregnancy test; a positive pregnancy test result should prompt an immediate visit to a provider to rule out ectopic pregnancy. Amenorrhea in women using the levonorgestrel intrauterine system is common. However, in a woman who misses a period and experiences pain, ectopic pregnancy should be ruled out. Women should be instructed about warning signs of pelvic infection, particularly in the first month after insertion of the device, when the risk of pelvic infection is increased.

Candidates for Intrauterine Device Use

- Multiparous and nulliparous women at low risk for sexually transmitted diseases
- Women who desire long-term reversible contraception
- Women with the following medical conditions, for which an intrauterine device may be an optimal method:
  - Diabetes*
  - Thromboembolism†
  - Menorrhagia/dysmenorrhea‡
  - Breastfeeding§
  - Breast cancer‖
  - Liver disease¶

*Limited data suggest no increased complications in women with diabetes. (Kimmerle R, Weiss R, Berger M, Kurz KH. Effectiveness, safety and acceptability of a copper intrauterine device [Cu safe 300] in type 1 diabetic women. Diabetes Care 1993;16:1227–30.)

†Consider the levonorgestrel intrauterine system for women with bleeding disorders or those taking anticoagulants because it decreases menstrual bleeding. (Siegel JE, Kouides PA. Menorrhagia from a haematologist's point of view. Part II: management. Haemophilia 2002;8:339–47.)

‡Consider the levonorgestrel intrauterine system for women with menorrhagia or dysmenorrhea. (Lethaby AE, Cooke I, Rees M. Progesterone/progestogen releasing intrauterine systems for heavy menstrual bleeding [Cochrane Review]. In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.)

§Copper only until 4–6 weeks postpartum.

‖Copper only for current breast cancer.

¶The levonorgestrel intrauterine system is not recommended for current liver disease.

Data from World Health Organization. Medical eligibility criteria for contraceptive use. 3rd ed. Geneva: WHO; 2004.

Contraindications to Intrauterine Device Use

- Pregnancy
- Pelvic inflammatory disease (current or within the past 3 months)
- Sexually transmitted diseases (current)
- Puerperal or postabortion sepsis (current or within the past 3 months)
- Purulent cervicitis
- Undiagnosed abnormal vaginal bleeding
- Malignancy of the genital tract
- Known uterine anomalies or fibroids distorting the cavity in a way incompatible with intrauterine device (IUD) insertion
- Allergy to any component of the IUD or Wilson's disease (for copper-containing IUDs)

Data from The intra-uterine device. Canadian Consensus Conference on Contraception. J SOGC 1998;20:769–73; IMAP statement on intrauterine devices. International Planned Parenthood Federation (IPPF). International Medical Advisory Panel (IMAP). IPPF Med Bull 1995;29:1–4; and World Health Organization. Medical eligibility criteria for contraceptive use. 3rd ed. Geneva: WHO; 2004

Intrauterine Device Insertion

For the treatment of pain during IUD insertion, a randomized nonblinded study compared pretreatment with 2% intracervical lignocaine gel versus an inert gel versus no treatment and found significantly lower pain scores in those who received the active gel (14). Many clinicians use ibuprofen or nonsteroidal antiinflammatory drugs for pain control on insertion, but there are limited data of their efficacy. No reports about other modalities, such as paracervical block, have appeared in the literature.

Clinical Considerations and Recommendations

▶ ***Does the IUD increase the risk of pelvic inflammatory disease (PID)? Are nulliparous women with an IUD at higher risk of PID or infertility?***

The concern about a causal association of IUDs with PID has been arguably the most important barrier to increased IUD use. A recent meta-analysis examined the large body of evidence regarding this association (15). The review concluded that the risk of PID after the first month following insertion is small. The increased risk of upper genital tract infection seen in the first month after IUD insertion is related to the contamination of the uterus with vaginal bacteria, despite aseptic technique (16). Although the relative risk of PID is increased by a factor of 6 in the first month after insertion, the absolute risk is still low. In 22,908 IUD insertions, investigators found a risk of PID after 20 days of 1.4 cases per 1,000 woman-years of use, compared with 9.7 cases per 1,000 woman-years in the first 20 days after IUD insertion (16).

Additionally, rates of PID remained low and stable for up to 8 years of follow-up monitoring, which demonstrates that PID is an uncommon event in IUD users after the first 20 days following insertion.

The appropriateness of IUD use in nulliparous women is controversial, largely because of fears of PID with subsequent infertility. Initial case–control studies from 1985 showed an increased risk of tubal infertility associated with certain IUDs but not with copper IUDs and not when controlling for the number of sexual partners (17, 18). In 2001, in a case–control study of 1,895 women with primary tubal infertility using several control groups to minimize bias, previous copper IUD use was not found to be associated with an increased risk of tubal occlusion in nulliparous women at low risk of sexually transmitted diseases (STDs) (19). Although some reports document higher rates of expulsion and lower rates of continuation in nulliparous IUD users (20, 21), others show rates of these complications similar to those found in parous women (22, 23). Contraception counseling should include information about risk factors for STDs and PID. Nulliparous and multiparous women at low risk of STDs are not at increased risk of PID and are good candidates for IUD use.

▶ *What are the difficulties associated with IUD insertion and removal, and how are they best addressed?*

Difficulties that may occur at IUD insertion include vasovagal reaction, the need for cervical dilation, severe pain, inability to insert the IUD, and uterine perforation. Overall, these conditions rarely occur. Uterine perforation, the most concerning complication, is estimated to occur in approximately 1 in 1,000 insertions (24). Adherence to insertion guidelines included with IUD packaging may help avoid uterine perforation; the risk of perforation appears to decrease with increasing experience. If either the copper T380A or the levonorgestrel intrauterine system perforates into the peritoneal cavity, the location of the IUD should be confirmed by ultrasonography, and the IUD should be removed by laparoscopy or laparotomy (25, 26).

A common challenge when removing IUDs is the lack of visible strings. A Cytobrush may be placed in the endocervix and gently swept downward to locate strings curled up in the canal (26, 27). If this maneuver is not helpful, ultrasonography should be performed to ensure intrauterine location of the IUD. The clinician may then attempt to remove the IUD with an "IUD hook" under sterile conditions in the outpatient setting or may elect to remove the IUD in the operating room, where hysteroscopic guidance may be helpful.

▶ *Is routine screening for STDs (eg, gonorrhea and chlamydia) required before insertion of an IUD?*

Current data do not support routine screening in women at low risk for STDs. However, because the rate of endometritis in women with gonorrhea and chlamydia is 25–75%, and because endometritis may be asymptomatic (28), women at high risk of STDs may benefit from screening. The prevalence of STDs is a more important predictor of subsequent upper genital tract infection than is IUD insertion (29). In a study of 4,031 women at low risk for STDs who had an IUD inserted, no cases of PID were reported (16). In contrast, 8 cases of PID were noted in 1,292 woman-years of follow-up in a study in which the prevalence of STDs was higher (30). Some case reports suggest that women with positive cultures for chlamydia performed at the time of IUD insertion are unlikely to develop PID if the chlamydia is treated with the IUD remaining in situ (31, 32). Clinical judgment should be used to determine whether the IUD should be removed.

▶ *Is the presence of bacterial vaginosis a contraindication to IUD insertion?*

The association between bacterial vaginosis and IUD use remains controversial. Studies have not addressed whether the presence of bacterial vaginosis at the time of IUD insertion leads to adverse effects. Although several early reports documented higher rates of bacterial vaginosis in IUD users (33, 34), these reports were hampered by methodological flaws. Two recent studies reexamined the association between IUD use and bacterial vaginosis and reached opposing conclusions. A case–control study comparing women with and without bacterial vaginosis showed no association between bacterial vaginosis and IUD use and a protective effect of oral contraceptives and condoms against bacterial vaginosis (35). However, a cross-sectional study of IUD users and nonusers did show a significant association between IUD use and bacterial vaginosis (relative risk: 2.78) (36). Despite this association, IUD users were no more likely to have STDs or PID than nonusers.

▶ *Does antibiotic prophylaxis before IUD insertion decrease the risk of subsequent pelvic infection?*

Four randomized controlled trials have examined the benefit of prophylactic doxycycline or azithromycin given at the time of IUD insertion (30, 37–39). Outcome measures included PID, unscheduled visits to the clinician, and removal of the IUD within the first 90 days of

use. A meta-analysis concluded that prophylactic antibiotics conferred little benefit (15). Antibiotics did not reduce the risk of PID, which was a rare outcome in both the antibiotic and placebo groups. In a U.S. trial, the rate of PID was 1 per 1,000 in both groups. Prophylaxis did not reduce the likelihood of IUD removal within the first 90 days. Use of antibiotics did, however, result in a small but significant decrease in unscheduled provider visits in some trials. Overall, use of prophylactic antibiotics is unlikely to be cost-effective in populations with a low prevalence of STDs.

Studies of prophylactic antibiotics for IUD insertion did not examine women at risk for subacute bacterial endocarditis. However, bacteremia is uncommon in clinically well women who undergo IUD insertion and removal. Therefore, on the basis of expert opinion, the American Heart Association does not recommend subacute bacterial endocarditis antibiotic prophylaxis for IUD insertion and removal (40).

▶ *What treatment options are appropriate for an asymptomatic patient with an IUD who has actinomyces identified on a Pap test?*

Actinomyces israelii, a gram-positive anaerobic bacterium normally found in the human gastrointestinal tract, may be a normal component of vaginal flora. This organism may be more prevalent in the genital tract of IUD users than in nonusers. The likelihood of colonization appears to increase with increasing duration of IUD use (41). Recent studies demonstrated that colonization may be lower in levonorgestrel intrauterine system users than in copper IUD users (2.9% versus 5–10%) (41–43). However, actinomyces found via a Pap test is not diagnostic of actinomycosis infection, nor is it predictive of future disease. Pelvic actinomycosis is a very rare but serious condition characterized by granulomatous pelvic abscesses. Its prevalence has been estimated to be less than 0.001%; because of its rarity, the relationship between actinomyces found on a Pap test in an asymptomatic IUD user and the eventual development of this infection is unclear.

Studies of pelvic actinomycosis are limited to case reports, so management of the asymptomatic IUD user whose Pap test shows actinomyces is not clearly established. A recent review of pelvic actinomycosis underlines the ubiquity of *Actinomyces israelii* in both IUD users and nonusers and the lack of an association between the finding of this organism on a Pap test and adverse outcomes when no treatment is offered (44). A single randomized controlled trial has looked at management of asymptomatic IUD users with actinomyces identified on a Pap test (45). Women were randomized to undergo either removal of the IUD and receive oral antibiotics or receive oral antibiotics alone. One month after treatment, the Pap test was repeated. No Pap tests revealed actinomyces in the women whose IUDs were removed. Thirty-three percent of Pap tests still showed actinomyces in the group of women who received antibiotics alone. However, the importance of clearing the actinomyces colonization is still not established. The options for management of asymptomatic IUD users with actinomyces on Pap test are expectant management, an extended course of oral antibiotics, removal of the IUD, and both antibiotic use and IUD removal.

▶ *Do IUDs cause ectopic pregnancy?*

A history of ectopic pregnancy has traditionally been considered a contraindication to use of an IUD because IUDs were thought to increase the risk of ectopic pregnancy. Both case–control studies and randomized controlled trials have addressed the question of IUDs and the risk of ectopic pregnancy. Findings from case–control studies have been inconsistent, and discrepancies in the choice of control groups have made accurate conclusions difficult to reach. The complexity of ascertaining an appropriate control group has been the major impediment to these studies. A recent meta-analysis of 16 case–control studies concluded that IUDs do not increase the risk of ectopic pregnancy because they generally prevent pregnancy effectively (46). However, if pregnancy does occur with an IUD in place, the pregnancy is more likely to be ectopic. The authors also concluded that past IUD use may slightly increase the risk of ectopic pregnancy.

Although case–control studies express relative risk, prospective data from randomized controlled trials describe the absolute risk of ectopic pregnancy associated with IUD use, a measure that is more useful clinically. U.S. cohort data with both the copper T380A and the levonorgestrel intrauterine system have shown an ectopic pregnancy rate of 0–0.5 per 1,000 woman-years, compared with an ectopic pregnancy rate of 3.25–5.25 per 1,000 woman-years among women who do not use contraception (47, 48). Given this very low risk, a history of ectopic pregnancy should not be considered a contraindication to IUD use. The most recent World Health Organization guidelines for appropriate candidates for an IUD support the routine use of IUDs (both copper T380A and the levonorgestrel intrauterine system) in women with a past history of ectopic pregnancy (49).

▶ *In a pregnant woman, does removal of the IUD affect pregnancy outcome?*

Complications that may occur in IUD users who become pregnant include an increased risk of spontaneous abortion and an increased risk of septic abortion. Several

reports suggest a higher rate of pregnancy loss in women who conceive an intrauterine pregnancy with an IUD in situ. The loss rate may be higher if the IUD is retained (50, 51) than if it is removed (52). Several cases of death associated with septic abortion from retained Dalkon Shields were reported shortly after distribution of these IUDs in the early 1970s (53). As a direct result of these cases, the FDA recommends that IUDs be removed from pregnant women when possible without an invasive procedure (54). No IUD-related deaths among pregnant women in the United States have been reported since that time.

▶ *What impact does IUD use have on menstrual blood loss in a woman with normal flow?*

The copper IUD and the levonorgestrel intrauterine system have different effects on menstrual bleeding. Long-term follow-up evaluation of a randomized trial of the 2 devices found that copper IUD users were more likely to discontinue the device because of heavy menstrual bleeding and dysmenorrhea, whereas levonorgestrel intrauterine system users were more likely to discontinue the device because of amenorrhea and spotting (55). The levonorgestrel released from the levonorgestrel intrauterine system concentrates in the endometrium and produces a thin decidualized endometrial lining, despite the presence of endogenous estrogen. Although most women continue to ovulate while using the levonorgestrel intrauterine system, the amount and duration of bleeding is reduced because of levonorgestrel's direct effect on the endometrium. Several randomized controlled trials comparing the levonorgestrel intrauterine system with copper devices demonstrate a mean increase in hemoglobin levels in levonorgestrel intrauterine system users of 0.5 g/dL at 2 years up to 1.5 g/dL at 5 years of use (56–58). Although women with a copper IUD initially demonstrate a slight decrease in hemoglobin levels, continuing users over a period of 5–7 years experience an increase over levels at insertion. In the largest trial comparing the levonorgestrel intrauterine system with a copper device, one third of women immediately and 70% of women at the end of 2 years developed oligomenorrhea (ie, no more than 1 episode of bleeding in a 90-day interval) or amenorrhea (58). Similarly, symptoms of dysmenorrhea were reduced in levonorgestrel intrauterine system users. Patients should be advised that menstrual bleeding and cramping may initially increase with the copper IUD and may decrease with the levonorgestrel intrauterine system. The number of bleeding days as well as the amount of bleeding decreases with use of the levonorgestrel intrauterine system. Approximately 8–10% of women discontinue the levonorgestrel intrauterine system over 2 years of use because of oligomenorrhea or amenorrhea; therefore, all women considering this form of contraception should be informed of the likelihood of these effects (59).

▶ *What is the efficacy of the levonorgestrel intrauterine system in treating menorrhagia?*

Five randomized controlled trials have compared the levonorgestrel intrauterine system with other treatments, including the oral progestin norethindrone and transcervical resection of the endometrium, for women with menorrhagia (60–64). A meta-analysis concluded that the levonorgestrel intrauterine system was significantly more effective than oral cyclical norethindrone as a treatment for heavy menstrual bleeding (59). Also, the levonorgestrel intrauterine system resulted in a smaller mean reduction in menstrual blood loss than transcervical resection of the endometrium although the decrease in blood loss was large in both groups and resulted in similar high rates of satisfaction. Several case series (65–67) also suggest a substantial reduction in menstrual blood loss, averaging 74–97%, with use of the levonorgestrel intrauterine system in women with idiopathic menorrhagia. Two recent clinical trials randomized women with menorrhagia who were scheduled to undergo hysterectomy to either treatment with the levonorgestrel intrauterine system or their previous medical treatment (60, 68). In these 2 trials, 64% and 80% of women with the levonorgestrel intrauterine system, respectively, canceled their surgery, compared with 14% and 9%, respectively, in the normal medical care groups. Therefore, the levonorgestrel intrauterine system may be an acceptable alternative to hysterectomy in women with menorrhagia.

▶ *When should an IUD be removed in a menopausal woman?*

An IUD placed for contraception should be removed in a woman who has become menopausal. Awaiting 1 year of amenorrhea to ensure menopausal status is advisable before removing the device. Many women experience dysfunctional bleeding in the perimenopausal period, and unexpected bleeding should prompt an endometrial biopsy in women with an IUD to evaluate the possibility of endometrial pathology (69). Although no clinical trials have been performed that document risks from prolonged IUD retention in asymptomatic menopausal women, several case reports discuss pelvic infection (eg, pelvic actinomycosis) in women with IUDs (70–72). In the absence of data, it seems prudent to remove the IUD placed for contraception from a menopausal woman.

When is an IUD appropriate for emergency contraception?

Use of a copper IUD for postcoital contraception, first reported in 1976 (73), has been studied in prospective cohort trials with pregnancy rates of 0–0.1% (74). In these trials, the IUD was inserted up to 5 days after unprotected intercourse. A more recent report of 1,013 women who underwent insertion of a copper IUD for postcoital contraception, including 170 nulliparous women, found a pregnancy rate of 0.2% (8). One advantage of the copper IUD for postcoital contraception is that it can be retained for continued long-term contraception. The same study found 86% of parous women and 80% of nulliparous women maintained the IUD for contraception. No randomized controlled trials have compared IUD insertion with medical regimens for emergency contraception. A recent meta-analysis concluded that the IUD is very effective for emergency contraception but that further comparative studies are needed (9).

The copper T380A is appropriate for emergency contraception in women who meet standard criteria for IUD insertion and is most effective if inserted within 5 days after unprotected intercourse. This method is particularly useful for women who desire long-term contraception and who are otherwise appropriate candidates for IUD use.

Conclusions

- Pelvic inflammatory disease complicating IUD insertion is uncommon, and the risk of PID decreases to the background risk after the first 20 days after insertion.
- Nulligravid and multiparous women at low risk of STDs who desire long-term reversible contraception are good candidates for IUDs.

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Routine use of prophylactic antibiotics at the time of IUD insertion confers little benefit.
- The copper T380A is very effective for postcoital emergency contraception and is most effective if inserted within 5 days after unprotected intercourse.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Intrauterine devices may be offered to women with a history of ectopic pregnancy.
- The levonorgestrel intrauterine system may be an acceptable alternative to hysterectomy in women with menorrhagia.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- The FDA recommends that IUDs be removed from pregnant women when possible without an invasive procedure.
- An IUD placed for contraception should be removed in a woman who has become menopausal.
- Contraception counseling should include information about risk factors for STDs and PID.

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and September 2004. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least 1 properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than 1 center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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