S. FAMILY PLANNING

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INTRODUCTION

Family planning encompasses the entire range of human reproductive experience. Medical family planning programs are concerned with individuals or couples who desire counseling about the potential influence of various environmental factors, medications, or substance abuse on the outcome of pregnancy; who have been attempting to conceive without success; who wish to use a temporary method of contraception in order to space their families according to their desires; or who have completed their families and may wish to use a method of permanent surgical sterilization. Counseling to reduce the risk for transmission of sexually transmitted diseases including HIV/AIDS is integral to all family planning programs.

The patient's wishes must take precedence in a medical family planning program. If a woman presents herself for a particular method of contraception and there are no contraindications for its use by this woman, the decisions are quite easy. However, the decisions are much more difficult 3if she is not sure, if she experiences language or communication barriers, or if she cannot afford the cost of her preferred method. She may have an unhappy experience if she encounters a provider who has biases regarding her ethnic background, marital status, age, number of children, or socio-economic status. A woman who has a negative experience with a family planning provider will often influence the attitudes of others in the community to the detriment of the provider and the program. A medical family planning program must exercise great care to respect the needs of each patient and to assure each patient that the provider's advice and counseling are based upon the scientific information available in the literature and upon the local program's actual experiences with the methods discussed.

In this context, the patient's prior understanding about family planning must be explored, including relevant attitudes about child rearing, fertility, and abortion. Group discussion and teaching sessions are often more effective than individual ones and will often bring out concerns which, if not otherwise addressed, might increase the risk of noncompliance with the methods selected. What is the patient's lifestyle? Is she at increased risk for infection if she uses an IUD? Does she have sufficient privacy at home to insert a diaphragm each time it is needed, or does she fear discovery of a package of birth control pills? Potential topics to be addressed with the patient include the fear of loss of libido, possible influence on development of cancer, effect on fertility, and possible conflict with her partner who may consider the use of contraception to mistakenly be a sign of promiscuity.

The Family Planning Services section of the Indian Health Service Manual[1] states the policies, objectives and responsibilities of the Indian Health Service and offers specific clinical care guidelines and policies for each local program. Services provided by the Indian Health Service include:

• Adoption	Counseling and referral.
• Contraception	All generally available methods, including: Natural family planning; chemical/spermicidal; barrier, including condom and diaphragm; hormonal including oral, implantable, and injectable; intrauterine device; and emergency contraception.
• Reproductive Education	Including family life and human sexuality education.
• Infertility	Including counseling and referral. Direct provision of, or payment for, specialized high cost medication or surgery may not be available due to budgetary limitations.
• Sterilization	Including counseling and referral for vasectomy and tubal ligation. Direct provision of, or payment for, surgery may not be available due to budgetary limitations.

- Sexual Abuse — Including counseling, evaluation and referral.
- Abortion — Services are limited by federal regulations.

ORAL CONTRACEPTION

Oral contraceptives are the most frequently used reliable form of reversible contraceptive therapy used in the United States. They are convenient and effective. However, the steroids in the pill may cause side effects which vary from simple nuisances to life-threatening complications. It is the provider's responsibility to rule out contraindications to a patient's use of the pill, to prescribe the formulation with the least risk of side effects for that patient, and to monitor the patient properly while she is taking this drug.

Most of the oral contraceptives in current use contain a combination of estrogen and a progestin, both of which have contraceptive effects. Estrogen can inhibit ovulation by suppressing hypothalamic secretion of FSH and LH and blocking the midcycle surge of LH, prevent implantation, and increase tubal transport of the ovum. The progestin maintains a barrier cervical mucus preventing the passage of sperm to the tubes, prevents capacitation of the sperm, and inhibits both ovulation and implantation.

Theoretically oral contraceptives are nearly 100 percent effective, with a *pharmacological failure rate* reported to be 0.1 pregnancy per 100 woman-years of correct use. That is, occasionally a woman who misses no pills at all becomes pregnant. Actual clinical *use effectiveness* is difficult to evaluate, but it is known that women on low dose pills often miss one or more pills in a cycle and thus are at an increased risk of becoming pregnant. Thus, clinical rates of failure are reported to range from 2% to 16% per year.

In balancing the risks versus the benefits of oral contraception for each patient, providers must maintain an awareness of the contraindications and precautions to their use:

Contraindications

- Vascular disease: Thrombophlebitis, thromboembolic disorders, or past history of thrombophlebitis or thromboembolic disorders
- Cerebrovascular or myocardial disease, or past history of these
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Estrogen dependent malignancy of the breast or reproductive system
- Abnormal, undiagnosed genital bleeding
- Pregnancy
- Hepatic adenomas or carcinomas

Relative Contraindications (Recommend OB/GYN Evaluation)

- Diabetes mellitus (requires closer monitoring of patient. Low dose OCs have less effect on glucose intolerance.)
- Hyperlipidemia, hypertriglyceridemia
- Hypertension, severe
- Cigarette smoking over age 35
- Severe depression
- Sickle cell disease

Precautions (recommend telephone consult with physician)

- Hypertension
- Migraine or other vascular headaches
- Visual disturbances related to pill use
- Headaches related to pill use
- Epilepsy, other seizure disorders
- Gall bladder disease (this risk is less with the newer low dose pills)
- Undiagnosed amenorrhea, oligomenorrhea
- Emotional disorders
- Obesity
- Chronic liver disease
- History of gestational diabetes

Selection of an oral contraceptive is based on using the lowest dose combination pill with an acceptable incidence of side effects.

- Too low a dose of estrogen may result in breakthrough bleeding and possible pill failure when a pill is missed (i.e. Loestrin, Modicon, and Brevicon).
- The higher androgen pills should be reserved for patients with breakthrough bleeding (i.e. Lo-Ovral, Ovral, Loestrin 1.5+30, and Norlestrin 2.5).
- More estrogen dominant pills should be reserved for patients with breakthrough bleeding not responsive to increased androgens (such as Ortho-Novum 1+50 or Norinyl 1+50).
- The triphasics may have increased breakthrough bleeding (Ortho-Novum 7/7/7) or increased androgens (Triphasil).
- Programs should minimize the changing of first-time pill selections to avoid patient comparisons.
- The newer progestins (desogestrel or norgestimate) can be excellent for cycle control while minimizing risk for acne.

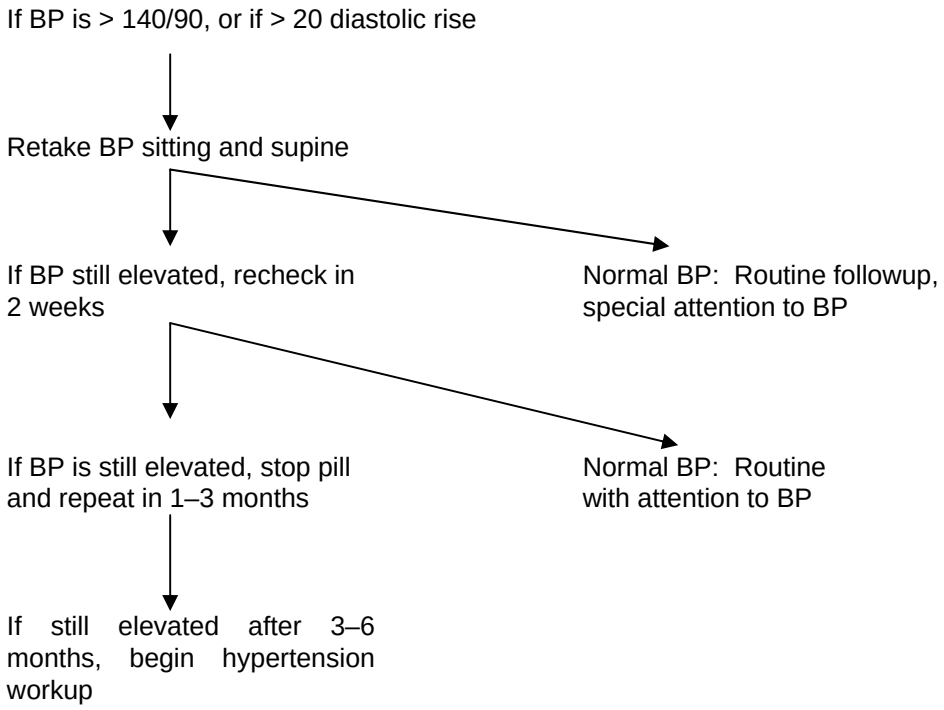
Advantages of oral contraceptive use

1. Reliable, not coitally related
2. Improved menstrual symptoms: less bleeding, pain and irregularity
3. Decreased incidence of ovarian cysts, ovarian cancer, endometrial cancer, and fibrocystic breast changes
4. Less acne, oily skin
    - 5. Protection of fertility by decreasing occurrences of endometriosis, ovarian cysts, and possibly pelvic infections

Serious complications of use of oral contraceptives

1. Liver disease: hepatic adenoma (rare) (estrogen)
2. Cholecystitis: 2 times risk (150 per 100,000 users)
3. Hypertension: 2 to 6 times risk (estrogen and progestin)
4. Thromboembolism: 9 times risk (45 per 100,000) (estrogen)
5. May potentiate growth of existing cancers: breast, endometrial, melanoma (estrogen)
6. Myocardial infarction: Risks are associated with cofactors to pill use such as obesity, hypertension, smoking, diabetes, hyperlipidemia, and age greater than 35 years.

Management of hypertension developing while on the pill



How to Take Pills

When should the patient start her first package of pills? The Sunday schedule and the Day 1 schedule are equally effective for the standard fixed-dose combination pill formulations. That is, the patient may begin her first pill on the first Sunday after the start of her next menses or on the first day of the next menstrual cycle, counting the first day of spotting or bleeding as day #1. A woman who has just had a first trimester abortion, spontaneous or induced, may begin her pills immediately (or on the first Sunday). It is best to wait 1-2 weeks after a midtrimester abortion and 2-6 weeks after a third trimester delivery in order to reduce the risk of thrombophlebitis. Nursing mothers may take the pill starting 2+ weeks postpartum and once lactation is well established so as to minimize any effect on breast milk volume. It should be noted that with the triphasic combination pills (levonorgestrel + ethinyl estradiol), the first pill is to be taken on day 1 of the cycle. Of note, studies are currently underway regarding continuous use of combination monophasic pills for 84 days and then 1 week off. It is anticipated that there will be an FDA-approved product on the market in 2004.

Screening of patients for risk

Patients with any one of the following risks should be screened for the others. Patients with two or more risks should consider alternate methods or have the risks fully explained and then consent to the use of combination OCs. Close medical follow-up is a necessity.

1. Age 35 years or greater
2. Hypertension
3. Obesity, >30% overweight
4. Hyperlipidemia
5. History in family of myocardial infarction under age 50
6. Smoking > 10 cigarettes per day
7. Diabetes

Common Questions and Problems on the Pill

Dose	• Using a formulation that contains 35 µg or less of estrogen reduces a number of the risks associated with pill use while still maintaining its effectiveness.
Need for a second method	• Added protection (condom, foam) for the first cycle may be prescribed since the first-time user may be more likely to miss a pill or two.
The pill and cancer	• Combination pills *reduce* the risk of endometrial and ovarian cancer. • Rare increased risk (1:50,000 users) of benign liver adenoma, with its risk of intra-abdominal hemorrhage; but not for liver cancer. • Relative risk for cervical cancer increases with increasing duration of use of oral and perhaps injectable contraceptives, with a relative risk of 1.1 at 5 years, 1.6 at 9 years, and 2.2 for more than 10 years of use. The risk appears to decrease after cessation of use.
The pill & vascular disease	• Pill users have a 3 to 9 fold increased risk of thromboembolic disease (1:10,000 are hospitalized, 1:200,000 die each year). • Pill users over 35 with additional risk factors (smoking, obesity, hypertension, diabetes, or hyperlipidemia) are at increased risk of death from vascular disease. • Otherwise healthy women over 35 who smoke should be counseled to stop smoking or to use an alternative method. • Women with blood type O are 3 times less likely to develop thromboembolic disease.
Weight change	• While a few women will lose weight on the pill many will gain a few pounds due to mild fluid retention and anabolic effect (increased appetite).
Breast changes, nausea	• Usually these are transient if they occur at all. If persisting, change to a pill lower in estrogen. If still persists, stop pill and evaluate further.
Missed pills	• If one pill is missed, take it as soon as it is discovered and the next pill at its regular time. A backup method may be used for the next 7 days. • If 2 pills in a row are missed, take 2 pills as soon as it is discovered and 2 the next day. Then return to the regular schedule. A backup method should be used for the next 7 days. • If 3 or more pills in a row are missed, discard the remaining pills in the pack and start a new pack that day or the next Sunday. A backup method should be used until back on the pills for 7 days.
Breakthrough bleeding	• If only spotting, continue the pills as prescribed. This is usually limited to the first few cycles. If it continues, switch to a pill higher in estrogen or with a stronger endometrial effect. • If heavy bleeding, the pills should be stopped and the bleeding considered as a period. Start a new pack on Sunday or 1 week later. • Breakthrough bleeding in a long term user should be evaluated for uterine pathology.
Amenorrhea	• Failure to have withdrawal bleeding early indicates insufficient estrogen priming and late indicates excessive progestin suppression (atrophic or exhausted endometrium).

Postpill amenorrhea	• Amenorrhea lasting more than 6 months after stopping the pill requires full evaluation. Amenorrhea plus galactorrhea should be evaluated for pituitary adenoma.
Leg pain	• Examine for deep vein thrombosis.
Chest pain	• Stop pill and evaluate as indicated clinically.
Headache	• Sudden or persistently severe headaches: Stop pill and evaluate for any relationship.
Elective major surgery	• To minimize risk of postoperative thrombophlebitis, stop pill 1 month prior to surgery and use an alternative method.
Gallbladder disease	• Risk of cholelithiasis is increased 2-fold in pill users. The risk is less with the lower dose pills.
Galactorrhea	• Prolactin levels may increase due to central effect of estrogen, but estrogen also has inhibitory effect on breast. Pill should be stopped if galactorrhea occurs and a prolactin level obtained to rule out pituitary adenoma. If prolactin is normal and spontaneous menses occur, pills may be resumed after consultation.
Rest periods	• There is NO benefit for periodic interruption in use of the pills. Such a practice increases the risk for unplanned pregnancy.
The teenager	• May use oral contraception if she has had at least 3 spontaneous consecutive monthly periods. • If oral contraception is indicated, generally use low dose estrogen (to minimize nausea, breast tenderness), avoid norgestrel (acne problems), and use 28-day packaging (compliance is better).

EMERGENCY ORAL CONTRACEPTION

As noted by ACOG in Practice Bulletin Number 25, *Emergency Oral Contraception*, “emergency contraception is a therapy for women who have had unprotected sexual intercourse, including sexual assault. It has also been called ‘the morning-after pill,’ interception, and postcoital contraception.” The most common methods in use are combination oral contraceptive pills (the Yuzpe method), progestin-only methods, antiprogestins, and insertion of an IUD. In contrast, insertion of an IUD is one of the least prescribed methods of emergency postcoital contraception and, simultaneously, one of the most effective ways of preventing an unplanned pregnancy. The same concerns that limit the use of the IUD in women as a primary form of contraception apply to its emergency use. Because of the risk of exacerbating a sexually transmitted infection, women who have multiple sexual partners, who have been sexually assaulted, or who are just beginning a new sexual relationship are not candidates for emergency postcoital insertion of an IUD.

The Yuzpe Method of Emergency Oral Contraception

Potential candidates for emergency oral contraception are women presenting within 72 hours of unprotected sexual intercourse. Typically, this occurs after use of no contraceptive method or with slippage or breakage of a condom. In the Yuzpe method, two tablets, each containing 0.5 mg ethinyl estradiol and 0.5 mg levo-norgestrel (Ovral), are taken immediately and again 12 hours later for a total of four tablets. This combination is marketed under the brand name “Preven.” Equivalent doses of other oral contraceptives include the following:

Lo/Ovral	4 tablets taken with each dose, for a total of 8 tablets
Nordette	4 tablets taken with each dose, for a total of 8 tablets

Levlen	4 tablets taken with each dose, for a total of 8 tablets
Triphasil	4 **yellow** tablets taken with each dose, for a total of 8 **yellow** tablets
Trilevlen	4 **yellow** tablets taken with each dose, for a total of 8 **yellow** tablets

NOTES

- Use of an anitemetic agent approximately one hour before taking the medication will reduce the risk of nausea or vomiting, common side effects.
- This treatment regimen can be initiated regardless of the time in the menstrual cycle.
- Most women will begin to menstruate by 21 days after the treatment.
- A number of studies have shown that use of this method will reduce the probability of pregnancy by 75%. That is, if 100 women have intercourse once in the middle 2 weeks of their cycles, approximately eight will become pregnant if no contraception is used. Use of emergency contraceptive pills reduces this number to 2 (a 75% reduction).

The Progestin-only Method of Emergency Contraception

The progestin-only method of emergency contraception consists of levonorgestrel 0.75 mg. It is marketed under the brand name "Plan B." As with the Yuzpe method, the first dose (only 1 tablet) is taken as soon as possible and a second tablet is taken 12 hours later. Since there is no estrogen component, nausea and vomiting are much less likely. This method reduces the probability of conception by an additional 10-15% beyond the reduction obtained with the Yuzpe method. It is 95% effective if taken within 24 hours of unprotected intercourse, 85% effective if taken between 24 and 48 hours, and 58% effective if taken within 49 and 72 hours. In contrast, the Yuzpe method reduces the probability of conception by 77%, 36%, and 31%, respectively.

Advance prescription of either the Yuzpe or the progestin-only method is highly encouraged. Because of their well-established safety profile, they are being considered for over-the-counter dispensing by pharmacists in an increasing number of states.

CONTRACEPTIVE IMPLANTS: NORPLANT (LEVONORGESTRAL CAPSULES) SUBDERMAL IMPLANTS

The use of long acting progestin implants has been recognized to be effective and was popular for a number of years. With a low failure rate comparable to that of injectable progestin or sterilization, the method offers both long term [5 years] effectiveness and reversibility by removal of the implants. However, progestin-related side effects and difficulty with removals led to decreased use of this method in the late 1990's. In 2000, clinicians were advised by the company that Norplant would no longer be marketed. An alternative 2-rod subdermal implant system has been approved by the FDA but it is not yet being marketed and a single rod system is expected to be approved by the FDA in 2004.

Advantages include highly effective [<1% failure rate], not requiring day-to-day motivation, rapid return of fertility, low annual maintenance requirements or costs, and long-term use [5 years].

Disadvantages include progestin related side effects, requirement of operative procedures for insertion and removal, expense of insertion and removal, need for trained providers to insert/remove devices, and need for follow-up because of increasing rates of failure and ectopic pregnancy after 5 years.

Indications for use include woman unable to use estrogens, patients who are breast feeding, desire for low-motivation long-term contraception, patients with poor compliance, and patients desiring to avoid sterilization.

Contraindications (labeled) include active liver disease, unexplained uterine bleeding, breast cancer, deep thrombophlebitis, pulmonary embolism, and pregnancy.

Side Effects relate to prolonged progestin use and include irregular menses, breakthrough bleeding, headaches, depression, weight gain, and complications related to insertion/removal site.

Use effectiveness measured in several studies shows that continuous acceptance of the method is similar to rates observed for IUD users, with 50% continuing use after 3 years and 30% after 5 years.

LONG-ACTING CONTRACEPTIVE INJECTIONS: DEPO-PROVERA (MEDROXYPROGESTERONE ACETATE)

Depo-Provera was approved by the FDA for labeling as a contraceptive in late 1992. Experience worldwide has demonstrated that it is very highly effective for contraception, with pregnancy rates of only approximately 0.3 per 100 woman-years of use when administered correctly every 3 months. The principal advantages are its simplicity of use coupled with its effectiveness. Other advantages include prevention of anemia and the avoidance of estrogen-related side effects.

Disadvantages must be carefully explored by the patient and the clinician prior to use of Depo-Provera. These include unpredictable menstrual patterns (eventually leading to complete amenorrhea, often an advantage), weight gain, headaches, and often a delayed return of fertility. There is evidence suggesting that long-term users may be at increased risk for osteoporosis.
The use of Depo-Provera Contraceptive Injections should be applied to situations where alternative methods cannot be used, where trained staff are available, and where adequate follow- up services are accessible to patient. As with any method of contraception, but particularly with regard to a long-term method such as Depo-Provera, it is incumbent upon the clinician to assure that the patient receives full, open, and non-directed information and guidance. This should be clearly documented in the clinical record.

To assist the clinician in considering the use of Depo-Provera Contraceptive Injections for an individual patient, the IHS Senior Clinician for Obstetrics and Gynecology prepared the following Guidelines:

Counseling: Each potential candidate for use of Depo-Provera Contraceptive Injection should be fully evaluated clinically as to the appropriateness of this drug for her. As when counseling potential users about any methods of contraception, but particularly with a long-acting agent such as Depo-Provera, **full, open, and non-directed information and guidance are required.**

A clinical instruction video *DMPA: A New Contraceptive Option* and a patient instruction video *Choosing a Birth Control Method* are available from the Association of Reproductive Health Professionals, 2401 Pennsylvania Avenue, NW, Suite 350, Washington, DC 20037-1718.

Selection: Since this long-acting progestin exerts a clinical effect very similar to Norplant, similar patient selection criteria are reasonable. Depo-Provera can be considered to be particularly useful for a woman who:

- is considering sterilization but is not ready to make a final decision, or

- wants long-term reversible contraception, or
- wants to avoid daily contraceptive use or coitus-related methods, or
- does not wish to use or should not use estrogen-containing contraceptives, or
- is not a candidate for IUD use.

Effectiveness: The effectiveness of Depo-Provera is dependent upon the woman returning for injection every 3 months. In this situation, Depo-Provera, Norplant, and bilateral tubal ligation have essentially the same failure rates of 0.3 pregnancies per 100 women in the first year of use.

Precautions: **Absolute contraindications** are the same as for other hormonal methods of contraception. Additional **precautions** include (1) avoiding use in women who plan to become pregnant within 1 year (i.e., patients must understand that they may be unable to become pregnant for 1 year or longer after the last injection of Depo-Provera) and (2) inability to tolerate the menstrual bleeding changes which are very common with Depo-Provera, ranging from irregular, frequent bleeding to complete amenorrhea.

Records: The **patient should be fully counseled** as to the benefits and the expected side effects of this method and this counseling should be documented in the Clinical Record in an explanatory progress note or by means of a specific consent form. Additionally, the FDA requires that the patient be given a copy of the *Patient Information* brochure that is included with each vial of Depo-Provera.

Dosage: The **contraceptive formulation of Depo-Provera** contains 150 mg/ml. The first injection of Depo-Provera should be given within 5 days of the onset of a normal menstrual period and then repeated every 3 months. If more than 14 weeks have passed since the last injection, pregnancy must be ruled out prior to the next injection. Note that only the 150 mg per vial dosage form is labeled for contraception. The more concentrated formulation previously utilized (400 mg/ml) stings when injected and has a higher pregnancy rate; thus, it is not recommended for contraception.

Side effects: The most **frequently encountered side effects** are unpredictable and unexpected vaginal bleeding, weight gain, and headaches. Patients should be made aware that, in contrast to Norplant, it takes significantly longer for fertility to return or for the side effects to clear after discontinuation of this method (from six to as long as eighteen months are not unusual). Further, they should understand that Depo-Provera cannot be “neutralized” if bothersome side effects are encountered:

In first year, only 30% of cycles are regular and 25% are amenorrheic
In fifth year, 17% of cycles are regular and 80% are amenorrheic
Weight gain averages two-three pounds a year
Increased risk for osteoporosis is reported in a study from New Zealand
Delayed return of fertility such that of women planning to become pregnant after discontinuing use of Depo-Provera, 68% became pregnant within 12 months, 83% within 15 months, and 93% within 18 months

Health benefits: The non-contraceptive health benefits of Depo-Provera include:

Improvements in iron deficiency anemia
Decreased risk of pelvic inflammatory disease

Anticonvulsant properties
Reduced incidence of sickle cell crises
Use of other medications does not reduce contraceptive efficacy
Long-term reduction in risk for endometrial carcinoma

NEWER HORMONAL CONTRACEPTIVE METHODS

A number of newer formulations of combination oral contraceptives have been released over the past several years and the number of generic products has increased dramatically, as well. In addition, several non-oral combination hormonal contraceptives are now available. They each have the advantage of longer duration of use. They include:

- **NuvaRing**

  This flexible vaginal ring released approximately 120 mcg/day of etonogestrel and 15 mcg/day of ethinyl estradiol. The ring is inserted by the patient and remains in place for 21 days, at the end of which time it is removed and discarded. A new ring is inserted 7 days later. Marketing for the ring was begun in 2001.

- **Ortho Evra Patch**

  The transdermal patch releases 150 mcg of norelgestromin and 20 mcg of ethinyl estradiol per day. The patch is worn and replaced weekly for 3 weeks followed by 1 week without a patch. Then a new series of 3 weeks on and 1 week off is begun. Marketing for the patch was begun in 2002.

- **Lunelle**

  The combination of medroxyprogesterone acetate and estradiol cypionate is injected intramuscularly into the deltoid or gluteus maximus muscle every 28 +/- 5 days.

All three of these newer methods are highly effective. They have the advantage of requiring less frequent dosing, ranging from weekly to monthly. Otherwise their risks and benefits are essentially the same as for combination oral contraceptives.

BARRIER METHODS

Diaphragm

The use of a diaphragm as a mechanical barrier together with a spermicidal cream or gel has a theoretical failure rate of approximately 3 pregnancies per 100 woman years. Use-failure rates have been reported to vary from 2-3 percent to more than 20 percent. However, the use failures can be dramatically minimized if the woman is well motivated and is fully educated in the use of this method, including practicing insertion and removal under supervision and advising a one-week follow-up visit with the diaphragm in place. A woman can be fitted for a diaphragm at any time except in the early postpartum period (up to 6 weeks). The fit should be checked annually and she should be refitted if she has a weight gain or loss of 15 pounds or more or if she delivered a pregnancy beyond 20 weeks of gestation.

The properly fitted diaphragm lies securely just posterior to the symphysis pubis and deep into the vaginal cul-de-sac behind the cervix. The largest diaphragm that comfortably fills this space is selected. Fitting is best performed using actual diaphragms of the various sizes rather than

rings that do not have the same spring and arching characteristics as actual diaphragms. In addition, teaching is much more effective if diaphragms are used for the fitting: the patient can see the actual arching, can observe the location of the dome of the cup, and can be instructed in the amount and placement of the spermicidal gel or cream. The arching spring diaphragm (e.g., All-flex) is the type most commonly fitted due to its generally predictable placement deep into the vagina around the cervix and secure location behind the symphysis pubis. Instructions to the woman should be clear and complete, including:

- The diaphragm should be inserted 6 hours or less before intercourse and left in place at least 6 hours afterward. An additional application of spermicide should be used for each coitus, but the diaphragm should not be removed.
- The upper edge of the diaphragm should fit securely posterior to the symphysis as determined by palpation and the cervix be covered by the membrane of the diaphragm as determined by palpation. The woman should not feel discomfort when standing or walking if the insertion has been performed properly, and she should be able to void easily.
- The instructions supplied by the manufacturer should be carefully read and studied. She should be asked about any unanswered questions and advised to return if she has any uncertainty about correct placement.

Spermicidal Foam

Spermicidal foam has a theoretic failure rate of 3 per 100 woman years but in actual use the rate is reported to be as high as 20-30/100 woman years. The foam acts both as a mechanical block against the passage of sperm and as a chemical spermicide. One to two applicators full should be inserted high into the vagina up to one half hour before coitus and the dose should be repeated after each coital exposure. Douching should be avoided for 8 hours. While some couples may object to the messiness or bad taste, this method requires no prescription, it adds lubrication for coitus, increases the effectiveness of condoms, and decreases the risk for acquiring a sexually transmitted disease. It can be used as an immediate backup method if a condom breaks.

Condoms

Condoms also have an excellent theoretic effectiveness rate (2.6/100 woman years) but in actual use the pregnancy rate is higher. The condom must be rolled onto the erect penis before the penis enters the vagina and the base of the condom should be held while withdrawing from the vagina after ejaculation. Condoms should not be reused, they should not be lubricated with petroleum jelly, and their effectiveness can be increased by using contraceptive foam, as well. If a condom breaks during use, an applicator full of contraceptive foam should immediately be inserted into the vagina. This method requires no prescription, has minimal risk for side effects, is readily available and clearly reduces the risk of acquiring a sexually transmitted disease. Currently the breakage rate is greater with non-latex polyurethane condoms, but product development is being further refined so as to decrease this rate of breakage. Latex and polyurethane condoms provide greater protection against STDs including HIV/AIDS than do natural membrane condoms. A couple relying on condoms for contraception should consider having emergency contraception such as Plan B or Preven readily available for this eventuality.

SURGICAL STERILIZATION

Sterilization by vasectomy or by bilateral tubal occlusion (ligation, clipping, banding, cauterization, transcervical microinserts (Essure), etc.) has become the most popular method of contraception in the United States among couples who have been married for more than 10 years. Aside from the initial risks of the surgical procedure there are no long-term sequelae of this method. A man

maintains his potency and a woman continues to ovulate and menstruate normally.

Expert, sensitive counseling is essential before a sterilizing operation. The patient should be fully aware that the decision to be sterilized is completely up to the individual, that the procedure is permanent and should be considered irreversible, and that there are other temporary methods of birth control available. The Indian Health Service, in compliance with the Department of Health and Human Services' regulations, requires the following:

- Hysterectomy cannot be used for sterilization alone.
- The individual must be at least age 21 and mentally competent.
- Consent cannot be obtained if the individual is under the influence of drugs and is in the hospital for abortion or labor and delivery.
- The designated consent forms must be signed at least 30 days and no more than 180 days before the sterilizing operation is performed. In the case of premature delivery or emergency abdominal surgery, at least 72 hours must elapse.
- If an interpreter has been used for obtaining a person's consent for sterilization, the interpreter must certify that the required information has been translated and the individual understands the proposed procedure.

INTRAUTERINE DEVICE

The intrauterine device (IUD) has the highest continuation rate (75%) of any of the prescription methods of contraception currently in use in the IHS and tribal settings. It is effective, with a pregnancy rate of <1 per 100 woman-years of use for the CuT-380A, and it is safe when the patient is *carefully selected*, the IUD is *properly inserted*, and the patient is *appropriately monitored* for possible side effects.

Medicated IUDs have an advantage of being smaller in size, and thus are less likely to cause excessive vaginal bleeding and possibly less likely to lead to infection complications than did earlier IUDs. The CuT-380A depends on the presence of copper for effectiveness, and Mirena depends on the very slow release of levonorgestrel, respectively, from the device. The CuT-380A must be replaced every ten years and Mirena every five years.

Patient Selection

Careful patient selection, counseling, and follow-up are essential in order to minimize the risk for serious complications with the IUD.

Contraindications

- Nulliparity (relative contraindication).
- Pregnancy, known or suspected.
- Abnormal uterus.

  A cavity that sounds less than 6.5 cm deep is smaller than the longitudinal diameter of the IUD. A cavity, which is distorted by congenital anomaly, large fibroids, polyps, etc., is not likely to tolerate the presence of an IUD. Previous cesarean delivery is <u>not</u> a contraindication to the use of an IUD.
- Past history of uterine or tubal infection.

  A <u>past</u> history of an asymptomatic positive culture for gonorrhea or chlamydia, properly treated, is not a contraindication.
- Carcinoma of the uterus or cervix.

  An abnormal Pap test should be evaluated and treated prior to insertion. If an abnormal

Pap is found while the IUD is in place, it can usually be evaluated and treated without removal of the IUD.

- Previous ectopic pregnancy.

  Since the IUD is associated with an increased probability of ectopic pregnancy if a pregnancy occurs, it is best to avoid its use in patients already predisposed to another ectopic pregnancy.
- Allergy to copper (for CuT-380A).

Insertion of an IUD

A complete gynecologic examination must be performed prior to inserting an IUD. The size and position of the uterus must be accurately determined—**if these cannot be determined with certainty, the patient should be referred to an Obstetrician-Gynecologist for further management.*** It is advised that IUDs used under the above guidelines and precautions should be prescribed and inserted only by an experienced clinician. In addition, the patient must be fully counseled about her chosen method of contraception including the anticipated benefits and possible risks *and* ***this counseling should be documented carefully in the clinical records*****.** The patient should sign the acknowledgment that she has read the FDA-required information and the acknowledgment should be affixed to her clinical record.

In general an IUD should be inserted at the time of the normal menses because it is technically easier and the patient is unlikely to be pregnant. An IUD may be inserted immediately after an uncomplicated first trimester abortion and 6-8 weeks after an uncomplicated delivery or a cesarean section. Since expulsion of the device is most common in the first month of use, an additional method of contraception such as foam or condoms may be recommended, as well. Manufacturers have very specific documentation requirements for counseling of patients who are considering the use of their IUD. Clinicians who plan to insert an IUD must meet very specific training and experience requirements as detailed in the accompanying literature.

Complications of Use

Even with the most careful patient selection and appropriate follow-up, complications can arise from the use of an IUD. Recommended follow-up includes a pelvic examination approximately 6 weeks after insertion and then annually thereafter.

Pregnancy ***

- Risk approximately 0.5-1% per year
- If IUD is in place and strings are visible, the IUD must be removed because of increased risk of infection and abortion: 40-50% will abort spontaneously if IUD remains in place. 20% will abort if IUD is removed.
- If strings are not visible, consider whether the IUD was expelled or pulled up into the pregnant uterus, or the uterus perforated. If pregnancy is still desired, the IUD may be left in place, but the patient must be very carefully counseled about the increased risk of infection.
- Always be alert to increased relative risk for ectopic pregnancy (1:20 pregnancies with IUD in place).

Bleeding, Pain

- Responsible for 50 percent of all discontinuations of IUD use.
- Rule out other causes of abnormal bleeding, such as infection or endometrial pathology.
- Pain (not controlled by mild analgesics), and excessive bleeding (beyond the spotting expected in the first 3 months of use) are indications for removal of IUD.

*Infection**

- Salpingitis risk is increased 3-5 fold in nulliparous women under the age of 25 with multiple sexual partners. The risk is not increased in multiparous women with a single partner.
- Women using an IUD are 60 percent more likely to develop salpingitis when exposed to gonococcus than nonusers who are exposed.
- If mild endometritis or salpingitis occurs, obtain a cervical culture, consider removal of device (authorities disagree whether removal is mandatory), and treat with an appropriate antibiotic orally.
- If severe endometritis or salpingitis (with any peritonitis), hospitalize, obtain routine, gonococcus and chlamydia cervical cultures, blood culture, treat with parenteral antibiotics and remove the device. (Authorities disagree whether IUD should be removed immediately or after antibiotics have been given, but it is probably best to start the antibiotics first.)
- Long-term users are at an increased risk for Actinomyces infection, which then can result in tuboovarian abscesses. If Actinomyces is found on Pap smear in an asymptomatic patient, the IUD can be removed and the Pap repeated in 1-2 months. If Actinomyces persists, then treat with oral penicillin for 4 weeks. Alternatively, the IUD can be left in place and the patient treated with Pen-V-K 250 mg tid for 2–4 weeks and then repeat the Pap. If symptomatic, treat as above.
- Patients with artificial heart valves should be considered for prophylactic antibiotics prior to insertion of IUD.

*Perforation of Uterus **

- Uterine perforation occurs in from 1:200 to 1:1000 insertions. Risk is minimized although not eliminated by proper insertion technique.
- Since copper is very tissue reactive, a perforated CuT-380A should be removed as soon as possible. Non-copper devices should be removed soon after the diagnosis, as well.
- Perforated non-copper IUD can usually be removed by laparoscopy. Copper IUDs will often require laparotomy for removal.

Expulsion

- Expulsion occurs most commonly in the first 3 months after IUD is inserted. One third go unnoticed. One third of IUD users who become pregnant do so after unnoticed expulsion.
- If strings are not visible and no history of expulsion: *
  1. Rule out pregnancy
  2. Explore cervical canal with Cytobrush or Kelly or Bozeman type clamp to try to retrieve the strings.
  3. Sound cervical canal and uterus. If IUD is felt, remove it using IUD extractor. If it is not felt, obtain X-ray or ultrasound to rule out expulsion or perforation. D&C or hysteroscopy may be needed.

* Indicates consultation with a qualified family practitioner or obstetrician-gynecologist and/or referral to an ob-gyn for management is indicated.

COMMON PROBLEMS WITH AN IUD AND THEIR MANAGEMENT

Complaint	What It May Be Due To	Management
Cramps and spotting	The effects of insertion. (If this occurs days or weeks after insertion, the uterus is trying to expel the device.)	Perform bimanual and speculum examination. If there is no pain when the uterus and adnexae are palpated, no masses felt, bloody secretions not malodorous, and no IUD on sounding only the cervical canal, reassure the patient, give analgesics (especially an NSAID) for cramps and advise patience for a few more weeks.
	Infection	* If there is tenderness of the uterus and/or adnexae or a mass in the pelvis, consult OB/GYN for confirmation of findings and treatment. Obtain cultures. Remove IUD. Pre-scribe antibiotics. Admit if peritonitis, pelvic mass or fever.
Bleeding prolonged postmenstrually or off and on between the menses. (menometrorrhagia)	IUD may be partially expelled or lodged in the cervical os.	Perform bimanual and speculum examination. Rule out pregnancy. Are the strings too long? Is the device protruding from the os? Grasp the cervix with tenaculum. Insert the uterine sound one inch into the cervix. Do you contact the device in the os? If so, remove IUD and insert another one if the patient desires it. If there is bleeding and pain, delay for one month and reinsert if desired.
	Incomplete abortion	* History of menses delayed, scanty or missed? Perform bimanual examination. Uterus enlarged? Soft? Os open? Urine for pregnancy test. R/O septic abortion. Remove IUD, complete the abortion, and prescribe antibiotics.

COMMON PROBLEMS WITH AN IUD AND THEIR MANAGEMENT		
Complaint	What It May Be Due To	Management
	Pelvic Inflammatory Disease	Perform bimanual and speculum examination. Pain when uterus is palpated? When cervix is manipulated? Adnexal tenderness or masses? Fecal odor to bloody discharge? Remove IUD, prescribe tetracycline if mild, Admit, IV antibiotics if fever, mass, or peritonitis.
	Cervical Erosion	Post coital bleeding or spotting? Polyps or erosion seen on speculum examination? Dyspareunia? Descensus of the uterus? Cervix sensitive to touch? Cervix bleeds on contact? Take Pap smear and gonorrhea culture. Treat cervicitis next visit. Prescribe clindamycin cream or metronidazole gel in the interim.
Low back pain with or without symptoms	Uterine Contractions	Is the uterus tender? Increased discharge? Bleeding between periods? Remove IUD.
	Menstrual Discomfort	Only during menses and since IUD was inserted? Due to contractions of the uterus. Advise moderate exercise and mild analgesics, especially an NSAID. If incapacitating, may have to remove IUD.
	Straining, sprains Back injuries	History of orthopedic trauma? If so and no GYN pathology is detected, refer for orthopedic evaluation.

COMMON PROBLEMS WITH AN IUD AND THEIR MANAGEMENT

Complaint	What It May Be Due To	Management
	Gonorrhea	Contact with an infected partner? Does partner have discharge or has recently been treated for one? Urinary symptoms? Vaginal discharge? Speculum examination, culture for gonorrhea, bimanual examination, "milk" the urethra for discharge. If positive for gonorrhea, prescribe penicillin and provide prophylaxis against chlamydia. Treat contacts.
	Genitourinary disease	History or genitourinary disease, kidney stones or gravel? Urinary symptoms? Costovertebral angle tenderness? Lower abdominal pain? Obtain midstream, clean catch urine specimen for analysis, culture and sensitivity. Prescribe antibiotics. Follow-up appropriately.
Excessive menses with or without clots	Presence of IUD	How long has the problem been going on? Recent insertion of IUD, or has IUD been in place for a long time? How many sanitary pads are used in one day? Are they soaked? Perform bimanual and speculum examination. Rule out any other pelvic pathology. If insertion of IUD is within the last three months, see if she can bear IUD for another few months. Test hemoglobin and hematocrit to rule out anemia. Remove IUD if patient and/or partner are unwilling to cope with it or if this problem arises more than 6 months after insertion. If patient reports only 1 episode and no other pathology detected, reassure her that it is possible to have excessive menses without an IUD. If it recurs, reevaluate. Use of an NSAID at the time of menses will often reduce the amount of flow.

COMMON PROBLEMS WITH AN IUD AND THEIR MANAGEMENT

Complaint	What It May Be Due To	Management
	Pelvic pathology: Leiomyomata, Endometrial polyps, Endometrial hyperplasia, Pelvic infection.	* Consult an ob-gyn if gyn pathology is suspected or or detected.
Delayed menses or Amenorrhea	Pregnancy	Take an *accurate* history. Blood or urine for pregnancy test. Perform speculum examination. Does IUD appear to be in situ? Strings visible? If positive pregnancy test remove IUD. Rule out ectopic pregnancy.
	Other causes	See text chapters on amenorrhea, breast disease and lactation, menopause, etc. for recommended management. If no pathology or untoward history, leave IUD in place. If pregnancy test is negative, repeat in two weeks. Consult OB/GYN for further management or referral.
Vaginal discharge	Vaginal Infection	Perform speculum examination. Culture for gonorrhea and chlamydia. Specimen of discharge on slide for wet smear. Microscopic examination for diagnosis of discharge. Treat appropriately. See text chapter on vaginitis. Leave IUD in place.
	Endometritis and/or Parametritis	Perform bimanual examination for the detection of pelvic masses or tenderness of the uterus and/or adnexae. If no pathology is detected clinically, microscopically, or by culture, and excessive vaginal secretions are present, they are most likely due to the presence of the device.

COMMON PROBLEMS WITH AN IUD AND THEIR MANAGEMENT

Complaint	What It May Be Due To	Management
Weight loss or weight gain	Not caused by the IUD	Evaluate for dietary habits, stress and other health problems.
Dyspareunia	IUD may be partially or completely expelled and lodged in the cervical canal or vagina.	Does patient feel hard plastic when she places her finger in her vagina? Is partner complaining about discomfort during coitus? Perform speculum examination. Are strings too long? Is the IUD partially out of the cervix or "floating" freely in the vagina? If no suspicion of pregnancy, grasp cervix with a tenaculum and pass a uterine sound into the cervix to see whether you contact it in the cervix. Perform bimanual examination to feel for the device in the cervix. Explore the vagina for the device. The blade of the speculum may have trapped it against the vaginal wall. Remove and reinsert.
	Vaginitis or other pathology	Perform bimanual examination. Manage according to findings.
	Marital or sexual problems	Investigate possible causes for marital or sexual discord such as another partner, alcoholism, drugs, employment, lack of privacy, foreplay, interest, personal hygiene, etc. Rule out vaginismus.
	Diseases of neighboring organs in abdomen or pelvis	Reproduce pain on bimanual examination. Workup for pelvic inflammatory disease, bowel disease, bladder infection, etc.
Cannot feel strings	Need instruction on where to feel for strings	Advise on correct positioning of body and fingers to find the strings. If unwilling to touch her genitalia, ask partner to search for strings.
	Strings not visible on speculum examination	See pregnancy, perforation of the uterus and expulsion of IUD in this text, above.

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American College of Obstetricians and Gynecologists web site contains extensive patient-oriented materials and the members-only side includes access to all ACOG publications and a robust search engine for full literature reviews. http://www.acog.org

Association of Reproductive Health Professionals web site contains extensive information for both health care providers and for patients on the public side of their web site. Resources include their newsletter and several slide presentations. Additional information is available on the AHRP members-only side of their web site. http://www.arhp.org