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# Non-oral contraception

**Stephanie Gibson, PharmD, BCPS, Sharon Lee Witt, DO**

*From Doctors Hospital Family Practice, OhioHealth, Grove City, OH.*

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Oral contraceptives are not appropriate for all women and their efficacy is hindered by many factors, including adverse effects and patient compliance. In the past, the oral route was the most popular method for contraception. Today, the routes and methods of contraception are varied, ranging from hormonal and non-hormonal options to surgical procedures and over-the-counter products. Increased efficacy of all forms can be obtained through patient education; thus, the primary care physician should be knowledgeable on all available methods.


Oral contraceptive pills (OCPs) are widely used by female patients to prevent pregnancy because of their ease of use. However, as with any contraceptive method, efficacy can be compromised and result in an unexpected pregnancy. Gilliam et al report that more than one million unintended pregnancies result from OCP method failure, misuse, and discontinuation.[1] Even in women who use OCPs exactly as prescribed (later referred to as "perfect use"), approximately 1% will still have an unintended pregnancy during the first year of use; with "typical use," that number increases to 8%.[2] Missed doses, taking the dose at the wrong time of day, or discontinuation because of side effects all contribute to the failure rate of oral contraceptives.

Since 2000, new delivery methods for providing contraception have become available to women searching for alternatives to the oral route. Whether hormonal or nonhormonal, permanent or temporary, prescription or over-the-counter, a wide variety of options exist to prevent unplanned pregnancy Prescription options available to provide temporary contraception include injectable hormones, a vaginal ring, a transdermal patch, a subdermal implant, and intrauterine devices. Male and female sterility procedures can be performed to provide a permanent and reliable method of contraception for those pursuing that option. Barrier methods include condoms, diaphragms, and cervical caps. Additional methods include spermicide, sponges, and natural family planning (NFP). When choosing a contraceptive option, it is important to consider the desired duration of contraception as well as the current age and concurrent disease states of the female patient.

Regardless of the method selected, each one has an inherent decrease in effectiveness from perfect to typical use. Table 1 illustrates these differences.[3] In an attempt to decrease this disparity and ultimately reduce the number of unintended pregnancies, the family physician needs to be prepared to fully counsel patients on all methods of birth control. Each contraceptive method should be discussed with the patient to select the method that will best suit her family planning desires. Counseling should address the correct usage of the selected method, including proper use of back-up methods.

## Hormonal contraceptive: intramuscular or subcutaneous injection

One of the oldest and most popular non-oral methods of contraception among women is an injectable progestin-only option, depot medroxyprogesterone acetate (DMPA).[4] It is available in two formulations: 150 mg intramuscular injec-

Corresponding author: Stephanie Gibson, PharmD, BCPS, Doctors Hospital Family Practice, OhioHealth, 2030 Stringtown Road, Suite 300, Grove City, OH 43054.
E-mail address: sgibson@OhioHealth.com.

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**Table 1** Non-oral contraceptive efficacy

| | Typical use | Perfect use |
|---|---|---|
| Spermicides | 29 | 18 |
| Natural family planning | 25 | — |
| Sponge | — | — |
| Parous | 32 | 20 |
| Nulliparous | 16 | 9 |
| Diaphragm | 16 | 6 |
| Cervical cap[19] | — | — |
| Parous | 32 | 26 |
| Nulliparous | 16 | 9 |
| Male condom | 15 | 2 |
| Female condom | 21 | 5 |
| Ortho Evra | 8 | 0.3 |
| NuvaRing | 8 | 0.3 |
| DMPA | 3 | 0.3 |
| IUD | — | — |
| Paragard | 0.8 | 0.6 |
| Mirena | 0.2 | 0.2 |
| Implanon | 0.05 | 0.05 |
| Female sterilization | 0.5 | 0.5 |
| Male sterilization | 0.15 | 0.10 |

Numbers reflect the percentage of women with unintended pregnancy in the first year of typical and perfect use.[3]

tion, Depo-Provera; or 104 mg subcutaneous injection, depo-subQ provera-104.

The efficacy of DMPA is a result of the accurate timing of the injections.[4] The initial dose should be administered within five days of the beginning of a normal menstrual cycle and is then immediately effective for contraception. Subsequent doses should be administered at 12-week intervals, although they can be safely administered between 11 and 13 weeks after the previous dose. When a woman presents after 13 weeks, a negative pregnancy test should be confirmed before the administration of the dose. At this time, the patient should be reminded that pregnancy is a possibility and should be instructed to use a barrier method of contraception for the following three to five days.[4]

The most common side effect reported with DMPA is abnormal bleeding within the first several months. However, after three years of DMPA use, 80% of women report complete amenorrhea.[4] Other common side effects include weight gain, nausea, increased or decreased hair growth, acne, and headache.

In 2004, the Food and Drug Administration (FDA) issued a warning regarding the use of DMPA correlated to a decrease in bone mineral density (BMD), especially in adolescents. However, clear recommendations to minimize the risk of decreasing BMD were not established. Currently, the World Health Organization and the American College of Obstetricians and Gynecologists state that DMPA is an effective and safe long-term method of contraception and do not suggest limits for the amount of time women can use DMPA. Both groups recommend that women use normal lifestyle modifications to prevent the development of decreased bone mass, including appropriate calcium and vitamin D intake, weight-bearing exercises, and smoking cessation.[4,5] The rate of unintended pregnancy in the first year of typical use is 3%.[3]

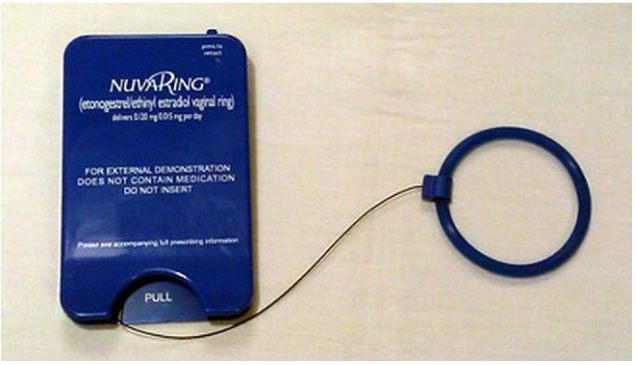


**Figure 1** NuvaRing patient education device. This latex-free, flexible ring has a cross-sectional diameter measuring 54 mm.[6]

## Hormonal contraceptive: intravaginal ring

In 2001, Schering-Plough/Organon introduced the first intravaginal contraceptive ring (NuvaRing), a combination hormonal agent containing etonogestrel (ETO) and ethinyl estradiol (EE) (Fig. 1). The ethylene-vinyl copolymer ring delivers 15 $\mu$g EE/120 $\mu$g ETO per day over a three-week period. The ring is inserted intravaginally, worn for three weeks, and removed on the fourth week to allow for menses. A new ring must be inserted no more than seven days later even if menstrual bleeding has not yet ceased.

The most common side effects reported with NuvaRing are very similar to those seen with combination oral contraceptives and include headache, nausea, breast tenderness, leukorrhea, and vaginitis. There are also some side effects specific to intravaginal ring use such as ring expulsion, foreign body sensation, and coital problems.

Ring expulsion is a common side effect and may decrease efficacy if it is not replaced in a timely manner. If the ring falls out before the three weeks have passed, it should be reinserted within three hours of expulsion to minimize the risk of pregnancy.[6] If the ring has been expelled for more than three hours and it is during weeks one or two of use, a secondary form of contraception should be used for seven days. If the ring is expelled for more than three hours during week three of use, the woman has two choices: (1) She can either immediately insert a new ring for 21 days, or (2) she can leave the ring out for seven days and then insert a new ring. The second method allows for breakthrough bleeding to occur. To minimize the chance for pregnancy, the manufacturer recommends the use of either a condom or spermicide as a backup method until the new ring has been inserted for seven consecutive days.[6]

Compared with other hormonal contraceptives for women, NuvaRing seems to be an effective and acceptable

contraceptive vaginal device with good cycle control, tolerability, and a safety profile, offering an alternative option for many women.[7] When used as prescribed, the ring is very effective at preventing conception, with a failure rate of 8% with typical use.[8]

## Hormonal contraceptive: transdermal patch

Ortho Evra is a contraceptive transdermal patch for women that has been available from Ortho-McNeil-Janssen Pharmaceuticals since 2002. This patch contains 0.75 mg of EE and 6 mg of norelgestromin. The patch is applied to a clean, dry area on the upper arm, upper back, buttocks, chest, or abdomen. It should not be placed on or near the breasts. Timing is important, because the patch must be applied on either the first day of the menstrual cycle or the first Sunday after the onset of menses. The day the patch is applied is referred to as the "Patch-change day." The same patch is worn for one week at a time, removed, and a new patch applied, for a total of three weeks. After the three "on weeks," the next week is the "patch-free week" for the hormone-free period.[9] It is recommended to rotate sites with each patch application to avoid skin irritation. The most common reported side effects of the patch include breast discomfort—both engorgement and pain—as well as nausea, headache, and skin irritation at the site of patch placement.[9]

When comparing Ortho Evra's pharmacokinetic profile with that of oral contraceptives, Ortho Evra demonstrates a higher steady state concentration and a lower peak concentration. Because of the increased steady state concentration of EE, it has been discussed that Ortho Evra may be linked to a higher occurrence of thromboembolic events. However, recent studies have shown that the risk of thrombosis with the patch is similar to that of combination oral contraceptives.[10] In 2005, the United States FDA updated labeling on the contraceptive patch to include a warning on increased estrogen levels; and in 2008,[11] they updated labeling again to include an increased risk of thrombosis while using the product.[12] Studies regarding cycle control and efficacy have shown the patch to be comparable with combination oral contraceptives, but exceeding the oral alternative in terms of patient compliance.[13]

**Table 2** Instructions for proper patch maintenance after patch detaches from the body[13]

| |
|---|
| *If patch has been off for less than 24 hours*: reapply old patch to the same location or replace it with a new patch immediately. "Patch change day" stays the same. No back-up contraceptive method needed. |
| *If patch has been off for greater than 24 hours:* apply a new patch immediately. This restarts your contraceptive cycle and becomes your new "Patch-change day." Back-up barrier contraceptive must be used for the first 7 days of the cycle. |

The failure rate of Ortho Evra is similar to other non-oral contraceptive options; one of 100 women will have an intended pregnancy within one year of typical use.[9] Like all medications, educating the patient on proper placement, duration, and expected side effects will decrease the likelihood of failure.

Questions often arise about the use of Ortho Evra during periods of heat, humidity, and exercise based on it being a topical product. Abrams et al concluded that the patch maintained its adhesion and consistent hormone levels during these conditions.[14] If the patch does fall off, educating the patient on the proper procedure for re-application will improve efficacy. Refer to Table 2 for patient education regarding patch placement after it has fallen off.

Specific instructions exist in the medication package insert to guide the physician and patient if the Ortho Evra patch is left in place for longer than seven days because this increases the risk of pregnancy.[9] When this occurs during the first week of the cycle, a new patch should be applied immediately and a back-up method—barrier or spermicidal—used for seven days. This is now the "Patch-change day." If the first or second patch of the cycle is left in place for longer than seven days but less than 48 hours longer than recommended, it should be replaced immediately and worn for the duration of the original cycle. Back-up contraception is not necessary in that scenario. If the third patch of the "patch cycle" is left in place more than seven days, it should be removed as soon as the patient remembers. The patient should remain patch free until the next scheduled "patch-cycle" begins. Back-up contraception is not needed.[9]

In clinical trials, a statistically significant increase in pregnancies occurred in patients with a baseline body weight of more than 198 pounds.[9] Because of this, the manufacturer does not recommend its use in patients who weight more than 198 pounds, or 90 kg.[9] With perfect use of the patch, the percentage of unintended pregnancy is less than 1%, and it is 8% with typical use, similar to the vaginal ring.[3]

## Hormonal contraceptive: subdermal implant

Implanon is a single rod, progestin-only subdermal implant placed in the upper arm that releases ETO daily. It inhibits ovulation and increases the viscosity of cervical mucous, thereby preventing implantation. Implanon must be inserted and removed by a physician trained by the manufacturer to perform the procedure. One of the most common and bothersome side effects is irregular bleeding. As with all hormonal contraceptive options, Implanon should not be used in women with undiagnosed abnormal uterine bleeding or hormone-related breast cancers. Because it does not contain estrogen, it is considered a good option for women with cardiovascular risk factors such as past history of deep vein thrombosis, hypertension, or smoking, and women who

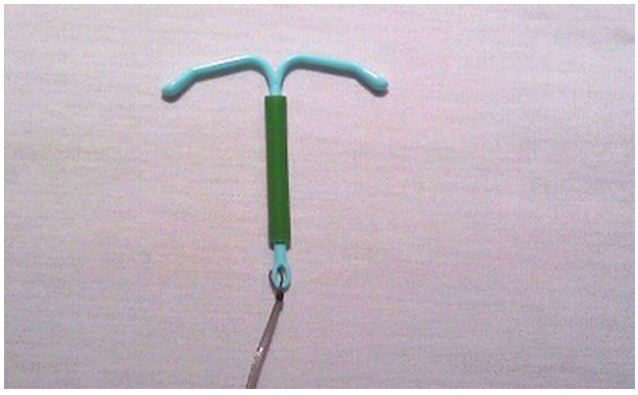

**Figure 2** Mirena patient education device. The stem of this T-shaped device contains a sleeve holding 52 mg levonorgestrel, releasing 20 $\mu$g daily into the uterine cavity.[16]

have migraine headaches.[15] Progestin only contraceptives are also recommended in lactating women because it should not affect the woman's milk supply.[15] The product is effective for three years and its contraceptive effects are quickly reversible after its removal. According to Trussell, it has the lowest pregnancy rate of the options discussed, approaching 0.05%.[3]

## Intrauterine devices: hormonal or nonhormonal devices

Two intrauterine devices (IUDs) are currently available in the United States—the levonorgestrel-containing IUD, Mirena, and the copper-containing IUD, Paragard. They are suitable choices for women who have completed their families and are in monogamous relationships, but their use is not limited to this population. Side effects of IUDs include expulsion, perforation (during insertion), and infections (in the uterus or fallopian tubes), which are more common during the first 20 days after insertion. Therefore, it is recommended to recheck the IUD up to four weeks after insertion.[15] If pregnancy occurs while an IUD is in place, it is more likely that it will be an ectopic pregnancy, and therefore any signs or symptoms of pregnancy should be evaluated quickly and thoroughly in a woman with an IUD.

The hormonal levonorgestrel IUD, Mirena, releases progestin locally to thicken cervical mucous and thin the endometrium. Although the exact mechanism of action has not yet been determined, it is better established that the abortifacient effect (thinning of the endometrium to prevent implantation of a fertilized ovum) is less likely than the prevention of fertilization.[16] Mirena can be left in place for up to five years. The rate of pregnancy is 0.2% during the first year of use (Fig. 2).[3]

The copper T380A IUD, Paragard, releases a small amount of copper to prevent fertilization and implantation. Side effects of Paragard include increased menstrual bleeding, which can contribute to anemia, and most practitioners recommend annual check of hemoglobin levels to recognize this possible side effect.[15] Paragard has the longest period for use and is effective for up to 10 years. The rate of pregnancy in the first year of use is 0.6 to 0.8%.[3]

Evaluation of the patient and her long-term family planning goals will aid in the selection of the appropriate agent. Because of the increased risk of thromboembolic events in female patients over the age of 35 years, estrogen-containing contraceptives are not recommended if these patients smoke or have high blood pressure.[17] For these patients, it would be prudent to select Implanon or an IUD. NuvaRing and Ortho Evra are good options in younger patients who do not desire long-term contraception, because the duration of both products is easily controlled by the user and easily reversible when pregnancy is desired. The Paragard IUD is a good option for patients who do not want hormone-related side effects and desire long-term contraception. All of these factors need to be considered when making a decision. For patients who want permanent contraceptive options, male and female surgical options exist to meet their needs.

## Surgical options

Sterilization provides permanent life-long contraception. It is available to both sexes through female tubal ligation or male vasectomy. Because of the permanent nature of sterilization and the risk of regret, patients must first be counseled on the decision to undergo a sterilization procedure. Historically, it was common practice to limit tubal ligation to patients who had already had children, to avoid later regret. It has since been shown that nulliparity or having only one child is not correlated with later regret and therefore is not a reason to deny the procedure.[18] Most insurance companies have implemented policies that require the surgical consent to be signed by the patient within a determined time frame from the procedure date to be covered. Tubal ligation is the most widely used form of contraception in the United States.[18] It is possible through a variety of techniques including partial salpingectomy, obstruction with clips or coils (Essure), or obstruction via coagulation. The procedures can be performed laproscopically, hysteroscopically, or by an open method, and can be done under local, regional, or general anesthesia, so they do carry the risk of the anesthesia-related side effects. The method chosen is usually based on the expertise and preference of the surgeon.[15] Pregnancy rates are less than 1 in 100 during the first year after the procedure.[3]

Vasectomy is the sterilization procedure available to men. Men should be counseled regarding the permanency of the procedure, although the odds for a successful reversal are about 50%.[15] Vasectomies can be performed in the practitioner's office under local anesthesia within 20 minutes. Peak efficacy is not reached until two to three weeks post-procedure and a follow-up is needed to obtain a sperm count to ensure the procedure was successful. The preg-

nancy rate is 0.10% to 0.15% for male sterilization as contraception.[3]

## Condoms

Male condoms are the most commonly used barrier method in the United States[19] and are the most readily available without a prescription. They are available in latex, polyurethane, or animal membrane (usually lamb cecum). The latex and polyurethane variety of condoms have the added benefit of considerable protection against sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV).[20] Effectiveness is dependent on the user; therefore, it should be recommended for more mature and highly motivated individuals who understand that sexual activity will be interrupted for placement. A new condom should be put on correctly before every sexual encounter, with attention paid to the reservoir tip so that the space is maintained at the tip of the penis and not taut against the skin. Patients should be instructed on how to properly remove a condom while the penis is still erect by holding the base of the condom during withdrawal.[20] Only water-based lubricants should be used in conjunction with condoms to reduce breakage and slippage. Rates of pregnancy during the first year of use range from a high of 15% with typical use to a low of 2% when used perfectly.[3]

Female condoms are also available over the counter. They should be recommended to sexually active females who cannot trust that their partners will always wear a male condom. They can be inserted up to eight hours before intercourse. The female condom is a polyurethane sheath with a flexible ring on each end. The closed ring is fitted under the symphysis and the open ring outside the vagina. They are not to be used concurrently with a male condom because of the increased risk of breakage, and therefore a higher failure rate. Female condoms also have the added benefit of protecting against viruses including HIV. The percentage of unintended pregnancy within the first year of use is 5% for perfect use and 21% with typical use; these percentages are slightly higher compared with the use of male condoms.[3]

## Spermicide

Spermicides—nonoxynol-9 or octoxynol-9—are available in suppository, foam, cream, jelly, and film preparations. Timing of placement is dependent on the preparation, so the package insert for the particular product should always be read and its directions followed. Typically, the effective time is no more than one hour.[15] Spermicide is placed high inside the vagina close to the cervix. Spermicide can be used with all barrier methods except for the sponge, which inherently contains it. Frequent use may cause vaginal tissue disruption and thus increase the risk of transmission of STDs.[20] Spermicide alone is effective 18% to 29% of the time.[3]


**Figure 3** Diaphragm fitting rings.

## Diaphragm

The diaphragm is currently a lower-yield barrier method for contraception. It is best suited for patients who are monogamous, more highly educated, at a lower risk for STDs, and desire female-controlled and -initiated contraception. The dome-shaped device requires a prescription and a fitting by a physician (Fig. 3). Diaphragm fitting rings (60–90 mm in size) can usually be obtained from the manufacturer. However, the fitting procedure also may be performed using a series of fitting diaphragms, each with a hole in the middle of the dome.[21] The diaphragm is placed up in the vagina, covering the cervix and resting against the pubic bone, similar to the female condom. It is used with spermicide, positioned on the cervix up to six hours before intercourse and left in place for six to eight hours post coitus. It should not be used during menstruation and should be replaced every two years. It is contraindicated in patients with a history of toxic shock syndrome. The diaphragm does have a slightly increased rate of urinary tract infections and may not be suitable for patients with significant pelvic organ prolapse.[15] It requires special attention for washing, storing, and checking monthly. The rate of effectiveness is similar to male condoms with typical use.[3]

## Cervical cap

The cervical cap is similar to a diaphragm but can be left in the vagina six to 48 hours after intercourse. It has more of a cup shape and adheres directly to the cervix via suction compared with a diaphragm. It also requires a prescription and fitting. The rates of pregnancy with the diaphragm and cervical cap are similar in nulliparous women. After parity, however, the use of the cervical cap has a dramatic increase in the rate of pregnancy during the first year of use, from 16% to 32% with typical use and 9% to 26% with perfect use.[22]

## Sponge

The sponge is a disk containing nonoxynol-9 that is wet with tap water before insertion and has a loop attached for easy retrieval. It can be reused for up to 24 hours and left in place for six to 24 hours, but it should not be used during menstruation. It is available over the counter, and its effectiveness, like that of the cervical cap, also varies based on parity. In the nulliparous female, rates of pregnancy within the first year of use are 16% in typical use and 9% for perfect use. These rates increase approximately twofold with parity.[3]

## Natural family planning

Natural family planning is also known as the *rhythm method* or *fertility awareness*. NFP requires that a woman recognize the signs of ovulation and abstain from sex during the fertile period or use another method of contraception during that time. There are multiple methods by which this can be accomplished: cervical mucous, basal body temperature, calendar, symptothermal methods, and lactational amenorrhea.

Women may learn to identify changes in the cervical mucous throughout the menstrual cycle. Mucous may change from thin and watery at the beginning of her cycle to thick just after ovulation. Sexual intercourse should be limited to four days after the peak day of thin watery secretions until the end of the dry days, after menstruation.

Basal body temperature (BBT) can also be measured, with an increase in temperature signaling ovulation. Abstinence or a back-up method is then used from the end of menstruation until three days after the rise in temperature is noted.

The calendar method tracks a woman's cycle over six months to predict the time of ovulation during a typical cycle, and sexual intercourse is avoided during that time.

The symptothermal method combines checking for cervical mucous changes, BBT, and symptoms of ovulation including abdominal pain or cramps, spotting, and changes in the position and firmness of the cervix. Again, on the basis of these findings, sexual intercourse is avoided during the fertile period.

Finally, lactational amenorrhea is natural contraception that occurs while a woman is lactating and ovulation ceases. The time between feedings should not be more than every four hours during the day and every six hours at night. It is effective for six months after delivery with a 2% chance of pregnancy during that time.[15]

These methods should be taught to the patient by a medical professional and require consistency for effectiveness.[18] In a study by Stanford et al, it was found that most of the physicians included in the study did not teach NFP methods to women, with only 11% mentioning it routinely; and that the physicians underestimated the effectiveness of the modern method during their discussions with patients. Thirty percent of the physicians, including general practitioners, family practice, internal medicine, and obstetric-gynecology physicians, stated that they would refer to a NFP instructor if the patient requested information on methods of NFP.[23]

The most common reason for failure of this method is a reduction in spontaneous sexual intercourse. Other factors that may decrease efficacy include change in body temperature because of illness, restless sleep, varying wake-sleep schedules, mucous changes caused by medications (antibiotics, thyroid medications, antihistamines, etc.), cervicitis or vaginitis, and menstrual irregularities. Pregnancy rates vary and approach 25% when the NFP is used.[3]

With so many options for birth control available, it should not be difficult to find a contraceptive option suitable for each and every patient. Newer agents are being tested and will expand the patients' choices even more. Merkatz et al discuss many different choices in development.[24] For example, nestorone (NES), a norprogesterone derivative that prevents ovulation, is currently being studied in combination with estrogen, in many various delivery systems: a vaginal ring containing NES and EE to be used for 13 cycles, NES/E skin spray to be used daily, and NES/EE daily skin gel.[24]

All of the contraceptive options discussed are only effective when used appropriately by the patient. Therefore, patient education is an important component of contraceptive use and should always include a description of the product, expected adverse events, and appropriately timing of each each dose/use. Special instructions exist to cover any situation that may arise that may cause a decrease in the efficacy of the products; however, patients should do their part as well to avoid these situations. For example, initiating and discontinuing Ortho Evra and NuvaRing on the appropriate day and receiving DMPA injections within the recommended time frame helps to maintain efficacy of each product. Even in male patients who undergo vasectomy, the importance of appropriate medical follow-up and sperm sample analysis cannot be stressed enough. Furthermore, patient education should include a reminder that most of these products do not protect against STDs, which is sometimes assumed by the patient. Patients who report having more than one sexual partner should be encouraged to use condoms with every sexual encounter to decrease the transmission of STDs, regardless of any other contraceptive method used.

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