

Barrier Methods

Q.1. Are there any risks to a fetus conceived while using spermicides or due to spermicide use during pregnancy for sexually transmitted disease (STD) prevention?

Recommendations	Rationale
<p>The weight of the evidence is that there is no risk to the fetus from spermicide exposure.</p>	<p>The active ingredient in most spermicide products, nonoxynol-9 (N-9), is absorbed in small quantities from the vagina during use. No adverse systemic effects from N-9 have ever been shown in women. One study found that users of spermicide products containing nonoxynol-9 or octoxynol had a higher risk of congenital malformations in pregnancies conceived during use than did non-users. But several subsequent studies on spermicide use and birth defects have not shown any association, and researchers do not believe that spermicide use has any adverse effects on the fetus.</p> <ol style="list-style-type: none"><li data-bbox="824 1129 1430 1226">1) Jick H, Walker AM, Rothman KJ, Hunter JR, Holmes LB, Watkins RN, et al. Vaginal spermicides and congenital disorders. <i>Journal of the American Medical Association</i> 1981;245:1329-32.<li data-bbox="824 1230 1430 1306">2) Simpson J, Phillips O. Spermicides, hormonal contraception and congenital malformations. <i>Advances in Contraception</i> 1990;6(3):141-67.<li data-bbox="824 1310 1430 1402">3) Einarson TR, Koren G, Mattice D, Schechter-Tsafiriri O. Maternal spermicide use and adverse reproductive outcome: a meta-analysis. <i>American Journal of Obstetrics and Gynecology</i> 1990;162:655-60.

Q.2. How often can spermicide be used in a given time period?

Recommendations	Rationale
<p>a) Continued spermicide use as frequently as once or twice a day may cause some tiny breaks in the vaginal lining, whereas use every other day does not cause significant irritation. If irritation is detected upon examination and if a reasonable alternative is available, then the client should be advised to discontinue the spermicidal product until healing is complete.</p>	<p>a) The active ingredients of most spermicide products are surfactants that disrupt cell membranes of spermatozoa, pathogens and genital epithelium. In one study of frequent nonoxynol-9 (N-9) insertion, erythema and microscopic epithelial lesions were equally frequent among women inserting N-9 every other day as among placebo users. The rate of irritation was twice as high among women inserting N-9 once or twice daily, and five times higher among women inserting four N-9 suppositories daily than among placebo users. Similar findings have been reported in a World Health Organization (WHO) sponsored study of the spermicide menfegol.</p> <p>Experts fear that the epithelial lesions of spermicide-associated irritation may increase the risk of contracting human immunodeficiency virus (HIV) infection if exposure to HIV occurs. This has not been demonstrated in a human study, but it is plausible, and local irritation should be avoided.</p> <ol style="list-style-type: none">1) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal of STDs and AIDS</i> 1993;4:165-70.2) Goeman J, Ndoye I, Sakho LM, Mboup S, Piot P, Karam M, et al. Frequent use of menfegol spermicidal vaginal foaming tablets associated with a high incidence of genital lesions. <i>Journal of Infectious Diseases</i> 1995;171:1611-4.

Recommendations	Rationale
<p>b) Discomfort with spermicide use is uncommon when used at typical family planning (FP) frequencies of once per day or less. If discomfort is reported, a different spermicide product with different ingredients may solve the problem. If discomfort persists, a different contraceptive method is indicated.</p>	<p>b) In studies of spermicide use (approximately one to two times per day) for FP purposes, roughly 5% to 10% of women have symptoms of discomfort after use. The clinical significance of discomfort is unclear, because discomfort is a self-perceived problem and it may not be correlated with signs of vaginal or cervical irritation detected during examination.</p> <ol style="list-style-type: none">1) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal STD & AIDS</i> 1993;4:165-70.2) Feldblum P, Morrison C, Roddy R, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.
<p>c) A woman should insert a new dose of her spermicide product before each act of intercourse. Furthermore, a woman should insert a new dose of spermicide if intercourse takes place an hour or more after initial insertion.</p>	<p>c) In order to be effective, the spermicide must be high in the vagina near the cervix, with a sufficient concentration of the active ingredient. Due to different delivery formulations, some products leak down toward the vulva more quickly than others; some spread better than others. Manufacturers of suppositories, gels and film generally claim that their product is effective for up to one hour after insertion, but the period of effectiveness might be longer. Since spermicides are typically less effective in preventing pregnancy than other methods, it is prudent to insert a new dose for each intercourse.</p> <ol style="list-style-type: none">1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. Vaginal spermicides. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:179-90.

**Q.3. Do spermicides protect one against:
a) pregnancy? b) HIV/AIDS? c) other STDs?**

Recommendations	Rationale
<p>a) Against pregnancy?</p> <p>Yes. Spermicides can be fairly protective for pregnancy prevention as long as they are used correctly and consistently. However, with typical use, spermicides provide much less protection against pregnancy than with perfect use.</p>	<p>a) The failure rates of spermicides in the first year of use range from 6% with perfect use to 21% with typical use. These rates are similar to those for the diaphragm and female condom.</p> <p>1) Trussell J, Kost K. Contraceptive failure in the United States: a critical review of the literature. <i>Studies in Family Planning</i> 1987;18(5):237-83.</p>

Recommendations	Rationale
<p>b) Against HIV/AIDS?</p> <p>Possibly. Spermicides are not generally recommended for human immunodeficiency virus (HIV) prevention.</p> <p>However, for sexually active women who cannot use male or female condoms, a spermicide product may be preferable to unprotected intercourse, unless there are multiple acts of intercourse per day.</p>	<p>b) Little research has been done on spermicide use and HIV risk, and the findings of the only two published studies conflict. In one study, nonoxynol-9 (N-9) contraceptive sponge users had a higher incidence of HIV infection. In the second study, N-9 suppository users had a lower incidence of HIV. Until large randomized studies currently under way can resolve the controversy, spermicide alone cannot currently be recommended for HIV prevention.</p> <p>Theoretically, spermicides may reduce the incidence of HIV indirectly by preventing bacterial STD co-factors. Spermicides have also been shown to have direct effects on HIV in vitro.</p> <ol style="list-style-type: none"> 1) Kreiss J, Ngugi E, Holmes K, Ndinya-Achola J, Waiyaki P, Roberts PL, et al. Efficacy of nonoxynol-9 contraceptive sponge use in preventing heterosexual acquisition of HIV in Nairobi prostitutes. <i>Journal of the American Medical Association</i> 1992;268:477-82. 2) Zekeng L, Feldblum PJ, Godwin SE, Oliver RM, Kaptue L. HIV infection and barrier contraceptive use among high-risk women in Cameroon. <i>AIDS</i> 1993;7:725-31. 3) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). <i>American Journal of Public Health</i> 1994;84:1032-4. 4) Centers for Disease Control. Update: barrier protection against HIV infection and other sexually transmitted diseases. <i>MMWR</i> 1993;42:589-91 and 597. 5) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93. 6) Jennings R, Clegg A. The inhibitory effect of spermicidal agents on replication of HSV-2 and HIV-1 in vitro. <i>Journal of Antimicrobial Chemotherapy</i> 1993;32:71-82. <p>The highest risk of sexually acquired HIV infection is associated with unprotected intercourse. Women need methods to protect themselves against HIV and other STDs, even if protection is only partial.</p> <ol style="list-style-type: none"> 1) Rosenberg MJ, Gollub EL. Methods women can use that may prevent sexually transmitted disease, including HIV (commentary). <i>American Journal of Public Health</i> 1992;82:1473-8. 2) Elias CJ, Heise LL. Challenges for the development of female-controlled vaginal microbicides. <i>AIDS</i> 1994;8:1-9.

Recommendations	Rationale
<p>c) Against other STDs?</p> <p>Yes, spermicides are modestly protective against cervical gonorrhea and chlamydia, compared to users of no method. While the level of protection may not be great, it may offer some protection that women can themselves control.</p> <p>The effectiveness of any coital-dependent method (i.e., one that must be applied at or around the time of intercourse) depends on the consistency and correctness of use. For these methods, acceptability and compliance are as important, if not more so, as their effectiveness during perfect use. Even if a female method is less efficacious than the male condom during perfect use, it may have a greater impact on disease rates if it is used more consistently. Consistent condom with spermicide use may be more effective.</p>	<p>c) Spermicides have been shown to provide protection against some bacterial STDs. Studies with different kinds of participants and different study designs have consistently demonstrated that spermicide use reduces the number of new gonorrheal and chlamydial infections. One study found an overall reduction in gonorrhea of about 50% in nonoxynol-9 users, but that figure includes both consistent and correct users as well as inconsistent users. A greater reduction was found in the most consistent users of the spermicide. Another study found a 25% reduction overall in nonoxynol-9 users. In studies that have compared bacterial STD risk among women relying on male condoms to those using a spermicidal method, the risks were about the same for infections. Most likely, the spermicides were used more consistently than were male condoms.</p> <ol style="list-style-type: none">1) Niruthisard S, Roddy RE, Chutivongse S. Use of nonoxynol-9 and reduction in rate of gonococcal and chlamydial cervical infections. <i>Lancet</i> 1992;339:1371-5.2) Weir SS, Feldblum PJ, Zekeng L, Roddy RE. The use of nonoxynol-9 for protection against cervical gonorrhea. <i>American Journal of Public Health</i> 1994;84:910-4.3) Louv W, Austin H, Alexander W, Stagno S, Cheeks J. A clinical trial of nonoxynol-9 for preventing gonococcal and chlamydial infections. <i>The Journal of Infectious Diseases</i> 1988;158(3):518-22.4) Rosenberg M, Rojanapithayakorn W, Feldblum P, Higgins J. Effect of the contraceptive sponge on chlamydial infection, gonorrhea, and candidiasis: a comparative clinical trial. <i>Journal of the American Medical Association</i> 1987;257:2308-12.

Q.4. How soon postpartum or postabortion can spermicides be used?

Recommendations	Rationale
<p>According to the World Health Organization (WHO) Eligibility Criteria, spermicides can be used any time postpartum or postabortion.</p> <p>Although some providers recommend that spermicide should not be used until six weeks after delivery or abortion, and after healing and uterine involution are complete, there is no evidence to support this practice.</p>	<p>Use of a spermicide by breastfeeding women both prior to and after six weeks postpartum and use after a first, second or post septic-abortion are WHO Category 1. Thus, the WHO recommends the use of spermicides in any of these circumstances. By extrapolation, nonbreastfeeding women can use spermicides any time postpartum as well.</p> <p>1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p>

Q.1. Do condoms protect against STDs/HIV/AIDS?

Recommendations	Rationale
<p>a) Male condoms?</p> <p>Yes, couples who use the male latex condom correctly and consistently have a lower risk of acquiring all sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), compared to non-users. The average reduction is about 50%, although recent studies of HIV show that protection with consistent condom use can be close to 100%.</p>	<p>a) All studies have found that male latex condom users have a lower risk of STD than non-users. The overall risk reduction appears to be about 50%, but that figure is a gross estimate that includes consistent and correct users as well as inconsistent users. In Thailand, a condom-only campaign in brothels is associated with population-based reductions in gonorrhea and HIV rates.</p> <p>Full-time latex condom users may reduce their risk to near-zero. A multi-center Italian study followed seronegative female sexual partners of HIV-infected men for a median of 24 months. The HIV incidence rate was reduced by 90% in women whose partners always used condoms compared with women whose partners used them inconsistently or never; women whose partners were inconsistent condom users did not benefit.</p> <p>In a multi-country European collaborative study, about half of 343 couples used condoms at every coital act, and no new HIV infections occurred among the consistent users. For the couples who used condoms inconsistently, new HIV infections occurred at the rate of 4.8 per 100 per year, even though 50% of the inconsistent users reported using condoms at least half the time. These two studies show that consistent condom use is highly effective protection against HIV transmission, but that inconsistent use carries considerable risks of HIV infection.</p> <p>1) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.</p>

Recommendations	Rationale
<p>b) Female condoms?</p> <p>If used correctly and consistently, the female condom should be very effective in preventing STDs (including HIV), but this has not been confirmed in human use studies.</p>	<p>2) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84.</p> <p>3) Hanenberg RS, Rojanapithayakorn W, Kunasol P, Sokal DS. Impact of Thailand's HIV-control programme as indicated by the decline of sexually transmitted diseases. <i>Lancet</i> 1994;344:243-5.</p> <p>4) Saracco A, Musicco M, Nicolosi A, Angarano G, Arici C, Gavazzeni G, et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. <i>Journal of Acquired Immune Deficiency Syndrome</i> 1993;6:497-502.</p> <p>5) de Vincenzi I, for the European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. <i>New England Journal of Medicine</i> 1994;331(6):341-6.</p> <p>b) Only one cross-sectional study of the female condom and STD re-occurrence has been done. Women with trichomoniasis were treated, enrolled and followed for 45 days. Consistent users had no re-infections, while 14% of inconsistent users and non-users were re-infected. The plastic membrane of the female condom is impermeable to HIV and other STD organisms, so the device may reduce the risk of HIV and other STDs in consistent users.</p> <p>1) Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. <i>Sexually Transmitted Diseases</i> 1993;20:137-9.</p> <p>2) Drew WL, Blair M, Miner RC, Conant M. Evaluation of the virus permeability of a new condom for women. <i>Sexually Transmitted Diseases</i> 1990;17:110-2.</p>

Q.2. Where may condoms be made available and how many can be provided?

Recommendations	Rationale
<p>Condoms may be made available anywhere. The greater the number of condom distribution outlets- e.g., clinics, pharmacies, street kiosks, community-based services (CBS) programs- the more accessible the devices will be.</p> <p>In clinic contexts, it may be best to allow the client to determine how many condoms the client needs. If the clinic's supply is limited, the number of condoms given should be based on client's projected need and distance from the clinic.</p>	<p>Condoms are generally not abused or used for anything besides sexual intercourse. If in doubt, a clinic should offer too many condoms rather than too few. Even if some devices are re-sold or otherwise distributed, they promote public health.</p>

Q.3. Can condoms (male and female) be re-used?

Recommendations	Rationale
a) Male condoms should not be re-used.	a) The re-use of male condoms cannot be recommended until further research is completed. Anecdotal reports suggest that re-use of male condoms is associated with higher breakage rates. The latex membranes are generally not strong enough to withstand repeated stretching, friction and cleaning. 1) Steiner M, Piedrahita C, Glover L, Joanis C. Can condom users likely to experience condom failure be identified? <i>Family Planning Perspectives</i> 1993;25:220-3,226.
b) Studies are underway, but currently re-use of female condoms is not recommended.	b) The re-use of female condoms is not currently recommended, pending further research. However, anecdotal reports from acceptability studies show that a minority of women use female condoms more than once. Re-use has not been associated with higher breakage rates; female condom breakage is rare in general. Research is currently under way to determine whether re-use reduces the structural strength of the device (increases breakage) and/or increases the risk of communicating sexually transmitted diseases.

Q.4. When should the condom be put into place?

Recommendations	Rationale
<p>a) Male condoms should be put on after erection and before genital and/or anal contact.</p> <p>b) The female condom should be put into place any time before the penis touches the vagina in order to prevent exposure to pre-ejaculate and semen.</p>	<p>a-b) Although viable sperm are generally absent from pre-ejaculatory fluid, human immunodeficiency virus (HIV) is present in the pre-ejaculate of HIV-positive men. Thus the pre-ejaculate may transmit disease, and the condom should be in place before genital contact occurs.</p> <p>1) Ilaria G, Jacobs JL, Polsky B, Koll B, Baron P, MacLow C, et al. Detection of HIV-1 DNA sequences in pre-ejaculatory fluid (letter). <i>Lancet</i> 1992;340:1469.</p> <p>2) Pudney J, Oneta M, Mayer K, Seage G III, Anderson D. Pre-ejaculatory fluid as potential vector for sexual transmission of HIV-1 (letter). <i>Lancet</i> 1992;340:1470.</p>

Q.5. Does providing condoms in more than one size reduce slippage and breakage?

Recommendations	Rationale
<p>No. There is no evidence that different sizes will reduce breakage and slippage.</p> <p>There is no need to provide more than one size latex condoms.</p>	<p>Some condom users complain of condoms being too small or too large, and some researchers have presumed that breakage could be minimized if condoms were made in different sizes. One study evaluated breakage rates and acceptability of larger (55 mm flat diameter) and smaller (49 mm) condoms against the industry standard condom (52 mm). In three countries, breakage rates were 5.5% and 7.4% for the standard and larger devices, respectively. In three other countries, breakage rates were under 5% and similar for the standard and smaller condoms; slippage rates were also similar. Further, condom size had a minimal impact on device acceptability. Certain individuals might benefit from different condom sizes, but the impact has not been demonstrated, and it is not justified for a program to invest in multiple condom sizes.</p> <p>1) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Research Triangle Park, NC: Family Health International, 1994.</p>

Q.6. Should latex condoms be used with oil-based lubricants?

Recommendations	Rationale
<p>a) No. Latex condoms should not be used with oil-based lubricants or products that have an oil as a major ingredient. Oils weaken condoms and can increase the risk of breakage.</p> <p>Clients who use condoms should be counseled on what locally available non-oil-based lubricants are appropriate with condom use.</p> <p>Some substances which cause deterioration of latex condoms within an hour of exposure are mineral oil, baby oil, petroleum jelly, suntan oil, olive oil, peanut oil, corn oil, sunflower oil, palm oil, margarine, coconut oil, dairy butter, insect repellents, burn and hemorrhoidal ointments, rubbing alcohol, cod oil and shark oil. Lubricants which contain these products should not be recommended for use with latex condoms.</p> <p>Other products that weaken latex condoms are specific vaginal creams, vaginal spermicides and sexual lubricants. Some of the brands that were identified as harmful to condoms are:</p> <ul style="list-style-type: none"> ● vaginal creams (Monistat, Estrace, Femstat, Vagisil, and Premarin); ● vaginal spermicides (Rendell's Cone and Pharmatex Ovule); and ● sexual lubricants (Elbow Grease, Hot Elbow Grease, and Shaft). <p>b) Products that are considered water-based have not been shown to be harmful to condoms. Water-based lubricants may reduce the risk of condom failure.</p>	<p>a) Mineral oil has been shown to weaken latex condoms significantly with an exposure time of 60 seconds.</p> <p>Studies have found that some condom users think products which wash off easily with water are water-based and therefore, acceptable to use with condoms. However, several of the lotions that clients labeled as water-based contained mineral oil as a main ingredient.</p> <ol style="list-style-type: none"> 1) Voeller B, Coulson A, Bernstein G, Nakamura R. Mineral oil lubricants cause rapid deterioration of latex condoms. <i>Contraception</i> 1989;39(1):95-102. 2) Tests show commonly used substances harm latex condoms. <i>Contraceptive Technology Update</i> 1989;10(2):20-21. 3) Hatcher RA, Trussell J, Stewart F, Stewart G, Kowal D, Guest F, et al. Condoms. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:145-78. <p>b) One study found lower condom failure rates when condoms were used with water-based lubricants. However, more research is needed.</p> <ol style="list-style-type: none"> 1) Gabbay M, Gibbs A. Does additional lubrication reduce condom failure? <i>Contraception</i> 1996;53:155-8.

Q.1. Does one size of a diaphragm or cervical cap fit all?

Recommendations	Rationale
<p>a) Diaphragms?</p> <p>No, diaphragms have to be fitted, and a variety of sizes need to be available where this method is offered.</p>	<p>a) Two studies of a Nonspermicidal Fit-Free Diaphragm (60 mm) have been done. The first report, an analysis of past diaphragm use, found the Pearl pregnancy rate to be 1 per 100 woman-years. In the second, a prospective non-randomized trial, the 12-month life table pregnancy rate was 24.1 per 100 women, and the high failure rate led to early termination of the study. The effectiveness of this modified approach to diaphragm use has not been confirmed.</p> <ol style="list-style-type: none">1) Stim EM. The nonspermicide fit-free diaphragm: a new contraceptive method. <i>Advances in Planned Parenthood</i> 1980;15(3):88-98.2) Smith C, Farr MG, Feldblum PJ, Spence A. Effectiveness of the non-spermicidal fit-free diaphragm. <i>Contraception</i> 1995;51:289-91.
<p>b) Cervical caps?</p> <p>No, currently available cervical caps must be fitted, and a variety of sizes need to be available where this method is offered.</p>	<p>b) Until one-size-fits-all caps are available, fitting caps to each client is recommended. New cervical barrier devices have been devised, at least one of which is one-size-fits-all, and human use studies are under way.</p> <ol style="list-style-type: none">1) Hunt WL, Gabbay L, Potts M. Lea's Shield, a new barrier contraceptive preliminary clinical evaluations three-day tolerance study. <i>Contraception</i> 1994;50:551-61.2) Mauck C, Glover L, Miller E, Allen S, Archer D, Blumenthal P, et al. Lea's Shield: a study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. <i>Contraception</i> 1996;53:329-35.

Q.2. Are there any restrictions to use of a diaphragm or cervical cap based on the number of births a woman has had?

Recommendations	Rationale
<p>a) Diaphragms?</p> <p>No. Women with any number of births can use the diaphragm. The fit of the device should be checked after delivery or second trimester abortion, however.</p>	<p>a) Since the diaphragm comes in sizes from 50 mm to 105 mm in different models, almost all vaginas can be accommodated. The size and muscle tone of the upper vagina can change after pregnancy, though, so a new device may be needed.</p> <p>It is unclear whether the effectiveness of the diaphragm varies according to parity. In one large study of diaphragm users, parous women had a lower pregnancy rate than nulliparous women; in another, the rate among parous women was higher than that in nulliparous women. Parous women do not need to be advised that they are at higher risk of pregnancy.</p> <ol style="list-style-type: none"> 1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222. 2) Trussell J, Strickler J, Vaughan B. Contraceptive efficacy of the diaphragm, the sponge and the cervical cap. <i>Family Planning Perspectives</i> 1993;25:100-5, 135.
<p>b) Cervical caps?</p> <p>No. Women of any parity can use the cervical cap, but the fit of the device should be checked after delivery or second trimester abortion. Parous women who use cervical caps tend to have a much higher pregnancy rate than nulliparous women users.</p>	<p>b) The cervical cap comes in four sizes: 22, 25, 28 and 31 mm. Most women can be fitted properly, but perhaps 10% of prospective users cannot be fit and must use a different method.</p> <p>In a large clinical trial, the pregnancy rate was substantially higher among parous women than nulliparous women for both typical and perfect use.</p> <ol style="list-style-type: none"> 1) Secor RMC. The cervical cap. <i>NAACOG's Clinical Issues</i> 1992;3(2):236-45. 2) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222. 3) Trussell J, Strickler J, Vaughan B. Contraceptive efficacy of the diaphragm, the sponge and the cervical cap. <i>Family Planning Perspectives</i> 1993;25:100-5, 135.

Q.3. How soon postpartum or postabortion can a diaphragm or cervical cap be used?

Recommendations	Rationale
<p>The diaphragm and the cervical cap should not be used until six weeks after delivery (vaginal or cesarean) or second trimester abortion and healing is complete. Re-fitting may be necessary at that time (re-fitting is not necessary after a first trimester abortion).</p> <p>If intercourse occurs prior to six weeks, the use of another appropriate method (i.e., condom) should be recommended.</p>	<p>The shape of the cervix, the size of the vaginal vault, and vaginal muscle tone may change after pregnancy and delivery or after second trimester abortion. It takes four to six weeks for the uterine involution to be complete, and bleeding/spotting can continue for up to eight weeks as well (cap use is contraindicated during bleeding).</p> <p>Additionally, there is marked weight loss after delivery, and many providers recommend re-fitting after a weight loss of more than seven kilograms.</p> <ol style="list-style-type: none">1) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.2) World Health Organization. <i>Improving access to quality care in family planning: medical eligibility criteria for contraceptive use</i>. Geneva: WHO, 1996.3) Wiley A. The diaphragm. In: Corson S, Derman R, Tyrer L, editors. <i>Fertility Control</i>. Boston: Little, Brown & Company, 1985:223-32.4) Secor RMC. The cervical cap. <i>NAACOG's Clinical Issues</i> 1992;3(2):236-45.

Q.4. Is pregnancy prevented if the diaphragm is used without spermicide?

Recommendations	Rationale
<p>Yes, but not as effectively as with spermicide.</p> <p>Until better data on contraceptive effectiveness refute the traditional recommendations, users should be advised to add spermicide to fitted diaphragms.</p>	<p>Two studies of non-fitted diaphragms without spermicide had conflicting results. Research on fitted diaphragm use without spermicide are also conflicting. In a retrospective review of patient records, women using fitted diaphragms continuously (removing them only to wash) without spermicide had a lower pregnancy rate than did women following the traditional instructions. In a randomized trial comparing fitted diaphragm use with versus without spermicide, the typical use and perfect use pregnancy rates were lower in the diaphragm with spermicide group, but the study was small and the difference was not statistically significant.</p> <p>Some providers believe that spermicide cost, messiness and potential for irritation have resulted in poor compliance, and recommend diaphragm use without spermicide in an effort to enhance acceptability. But another important attribute of the diaphragm is that diaphragms used with spermicide protect against cervical infections and that spermicide use may reduce the risk of human immunodeficiency virus infection. If spermicide use is partly responsible for reducing the risk of sexually transmitted disease infection in women using diaphragms, it would be a disservice to instruct women to omit spermicide.</p> <ol style="list-style-type: none">1) Ferreira AE, Araujo MJ, Regina CH, Diniz SG, Faundes A. Effectiveness of the diaphragm, used continuously, without spermicide. <i>Contraception</i> 1993;48:29-35.2) Stim EM. The nonspermicide fit-free diaphragm: a new contraceptive method. <i>Advances in Planned Parenthood</i> 1980;15(3):88-98.

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| | <ul style="list-style-type: none">3) Smith C, Farr G, Feldblum PJ, Spence A. Effectiveness of the non-spermicidal fit-free diaphragm. <i>Contraception</i> 1995;51:289-91.4) Bounds W, Guillebaud J, Dominik R, Dalberth BT. The diaphragm with and without spermicide: a randomized, comparative efficacy trial. <i>Journal of Reproductive Medicine</i> 1995;40:764-74.5) Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. <i>International Journal of STD & AIDS</i> 1993;4:165-70.6) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84. |

Q.5. How long must a woman wait after the last act of intercourse to remove the diaphragm or cervical cap?

Recommendations	Rationale
<p>Diaphragm and cervical cap users should wait at least six hours after intercourse before removing the device or douching.</p> <p>Upon removal, diaphragms should be washed (and dried prior to storing).</p>	<p>Spermatozoa remain viable in the vagina for several hours, but the great majority of sperm cells that are capable of entering the cervix do so within two hours post-ejaculation.</p> <p>Nonoxynol-9 (N-9) spermicide can retain its contraceptive effect for a longer time: more than a day inside a cervical cap, and 12 hours inside a diaphragm. The optimum time that diaphragms and caps should remain in place has not been tested, and in the absence of evidence to the contrary, the traditional six-hour recommendation is a sensible compromise.</p> <ol style="list-style-type: none">1) Overstreet JW, Katz DF, Yanagimachi R. Sperm transport and capacitation. In Sciarra JJ (editor). <i>Gynecology and Obstetrics</i>. Philadelphia: J.B. Lippincott Co., 1994.2) Leitch WS. Longevity of Gynol II and Ortho Creme in the Prentif cervical cap. <i>Contraception</i> 1986;34(4):363-79.3) Leitch WS. Longevity of Ortho Creme and Gynol II in the contraceptive diaphragm. <i>Contraception</i> 1986;34(4):381-93.4) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.

Q.6. Should a diaphragm user insert extra spermicide before having a second intercourse?

Recommendations	Rationale
<p>Yes, a diaphragm user should insert a new dose of spermicide before each episode of intercourse. A woman should insert a new dose of spermicide if intercourse takes place six hours or more after diaphragm insertion.</p>	<p>No research has been done to compare diaphragm users who insert more spermicide before a second episode of intercourse, and those who do not. Nonoxynol-9 (N-9) spermicide may retain its contraceptive effect for more than a day inside a cervical cap, and for 12 hours inside a diaphragm, but the impact of multiple ejaculations on N-9 potency is not known. In the absence of concrete data, it is prudent to insert a new dose of spermicide for each intercourse.</p> <ol style="list-style-type: none">1) Leitch WS. Longevity of Gynol II and Ortho Creme in the Prentif cervical cap. <i>Contraception</i> 1986;34(4):363-79.2) Leitch WS. Longevity of Ortho Creme and Gynol II in the contraceptive diaphragm. <i>Contraception</i> 1986;34(4):381-93.3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.

Q.7. Does use of a diaphragm or cervical cap increase the risk of urinary tract infections?

Recommendations	Rationale
a) Yes, diaphragm use increases the risk of urinary tract infections (UTI).	<p>a) Most studies have found that diaphragm users develop UTI at a rate two to three times higher than non-diaphragm users. However, it is not understood why this is the case. Foreplay and intercourse seem to introduce <i>E. coli</i> bacteria into the vagina. The spermicide, and probably the diaphragm itself, encourages vaginal and urethral colonization of the <i>E. coli</i>.</p> <p>Several approaches may solve the UTI problem. Urination just before and just after intercourse may offer some protection. Wearing the diaphragm for less time may help. A smaller device, or a different rim style, may relieve pressure on the urethra. Switching to a cervical cap may be an option that retains many of the same advantages as the diaphragm.</p> <ol style="list-style-type: none">1) Foxman B, Chi J-W. Health behavior and urinary tract infection in college-aged women. <i>Journal of Clinical Epidemiology</i> 1990;43(4):329-37.2) Hooton TM, Hillier S, Johnson C, Roberts PL, Stamm WE. <i>Escherichia coli</i> bacteriuria and contraceptive method. <i>Journal of the American Medical Association</i> 1991;265(1):64-9.3) Hatcher RA, Trussell J, Stewart F, Stewart GK, Kowal D, Guest F, et al. The diaphragm, contraceptive sponge, cervical cap and female condom. In: <i>Contraceptive Technology</i>. New York: Irvington Publishers, 1994:191-222.
b) There is no evidence that the cervical cap increases the risk of UTI, although it may do so.	<p>b) Since there are relatively few cervical cap users, it is difficult to study side effects of cap use. Since the cervical cap shares with the diaphragm the feature of extended spermicide exposure, it is possible that cap use will increase the risk of UTI to a similar extent.</p> <ol style="list-style-type: none">1) Hooton TM, Hillier S, Johnson C, Roberts PL, Stamm WE. <i>Escherichia coli</i> bacteriuria and contraceptive method. <i>Journal of the American Medical Association</i> 1991;265:64-9.

**Q.8. Diaphragm or cervical cap protect against:
a) HIV/AIDS? b) other STDs?**

Recommendations	Rationale
<p>a) Against HIV/AIDS?</p> <p>Possibly. Diaphragms and caps, even with spermicides, cannot be currently recommended for human immunodeficiency virus (HIV) prevention. Diaphragm use may indirectly reduce the incidence of HIV, however, by preventing bacterial sexually transmitted disease (STD) co-factors which increase the risk of HIV transmission.</p> <p>For sexually active women who cannot use male or female condoms, a diaphragm, cap with spermicide, or spermicide alone, is unlikely to be riskier than completely unprotected intercourse and may help prevent upper reproductive tract infections (RTI).</p>	<p>a) The effectiveness of the diaphragm and cap against HIV is not known. Much depends on the site of infection; if the portal of virus entry is the cervix, the diaphragm and cap should confer good protection. Until the effectiveness of nonoxynol-9 (N-9) spermicide is established, diaphragm or cap use with N-9 spermicide cannot be recommended for HIV prevention.</p> <ol style="list-style-type: none">1) Stein ZA. More on women and the prevention of HIV infection (editorial). <i>American Journal of Public Health</i> 1995;85(11):1485-8.2) Centers for Disease Control. Update: barrier protection against HIV infection and other sexually transmitted diseases. <i>Morbidity and Mortality Weekly Report</i> 1993;42:589-91, 597. <p>The highest risk of sexually acquired HIV infection is associated with unprotected intercourse. Women need methods to protect themselves against HIV and other STDs, even if protection is only partial.</p> <ol style="list-style-type: none">1) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). <i>American Journal of Public Health</i> 1994;84:1032-4.2) Rosenberg MJ, Gollub EL. Methods women can use that may prevent sexually transmitted disease, including HIV (commentary). <i>American Journal of Public Health</i> 1992;82:1473-8.3) Elias CJ, Heise LL. Challenges for the development of female-controlled vaginal microbicides. <i>AIDS</i> 1994;8:1-9.

Recommendations	Rationale
<p data-bbox="196 216 532 247">b) Against other STDs?</p> <p data-bbox="196 275 727 415">Probably. Users of diaphragms (and probably cervical caps) with spermicides probably have a modestly lower risk of gonorrhea and chlamydia than non-users.</p>	<p data-bbox="776 216 1422 1409">b) Diaphragm use has been found to reduce the risk of bacterial STD and pelvic inflammatory disease (PID). One study found a 60% reduction in the risk of PID in diaphragm users compared to women using no contraceptive method. The overall reduction of bacterial cervical infections from spermicide use alone is about 25-50%, but that figure is a gross estimate that includes consistent and correct users as well as inconsistent users. Thus, use of spermicides with diaphragms or cap may reduce the risk of cervical infections. In studies of bacterial STDs among diaphragm users and women whose partners used male condoms, diaphragm users had lower STD risk than women depending on their partners' use of a male condom. The effectiveness of any coital-dependent method (i.e., one that must be applied at or around the time of intercourse) depends on the consistency and correctness of use. For these methods, acceptability and compliance are as important, if not more so, as their efficacy in preventing disease. Even if a female method is less efficacious than the male condom, it may have a greater impact on disease rates if it is used more consistently. Since the diaphragm is a method that combines a physical barrier (the latex or silicon device) and a chemical barrier (the spermicide), it may be more effective than spermicide alone, although there are no data to confirm this.</p> <ol data-bbox="821 1415 1422 1791" style="list-style-type: none">1) Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part 1. <i>Family Planning Perspectives</i> 1992;24:75-84.2) Kelaghan J, Rubin GL, Ory HW, Layde PM. Barrier-method contraceptives and pelvic inflammatory disease. <i>Journal of the American Medical Association</i> 1982;248(2):184-7.3) Austin H, Louv WC, Alexander WJ. A case-control study of spermicides and gonorrhea. <i>Journal of the American Medical Association</i> 1984;251:2822-4.4) Feldblum PJ, Morrison CS, Roddy RE, Cates W Jr. The effectiveness of barrier methods of contraception in preventing the spread of HIV. <i>AIDS</i> 1995;9(Suppl A):S85-S93.5) Cates W Jr, Hinman AR. AIDS and absolutism--the demand for perfection in prevention (sounding board). <i>New England Journal of Medicine</i> 1992;327:492-4.

Q.1. What should be the role of barrier methods in family planning/reproductive health programs?

Recommendations	Rationale
<p>Barrier methods should be part of the method mix in all family planning/reproductive health (FP/RH) clinics. The advantages of barrier methods, such as sexually transmitted disease (STD) protection, should be emphasized to providers and clients, as well as the importance of correct and consistent use to achieve pregnancy protection. Barrier methods provide less protection against pregnancy and STDs with typical use.</p> <p>Barrier methods should be presented to clients equally with other methods, allowing the client to choose the method most suitable for him or her.</p>	<p>Many users of FP are at risk of contracting STDs including human immunodeficiency virus (HIV), yet are unable to avoid their risky sexual encounters and so need preventive methods. Barrier methods are the only class of FP methods that protect users against STDs. A second reason that barrier methods are important is that some people in need of FP are not medically eligible to use, or unwilling to use, hormonal methods, intrauterine devices (IUDs), natural family planning or surgical contraception.</p> <p>Yet anecdotal evidence points to provider bias against barrier methods. Providers may perceive barriers to be ineffective; they may also worry about the time required for client education, motivation and fitting (in the case of the diaphragm and cervical cap).</p> <p>While the typical effectiveness of barrier methods is indeed less than that of hormonal methods and IUDs, for consistent and correct users, barrier method effectiveness is quite high. Although some barrier methods do require more time with new acceptors, the potential benefits of STD prevention, and communication with sexual partners are considerable.</p> <ol style="list-style-type: none"> 1) Cervical cap: effective, convenient, but overlooked. <i>Contraceptive Technology Update</i> 1990;11:49-54. 2) Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. <i>Family Planning Perspectives</i> 1994;26:66-72. 3) Norsigian J. Feminist perspective on barrier use. In: Mauck CK, Cordero M, Gabelnick HL, Spieler JM, Rivera R (editors). <i>Barrier contraceptives: current status and future prospects</i>. New York: Wiley-Liss, 1994. 4) Feldblum P, Joanis C. Modern barrier methods: effective contraception and disease prevention. Research Triangle Park, NC: Family Health International, 1994.

Classification of Selected Procedures for Barrier Methods

Procedure	Class	Class	Class	Rationale
	DIAPHRAGM	CONDOM	SPERMICIDE	
Pelvic examination (bimanual and speculum)	A	C	C	<ul style="list-style-type: none"> • A pelvic exam is required for diaphragm/cap fitting. • A pelvic exam is not required for safe use of other barrier methods.
Blood pressure	C	C	C	Barrier method use does not affect blood pressure ¹ .
Breast examination	C	C	C	Barrier method use does not affect breast cancer risk ¹ .
STD screening by lab tests (for asymptomatic persons)	C	C	C	<ul style="list-style-type: none"> • Presence of an STD will not affect the safe use of barrier methods. • If an infected person chooses to have intercourse, use of a barrier may reduce the risk of transmission to the partner²⁻⁴.
Cervical cancer screening	C	C	C	<ul style="list-style-type: none"> • Cervical screening is not needed for the safe use of barrier methods¹. • Use of barrier methods may reduce the risk of developing cervical cancer⁵⁻⁶.
Routine mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	D	D	Routine lab tests are not applicable to the use of barrier methods for contraception.
Proper infection prevention procedures	A	C	C	Proper infection prevention procedures are not applicable to barrier method use, except for fitting of diaphragms.

Procedure	Class DIAPHRAGM	Class CONDOM	Class SPERMICIDE	Rationale
<p>Specific counseling points for barrier method use:</p> <ul style="list-style-type: none"> ● correct use of method ● efficacy ● what to do in the event of condom breakage, or discomfort following spermicide or barrier method use ● STD protection (when/as appropriate) 	A	B	B	<ul style="list-style-type: none"> ● Accurate client education is essential for maximum quality of FP services. ● Appropriate counseling about contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation⁷. ● Clients should know that only barrier methods can protect against STDs. Consistent condom use reduces the risk of becoming infected with any STD⁸⁻¹¹. Spermicidal methods, including diaphragms and caps, probably reduce the risk of bacterial STDs and may have an effect against viral STDs^{8,12-16}. ● The woman should be encouraged to return if she has any problems or at any time she has questions or concerns. ● For condoms and spermicides, counseling is desirable, but perhaps not feasible for over the counter use. However, it should be encouraged. ● When methods are dispensed in clinical settings, counseling should be provided.

KEY:

- Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method
- Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings
- Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method
- Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

Citations for Procedures Table:

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- 5) Hildesheim A, Brinton LA, Mallin K, Lehman HF, Stolley P, Savitz DA, et al. Barrier and spermicidal contraceptive methods and risk of invasive cervical cancer. *Epidemiology* 1990;1(4):266-72.
- 6) Coker AL, Hulka BS, McCann MF, Walton LA. Barrier methods of contraception and cervical intraepithelial neoplasia. *Contraception* 1992;45(1):1-10.
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- 8) Update: barrier protection against HIV infection and other sexually transmitted diseases. *Morbidity and Mortality Weekly Report* 1993;42:589-91, 597.
- 9) Saracco A, Musicco M, Nicolosi A, Angarano G, Arici C, Gavazzeni G, et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. *Journal of Acquired Immune Deficiency Syndrome* 1993;6:497-502.
- 10) de Vincenzi I, for the European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *New England Journal of Medicine* 1994;331(6):341-6.
- 11) Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases* 1993;20:137-9.
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- 13) Weir SS, Feldblum PJ, Zekeng L, Roddy RE. The use of nonoxynol-9 for protection against cervical gonorrhea. *American Journal of Public Health* 1994;84:910-4.
- 14) Kreiss J, Ngugi E, Holmes K, Ndinya-Achola J, Waiyaki P, Roberts PL, et al. Efficacy of nonoxynol 9 contraceptive sponge use in preventing heterosexual acquisition of HIV in Nairobi prostitutes. *Journal of the American Medical Association* 1992;268:477-82.
- 15) Zekeng L, Feldblum PJ, Godwin SE, Oliver RM, Kaptue L. HIV infection and barrier contraceptive use among high-risk women in Cameroon. *AIDS* 1993;7:725-31.
- 16) Feldblum PJ, Weir SS. The protective effect of nonoxynol-9 against HIV infection (letter). *American Journal of Public Health* 1994;84:1032-4.