

CANADIAN CONTRACEPTION CONSENSUS

PRINCIPAL AUTHORS

Amanda Black, MD, FRCSC, Ottawa ON
 Diane Francoeur, MD, FRCSC, Montréal QC
 Timothy Rowe, MB, FRCSC, Vancouver BC

CONTRACEPTION GUIDELINES COMMITTEE

Thomas Brown, PharmD, Toronto ON
 Michèle David, MD, FRCPC, Montréal QC
 Sheila Dunn, MD, CCFP(EM), Toronto ON
 William A. Fisher, PhD, London ON
 Nathalie Fleming, MD, FRCSC, Ottawa ON
 Claude A. Fortin, MD, FRCSC, Montréal QC
 Edith Guilbert, MD, MSc, Quebec City QC
 Louise Hanvey, BN, MHA, Chelsea QC
 André Lalonde, MD, FRCSC, Ottawa ON
 Ruth Miller, MEd, Toronto ON
 Margaret Morris, MD, FRCS, Winnipeg MB
 Teresa O'Grady, MD, FRCSC, St. John's NL
 Helen Pymar, MD, MPH, FRCSC, Toronto ON
 Thirza Smith, MD, FRCSC, Saskatoon SK

CONTRIBUTING AUTHORS

John Collins, MD, FRCSC, Mahone Bay NS
 Dianne Miller, MD, FRCSC, Vancouver BC

PROJECT COORDINATOR

Elke Henneberg, Communications Message & More Inc., Montréal QC

Abstract

Objective: To provide guidelines for health-care providers on the use of contraceptive methods to prevent pregnancy and sexually transmitted diseases.

Outcomes: Overall efficacy of cited contraceptive methods, assessing reduction in pregnancy rate, risk of infection, safety, ease of use, and side effects; the effect of cited contraceptive methods on sexual health and general well-being; and the cost and availability of cited contraceptive methods in Canada.

Evidence: Medline and the Cochrane Database were searched for articles in English on subjects related to contraception, sexuality, and sexual health from January 1988 to March 2003, in order to update the Report of the Consensus Committee on Contraception published in May–July 1998. Relevant Canadian Government publications and position papers from appropriate health and family planning organizations were also reviewed.

Values: The quality of the evidence is rated using the criteria described in the Report of the Canadian Task Force on the Periodic Health Examination. Recommendations for practice are ranked according to the method described in this Report.

Key Words

Contraception, statistics, Canada, sexuality, sexual health, hormonal contraception, emergency contraception, barrier methods of contraception, contraceptive sponge, female condoms, contraceptive diaphragm, cervical cap, spermicide, fertility awareness, abstinence, tubal ligation, vasectomy, sterilization, intrauterine devices

Recommendations

Chapter 8: Barrier Methods

1. Health-care providers should promote the consistent and correct use of latex condoms to protect against pregnancy, human immunodeficiency virus (HIV) infection, and other STIs. (Grade A) Men and women should be provided with information on the male and female condom.
2. Women who use barrier methods of contraception should be provided with emergency contraception and relevant counselling. (Grade B)
3. Health-care providers should educate women and men about the correct use of barrier methods. They should emphasize the need for dual protection against pregnancy and infections. (Grade B)
4. The use of spermicide-coated condoms should no longer be promoted. Nevertheless, the use of a nonoxynol-9 lubricated condom is preferable to the use of no condom at all. (Grade C)
5. Health-care providers should be encouraged to be familiar with the technique of fitting a diaphragm. Diaphragms and cervical caps should continue to be available in Canada. (Grade C)
6. Nonoxynol-9 should not be used to reduce the risk of STIs and HIV infection. Condoms should always be used to reduce the risk of infections. (Grade A)
7. Since frequent use of nonoxynol-9 products may cause epithelial damage and increase the risk of HIV infection, women who have multiple daily acts of intercourse should be advised to avoid using nonoxynol-9 products. (Grade A)

Chapter 9: Natural Family Planning Methods

1. Health-care providers should respect the choice of a natural family planning method and be able to provide resources to support the correct use of this method. (Grade C)
2. The use of coitus interruptus (“withdrawal”) should be recognized as a risk-reduction strategy. When couples use coitus interruptus or other natural family planning methods, health-care providers should provide information about emergency contraception. (Grade C)
3. Health-care providers should acknowledge and legitimize abstinence as a valid contraceptive choice. (Grade B)
4. Comprehensive sex education should be available to all Canadians. Education programs should provide information on abstinence as well as on contraception and STI prevention. (Grade B)
5. Health-care providers should be able to counsel postpartum women about the contraceptive efficacy and correct use of the lactational amenorrhea method. (Grade A)

Chapter 10: Sterilization

1. Couples choosing a sterilization procedure should be informed that vasectomy carries fewer risks than tubal ligation. However, social, cultural, and individual considerations should be taken into account before a choice of procedure is made. (Grade A)
2. Before recommending a transcervical sterilization (cornual occlusion technique), extensive counselling should be offered and the permanence of the procedure reinforced. (Grade B)
3. Counselling before sterilization should include discussion of alternative contraceptive methods. Counselling should address the risks, complications, potential for regret, and failure rates associated with the procedure. (Grade B)
4. New techniques of female and male sterilization should be available to all Canadians. (Grade C)

Chapter 11: Contraception — Meeting Special Needs Contraception in Perimenopause

1. Health-care providers should emphasize the need for effective contraception in the perimenopausal woman. Non-contraceptive benefits of each method should be taken into account when counselling these women. (Grade A)

Postpartum Contraception

1. Initiation of combined OC use should be delayed until breastfeeding is established, usually by 6 weeks postpartum. If the woman is not breastfeeding, combined OCs can be started at 3 to 4 weeks postpartum. (Grade B)
2. Progestin-only methods should be considered as contraceptive options for postpartum women, regardless of breastfeeding status, and may be introduced immediately after delivery. (Grade B)

Post-Abortion Contraception

1. Contraceptive counselling should be offered at the time of abortion, and contraceptive methods should be provided immediately following the procedure. (Grade A)
2. Canadian women should have access to safe abortion procedures regardless of geographical location. (Grade A)

Contraception for the Adolescent

1. Adolescents should have ready access to contraception and methods of STI prevention. (Grade A)
2. Health-care providers should respect a patient’s right to confidentiality. (Grade A)
3. The health-care provider should help to ascertain that sexually active adolescents are involved in a consensual relationship that is free of coercion and abuse. (Grade B)

Contraception in Individuals with Intellectual Disabilities

1. Health-care providers should include sexual health in the counselling of women and men with intellectual disabilities, explore potential coercion and abuse and should provide counselling to help them avoid coercive and abusive situations. (Grade B)

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CHAPTER 8: BARRIER METHODS

Diane Francoeur, MD, FRCSC,¹ Louise Hanvey, BN, MHA,² Ruth Miller, MEd,³ Helen Pymar, MD, MPH, FRCSC⁴

¹Montréal QC

²Chelsea QC

³Toronto ON

⁴Toronto ON

Barrier methods of contraception use a mechanical or chemical barrier to obstruct the entry of spermatozoa into the upper female genital tract. Some of these methods (condoms, spermicides, sponge) do not require consultation with a health-care provider before use, and are widely available. Others (diaphragm, cervical cap) require an initial visit to a health-care provider for fitting. Each method provides variable protection against both unplanned pregnancy and sexually transmitted infection (STI).

I. CONDOMS

INTRODUCTION

When placed correctly over the penis, the condom acts as a mechanical barrier that prevents contact between semen and the sexual partner. Most condoms are made of latex, although polyurethane, silicone, and lambskin condoms are available.

The latex condom is the most popular barrier method of contraception.¹ Latex condoms are 0.3–0.8 mm thick. Sperm cannot penetrate condoms. Latex condoms are offered in a variety of shapes and colours. Novelty condoms, offered in sex toy supply stores or catalogues do not offer pregnancy and STI prevention.

A number of polyurethane condoms have recently become available in Canada. These new condoms may offer better physical properties than latex condoms, and thus may be stronger. They transmit more body heat, allowing more sensitivity. They can be formulated to feel thinner than they actually are, with a less constricting fit. They are more resistant to deterioration. Unlike latex condoms, polyurethane condoms are compatible with oil-based lubricants. They can be used by those who are sensitive or allergic to latex.^{2,3}

Three polyurethane condom brands are currently available in Canada: Avanti, Trojan Supra (lubricated with or without sper-

micide), and eZ.on. They cost twice as much as latex condoms.⁴

Plastic condoms manufactured from materials other than polyurethane have also been developed. The Tactylon condom, manufactured from a plastic material used in non-allergenic examination gloves, was recently approved by the U.S. Food and Drug Administration.^{2,5}

Lambskin (also called sheepskin or natural membrane) condoms are made from a lamb's intestine. While both latex condoms and lambskin condoms prevent pregnancy by blocking the passage of sperm through their surfaces, lambskin condoms are not recommended for protection against STI. Laboratory tests have shown the passage of viruses, including hepatitis B, herpes simplex virus and HIV through small pores on the surface of lambskin condoms.⁶

EFFICACY

LATEX CONDOMS

The efficacy of condoms refers to both pregnancy prevention and prevention of sexually transmitted infection.

Condoms are very effective when used consistently and correctly. The percentage of women experiencing an accidental pregnancy within the first year of perfect use of condoms is estimated at 3%, whereas the typical failure rate is approximately 14%.⁷ The highest failure rates are from age 20 to 24, while the second-highest failure rate is under the age of 20.⁸ Non-use probably accounts for most of the difference in condom failure rates between typical and perfect users. Factors positively associated with delayed condom use include younger age, primary partner, lack of partner support, and multiple recent sexual partners.⁹ Women identified a low perceived risk of pregnancy or infection as the most common reason for not using condoms, while men identified the inconvenience or unavailability of the condom as the most common reason.¹⁰

Condoms used in conjunction with other methods of birth control will provide additional protection against pregnancy and possibly STIs, depending on the method used. Ideal use of the condom with separate spermicide increases the contraceptive efficacy close to that of perfect use of combined oral contraceptives, which is 99.9%.¹¹ The use of intravaginally applied spermicide, in contrast to spermicide incorporated in condoms, guarantees its presence in the vaginal region in the event of condom breakage or leakage.¹¹

In 2000, the U.S. Centers for Disease Control and Prevention, the U.S. National Institutes of Health, the U.S. Food and Drug Administration, and the United States Agency for International Development made clear recommendations regarding the use of male latex condoms. A summary report was published in July 2001,¹² suggesting that correct and consistent use of male latex condoms will reduce the risk of sexually transmitted infections.^{11,13,14}

The data regarding individual use of condoms and risk of

STI are inconclusive, but STI rates in populations have been shown to decline when condoms are used. Condoms lubricated with spermicides are no more effective than latex condoms without spermicide.¹¹ Latex condoms decrease the risk of transmission of STI associated with vaginal discharge (chlamydia, gonorrhea, trichomoniasis, and human immunodeficiency virus).¹⁴⁻¹⁶ A lesser level of protection is provided for STI associated with genital ulcer or human papilloma virus (HPV), because these infections may be transmitted by exposure to areas such as infected skin or mucosal surfaces that are not covered by the condom. The ability of condoms to prevent HPV infection is unknown because HPV is often only intermittently detectable. Nevertheless, condom use has been associated with lower incidence rates of cervical cancer, genital warts, and cervical dysplasia, all of which are HPV-associated conditions.¹⁷⁻²⁰

Several carefully conducted studies have demonstrated in vivo and in vitro that consistent condom use is a highly effective means of preventing human immunodeficiency virus (HIV) transmission. From incidence estimates, consistent use of condoms can decrease AIDS/HIV transmission by 85%.²¹⁻²⁴

POLYURETHANE AND OTHER PLASTIC CONDOMS

Comparisons between Avanti polyurethane condoms and latex condoms showed equivalent levels of contraceptive protection, but the polyurethane condoms had a higher frequency of breakage and slippage. These condoms may therefore confer less protection from STI than do latex condoms.²⁵⁻²⁷ The eZ.on polyurethane condom has not been shown to be as effective as the latex condom for pregnancy prevention, although the risk of pregnancy in the polyurethane condom group lies in the range of other barrier methods. Clinical failures (breakage and slippage) are also higher for eZ.on polyurethane condoms than for latex condoms.^{28,29}

Polyurethane and other plastic condoms have not been well studied for protection against STIs, but they are believed to provide protection similar to that of latex condoms. Studies of their effectiveness are in progress.

TACTYLON CONDOMS

The Tactylon condoms are equivalent to latex condoms in risk of slippage, but the breakage rate for the Tactylon condom is three to five times higher than the latex condom. Fewer medical events (irritation, burning, itching, and genital pain) were reported with Tactylon condoms than with latex condoms.^{30,31}

LAMBSKIN CONDOMS

Lambskin condoms are no longer recommended because of their lack of protection against STI.⁶

MECHANISM OF ACTION

The condom acts as a mechanical barrier to prevent exchange

of fluid and semen and to decrease contact with genital lesions. While both latex and lambskin condoms prevent pregnancy by blocking the passage of sperm through their surfaces, lambskin condoms are not recommended for protection against STIs.⁶ Laboratory tests have shown the passage of viruses, including hepatitis B, herpes simplex, and HIV, through small pores on the surface of lambskin condoms.⁶ Some condoms are supplied pre-lubricated with either a water-based lubricant or a small amount of spermicide. Condom choices include plain or reservoir-tipped, straight or shaped, smooth or textured, natural or brightly coloured, and a variety of sizes. Some condoms tend to fit better than others; optimal fitting requires trying a variety of condoms.

INDICATIONS

Condoms are indicated for the prevention of pregnancy, STI, and cervical dysplasia. The chief motivation for condom use in women is pregnancy prevention rather than STI.³²

Ideally, condoms should be used in addition to another primary contraceptive method (dual protection), because condom use potentially increases the contraceptive and STI protective effects of other methods.

CONTRAINDICATIONS

The only contraindication to latex condom use is an allergy or sensitivity to latex, or lanolin sensitivity in the case of lambskin condoms. Effective use of condoms requires high motivation and a strong sense of responsibility.

NON-CONTRACEPTIVE BENEFITS

Use of a condom increases the contraceptive and STI protective effects of other methods. When the use of a condom is insisted upon, this may have a positive effect on the nature and duration of the relationship.³³

SIDE EFFECTS

Side effects with condom use include allergy to latex and irritation. The use of spermicides increases the incidence of *E. coli* urinary tract infection because of alteration of the vaginal flora.^{34,35} Some men may complain of decreased sensation or loss of erection.³⁶

RISKS

Technical problems with condom use (occurrence of an unrecognized leak, slippage) are more common when men are not used to the method.³⁷ Condoms are not always available when needed. A recent study in college men showed that errors are

still common: 43% of users applied the condom after penetration, 15% removed it before ejaculation, 40% did not leave space at the tip, 30% placed the condom upside down on the penis and thus rolled it on inside out, and 32% were unable to maintain erection.³⁷

MYTHS AND MISCONCEPTIONS

1. Everybody knows how to use a condom.
Fact: Women, and especially adolescents seem to expect that all men know how to use the condom correctly to prevent breakage or spillage, but this is untrue.
2. I can't get a sexually-transmitted infection if I always use a condom.
Fact: Some users believe that condoms prevent all STIs, and they will have intercourse even in the presence of ulcers or genital lesions. Any skin-to-skin contact can lead to transmission of STIs.

INITIATION

PROVISION OF CONDOMS

Innovative programs have been developed to improve access to condoms for individuals who find them difficult or embarrassing to purchase. Whether condoms should be readily available to young people through school-based clinics or dispensing machines is a matter for debate. It is of interest that the lowest unwanted pregnancy rates occur in those countries that have more liberated sexual norms, mandated sex education, and provide easy access to family planning information and services through school-based clinics.³⁷

PROPER USE AND PRECAUTIONS

Packaged condoms that are stored dry and away from light and heat can be kept for up to 5 years. The approved lifespan of spermicide-containing condoms is 2 years. The expiration date must be respected. Condoms deteriorate more quickly when exposed to temperatures over 37 degrees Celsius, high humidity, and air pollution.³⁸ Unpackaged condoms exposed to ultraviolet light are weakened by 80% to 90% within 8 to 10 hours.³⁹ The most common error in using condoms is the additional use of oil-based lubricants, which, unlike water lubricants, have been shown to affect condom integrity by reducing tensile strength, elongation, burst pressure, and burst volume.⁴⁰ Table 1 lists lubricants that are safe or unsafe to use with condoms. Condoms should not be disposed of in toilets.

In case of condom breakage or leakage, emergency contraception should be provided, as well as STI testing if necessary.

USING A CONDOM

When this is the only contraceptive method selected, a health-care provider ideally should instruct both the woman and her

partner in the use of condoms, and should provide the woman with a prescription for emergency contraception. (See Table 2.)

TROUBLESHOOTING

The health-care provider should be prepared to deal with comments and concerns voiced by the patient regarding condom use. Here are some suggestions for dealing with common complaints.

“I DON’T HAVE THE SAME FEELING WITH A CONDOM.”

While condom use may reduce sensitivity, there is no objective evidence for this. Reduced sensitivity may be an advantage for some men by enhancing erection and preventing premature ejaculation, but others find this frustrating and will stop using a condom. To increase sensation, the male partner may use a textured or ultra-thin condom, or place a water-soluble lubricant inside the reservoir of the condom.

“I LOSE MY ERECTION WHEN USING A CONDOM.”

Making the application of the condom by the partner a routine part of sex play — during oral sex or masturbation, for example — may help overcome this obstacle.

Table 1.⁴¹ Lubricants and Products that are Safe or Unsafe to Use with Condoms

Safe	Unsafe
Aloe-9	Baby oils
Aqua-Lube	Burn ointments
Aqua-Lube Plus (spermicidal)	Coconut oil/butter
Astroglide	Edible oils (e.g., olive, peanut, corn, sunflower)
Carbowax	Fish oils
Condom-Mate	Haemorrhoid ointments
Contraceptive foams (e.g., Emko, Delfen, Koromax)	Insect repellants
Contraceptive creams and gels (e.g., PrePair, Conceptrol, Ramses)	Margarine, dairy butter
Duragel	Mineral oil
Egg white	Palm oil
ForPlay lubricant	Petroleum jelly (e.g., Vaseline)
Glycerin USP	Rubbing alcohol
Intercept	Suntan oil
Koromex Gel	Vaginal creams/spermicides (e.g., Monistat, Estrace, Femstat, Vagisil, Premarin, Rendell’s Cone, Pharmatex Ovule)
Lubafax	Some sexual lubricants (e.g., Elbow Grease, Hot Elbow Grease, and Shaft)
Lubrin Insert	
Norform Insert	
Ortho-Gynol	
Personal Lubricant	
PrePair Lubricant	
Probe	
Saliva	
Semicid	
Silicones DC 360	
Transi-Lube	
Water	

“USING A CONDOM INTERFERES WITH THE SPONTANEITY OF SEX.”

Condom use may interfere with, or interrupt, foreplay and impair erection. Encouraging the partner to put the condom on as a part of sex play, eroticizing condom use, and using a condom during sex play before intercourse often alleviates this problem.

“I AM ALLERGIC TO LATEX.”

While sensitivity may be related to the spermicide or lubricant, latex sensitivity is increasing, particularly among workers with repeated exposure to latex medical devices.⁴² Lambskin condoms may be used for contraception, but polyurethane condoms should be used for STI prevention.

“WHAT DO I DO ABOUT CONDOM BREAKAGE AND SLIPPAGE?”

Most condoms (92%–98%) will neither break nor come off completely during intercourse.⁴³ The risk of pregnancy has been estimated at one pregnancy in 23 episodes of condom breakage, and the probability of HIV infection resulting from a single exposure ranges from less than 0.1% to 10%, depending on the type of transmission (male to male, male to female, or female to male) and the presence or absence of genital ulcers.^{44,45} STI testing is recommended if there is any fear of infection.

Common reasons for breakage include rough handling of condoms, the use of oil-based lubricants, and incorrect storage or usage after the expiry date. While condoms rarely slip off completely during intercourse, they may slide down the shaft of the penis without falling off. The condom must be held at the base of the penis during withdrawal.⁴³ Excessive lubricant inside the condom will increase the risk of slippage. Emergency contraception should be recommended if there is doubt.

“I HAVE TROUBLE CONVINCING MY PARTNER THAT WE SHOULD USE CONDOMS.”

Health-care providers can rehearse specific scenarios with their

Table 2. Using a Condom

- Put a drop or two of water-based lubricant or saliva inside the condom
- Place the rolled condom over the tip of the hard penis
- Leave a half-inch space at the tip to collect semen
- If not circumcised, pull back the foreskin before rolling on the condom
- Pinch the air out of the tip with one hand (friction against air bubbles causes most condom breaks)
- Unroll the condom over the penis with the other hand
- Roll it all the way down to the base of the penis
- Smooth out any air bubbles
- Lubricate the outside of the condom — pull out before the penis softens
- Don’t spill the semen — hold the condom against the base of the penis while you pull out
- Throw the condom away
- Wash the penis with soap and water before any further contact

Table 3. How to Talk About Condoms with a Partner

If the partner says ...	You can say ...
"I'm on the pill. You don't need a condom."	"I want to use it anyway. We will be protected from infections we may not realize we have."
"Condoms aren't romantic."	"What's more romantic than making love and protecting each other's health at the same time?"
"I know I'm clean of disease. I haven't had sex with anyone in 'X' months."	"As far as I know, I am disease-free too, but I still want to use a condom since a person can't always tell if they have an infection."
"I can't feel a thing when I use a condom. It's like wearing a raincoat in a shower."	"Maybe that way you'll last even longer, and that will make up for it." OR "I think I am woman (man) enough to make you feel something."
"I don't stay hard when I put on a condom."	"I can do something about that."
"Putting it on interrupts everything and destroys the romantic atmosphere."	"Not if I help put it on." OR "We can make it erotic together."
"But I love you."	"Then, if you love me, you'll help me protect myself."
"I guess you don't really love me."	"I do, but I'm not risking my future to prove it."
"Just this once."	"Once is all it takes."
"You carry a condom around with you? You were planning on having sex?"	"I always carry condoms because I care about myself and I care about us."
"I won't have sex with you if you insist on using a condom."	"OK. Let's put it off until we can agree. Let's satisfy each other without intercourse."
"I don't have a condom with me."	"I do."

patients, walk through mentally when and how to purchase condoms, where to carry them, and when and how to bring up the subject of condom use. They should teach negotiating skills when there is resistance to condom use. (See Table 3.)

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2. FEMALE CONDOM

INTRODUCTION

The female condom is a soft, loose-fitting polyurethane sheath which acts as an intravaginal barrier. (See Figure 1.) The Reality

Female Condom is the only product of this kind available in Canada. Like the condom for men, the female condom can be bought in pharmacies without prescription.

EFFICACY

Contraceptive failure rates for the female condom vary across studies. The use of the female condom for contraception is approximately as effective as the use of the male condom, and it is more effective than vaginal spermicidal methods. The 12-month pregnancy rate for perfect (correct and consistent) use of the female condom is 5%, compared to 3% for the male condom and 6% with use of the diaphragm.¹ The 12-month pregnancy rate for typical use is similar to the diaphragm with spermicide (20%), but not as effective as the condom for men (14%).¹⁻⁵ These rates are much lower than those reported in previous studies.⁶

MECHANISM OF ACTION

The female condom is a polyurethane sheath which is placed in the vagina. It lines the vagina completely, preventing contact between the penis and vagina. The condom traps semen and is then discarded.

The female condom is 7.8 cm in diameter and 17 cm long. It has 2 flexible rings, one attached to the sheath and one unattached. The attached external ring at the open end of the condom sits outside the vagina and provides some protection to the perineum. The unattached ring lies within the closed end of the pouch, allowing the condom to be inserted into the vagina and kept in place. The sheath is coated on the inside with a silicone-based lubricant. The condom can be placed in the vagina up to 8 hours before intercourse.^{4,7}

The polyurethane used in the female condom is less likely to tear or break than the latex in male condoms. In a study of post-intercourse leakage designed to detect pinholes and tears after actual condom use, 3.5% of male latex condoms showed leakage when tested after use, compared with 0.6% of female condoms.⁸ The female condom does not deteriorate with exposure to oil-based products, and withstands storage better than latex. It has a longer shelf-life (of up to 5 years) than the male condom. It should be noted that the female condom is not intended for use with a male condom, because the two condoms may adhere to one another and slip or become displaced.

INDICATIONS

The female condom prevents semen from contacting the vagina. A woman who finds spermicides irritating, or does not like the messiness of other vaginal barrier methods, may prefer to use the female condom.

Advantages of the female condom include the following:

- A woman can place it autonomously and has full control of the effectiveness.
- When used correctly, it can provide a high level of protection.
- It adjusts well to the anatomy of the vagina.⁹

CONTRAINDICATIONS

Some conditions prohibit the use of the female condom. They are:

- Allergy to polyurethane
- Abnormalities in vaginal anatomy that interfere with a satisfactory fit or stable placement
- Inability to learn the correct insertion technique.

NON-CONTRACEPTIVE BENEFITS

PROTECTION FROM SEXUALLY TRANSMITTED INFECTION

Polyurethane is impenetrable in vitro to organisms the size of the human immunodeficiency virus (HIV).¹⁰ The female condom provides protection from sexually transmitted infection (STI) that is similar to that of the male condom, although specific clinical evidence is limited. The incidence of STI in sex workers given the choice of using male or female condoms has been reported lower than the incidence in women using male condoms only.^{11,12}

WOMEN'S EMPOWERMENT

One of the most important features of the female condom is that it is a female-controlled method of contraception and STI prevention.^{9,13-15}

SIDE EFFECTS, RISKS, AND CHALLENGES

Problems are uncommon with the use of the female condom. Slippage has been cited as a problem specific to the use of the female condom.⁷



Figure 1. The Female Condom

Disadvantages of the female condom include

- the need to practise insertion and to use the device several times before becoming confident with its use
- the inner ring may cause discomfort during coitus⁹
- cost
- noise during coitus¹⁶

Promotion of use of the female condom has been met with challenges such as the perceived high cost (approximately \$3.00 per condom in Canada). There is also evidence of bias against the method on the part of health-care providers.¹⁷ Their attitudes may improve through more positive and well-designed training programs.¹⁸

INITIATION

Women who plan to use female condoms do not require a fitting, but they need to:

- understand how to use them correctly
- insert them just prior to intercourse or up to 8 hours before
- use a new condom for each act of intercourse
- remove the female condom immediately after intercourse, squeezing and twisting the outer ring to keep semen inside the pouch, before standing up

TROUBLESHOOTING

If the female condom slips or breaks, women should be counselled to use emergency contraception.

ACCEPTABILITY

Acceptability varies with study groups. For example, female condoms are well-accepted in sex workers, a group in which as many as 98% were satisfied with the method.¹⁶ The percentage of satisfaction went down to as little as 65.2% in a survey of volunteers from hospital staff.¹⁹

COST

Like the male condom, the female condom is made for single use only, so the cost of sustained use can be prohibitive. In Canada the average cost is \$3.00 per condom. Re-using the female condom has been considered as one approach to make the female condom more cost-effective; the safety and feasibility of re-use is currently the subject of research.^{20,21}

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3. DIAPHRAGM

INTRODUCTION

The diaphragm is an intravaginal barrier method of contraception that is used in conjunction with a spermicide (jelly or cream). It consists of a latex dome with an encased flexible steel ring around its edge. It fits into the vagina to cover the cervix.

Diaphragms are available in a variety of sizes and types. The three types of diaphragm available in Canada are the coil spring,

which is the most common; the arcing spring; and the flat spring. The coil spring diaphragm has a sturdy rim which folds easily for insertion. It remains in a straight line when pinched at the edges. Women need good pelvic support to feel comfortable with this type of diaphragm, because it is difficult to secure the posterior edge into the cul-de-sac over the cervix. It is often preferred by parous women.

The arcing spring diaphragm slips more easily past the cervix and is easier to use for most women.¹ It is more suitable for nulliparous women.

A flat spring diaphragm (also called a wideseal diaphragm) made of silicone is an option for women who are allergic to latex, and is available over the Internet.²

Ultimately, the choice of diaphragm will be based on individual preferences for comfort and ease of checking for position. A diaphragm can be inserted into the vagina with an introducer, but the manual method of insertion is superior because it offers the user the opportunity to check for fit. (See Figure 2.)

EFFICACY

Efficacy rates vary depending on the study and the methodology used. The WHO failure rate for the diaphragm in the first 12 months of use is 20% with typical use and 6% with perfect use.³

While consistent and correct use of the diaphragm is essential for effectiveness, approximately one-half of method failures occur despite diligent use. Therefore, a woman's ability to accept an unplanned pregnancy may be a determinant in her suitability for this barrier method.

A recent study found use of the diaphragm and spermicide to provide significantly more effective contraception than use of the contraceptive sponge.⁴

MECHANISM OF ACTION

The diaphragm serves as a physical barrier between sperm and the cervix and should always be used in conjunction with a spermicide. The spermicidal action of the jelly or cream used increases the contraceptive effect. In addition, the use of a diaphragm is associated with a reduced incidence of cervical neoplasia,^{1,6} dysplasia,^{6,7} gonorrhoea,⁸ pelvic inflammatory disease,⁹ and tubal infertility.¹⁰

The use of a diaphragm without the addition of a spermicidal agent shows variable contraceptive effectiveness.^{11,12} A recent review found no rigorous studies which were able to distinguish the effectiveness of the device with as opposed to without spermicide.¹³ Diaphragms should always be used together with a spermicide.¹⁴

A diaphragm can be inserted up to 6 hours before intercourse.⁵ Each repeated act of intercourse requires the application of extra spermicide (an applicator is necessary for this repeat insertion).

A refitting of the diaphragm is required after childbirth, surgery, or if the woman gains or loses at least 10 pounds.

INDICATIONS

Diaphragms are well suited for those women who do not wish to use hormonal contraception or for whom hormonal contraception is contraindicated.¹ Diaphragms can also be used by breastfeeding women.

CONTRAINDICATIONS AND CAUTIONS

The health-care provider must rule out the presence of a large cystocele, rectocele, or marked uterine prolapse,¹⁰ which would reduce the efficacy of the method.

Some women are sensitive to spermicides and to latex. There is also evidence of an increased risk of developing bacterial vaginosis in diaphragm users.¹⁵ Women with recurrent urinary tract infections (UTI) may need postcoital prophylaxis with antibiotics, since there is a 2 to 3 fold increase in UTI risk with the use of spermicides. This is probably related to changes in the vaginal flora and increased growth of *E. coli*.^{16,17}

NON-CONTRACEPTIVE BENEFITS

The use of a diaphragm offers potential protection from STIs and their consequences by decreasing cervical exposure to the causative organisms. Protection from HIV transmission is limited because of the exposure of the vaginal mucosa during the use of this method. The use of the diaphragm is also associated with a reduced incidence of cervical neoplasia.^{6,7}

RISKS AND SIDE EFFECTS

The use of a diaphragm may also increase the risk of persistent or recurrent UTI, possibly because of pressure from the

diaphragm's rim on the urethra and the concurrent use of spermicides.¹⁵ Of these, the use of a spermicide may be a more important cause.¹

The diaphragm is contraindicated for women or their partners who have allergies or sensitivities to latex, rubber, or spermicides.

Use of a diaphragm can be associated with toxic shock syndrome (TSS). Toxic shock syndrome, caused by toxins released by some strains of *Staphylococcus aureus*, is a rare but serious disorder. The risk of TSS, although low, is increased in women who use vaginal barrier methods of contraception.

MYTHS AND MISCONCEPTIONS

1. All barrier methods protect against HIV infection.

Fact: Protection from HIV is limited because of the exposure of vaginal mucosa.

2. Using a diaphragm alone (without spermicide) is equally effective.

Fact: Studies suggest a decreased efficacy when used alone.¹⁴

INITIATION

A pelvic examination by a qualified clinician is required for fitting diaphragms. (See Table 4.) Fitting rings are produced by diaphragm manufacturers in various sizes and with different rim types. Sizes range from 50 to 105 mm in diameter. The fitting rings are most commonly available as flat spring or coil spring rim types. It is important to fit the woman with the rim type that she will ultimately use, and to have her practise with it under the supervision of the clinician.

A sample sized diaphragm or fitting ring can then be inserted into the correct position in the vagina. The diaphragm should fit snugly in the upper half of the vagina, immediately behind the pubic bone, with its rim in contact with the lateral walls of the vagina and the posterior fornix.¹

Before a woman can successfully use the diaphragm or cervical cap, she will require detailed instructions for insertion, the opportunity to practise, and reassurance from the clinician. Reinforcement of the correct procedures is valuable, as are tips to becoming more comfortable with one's body. Providing information about the menstrual cycle will help women use their barrier method more effectively. Providing information



Figure 2. Diaphragm

Table 4. Fitting for a Diaphragm

The correct diaphragm size can be estimated by

- inserting the index and middle fingers into the vagina until the posterior wall is reached (by middle finger);
- marking the point at which the index finger touches the pubic bone with the tip of the thumb; and
- removing the fingers, then placing rim of diaphragm on tip of the middle finger. The opposite side rim should be lying just in front of the thumb.

about the availability of emergency (post-coital) contraception will also be essential.

Diaphragm users do not require any special follow-up other than a refitting after a full-term pregnancy, pelvic surgery, or abortion, or if they have a significant change in weight.

TROUBLESHOOTING

If a diaphragm user is experiencing recurrent UTIs, a refit or change of rim type may help, but the problem may be due to spermicide exposure. Post-coital voiding or prophylactic antibiotic may help.¹⁷ For some women, having recurrent UTIs may be a contraindication to diaphragm use.

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4. CERVICAL CAP

INTRODUCTION

The cervical cap is a barrier method of contraception used intravaginally in conjunction with a spermicide (jelly or cream). (See Figure 3b.) The only cervical cap approved by Health Canada is the Ovès contraceptive cap, which is available through the Internet.¹

EFFICACY

The World Health Organization cites a contraceptive failure rate of 20% with typical use and 9% with perfect use in nulliparous women. The failure rate for multiparous women in the first 12 months of use of the cap is 40% with typical use and 26% with perfect use.²

MECHANISM OF ACTION

The Ovès cap is made of silicone and places a physical barrier between sperm and the cervix; the spermicidal action of the jelly or cream increases the contraceptive effect. The cap is held in place over the cervix by suction and must therefore be snugly fitted. It can be left in place for up to 72 hours.

INDICATIONS

Women who do not wish to use hormonal contraception, or for whom it is contraindicated, may choose to use this barrier method. It must be used consistently and correctly. A woman's ability to accept an unplanned pregnancy may be a determinant in her suitability for a barrier method such as the cervical cap. Cervical caps can be used by lactating women.

CONTRAINDICATIONS AND CAUTIONS

The cervical cap should not be used in women with a current vaginal or cervical infection, current pelvic inflammatory disease, cervical or uterine cancer or dysplasia, or in women with allergy or sensitivity to spermicides. Additionally, it is not recommended in a woman who has recurrent vaginal, cervical, or urinary tract infections, who does not feel comfortable touching her genital area; or who has difficulty applying the cap to the cervix.

The cervical cap cannot be used within 6 weeks of a delivery, after a recent miscarriage or an abortion, or during any vaginal bleeding including menstruation.

NON-CONTRACEPTIVE BENEFITS

The cervical cap offers potential protection from gonorrheal and chlamydial infections and their consequences.³

RISKS AND SIDE EFFECTS

Use of the cervical cap may aggravate symptoms in women with sexually transmitted infections and vaginitis. The risk of toxic shock syndrome is increased. Cervical caps may cause more vaginal odour and discharge than diaphragms, and can be dislodged during intercourse. Concerns about abnormal cervical cytology associated with cervical cap use have been shown to be unfounded.^{4,5}

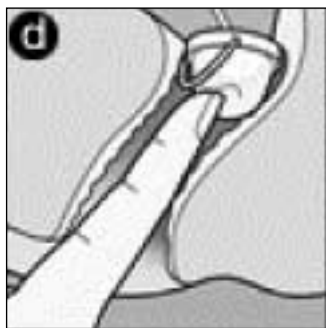


Figure 3a. Inserting a cervical cap



Figure 3b. Cervical caps

MYTHS AND MISCONCEPTIONS

1. Cervical caps increase the risk of cervical dysplasia.
Fact: Cervical caps are not associated with an increased risk of cervical cancer, although inflammatory changes have been reported.³⁻⁵
2. It is impossible to obtain a cervical cap in Canada.
Fact: Cervical caps are available in Canada in some family planning clinics and they can also be ordered through the Internet.¹

Table 5. Fitting for a Contraceptive Cervical Cap

Most women will use the 28 mm cervical cap. The rim of the cervical cap should be seated in the vaginal fornices around the entire base of the cervix with a snug seal and no laxity.

Table 6. Instructions for Inserting a Cervical Cap

1. Wash your hands carefully before inserting or removing the cap.
 2. To make it easier to insert or remove the cap, stand with one leg supported higher than the other (using a chair or the edge of the bath) or use a squatting position.
 3. Remove the cap from its protective sachet.
 4. It is recommended that the cap be used with a spermicidal gel or cream. Place a small amount of the spermicide recommended by your health-care professional inside the dome.
 5. No additional spermicide is required during the 72-hour wearing period.
 6. Locate the cervix by inserting a finger inside your vagina.
 7. Pinch the cap at its base with the dome facing downwards.
 8. Introduce the cap into the vagina and push it toward the cervix.
 9. When the bottom of the cap comes into contact with the cervix, position the cap so that it covers the cervix correctly.
 10. When the cap cannot be pushed any further, you will know that it is placed correctly.
 11. Now carefully remove your finger without disturbing the position of the cap.
-

Table 7. Instructions for Removing a Cervical Cap

1. The cap must not be removed until at least 6 hours after the most recent sexual intercourse.
2. Introduce the index finger into the vagina and find the cervix covered by the cap.
3. Run your finger around the base of the cap until you locate the loop.
4. Hook the loop of the cap with the end of the index finger.
5. Remove the cap using a slow steady movement.
6. Remove the cap, wash it with warm soapy water and store the cap in a dark and cool place.

The cap may stay in place for a minimum of 6 hours after the last intercourse but no longer than 2 days. If an odour develops after 6 hours, a break and a bath are recommended. After cleaning and drying the device it can be used again as described.

A woman with a very busy sex life who cannot wait should consider another method.

The cervical cap can be reused until it is damaged.

INITIATION

A bimanual pelvic examination must be performed by a qualified clinician to ascertain the position and size of the uterus and cervix. Some abnormalities of the cervix, such as a large Nabothian follicle, may interfere with the ability of the cervical cap to cover and adhere to the cervix. Three sizes of cervical caps are available: these are 26, 28, and 30 mm in diameter. Women can bring a “fitting pack” containing one of each size cap to the examination to be sure they are fitted with the correct size.

Before a woman can successfully use the cervical cap, she will require detailed instructions for insertion, the opportunity to practise, and reassurance from the clinician. (See Figure 3a, Tables 6 and 7.) Providing information about the availability of emergency (post-coital) contraception will also be essential. The combination of a female barrier method with a male latex condom will provide additional contraception and additional protection from sexually transmitted infection.

TROUBLESHOOTING

The manufacturer recommends that cervical cap users have a health-care provider check the fitting of the cap after a miscarriage, term delivery, abortion, or after gaining or losing 3 kg or more in weight.

Cervical caps users should be monitored for cervical inflammation and abnormal Pap smears, since inflammatory changes have been reported.³

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5. CONTRACEPTIVE SPONGE

INTRODUCTION

The contraceptive sponge is an intravaginal one-size-fits-all barrier method which does not require a visit to a physician or birth control clinic. The sponge is available in pharmacies.

There are 2 forms of the contraceptive sponge available in Canada — both are small, disposable polyurethane foam devices intended to fit over the cervix. The Protectaid sponge is im-

pregnated with a combination of spermicidal agents (nonoxynol-9, benzalkonium chloride, and sodium cholate).¹ The Today Sponge is pillow-shaped and contains nonoxynol-9. The concave dimple on one side is designed to fit over the cervix and to decrease the chance of dislodgement during intercourse. The other side of the sponge incorporates a woven polyester loop to facilitate removal. (See Figure 4.)

EFFICACY

The Protectaid sponge has a theoretical efficacy rate of 90%² in nulliparous women, but it is much less effective in parous women — 20% of whom conceive unexpectedly within the first year of “perfect” use. The actual failure rates for typical users are 18% for nulliparous women and 36% for parous women.^{3,4} The Today Sponge has a theoretical efficacy rate of 91% in nulliparous women, but 20% of parous women conceive unexpectedly within the first year of “perfect” use. The actual failure rates for typical users are 40% in parous users and 20% in nulliparous women.³ As with other female barrier methods, efficacy rates can be increased by using the sponge in combination with a male condom.³ A recent review of clinical trials found that the sponge was less effective than the diaphragm in preventing pregnancy, and discontinuation rates were higher.⁵

MECHANISM OF ACTION

The contraceptive action of the sponge is primarily provided by the action of the impregnated spermicide, augmented by its ability to absorb and trap sperm. The sponge acts as a sustained-release spermicidal reservoir for a period of 12 hours.

INDICATIONS

The sponge may best meet the needs of women who wish to or must avoid hormonal contraception.³ Some women choose the sponge because of its prolonged 12 hours of protection. It is less messy than spermicide used alone or with a



Figure 4. Contraceptive Sponge

cervical cap or diaphragm. The sponge may be used with other barrier methods such as the male condom to increase its efficacy.

CONTRAINDICATIONS

The sponge should not be used by women who have

- an allergy to spermicide
- abnormalities in vaginal anatomy that interfere with satisfactory or stable placement of the sponge
- an inability to learn correct insertion technique
- a history of toxic shock syndrome
- repeated urinary tract infections
- a need for protection from HIV infection
- had a full-term delivery within the past 6 weeks, a recent spontaneous or induced abortion, or abnormal vaginal bleeding³

RISKS AND SIDE EFFECTS

The risk of toxic shock syndrome (TSS) is increased in women who use vaginal barrier methods of contraception; they have an annual incidence of 2 to 3 cases per 100 000 women. The overall health risks attributable to TSS are very low. These cases of TSS would result in less than 1 death (0.18) annually for every 100 000 vaginal barrier users.⁶

Women using the sponge must be aware of the symptoms and signs of TSS, and must receive instructions consistent with recommended TSS precautions.

MYTHS AND MISCONCEPTIONS

1. Sponges offer protection against STIs.

Fact: The contraceptive sponge may potentially damage vaginal mucosa and thus may enhance HIV transmission.⁷

INITIATION

Women using the contraceptive sponge need to know how to insert and use it correctly. They should

- be aware that the sponge provides effective contraceptive protection for 12 hours, regardless of the number of acts of intercourse.
- wash their hands carefully with soap and water before inserting, checking, or removing the sponge.
- remove and discard the sponge after use; sponges should not be reused.
- ensure that the device is in place before the penis enters the vagina.
- be familiar with the signs of toxic shock syndrome.
- discuss problems of recurring bladder infections or vaginal yeast infections with their health-care provider.

Douching after intercourse is not recommended. If sponge users choose to douche, they should wait for at least 6 hours after intercourse to avoid the removal of spermicide. They can use male condoms with the sponge for added protection against both pregnancy and sexually transmitted infection.

Before insertion, the Today Sponge should be moistened with about 2 tablespoons of clean water and squeezed once. The user should insert the dimpled side so that it faces the cervix, with the loop away from the cervix. She can use her finger to confirm that the sponge covers the cervix.

TROUBLESHOOTING

Recurrent vaginal yeast infections or bacterial vaginosis must be appropriately treated. This may require switching to another method of contraception.^{3,8}

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6. SPERMICIDES

INTRODUCTION

Spermicides are composed of a spermicidal agent in a carrier that allows dispersion and retention of the agent in the vagina. Nonoxynol-9 (N-9) is the most commonly used spermicidal agent in Canada. Spermicides are easily obtained without a prescription and have no systemic effects. Spermicides are also important contributors to the efficacy of the contraceptive sponge, diaphragm, and cervical caps.

The use of a spermicide alone provides less effective contraception than using it in combination with a barrier method.¹

Spermicides are available as film, jelly, suppository, cream, tablet, and as a foam.

The *Vaginal Contraceptive Film* (VCF) is a 2-by-2 in. sheet of film containing 28% nonoxynol-9. It must be inserted at least 15 minutes before intercourse in order to melt and disperse. If more than one hour has elapsed before intercourse, another film must be inserted. Inserting the film correctly requires practice. Women who are accustomed to douche after intercourse must be advised not to do so for at least 6 hours after intercourse.¹

Advantage 24 is a *bioadhesive jelly* that adheres to the cervix and vagina, slowly releasing nonoxynol-9. It can be inserted up to 24 hours before intercourse, but a repeat application is required prior to each additional act of intercourse. Each application comes separately packaged in inserters that resemble tampon inserters.¹

Spermicidal foam is effective immediately and for up to one hour after insertion. This preparation contains 12.5% nonoxynol-9. It is inserted in the vagina using a supplied applicator. A repeat application is required prior to each additional act of intercourse.

Spermicidal jellies (e.g., Orthogynol II, K-Y Plus, Sure-seal Gel) are intended for use with a diaphragm.

The *Encare suppository*, containing nonoxynol-9, must be inserted 10 to 15 minutes prior to intercourse.

EFFICACY

Studies are difficult to compare and vary widely in size, focus, and quality.² Failure rates in the first year of use vary from 26% with typical use to 6% with perfect use.³

MECHANISM OF ACTION

Spermicides are composed of a spermicidal agent in a carrier that allows dispersal and retention of the agent in the vagina. Spermicides are surfactants that destroy the sperm cell membrane by altering the lipid layer; the spermatozoon thus becomes permeable and swells, with breakage of plasma and acrosomal membranes.

INDICATIONS

The use of spermicides is only recommended as an adjunct with other methods of contraception. Spermicide can be used alone when fertility is naturally reduced. Spermicides are also used as a backup contraceptive with the use of condoms, the diaphragm, and the cervical cap; it is also used as a backup method in lactating women.

CONTRAINDICATIONS

An allergy to a spermicide or its carrier is the only absolute

contraindication to its use. Spermicides should not be used in the presence of any condition that prohibits proper placement high in the vagina over the cervix. Such genital tract abnormalities as a vaginal septum or double cervix will make the correct placement of spermicide difficult, and are potential contraindications to its use. Women who are uncomfortable touching their genital area will likely be uncomfortable using spermicides. If there is a personal or medical need for highly effective contraception, spermicides should not be the first contraceptive choice. Spermicides with nonoxynol-9 should also not be recommended to sex workers or to women with an increased risk of human immunodeficiency virus (HIV) infection.⁴⁻⁶

NON-CONTRACEPTIVE BENEFITS

The foams, creams, and jellies may be used as lubricants with condoms.

RISKS AND SIDE EFFECTS

Genital irritation could lead to easier transmission of HIV.^{4,7} The use of spermicides has also been associated with an increased risk of urinary tract infection.⁸

MYTHS AND MISCONCEPTIONS

1. Use of a spermicide alone provides contraception that is as reliable as the use of a barrier method.
Fact: Spermicides used alone have a substantially higher failure rate than other contraceptive methods.^{3,9}
2. Nonoxynol-9 lubricated condoms are more effective than regular condoms.
Fact: Condoms lubricated with or without N-9 are similarly effective in preventing pregnancy.¹⁰
3. Spermicides are effective microbicides.
Fact: Nonoxynol-9 is *not* an effective microbicide; in fact, its use may increase the risk of sexually transmitted infection (STI) or infection with HIV.^{4,7,11} Spermicides appear to have no protective effect against chlamydial and gonorrheal infections.⁷

Most of the clinical evidence on the risk of HIV infection with use of N-9 comes from studies conducted among women who were either sex workers or attending STI clinics. It is not known whether these results also apply to situations in which the dosage or frequency of N-9 use is lower.⁴⁻⁶

In keeping with the World Health Organization's statements,¹⁰ it is recommended that:

- nonoxynol-9 not be used for the purpose of preventing STI or HIV infection. Condoms should always be used to prevent infection.
- although nonoxynol-9 has been shown to increase the risk

of HIV infection when used frequently by women at high risk of infection, it remains a contraceptive option for women at low risk.

- since high-frequency use of nonoxynol-9 products may cause epithelial damage and increase the risk of HIV infection, women who have multiple daily acts of intercourse should be advised to choose another method of contraception.
- condoms lubricated with nonoxynol-9 are no more effective in preventing pregnancy or infection than are condoms lubricated with other products. Since adverse effects due to the addition of nonoxynol-9 to condoms cannot be excluded, such condoms should no longer be promoted. However, it is better to use a nonoxynol-9 lubricated condom than no condom at all.
- nonoxynol-9 should not be used rectally.

INITIATION

Instructions should be read and followed carefully, especially the length of time from insertion of the spermicide to intercourse, and the duration of effectiveness. (See Table 8.) Fertility awareness will increase the likelihood that another barrier method of contraception will be added to the spermicide at the fertile time of the cycle, thus enhancing efficacy. However, use of a spermicide may interfere with the assessment of cervical mucus.

Spermicide users should be counselled about the use of emergency contraception in the event that they fail to use the spermicide correctly.

TROUBLESHOOTING

Inserting a spermicide should be practised before coitus takes place, in order to increase comfort with use. If genital irritation develops, steps must be taken to rule out an STI, vaginal moniliasis, and bacterial vaginosis. If there is an unpleasant genital odour, cultures should be taken and any specific infection treated.

If “messiness” is a problem, spermicidal film or bioadhesive jelly should be recommended.

If lack of spontaneity is an issue, bioadhesive jelly can be inserted up to 24 hours before intercourse.

Table 8. How to Use Spermicides

- Read and follow the package instructions.
- Insert spermicide high in the vagina to cover the cervix.
- Use the appropriate amount of spermicide.
- Wait the recommended time between insertion and intercourse.
- Insert an additional application of spermicide with every act of intercourse.
- Do not douche for at least 6 hours after intercourse.
- Always have additional supply of spermicides.

SUMMARY STATEMENTS

1. Latex condoms, used consistently and correctly, will provide protection against pregnancy (Level II-2) and STIs, including HIV infection (Level II-1). However, no barrier contraceptive method can provide 100% protection from all STIs.
2. Polyurethane and other non-latex condoms have an increased incidence of breakage and slippage compared to latex condoms; hence, the protection they provide against STIs and HIV infection is inferior to that of latex condoms (Level I). Polyurethane condoms remain important options for reducing the risk of STIs in the presence of latex allergies. Lambskin condoms do not protect against HIV infection.
3. The use of spermicide-coated condoms is associated with an increased incidence of urinary tract infections. (Level II-1)
4. The effectiveness of barrier methods will be complemented by the use of emergency contraception and fertility awareness. (Level III)
5. Condoms lubricated with nonoxynol-9 are no more effective in reducing the risk of pregnancy or infection than condoms lubricated with other products. (Level III)
6. Spermicides used alone are not a highly effective contraceptive method, although their efficacy may be enhanced when used in combination with another contraceptive method. (Level II-2)
7. The frequent use of nonoxynol-9 products may cause vaginal epithelial damage and may increase the risk of HIV infection. (Level 1)

RECOMMENDATIONS

1. **Health-care providers should promote the consistent and correct use of latex condoms to protect against pregnancy, human immunodeficiency virus (HIV) infection, and other STIs. Health-care providers should provide men and women with information on the male and female condom. (Grade A)**
2. **Women who use barrier methods of contraception should be provided with emergency contraception and relevant counselling. (Grade B)**
3. **Health-care providers should educate women and men about the correct use of barrier methods. They should emphasize the need for dual protection against pregnancy and infections. (Grade B)**
4. **The use of spermicide-coated condoms should no longer be promoted. Nevertheless, the use of a nonoxynol-9 lubricated condom is preferable to the use of no condom at all. (Grade C)**
5. **Health-care providers should be encouraged to be familiar with the technique of fitting a diaphragm. Diaphragms and cervical caps should continue to be available in Canada. (Grade C)**

6. **Nonoxynol-9 should not be used to reduce the risk of STIs and HIV infection. Condoms should always be used to reduce the risk of infections. (Grade A)**
7. **Since frequent use of nonoxynol-9 products may cause epithelial damage and increase the risk of HIV infection, health-care providers should advise women who have multiple daily acts of intercourse to avoid using nonoxynol-9 products. (Grade A)**

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CHAPTER 9: NATURAL FAMILY PLANNING METHODS

Ruth Miller, MEd,¹ Louise Hanvey, BN, MHA²

¹Toronto ON

²Chelsea QC

Natural family planning (NFP) refers to methods of controlling fertility that do not involve the use of contraceptive devices or chemicals. It relies on an understanding of the physiology of the menstrual cycle and on the timing of ovulation to schedule

coitus in order to reduce or eliminate the potential for conception to occur. This understanding is also used to maximize the potential for conception in couples who wish to conceive. Natural family planning methods include fertility awareness, coitus interruptus (withdrawal), and abstinence.

I. FERTILITY AWARENESS

INTRODUCTION

Some natural family planning methods use fertility awareness as their basis. Fertility awareness methods identify the woman's fertile period and thereby the days on which intercourse should be avoided or carefully protected with barrier methods. Couples can use this information to guide their efforts to avoid or achieve pregnancy.^{1,2}

The 3 primary fertility signs are changes in cervical mucus, basal body temperature (BBT), and cervical position. In addition to methods that observe biological signs of fertility, some methods rely only on calculations using the calendar.

EFFICACY

The effectiveness of NFP methods is difficult to calculate. Most published studies are flawed in design and calculate pregnancy rates incorrectly. Reports of effectiveness do not usually include data on methods of teaching, content of teaching, time spent teaching, and whether one or both partners were taught.¹ The World Health Organization cites a failure rate of 20% for common use and 1% to 9% for perfect use.³

MECHANISM OF ACTION

FERTILITY AWARENESS AND THE SYMPTOTHERMAL METHOD

This method uses all 3 fertility signs.

CERVICAL MUCUS

The woman is taught to monitor the volume and changes in quality of cervical mucus before ovulation. The mucus becomes clearer and more elastic (described as showing spinnbarkeit) as ovulation approaches. After ovulation, the mucus becomes viscid, opaque, and impenetrable to sperm, and mucus volume reduces abruptly. Three days after "peak" (clearest and most elastic) mucus, the woman enters the less fertile phase. Although there may be a first infertile phase starting with the first day of menses, it varies in length depending on the rapidity of the ovarian follicular response. If the follicular response is very rapid, there may be mucus present during menstruation. Although the timing of ovulation may be unpredictable, observing cervical mucus changes can alert women to its approach.

BASAL BODY TEMPERATURE

Body temperature is measured orally or vaginally, using a special BBT thermometer, after at least 6 hours of sleep. Following the post-ovulatory elevation of progesterone, basal temperature should rise in the luteal phase of the cycle by at least 0.5°C. Given that this temperature rise follows ovulation, it indicates that the fertile period has ended. However, for women who wish to conceive, it may reveal a pattern of ovulation for future cycles. To avoid pregnancy, unprotected intercourse should be delayed until after 3 consecutive days of temperature elevation.

CERVICAL POSITION

Women are taught to detect the changes in the position of the cervix and in the size of the cervical os. The cervix can be felt close to the introitus post-menstrually, and its position rises appreciably within the vagina during the follicular phase. It reaches its highest point at ovulation. The consistency of the cervix becomes soft and the os more open. During the luteal phase it descends within the vagina and becomes firm, closed, and closer to the introitus. This sign is the most difficult to assess for most women.

BILLINGS OVULATION METHOD

The Billings method relies on cervical mucus changes only, as described above. It is used primarily by couples for whom the teachings of the Roman Catholic Church allow no recourse to barrier methods. In those for whom pregnancy would be undesired, reliance on the second infertile phase only (post-ovulation) is advised.⁴

TWO-DAY ALGORITHM

This is a simple method for identifying the fertile window. It classifies a day as “fertile” if the cervical secretions are present on that day or were present on the previous day. This method may be useful in populations where other NFP methods are difficult to implement due to lack of trained NFP teachers or to the cost and availability of BBT thermometers.⁵

STANDARD DAY METHOD

This method defines menstrual cycle days 8 to 19 as the fertile window.⁶ During this time the couple abstains from intercourse. This method is only useful for women with cycles ranging from 26 to 32 days in length. It requires a long period of abstinence but can be combined with a barrier method. It is not as reliable as methods that chart fertility signs, as it does not account for circumstances that would affect the timing of ovulation such as stress or illness.

CALENDAR METHOD

Women must calculate the onset and duration of their fertile period based on the assumptions that ovulation occurs 12 to

16 days before the onset of the next menses, that sperm remain viable for up to 5 days, and that the oocyte survives unfertilized for 24 hours. Based on this method, a couple would avoid intercourse or use another contraceptive method during an 8- to 10-day period in each cycle. The woman must chart a menstrual calendar over several months. Her fertile period is determined by subtracting 20 days from the length of her shortest cycle (to establish when the fertile period begins) and subtracting 10 days from the length of her longest cycle (to establish when the fertile period ends.) This method is not recommended as a sole method of contraception.

OVULATION PREDICTOR KITS

Most research on ovulation prediction and detection devices has focused on helping women who wish to conceive. Most ovulation-predictor home test kits detect a specific level of luteinizing hormone (LH) in urine or saliva which will be present on the day before or the day of ovulation. Women seeking to conceive can time intercourse to coincide with these days (or earlier in the fertile time if she is using a fertility awareness-based method). Two fertility indicator kits available in Canada monitor saliva patterns which correlate with serum estradiol levels and ovarian follicular activity. All of these products are marketed as aids for women to determine the best time for conception — not for contraception.^{7,8}

A new test kit has been developed to help women avoid pregnancy. The test uses a small hand-held electronic monitor and disposable urine test sticks. The monitor measures a urinary metabolite of estrogen and LH.^{9,10} An independent prospective study showed a method failure rate of 6.2%,^{11,12} although others consider it to be higher.¹³ It is available in some countries in Europe.

LACTATIONAL AMENORRHEA METHOD

The lactational amenorrhea method (LAM) of contraception is highly effective as a temporary postpartum method in a variety of cultures, health-care settings, socio-economic strata, and in both industrial and developing country locales.¹⁴ The method is based on the physiological infertility of breastfeeding women caused by hormonal suppression of ovulation.

This method is 98% effective for a breastfeeding woman if

1. her menses have not returned *and*
2. she is fully or nearly fully breastfeeding (i.e., the only additional intake is infrequent water, juice, or vitamins); *and*
3. her baby is under 6 months of age.

Intervals between breastfeedings should not exceed 4 hours during the day and 6 hours at night.¹⁵ Since the pregnancy rate increases in women whose infants are receiving supplementary food,¹⁶ despite continued lactational amenorrhea, a supplementary contraceptive method should be used by these women if they wish to avoid conception.

INDICATIONS

Natural family planning may be a contraceptive option for

- couples who wish to avoid using barrier or hormonal methods of contraception
- couples who wish to increase the effectiveness of barrier methods or withdrawal during the fertile phase
- couples for whom an accidental pregnancy would be acceptable

Please note: One additional indication for LAM is being post-partum which is a contra-indication for the other natural family planning methods.

CONTRAINDICATIONS

Natural family planning may not be a suitable option for

- couples who are unwilling or unable to be diligent about observing and charting the signs of fertility, and about complying with the rules to prevent pregnancy
- women whose menstrual cycles are erratic
- women post-partum (except for LAM)
- women who have difficulty assessing cervical mucus because of vaginal infection or use of vaginal agents (e.g., lubricants, spermicides)

NON-CONTRACEPTIVE BENEFITS

Women who monitor or chart their fertility signs often have greater awareness of their own gynaecological health and are better able to discern the difference between normal and abnormal cervical secretions. As well, charting fertility signs can alert women to factors that may contribute to infertility, such as anovulation.⁴ Incorporating this information into family planning programs generally would greatly benefit women.¹⁷

RISKS AND SIDE EFFECTS

There is a high probability of failure with all fertility awareness methods if they are not used consistently and correctly. Also, for the protection against STIs condoms need to be used in addition to NFP.

MYTHS AND MISCONCEPTIONS

1. Most women know when they are fertile.

Fact: Numerous studies have shown that many women are not well informed about when they are fertile during each month.¹⁷

2. NFP is unreliable.

Fact: These methods can be quite reliable when used correctly. The World Health Organization cites a failure rate of 20% for common use and 1% to 9% for perfect use.³

INITIATION

Instruction in NFP is recommended, although women can learn this method from a number of reference books — the most comprehensive of which is *Taking Charge of Your Fertility*.¹⁸ Courses may be given in the community, although potential users should be aware that some organizations teach natural family planning within a religious context and do not condone the use of barrier methods as an adjunct to this method (e.g., the Serena organization). This organization uses a couple-to-couple approach to teach the Symptothermal method of NFP within a religious framework.

When fertility signs are difficult to assess (such as in the presence of a vaginal discharge), either barrier contraceptives or abstinence should be used. A woman who has intercourse within the fertile period could use emergency contraception.

The Billings ovulation method is taught by Billings certified instructors who work within the framework of the Roman Catholic Church.

TROUBLESHOOTING

Couples who chose NFP should be counselled about emergency contraception.

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2. COITUS INTERRUPTUS (WITHDRAWAL)

INTRODUCTION

Coitus interruptus is probably more widely used for contraception than is acknowledged. Up to 9% of sexually active women in Canada report using withdrawal as a method of contraception.¹ Family planning professionals and survey respondents may not regard coitus interruptus as a legitimate contraceptive method, and may therefore fail either to ask about or to acknowledge its use. It is widely used in both developed and developing countries.²

EFFICACY

It is difficult to accurately assess the effectiveness of this method because data are lacking.³ Failure rates for the first year of using withdrawal have been described as 4% with perfect use and 19% with typical use, although the estimate of failure with typical use is probably high.⁴

MECHANISM OF ACTION

During coitus the male withdraws the penis from the vagina prior to ejaculation.

INDICATIONS

Withdrawal may be a contraceptive option when

- no other contraception is available
- the couple prefers to avoid hormonal, barrier, and permanent methods of contraception
- religious considerations preclude the use of other methods
- intercourse is infrequent

CONTRAINDICATIONS

Since intromission occurs, this method of contraception should not be used if there is a known risk of sexually

transmitted infection (STI).

Women who need to avoid pregnancy should not rely on this method alone.

NON-CONTRACEPTIVE BENEFITS

There are no costs involved. Theoretically, withdrawal reduces the risk of male-to-female transfer of human immunodeficiency virus (HIV) because the virus is concentrated in semen.⁵

RISKS AND SIDE EFFECTS

Use of withdrawal requires self-control. The man must have the ability to recognize impending ejaculation and to resist the urge to pursue coital movement.

Theoretically, the pre-ejaculate contains no spermatozoa. One study has shown the presence of a small number of clumped spermatozoa in the pre-ejaculate, presumably from a prior ejaculation.⁵ In HIV-infected men, the pre-ejaculate may contain HIV-infected cells.⁶ Other STIs may also be transferred, if they are transmitted by mucosal or skin contact.

MYTHS AND MISCONCEPTIONS

1. Withdrawal is not an effective method of contraception.
Fact: This method is widely used around the world and can be effective if followed carefully.
2. The pre-ejaculate contains enough sperm to achieve a pregnancy.
Fact: Although there have been few studies in this area, existing research suggests that the pre-ejaculate does not contain sperm.⁶

INITIATION

Health care providers should make people aware that withdrawal should not be used permanently. Other options of contraception should be offered. The patient should know about all the risks involved since the withdrawal requires considerable self-control.

TROUBLESHOOTING

The couple should be counselled about emergency contraception, should there be inadvertent contact between the ejaculate and the vagina or external genitalia.

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3. ABSTINENCE

INTRODUCTION

Abstinence is defined by some as refraining from all sexual behaviour, including masturbation; by some as refraining from sexual behaviour involving genital contact; and by others as refraining from penetrative sexual practices.¹

Giving and receiving sexual pleasure without penetration is an important part of sexual expression for both men and women and is effective in decreasing the risk of sexually transmitted infection (STI) and pregnancy.

EFFICACY

If the goal of abstinence is to avoid unwanted pregnancy, this method is very effective and allows people to be involved in other forms of sexual expression without increasing the risk of pregnancy. However, if the goal is to avoid STIs, then oral-genital sex, anal-genital sex, and other activities that expose the partner to pre-ejaculatory fluid, semen, cervical-vaginal secretions, or blood must be avoided.

Although very few cases of human immunodeficiency virus (HIV) transmission have been reported if the only transmission of fluid has been during oral sex,^{2,3} it is possible to transmit gonorrhoea, syphilis, hepatitis B, herpes simplex virus, and chlamydia by mouth-to-penis contact (fellatio).⁴ Mouth-to-vulva contact (cunnilingus) can transmit herpes and syphilis.^{4,5}

ADDITIONAL DEVICES

The use of a dry latex condom during fellatio or a dam during cunnilingus can be effective. Spermicidal condoms are not recommended, since they are unlikely to provide better protection, and the taste is very often unpleasant.

INDICATIONS

Primary abstinence (i.e., abstaining from some or all sexual behaviour by a person who has not yet been sexually active) is not uncommon among young people. Indeed, people of all ages

deliberately choose to abstain at a number of times throughout their lives.¹

CONTRAINDICATIONS

Both partners in a relationship should choose this method to avoid frustration on the part of one.

NON-CONTRACEPTIVE BENEFITS

Non-contraceptive benefits of abstinence include

- freedom from the threat of STI and HIV infection if there is no exchange of body fluids
- no physical side effects
- no need to visit a health-care provider. However, health-care providers can offer valuable support, information, and alternative options should individuals wish to consult about this method
- no cost, unless condoms and dams are used

RISKS AND SIDE EFFECTS

Risks and side effects include concern that abstinence

- may be too restrictive for some couples
- does not encourage the use of other methods of contraception, if behaviour patterns change

MYTHS AND MISCONCEPTIONS

1. “Just say no,” or abstinence-only education, is an effective approach to sex education for young people.

Fact: No abstinence-only sex education program has been shown to increase the likelihood that young people will delay first intercourse for any longer than those who do not receive such programs.⁶ This is in contrast to the results of “abstinence-plus” programs that strongly encourage youth to be abstinent but also encourage youth to use condoms and contraceptives if they do have intercourse; these programs have been found to delay first intercourse for an appreciable time period.⁶ Many studies with very strong research designs have demonstrated that programs with common characteristics, (such as that they clearly focus on reducing specific sexual risk-taking behaviours, provide directly relevant information, give students the opportunity to develop the motivation and personal insight to use the information, and help them develop the necessary behavioural skills), can delay sexual intercourse, reduce its frequency, and increase use of condoms and other contraceptives.^{7,8}

2. Once people have had sexual intercourse, they will not willingly choose abstinence.

Fact: Once young men and women have satisfied their initial curiosity about intercourse, and once they feel socially

comfortable with their level of sexual sophistication, they may decide to become abstinent, removing themselves at least temporarily from the health risks of intercourse. Health-care providers can help young people learn that the door between abstinence and sexual activity opens in both directions.¹

INITIATION

Asking individuals what they define as abstinence is an important question with clinical implications.

Couples and individuals practising abstinence deserve respect, encouragement, and non-judgemental support. They should be offered education about other methods of birth control and safer sex to help them if their sexual agenda changes. Assisting with communication skills to transmit intentions to partners can be valuable, especially for young people. Those who practise abstinence should be informed about emergency contraception and its availability in their community.

TROUBLESHOOTING

Health-care providers should determine with those choosing abstinence why they made this choice, what sexual activities they will say “yes” to, and whether they have discussed these with their partner. It is important to help them avoid high-pressure sexual situations and teach them techniques for saying “no.”

It is also important to suggest that condoms be readily available in case they change their minds; in addition, they must be aware of options for emergency contraception.

SUMMARY STATEMENTS

1. Natural family planning methods may provide effective contraception when used diligently and selectively. (Level II-2) These methods may be appropriate methods of contraception for couples who are willing to accept a potentially higher rate of contraceptive failure. (Level III)
2. Fertility awareness may be used in combination with non-hormonal methods of contraception to enhance the effectiveness of these other methods. (Level III)
3. Coitus interruptus (“withdrawal”) is preferable to no contraception at all, but failure rates may be high and it does not provide protection against STIs. (Level II-2)
4. The lactational amenorrhea method is an effective method of contraception for the first 6 months postpartum in women who are exclusively breastfeeding and have not yet resumed menstrual cycling. (Level II-2)
5. Abstinence is a valid contraceptive choice. Although programs have been introduced to promote abstinence among young people, there is no evidence that abstinence-only programs are successful in delaying first intercourse among adolescents. (Level I)

RECOMMENDATIONS

1. **Health-care providers should respect the choice of a natural family planning method and be able to provide resources to support the correct use of this method. (Grade C)**
2. **The use of coitus interruptus (“withdrawal”) should be recognized as a risk-reduction strategy. When couples use coitus interruptus or other natural family planning methods, health-care providers should provide information about emergency contraception. (Grade C)**
3. **Health-care providers should acknowledge and legitimize abstinence as a valid contraceptive choice. (Grade B)**
4. **Comprehensive sex education should be available to all Canadians. Education programs should provide information on abstinence as well as on contraception and STI prevention. (Grade B)**
5. **Health-care providers should be able to counsel postpartum women about the contraceptive efficacy and correct use of the lactational amenorrhea method. (Grade A)**

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CHAPTER 10: STERILIZATION

Claude A. Fortin, MD, FRCSC,¹ Edith Guilbert, MD, MSc²

¹Montreal QC

²Quebec City QC

INTRODUCTION

It is important that individuals who consult for sterilization want no more children, or want to remain childless, and they need a highly effective contraceptive method. To make an informed decision, these individuals should have an accurate

understanding of sterilization and should consider their own needs and those of their family. The decision should be made without pressure or coercion from anyone else.¹

I. TUBAL LIGATION

EFFICACY

Although in theory tubal ligation will prevent pregnancy absolutely, conceptions do occur. Failure of tubal ligation continues to occur well beyond the first year after surgery, and at 10 years post-surgery, the overall figure rises to 1.8%.² In one Canadian province, the failure rate of tubal ligation at 20 years was 0.9%.³

The 10- and 20-year cumulative probabilities of failure are affected by age at tubal ligation. The probability of failure for women sterilized at age 28 or less is greater than for women sterilized beyond age 34, for all methods of sterilization except for interval partial salpingectomy.^{2,3} Tubal ligation performed vaginally may be technically difficult, and may therefore carry a higher chance of failure. A New Zealand review⁴ described a failure rate after vaginal tubal ligation of 4.8%, compared with a rate of 1.2% after Filshie clip application, 1.4% after application of Falope rings, and 3.4% after application of Hulka clips. Two randomized controlled trials comparing use of Hulka and Filshie clips for sterilization showed 24-month cumulative pregnancy rates of 28.1/1000 women and 9.7/1000 women, respectively — although this difference was not statistically significant.⁵ The World Health Organization cites a failure rate after tubal ligation of 0.5%.⁶

MECHANISM OF ACTION

Tubal ligation techniques result in the occlusion of the fallopian tubes, preventing the ovum and spermatozoa from meeting.

The choice of occlusion method depends upon the surgeon's training, personal experience, and the technical facilities. It will also depend on whether the sterilization is performed remote from a pregnancy (interval sterilization), or post-abortion, or post-partum.

Interval sterilizations are most commonly performed via laparoscopy. The techniques used for tubal ligation performed

laparoscopically are the application of tubal clips or rings, or electrocautery of a portion of tube.

Interval sterilizations may also be performed via a small ("mini") laparotomy incision, or they may be performed at the time of a laparotomy done for an unrelated indication. With a laparotomy approach, any of the laparoscopic techniques for occlusion may be used; more commonly, an intervening segment of tube is excised and the ends ligated (the Pomeroy method). The vaginal colpotomy approach to interval tubal ligation has now been largely abandoned because of increased risks of infection and post-sterilization failure and dyspareunia.⁷

The frequency of concurrent sterilization and abortion is unknown, but effective counselling is mandatory and has to be provided with expertise.⁸

Post-partum sterilization must also be performed after careful counselling. Post-partum sterilization should be performed either within 7 days of delivery or postponed until at least 4 weeks after delivery.⁹ Usually a tubal excision method will be used rather than an occlusive method. Tubal ligation may also be performed by an excisional technique at the time of Caesarean section. If partial salpingectomy is performed, the superior long-term success appears to be higher.²

TRANSCERVICAL STERILIZATION

As of 2002, a new transcervical approach for tubal occlusion has gained popularity and received acceptance by the Canadian Therapeutic Products Directorate and the U.S. Food and Drug Administration.¹⁰ It is a method of sterilization that involves accessing the tubes through hysteroscopic or blind placement of a device or occlusive material that blocks the tubes.

The procedure offers numerous potential advantages over other sterilization methods: no incision is required; it is performed under local anaesthesia or minimal sedation, in an office setting with a rapid recovery; and it has been shown to be highly reliable and cost-effective.¹¹ However, health professionals need special training to perform this technique, and women must use another method of birth control for at least 3 months before the technique is felt to be fully reliable.

The only device available for clinical use in Canada is the Essure System. The device consists of an expandable outer nitinol coil, containing polyester fibres and a stainless steel inner coil that dynamically expands into the proximal portion of the fallopian tube. Over a 3 month period, tissue grows over the device to occlude the tubes completely. In women in whom both tubes were accessible and the devices properly placed, no pregnancies and a low complication rate have been reported.¹¹

Other transcervical approaches are currently under different phases of trials or animal studies. These include the Adiana system, the Intratubal Ligation Device, and the use of

Table 1. 10-Year Failure Rates (Crest Study)²

Method	Rate (%)
Bipolar tubal coagulation	2.48 (1.63–3.33)
Unipolar tubal coagulation	0.75 (0.11–1.39)
Silicone ring	1.77 (1.01–2.53)
Spring clip (Hulka)	3.65 (2.53–4.77)
Interval partial salpingectomy	2.01 (0.47–3.56)
Postpartum partial salpingectomy	0.75 (0.27–1.23)
All methods	1.85 (1.51–2.18)

quinacrine pellets or erythromycin tablets for tubal occlusion.¹² Effects of the presence of any of these devices on the success of subsequent in vitro fertilization are unknown.

INDICATION

Assessing the needs of individuals who consult for a sterilization procedure is crucial, because the procedure should be considered permanent. Reversal of sterilization, although feasible, is difficult to obtain, involves riskier surgery than sterilization itself, is expensive, and often does not succeed in restoring fertility.^{13,14} There are contraceptive methods other than sterilization that are easily available to both men and women, and the sterilization procedure may have unwanted side effects.

Health care providers should be aware of the legal requirements for obtaining informed consent for sterilization, including an explanation of benefits and risks, options, and determination of whether the person is competent to understand the information.¹⁵ When the person has a mental disability, it is even more difficult for the physician to determine their capacity to provide informed consent.¹⁶ Contraceptive sterilization of an incompetent, mentally disabled person is illegal.¹⁷

SPECIAL CONSIDERATION WITH THE TRANSCERVICAL PROCEDURE

Since reversibility of this procedure is virtually impossible, appropriate counselling is extremely important. Women with uterine or tubal disease, who are ambivalent about sterilization, or who feel uncomfortable about having a device or materials inserted into their fallopian tubes should not be offered this technique. Women who have a contraindication to laparoscopic sterilization (obese or severe medical conditions), and who are over age 30 with no uterine or tubal anomaly, might be eligible for transcervical sterilization. Long-term efficacy and potential hidden side effects are not known for this method.

CONTRAINDICATIONS

The following are considered contraindications to performing tubal ligation:

1. systemic health problems, especially cardiopulmonary conditions that may be aggravated by general anaesthesia
2. pregnancy (unless the sterilization procedure is done at the time of abortion or immediately postpartum)
3. the presence of pelvic infection, or inability to access the fallopian tubes at surgery
4. uncertainty about whether permanent contraception is desired

The major concern with sterilization is regret. The cumulative like-

lihood of expressing regret, requesting information about reversal of sterilization, and obtaining reversal, increase over the years following sterilization.^{3,18-21} During a follow-up interview within 14 years of tubal sterilization, 20.3% of women who have been sterilized before age 30 expressed regret about undergoing the procedure, compared to 5.9% of those sterilized after age 30.¹⁸ The probability of reversal in one Canadian province, over 20 years, was respectively 4.2% and 3.9% for women and men who were sterilized before age 30, and 0.4% and 1.0% for those sterilized in their late 30s.³ Other known risk factors for regret and reversal are having young children; experiencing couple disharmony; and being sterilized at the time of Caesarean section or shortly after delivery, spontaneous or induced abortion.^{3,18-24} Common reasons given for requesting reversal are: "did not receive enough information," "was pushed into this procedure," sexual side effects from sterilization, the establishment of a new relationship, improvement in housing or financial circumstances, or the loss of a child.²²⁻²⁴

NON-CONTRACEPTIVE BENEFITS

Tubal ligation, although somewhat invasive, provides women with a very private and cost-effective method of contraception, with no significant long-term side effects, no compliance issues, and no interference with intercourse.

SIDE EFFECTS

The following are possible short-term side effects from tubal ligation:

- shoulder tip pain secondary to usage and remaining of some gas (CO₂) inside the peritoneal cavity
- lower abdominal pain or cramps
- bruising, bleeding from incisions
- post-operative nausea and light-headedness

RISKS

SHORT-TERM COMPLICATIONS

The incidence of complications depends on the procedure performed (laparoscopy or laparotomy, mechanical or thermal), the anaesthesia used (local or general), and the experience of the surgeon.²

Potential complications include the following:

- anaesthesia-related risks
- wound infection
- bruising
- hematoma formation
- urinary complications
- mesosalpingeal tears and trans-section of the tube from ring or clip application (may require laparotomy to control bleeding)

- mechanical trauma, including uterine perforation with uterine elevator
- injury to blood vessels, intestines or other organs (incidence approximately 0.6 per 1000 cases).²⁵ Bowel burns complicating tubal electrocoagulation may result in delayed perforation and peritonitis.

POTENTIAL RISKS WITH USE OF THE TRANSCERVICAL PROCEDURE

Some risks that are possible with the transcervical procedure include the following:

- perforation or dissection of fallopian tube or uterine cornu
- uterine perforation by the hysteroscope
- placement of micro-insert into the myometrium or into the distal tube
- subsequent procedures such as electrocautery, endometrial biopsy, dilatation and curettage, or endometrial ablation potentially could dislodge a micro-insert or interrupt its ability to prevent pregnancy¹¹

LONG-TERM COMPLICATIONS

ECTOPIC PREGNANCY

Ectopic pregnancy should be ruled out whenever a woman shows signs of pregnancy following tubal occlusion. The CREST study demonstrated a 10-year cumulative probability of ectopic pregnancy of 7.3 per 1000 women for all methods combined.² A report from Korea of ectopic pregnancies following sterilization showed an approximately 3-fold greater incidence of ectopic pregnancies after electro-coagulation than after the use of silastic rings or clips.²⁶ Ectopic pregnancy was most often related to the following: utero-peritoneal fistula after unipolar electro-coagulation; inadequate coagulation or recanalization after bipolar procedures; recanalization or fistula formation after Pomeroy, tubal ring, or clip procedures.²⁷

MENSTRUAL PATTERN CHANGES

Abnormal menstrual patterns have been thought to occur following sterilization, and a “post-tubal ligation syndrome” has been proposed. There is no supportive evidence.²⁸⁻³¹

A recent review of the literature comparing sterilized and control women found no difference in hormones levels and little difference in menstrual cycle characteristics.³²

PSYCHOSEXUAL PROBLEMS

No evidence of psychological problems or detrimental long-term effects on sexuality has been demonstrated.

MYTHS AND MISCONCEPTIONS

1. The risk of having a hysterectomy is increased after tubal ligation.

Fact: A single study found an increased risk of hysterectomy in women who underwent sterilization between the ages of 20 and 29, but not among women sterilized over the age of 30.³³ No biological basis for these results has been found.^{33,34}

INITIATION

Taking a medical and a contraceptive history is essential. Key elements in the medical history are the patient’s age, marital status, spouse’s age, type of relationship, number and age of children, contraceptive experience, reasons for sterilization, and systemic health problems. The medical history will emphasize any history of pelvic disease, previous abdominal or pelvic surgery, heart or lung disease, bleeding problems, allergies, medication, and previous problems with general anaesthesia.

A complete physical examination must be performed shortly before sterilization.

Laboratory evaluation may be limited to measurement of haemoglobin level. Effective contraception must be used until the time of the tubal ligation.

Since post-sterilization regret is common, careful pre-surgery counselling with awareness of risk factors is essential. Information about the type of operation — including risks and benefits, the availability of alternative methods of family planning, the possibility of failure, and the possibility of reversal — must all be discussed so that the individual can provide informed consent for surgical sterilization. A consent document, readily understandable in the individual’s own language, must be signed. It is recommended that the sterilization be performed a few weeks after the initial interview, to allow more consideration of the choice of sterilization. Written information may be useful.

TROUBLESHOOTING

REVERSAL

Reversal of tubal ligation requires major surgery and special surgical skills. Some women are not appropriate candidates because of the way the sterilization was performed. Success cannot be guaranteed and reversal surgery is usually expensive. There are operative risks due to anaesthesia and the usual risks of major abdominal surgery. The risk of ectopic pregnancy is about 5% following reversal surgery and depends on the type of tubal ligation.² Pre-reversal assessment includes exclusion of male possible infertility factors, female ovulation disorders and laparoscopic assessment of the tubal segments.

Rates of subsequent term delivery vary, but they are highest after reversal of occlusion techniques that damage a small segment of the tube (such as with a tubal clip or ring) and lowest after electrocoagulation. (See Table 2.) The occurrence of ectopic pregnancy after reversal surgery may be due to pre-existing abnormal tubal function, or to factors arising from the surgical technique used. In vitro fertilization (IVF) may be an

option for women who are poor candidates for reversal surgery.²³

IN VITRO FERTILIZATION AND FAILED REVERSAL

In 37 couples in whom reversal of sterilization either failed or was not attempted, the probability of pregnancy after IVF related more to patient age than to previous fertility. Compared to a control group of women with tubal pathology, women who underwent tubal ligation below age 38 produced a similar number of oocytes and an identical number of embryos for transfer.²⁶

2. VASECTOMY

EFFICACY

Pregnancy rates following vasectomy vary from 0% to 2.2% with any occlusion method.^{35,36} No carefully controlled studies have compared the different occlusion methods.³⁶

Failure rate of vasectomy is also measured through the occurrence of recanalization. Because spermatozoa persist in the seminal vesicles, and thus in the ejaculate, for 2 to 3 months or 10 to 30 ejaculations after vasectomy, recanalization cannot be assessed before such time or number of ejaculations have passed.^{37,38} Recanalization occurs in up to 2.6% of cases within 3 months after vasectomy.^{35-37,39-42} It is important to realise that the main reason for conception post-vasectomy is the failure of couples to use back-up contraception immediately after the procedure.^{35,36}

Use of an electrocoagulation technique,^{40,41} fascial interposition,^{41,43} removing a larger piece of vas,⁴⁰ and experience on the part of the physician⁴⁴ may increase the efficacy of vasectomy, although well-controlled trials are yet to be done to confirm the importance of these factors. Sterile water irrigation of the vas deferens does not seem to increase efficacy or reduce the possibility of lingering sperm.^{45,46}

MECHANISM OF ACTION

There are 2 principal techniques for vasectomy:

- **Conventional vasectomy**¹ involves making 1 or 2 incisions in the scrotal skin; exposing, isolating, and dividing the vas; removing a 1.5-cm segment from each side; sealing the ends of the vas with non-absorbable suture, cautery-induced burn, or clips; and finally closing the scrotal incision.

Table 2. Probability of Pregnancy Following Reversal of Tubal Ligation²³

Technique	Pregnancy Rate (%)
Clip	90
Ring	76–80
Pomeroy	67
Monopolar cautery	52

- **No-scalpel vasectomy**^{38,47} is done through a tiny puncture opening in the scrotal skin; the rest of the technique is identical to the conventional procedure. No skin sutures are needed. The operating time is reduced to about one-half of the time of the conventional method.³⁸

Other approaches to male sterilization involve percutaneous chemical occlusion of the vas,⁴⁸ or use of silver, silicone rubber–silver, or tantalum ring clips — the latter of which is compatible with reversible vasectomy.^{1,47}

INDICATIONS

This method is suitable only for men who seek a permanent method of contraception.

CONTRAINDICATIONS

Contraindications of the vasectomy include the following:

1. systemic health problems, such as allergy to local anaesthetics, immunosuppression, acute infectious diseases, or coagulation problems that cannot be controlled with vasopressin
2. local infection
3. local genital abnormalities impairing adequate localization of the vas deferens, such as hernia, varicocele, hydrocele, or tumour
4. uncertainty about permanent contraception
5. sexual dysfunction

NON-CONTRACEPTIVE BENEFITS

Vasectomy provides the same advantages as tubal ligation. In addition, it is a simple intervention with very few complications, is easy to perform and to obtain, and does not require general anaesthesia.

RISKS AND SIDE EFFECTS

SIDE EFFECTS

The side effects of the vasectomy include

- local pain and
- scrotal ecchymosis and swelling.

SHORT-TERM COMPLICATIONS

The following complications are less common with the no-scalpel vasectomy³⁸ and the use of suturing clips⁴⁹:

- vasovagal reaction: up to 30%^{50,51}
- hematoma: 1% to 10%^{40,44,49-51}
- infection^{38,40,44,51}: 0.4% to 16% (from mild erythema and stitch abscess to fulminant Fournier's gangrene)⁵²
- granuloma formation from extruded sperm, either at the vas or in the epididymis: 1% to 50%^{40,42,51}; this is reduced when the proximal vas is left open.^{53,54} It pre-

disposes to recanalisation⁵¹ and may cause significant pain with palpation or during intercourse and ejaculation

- epididymitis and vasitis: 0.1% to 8%^{49,51,55}

RARE COMPLICATIONS

- congestive epididymitis (reduced with open-ended vasectomy)⁵³
- congestive orchalgia⁵¹
- vasocutaneous fistula⁵¹
- hydrocele⁴⁹
- missed vas deferens or damage to scrotal structures^{49,51}
- impotence and depression, which usually respond to psychological treatment⁵¹; improved psychosexual adjustment and enjoyment is usually reported following vasectomy.⁵⁶

LONG-TERM COMPLICATIONS

IMMUNOLOGICAL CONSEQUENCES

It is now well documented that one-half to two-thirds of vasectomized men develop circulating antibodies to sperm after vasectomy,⁵⁷ and that antibodies may persist for as long as 10 years after surgery.⁵⁸ However, several studies^{55,57,58} did not report any other laboratory abnormalities, nor immunological diseases of any kind.^{57,59,60}

CARDIOVASCULAR DISEASES

Following the identification of a marked increase of atherosclerosis in vasectomized cynomolgus monkeys fed high-cholesterol diets,^{61,62} several large studies (more than 4000 men with observation over 20 years)^{59,60,63} explored the possible relationship between cardiovascular diseases and vasectomy. None found any significant association, and the estimates of relative risk were always near the reference point.^{59,60,63-68} Stroke is the only vascular disease still requiring more long-term studies; at the present time, there does not seem to be any increased risk of stroke in vasectomized men.^{36,58}

TESTICULAR CANCER

Although a few studies reported an association between vasectomy and testicular cancer,⁶⁹⁻⁷¹ most large studies did not find evidence of any risk of testicular cancer in vasectomized men.^{36,58,59,72,73}

MYTHS AND MISCONCEPTIONS

1. Vasectomy increases the risk of prostate cancer.

Fact: In population-based or hospital-based case-control studies, odds ratios for the risk of prostate cancer in vasectomized men ranged from 0.5 to 6.7,^{36,74-76} while in large cohort studies the relative risks varied from 0.8 to 2.1.^{36,77} The findings concerning the association between vasectomy and prostate cancer suggest that the heterogeneity of study

results is likely to be explained by bias, such that the studies with bias operating will have higher risk estimates than those in which the bias has been adequately controlled.³⁶

To date, there is no obvious biological mechanism for a relationship between vasectomy and prostatic cancer,^{75,78} and, overall, the weight of evidence suggests that there is no association.

INITIATION

Taking a medical and a contraceptive history is essential. Key elements in the medical history are the patient's age, marital status, spouse's age, type of relationship, number and age of children, contraceptive experience, reasons for sterilization, systemic health problems, and use of medication that may affect coagulation. It is important to inquire about genital anomalies or diseases and about sexual dysfunction. Examination of the genital area is usually sufficient. Other tests and examinations are done if medically necessary. Measurement of haemoglobin is usually unnecessary for men before vasectomy.

Use of effective contraception is warranted until the time semen analysis shows no spermatozoa. Since post-sterilization regret is common, careful pre-surgery counselling to ensure awareness of risk factors is essential. Information about the type of operation — including risks and benefits, the availability of alternative methods of family planning, the possibility of failure, and the possibility of reversal — must all be discussed so that the individual can provide informed consent for surgical sterilization. A consent document, readily understandable in the individual's own language, must be signed. It is recommended that the sterilization be performed a few weeks after the initial interview, to allow more consideration of the choice of sterilization. Written information may be useful.

MONITORING

No sports or physical strain should be undertaken for 7 days post-operatively; sexual intercourse is prohibited for 5 days, and local or systemic analgesia (ice pack, acetaminophen) can be used if necessary. Post-operative warning signs should be described, specifically extended scrotal edema, severe pain, or fever. The physician should be made aware as quickly as possible if any of these conditions are present.

Standard practice is to require 2 consecutive azoospermic samples, usually at 3 and 4 months, to confirm success.⁷⁹

If the semen analysis shows the presence of motile spermatozoa in 2 consecutive samples, 3 months or more after vasectomy, a repeat procedure is required.⁴⁴

If the semen analysis shows the presence of non-motile spermatozoa, one year or more after surgery, a cautious assurance of sterilization can be given³⁶; annual semen tests may be undertaken for additional reassurance.⁴²

TROUBLESHOOTING

REVERSAL

Vasectomy reversal may be performed under local, regional, or general anaesthesia.¹⁴ Various techniques are used (vasovasotomy or vasoepididymostomy, microsurgery or macrosurgery, one-layer or two-layer), and success depends on the patency of both ends of the vas and on the sperm quality.^{14,80} The sperm count rises slowly after vasectomy reversal, and usually reaches a plateau by 6 months after surgery. The chance of effective recanalization and pregnancy declines with increasing time from the original procedure^{14,80} (see Table 3); however, even after prolonged obstructive intervals or in men with older female partners,⁸¹ vasectomy reversal may offer comparable success rates to intracytoplasmic sperm injection. Before performing vasectomy reversal, counselling should focus on the fertility potential of the partner, potential complications, the probability of success of the reversal, and cost-effectiveness.

SUMMARY STATEMENTS

1. Vasectomy is a less invasive and more cost-effective sterilization procedure than conventional tubal ligation. (Level II-2)
2. Female sterilization using newer transcervical (cornual occlusion) techniques is effective, safe, and less invasive (Level II-2), but virtually impossible to reverse. (Level III)
3. Although tubal ligation and vasectomy are considered safe and very effective family planning methods, complications may occur and failure is possible, even several years after the procedure. (Level II-2)
4. Regret after sterilization is not infrequent, and is likely to be associated with the following factors (Level II-2):
 - young age at the time of sterilization
 - having small children at the time of sterilization
 - sterilization performed soon after delivery, Cesarean section, induced abortion, or the loss of a child
 - when there is discord in the relationship

RECOMMENDATIONS

1. **Couples choosing a sterilization procedure should be informed that vasectomy carries fewer risks than tubal ligation. However, social, cultural, and individual considerations should be taken into account before a**

choice of procedure is made. (Grade A)

2. **Before recommending a transcervical sterilization (cornual occlusion technique), extensive counselling should be offered and the permanence of the procedure reinforced. (Grade B)**
3. **Counselling before sterilization should include discussion of alternative contraceptive methods. Counselling should address the risks, complications, potential for regret, and failure rates associated with the procedure. (Grade B)**
4. **New techniques of female and male sterilization should be available to all Canadians. (Grade C)**

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Table 3. Probability of Pregnancy Following Vasectomy Reversal^{14,80}

Time Since Vasectomy	Sperm in the Semen (%)	Pregnancy (%)
Less than 3 years	97	76
3 to 8 years	88	53
9 to 14 years	79	44
More than 14 years	71	30

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CHAPTER 11: CONTRACEPTION — MEETING SPECIAL NEEDS

Nathalie Fleming, MD, FRCSC,¹ Margaret Morris, MD, FRSCS,² Helen Pymar, MD, MPH, FRCSC,³ Thirza Smith, MD, FRCSC⁴

¹Ottawa ON

²Winnipeg MB

³Toronto ON

⁴Saskatoon SK

At different stages of a woman's reproductive life, or in the face of disability, contraceptive needs require a unique approach. The special needs of these circumstances are considered in the following sections.

I. CONTRACEPTION IN PERIMENOPAUSE

INTRODUCTION

Perimenopause is characterized by fluctuating hormone levels, irregular menstrual cycles, and the onset of symptoms such as hot flashes and insomnia that may increase in number and severity as menopause approaches.^{1,2} While women over the age of 40 may have difficulty in conceiving, most are still fertile and do not seek pregnancy.³

Pregnancy in perimenopause is associated with increased obstetrical and genetic risks, including miscarriage, fetal

abnormalities, and perinatal and maternal mortality.⁴ Contraception should be recommended until menopause is confirmed clinically (usually when amenorrhea has been present for 1 year).¹

Most contraceptive options are open to women in perimenopause. This section will discuss some of the considerations for perimenopausal women, but the details of the methods are located in the respective sections of these guidelines. The choice of method will be moderated by the possible desire for non-contraceptive benefits or the desire for permanent contraception. Women who are not in a steady relationship may choose an intermittent method and may need the protection against sexually transmitted infections (STIs) that a barrier method provides.

ORAL CONTRACEPTIVES

The use of combined oral contraceptives (OCs) is no longer contraindicated in non-smoking women over age 35.^{5,6} Non-contraceptive benefits may be especially helpful in this age group. Low-dose OCs containing 20 to 35 µg of ethinyl estradiol offer many benefits for the perimenopausal woman. A combined OC containing 20 µg of ethinyl estradiol has been shown to provide effective contraception, reduce menstrual cycle irregularity, decrease bleeding, and relieve menopausal symptoms.⁷ Important additional benefits of such treatment include a decrease in the risk of ovarian cancer⁸ and endometrial cancer,⁹ reduced dysmenorrhea and menorrhagia,¹⁰ and a lower risk of functional ovarian cysts.^{11,12} There is a decreased risk of hereditary cancers.¹³ Longer duration of use is associated with decreased risk. The risk of colorectal cancer may also be reduced with OC use.^{14,15}

Women taking a combined OC may experience a return of symptoms during the hormone-free interval, although supplementation during that time with a low dose of estrogen may be helpful. Alternatively, combined OCs may be taken continuously; this may have a number of advantages, including a decreased incidence of pelvic pain, headaches, bloating/swelling, and breast tenderness for women who experience these symptoms during the hormone-free interval.¹⁶

INTRAUTERINE DEVICE

The intrauterine device (IUD) is an effective method of contraception that is well-suited to perimenopause. The copper-bearing IUD has been shown to decrease the risk of endometrial cancer.¹⁷ The levonorgestrel-containing intrauterine system (LNG-IUS) decreases the amount of blood flow and may lead to amenorrhea.¹⁸

Menorrhagia responds favourably to use of the LNG-IUS. In 2 studies of women scheduled to undergo hysterectomy for menorrhagia, 64% to 80% of women randomized pre-operatively to LNG-IUS insertion subsequently cancelled their hysterectomy, compared with 9% to 14% of women randomized

to receive other medical treatments.^{19,20} Dysmenorrhea may also improve in LNG-IUS users.²¹

PROGESTIN-ONLY METHODS

The use of depot medroxyprogesterone acetate or the progestin-only pill are methods that can be used for contraception in perimenopause. These methods may be associated with amenorrhea²² or irregular vaginal bleeding.^{23,24}

BARRIER METHODS

Barrier methods may be appropriate for use in perimenopausal women. Since an unplanned pregnancy may be more undesirable in this age group, the relatively lower contraceptive effectiveness of barrier methods may be a disadvantage.

PERMANENT CONTRACEPTION

In the perimenopausal age group, many couples choose male or female sterilization if they are certain further pregnancy is not desired. Post-sterilization regret is decreased in this age group.²⁵ Menstrual abnormalities are not usually worsened after tubal ligation,²⁶ but the positive effects of combined OCs, the copper IUD, or the LNG-IUS will be lost once their use is discontinued.

Other contraceptive methods are not contraindicated solely by age and may also be valuable for some women.

SUMMARY STATEMENTS

1. In addition to providing effective contraception, low-dose combined OCs provide non-contraceptive benefits for healthy, non-smoking perimenopausal women. Non-contraceptive benefits include suppression of vasomotor symptoms (Level I), cycle control, decreased incidence of anemia (Level II-1), and decreased incidence of endometrial cancer. (Level II-2)
2. The IUD may be a suitable contraceptive method for perimenopausal women. The levonorgestrel-releasing IUS (LNG-IUS) decreases heavy bleeding and may eliminate the need for hysterectomy. (Level I)

RECOMMENDATION

1. **Health-care providers should emphasize the need for effective contraception in perimenopausal women. Non-contraceptive benefits of each method should be taken into account when counselling these women. (Grade A)**

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2. POSTPARTUM CONTRACEPTION

Barrier methods of contraception and spermicides may be used in breastfeeding and postpartum women when they are ready to resume sexual activity. If a woman chooses a hormonal method of contraception, certain restrictions may apply.¹

COMBINED ORAL CONTRACEPTIVES

In breastfeeding women, use of combined oral contraceptives (OCs) may diminish both the quality and quantity of breast milk in the postpartum period. It is suggested that combined OCs should not be used until after lactation is well established (usually 6 weeks postpartum).² A significant amount of progestational component is present in the breast milk when the mother is taking combined OCs. Nevertheless, no adverse effects have thus far been identified. In an 8-year follow-up study of children breastfed by mothers using combined OCs, no effect could be detected on diseases, intelligence, or psychological behavior.^{3,4}

If the woman is not breastfeeding, combined OCs may be introduced 3 to 4 weeks postpartum.²

PROGESTIN-ONLY PILLS

No adverse effects of contraceptive steroids secreted in breast milk, from use of either combined OCs or the progestin-only pill (POP), have been identified in infants.^{5–8} The POP provides a small increase in milk production and women using them breastfeed a longer time.⁸

Progestins administered within the first 72 hours after delivery may theoretically interfere with the fall in serum progesterone levels that triggers lactogenesis, thereby interfering with breast milk production. However, a prospective study did not detect any adverse effect on breastfeeding when progestin-only contraceptive methods were used within the first 72 hours after delivery.⁷

INJECTABLE PROGESTIN

Administration of depot medroxyprogesterone acetate (DMPA) has been shown to be an effective method of postpartum contraception with little or no effect on breast milk production or on infant development.^{9–13}

It may be preferable to wait until breast milk is established before giving the first dose of DMPA. If the woman is not breastfeeding, the first DMPA dose can be given immediately after delivery.

INTRAUTERINE DEVICE

Women who are breastfeeding may be good candidates for use of an intrauterine device (IUD). The IUD can be inserted immediately postpartum (within 10–15 minutes after delivery of the placenta). Women who have an IUD inserted immediately after delivery are at higher risk of expulsion and uterine perforation than women who have an IUD inserted later.¹⁴ In most circumstances, it is prudent to wait until the uterus is completely involuted, usually at 4 to 6 weeks postpartum, before inserting an IUD. Women should wait until 6 weeks postpartum to have the LNG-IUS inserted.

LACTATIONNAL AMENORRHEA

Some women prefer to avoid all hormonal contraceptive methods while they breastfeed. For these women, it is important to emphasize that only amenorrheic women who exclusively breastfeed at regular intervals, even during the night, have this contraceptive effect of lactation during the first 6 months. Supplements increase the risk of ovulation even in the absence of menstruation.¹⁵ This method is dealt with in more detail in Chapter 9.

SUMMARY STATEMENTS

1. The use of combined OCs decreases breast milk production. (Level I)
2. Use of progestin-only preparations has not been shown to decrease breast milk production. The small amounts of steroid hormones secreted into breast milk do not have an adverse effect on the baby. (Level II-2)

RECOMMENDATIONS

1. **Initiation of combined OC use should be delayed until breastfeeding is established, usually by 6 weeks postpartum. If the woman is not breastfeeding, combined OCs can be started at 3 to 4 weeks postpartum. (Grade B)**
2. **Progestin-only methods should be considered as contraceptive options for postpartum women, regardless of breastfeeding status, and may be introduced immediately after delivery. (Grade B)**

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3. POST-ABORTION CONTRACEPTION

Women who have had a miscarriage or elective pregnancy

termination often require contraceptive counselling at the time of their procedure. Women may ovulate as early as 16 days after the procedure.¹ There is a rapid return (within 1 week) of estrogen and progesterone levels to near normal range after abortion.¹

The patient's visit at the clinic to seek an abortion offers a good opportunity for the health-care provider to talk about contraceptive options.^{2,3} Women seeking abortion due to contraceptive failure or non-use of contraception should not leave the clinic without receiving counselling on how to avoid unwanted pregnancy in the future. Advance provision of emergency contraception should be considered for all post-abortion patients. The following Table 1 lists the recommended timing of initiation of contraceptive options after abortion.

SUMMARY STATEMENT

1. Legalized abortion is associated with a lower incidence of abortion-related maternal mortality. (Level II-2)

RECOMMENDATIONS

1. Contraceptive counselling should be offered at the time of abortion, and contraceptive methods should be provided immediately following the procedure. (Grade A)
2. Canadian women should have access to safe abortion procedures regardless of geographical location. (Grade A)

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Table 1. Recommended Initiation of Contraceptive Options After Abortion

Contraceptive Method	Initiation (in Relation to Abortion)	Comment ⁴
Female sterilization	Start at time of abortion for first and early-second trimester; can be done laparoscopically and by minilaparotomy for second trimester.	Consider interval for severe anemia. Ensure adequate counselling.
Combination oral contraceptives	Start anytime from evening of surgery to 5 days after surgery.	Nausea may be confused with continuing pregnancy if started right away.
Progestin-only oral contraceptives	Start on the day of abortion.	Breakthrough bleeding may cause confusion post-operatively.
Injectable contraceptives	Start immediately after abortion, or up to 5 days afterwards.	Ensure plans for next injection are made. Breakthrough bleeding may cause confusion post-operatively.
IUD/IUS	Start at time of abortion in first trimester or during/after first menses after abortion.	No significant increase in bleeding, perforation, pain with immediate vs. delayed initiation in first trimester. ⁵ Higher rates of expulsion if greater than 12 weeks compared with shorter gestations. ⁶

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4. CONTRACEPTION FOR THE ADOLESCENT

Most contraceptive options are a good choice for adolescents. Adolescents are commonly involved in serial monogamous relationships in which they are less likely to use a contraceptive method on a regular basis. They are more willing to seek contraceptive advice in a steady relationship. In all these cases, double protection against pregnancy and sexually transmitted infections (STIs) should always be recommended. In this specific age group it is also important to emphasize that the use of barrier methods does not always prevent viral STIs such as herpes and the human papilloma virus (HPV).^{1,2}

BACKGROUND

It is important to note that in Canada

- 11% of 15-year-olds, 27% of 16-year-olds, 42% of 17-year-olds, and 55% of 18-year-olds have had sexual intercourse.³
- between 85% and 91% (depending on age) used contraception at the time of first intercourse.³
- among coitally experienced adolescents, none were currently using spermicidal methods, none were sterilized, and none were using IUDs. As in other age groups, the dominant methods used by coitally experienced teenagers aged 15 to 18 were OCs (66%) and condoms (44%); others included withdrawal (6%) and DMPA (6%); and 11% reported no current sexual activity.³

The most important reasons adolescents cite for *not* using contraceptive methods when they are sexually active are as follows⁴:

- sexual activity was unexpected and unplanned;
- a lack of information and knowledge about contraceptives and where to get them;
- fear of medical procedures;
- fear of judgmental attitudes and resistance from health-care providers; and
- fear of lack of confidentiality.

LEGAL ASPECTS

There is no lower age limit for prescribing hormonal contraceptives. The medical and social risks of unplanned pregnancy exceed the risks of taking hormonal contraceptives; the World Health Organization states that age alone does not constitute a medical reason for denying any available contraceptive method to adolescents.⁵

However, to give valid consent for medical treatment, an individual under the legal age of consent must be deemed to be a “mature minor.” Determining whether or not an adolescent is a “mature minor” requires an assessment of whether or not the young person’s physical, mental, and emotional development will allow for full appreciation of the nature and consequences of a proposed treatment, including the consequences of refusal of such treatment.⁶

CLINICAL CONSIDERATIONS

The following should be considered in determining the optimal hormonal contraceptive method for a female adolescent:

- There is no evidence that the estrogen in current low-dose combined OCs has any effect on growth.⁷
- In users of low-dose combined OCs, weight gain is minimal and is often related to normal weight gain for age in the adolescent population. Combined OC users have not been shown to have any significant weight gain on therapy.^{8–12}
- Combined OC use appears to have a favourable effect on bone mineral density.^{13–15}
- In one study, 56% of DMPA users reported an increase in weight (mean gain of 4.1 kg), while 44% either lost weight or maintained their baseline weight (mean loss of 1.7 kg).¹⁶ Other studies have failed to find an effect of DMPA on weight.^{17–19} Weight gain associated with DMPA use is thought to be due to appetite stimulation and a possible mild anabolic effect.²⁰
- Adolescent mothers using DMPA for contraception have a higher method continuation rate and a lower incidence of repeat pregnancy at 12 months postpartum than those selecting combined OCs during the same period.²¹

ADHERENCE TO CONTRACEPTIVE CHOICE

The greatest challenges in adolescent users of combined OCs are incorrect or inconsistent use and high discontinuation rates.²²

Three months after beginning, 76% of teenage women remain on oral contraceptives, and 50% continue after 12 months.²³ The most common reason given for discontinuing hormonal contraception is side effects,²⁴ especially breakthrough bleeding.^{20,23}

Many adolescents believe that their risk of getting cancer or blood clots while using hormonal contraception is very high. It is possible that the adolescent sees unscheduled bleeding or other side effects as an indication of a serious consequence such as cancer. They may also believe that these effects are long-term, lead to sterility, or affect the health of future offspring.²⁴ As a result, they will feel less confident about the efficacy of the contraceptive. This can lead to non-compliance and discontinuation of the contraceptive.²⁵

STRATEGIES TO IMPROVE ADHERENCE

A supportive, encouraging, and non-judgmental environment, where confidentiality is assured, is essential when counselling adolescents. It is also important to counsel them about the value of dual protection for the prevention of both pregnancy and STI.^{26,27}

The following strategies will increase the probability of an adolescent adhering to a contraceptive plan:

1. Explain how the hormonal method works.
2. Dispel myths and misconceptions.
3. Demystify the side effects, and reassure the adolescent that the minor side effects are usually short-lived.
4. Emphasize the non-contraceptive benefits of the hormonal contraceptive.
5. Schedule frequent follow-ups.
6. Provide written material that lists myths and misconceptions, non-contraceptive benefits, and side effects.

SUMMARY STATEMENTS

1. Age alone is not a reason to deny any available contraceptive methods to adolescents.
2. A health-care provider can supply contraception to a minor without parental consent as long as informed consent can be obtained from the individual.
3. A pelvic examination is *not* a prerequisite for providing contraception or emergency contraception. The timing of the pelvic examination may be negotiated with the adolescent. (Level III)

RECOMMENDATIONS

1. **Adolescents should have ready access to contraception and methods of STI prevention. (Grade A)**
2. **Health-care providers should respect a patient's right to confidentiality. (Grade A)**
3. **The health-care provider should help to ascertain that sexually active adolescents are involved in a consensual relationship that is free of coercion and abuse. (Grade B)**

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5. CONTRACEPTION IN INDIVIDUALS WITH INTELLECTUAL DISABILITIES

Finding the most appropriate contraceptive method for the mentally disabled young woman poses a tremendous challenge to the health-care provider.

Women with mental disabilities may be at risk for pregnancy, sexually transmitted infections, and/or abuse, since they

- lack knowledge of sexuality and contraception;
- may be very affectionate and trusting;
- struggle to be accepted, and may become compliant to sexual advances.¹

The parents of these young women may be concerned about their daughters' ability to cope with menses, the risk of sexual exploitation,² and pregnancy.³

Many will request medication to arrest menses and offer contraception, while others may request permanent sterilization. Reproductive health services should not be coercive; informed consent is required for all contraceptive methods.^{4,5}

Contraception can prevent pregnancy, but does not replace the need for a safe environment for these women.³ In addition, counselling and assertiveness training to help them avoid abusive situations are necessary.^{2,6}

The literature regarding management of menstrual hygiene and contraception in a woman with a mental disability is sparse. However, several medical options are available to improve menstrual hygiene and to provide contraception: low-dose combined oral contraceptives (OCs), depot medroxyprogesterone acetate (DMPA), levonorgestrel intrauterine system (LNG-IUS), and sterilization.

LOW-DOSE COMBINED ORAL CONTRACEPTIVES

Oral medications must be well tolerated for combined OCs to be a useful option for these women. Oral contraceptives may be used in a cyclical, tri-cyclic (63 days on, 7 days off), or continuous fashion.⁷⁻⁹

The risk of venous thromboembolism may be increased significantly if the woman is confined to a wheelchair.¹⁰ The dose of combined OCs used may need to be adjusted if the woman also takes anticonvulsants.¹¹

DEPOT MEDROXYPROGESTERONE ACETATE

Use of DMPA should be considered if oral medications are not well tolerated or are contraindicated. However, the potential for a reduction in bone mineral density¹² and an increase in weight¹³ with this treatment may not be desirable. If a woman's family requests a hysterectomy for hygiene purposes, use of DMPA provides a good long-term alternative for management when it is well tolerated.

LEVONORGESTREL INTRAUTERINE SYSTEM

The use of this system in women with mental disabilities has not been examined. It provides effective management of menstrual problems as well as reversible contraception.¹⁴ However, a general anaesthetic or profound sedation for insertion of the device may be necessary for many disabled women.¹⁵ The possibility that the system may induce amenorrhea or a major decrease in bleeding¹⁶ is usually considered a positive aspect by the parents or caregivers.

STERILIZATION

Health-care providers should be aware of the legal requirements for obtaining informed consent for sterilization, including an explanation of benefits and risks, options, and determination of whether the person is competent to understand the information.² When the person has a mental disability, it is even more difficult for the physician to determine their capacity to provide informed consent.¹⁷ Contraceptive sterilization of an incompetent, mentally disabled person is illegal.⁴ Physicians need to be very respectful and provide comprehensive information for the parents of these individuals, since they are frequently concerned about their responsibility for any offspring if their daughter conceives.

SUMMARY STATEMENT

1. The non-therapeutic sterilization of any individual who is not competent to give informed consent is illegal in Canada.

RECOMMENDATION

1. **Health-care providers should include sexual health in the counselling of women and men with intellectual disabilities, explore potential coercion and abuse and should provide counselling to help them avoid coercive and abusive situations. (Grade B)**

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CHAPTER 12: THE FUTURE OF CONTRACEPTION

Timothy Rowe, MB, FRCSC

Vancouver BC

INTRODUCTION

Control of fertility is now an assumed fact of life for many people living in industrialized countries. The current generation of women in the reproductive age group has, for the most part, grown up with the assumption that they can have the families that they want, when they want. There is a trend towards later childbearing, with at least 20% of Canadian women having their first child after age 35. Thus, a growing number of women spend decades using contraception, much of which is intrusive, messy, or associated with side effects.

Contraception ideally should be simple, inexpensive, readily available, highly effective, entirely safe, free of any symptoms or adverse effects, immediately reversible, and coitally independent. In addition, since it is used mostly by healthy young women, contraception should confer some health benefit as an incentive for consistent use. Of the currently available approaches in Canada, hormonal contraception for women in one form or another comes closest to the ideal; but there are many women for whom no ideal contraceptive exists. Refinements of current approaches, or new approaches, to the prevention of fertilization or implantation are still needed.

NATURAL FAMILY PLANNING

Natural methods of contraception include abstinence, coitus interruptus, and the application of fertility awareness for the timing of coitus.

Abstinence as a choice for contraception is unlikely to be a widely applicable option to reduce the incidence of unplanned pregnancy, given that it requires a continuous exertion of will against instinct. There is considerable political will, particularly in the United States, to validate abstinence as an appropriate sexual behaviour for young unmarried men and women, and federal funding has been provided to “market” the idea — although not without concern expressed by human rights groups.¹ Nevertheless, in California, a large randomized study of strategies designed to enhance postponement of sexual involvement showed no benefit; paradoxically, they even showed potential for encouraging sexual involvement.²

Fertility awareness is based on knowledge of both male and female reproduction and on a reliable ability to predict ovulation. Traditionally, predicting ovulation has been based on symptoms, basal body temperature recordings, and the calendar. More recently, electronic hand-held devices have recorded information about temperature and menstrual cycle characteristics in order to predict the fertile time and alert women to the need for abstinence or the use of barrier methods of contraception. There are many kits available for predicting ovulation through detection of increased urinary LH excretion, but the range of prediction is only 12–24 hours — insufficient to allow prevention of conception. The Persona kit offers women a home monitoring system to measure urinary estrone-3-glucuronide as well as LH in order to predict, more remotely, the fertile time of the cycle.³

BARRIER METHODS

These include condoms, spermicides, diaphragms, and cervical occlusive devices. The potential for improvement in the design or applicability of the last two categories is limited, although improving these options remains desirable.

Spermicides tend to irritate the vagina, because their spermicidal action relies on a detergent effect on sperm which also affects the vaginal flora. Future spermicides may focus on a mode of action that interferes instead with the acrosome reaction of sperm, and does not affect the vaginal flora. A promising candidate with these properties is cellulose sulfate, which has shown less genital irritation than nonoxynol-9 while still providing antifertility and antimicrobial effects.⁴ Spermicides that coincidentally have antiviral properties are highly desirable in the era of the human immunodeficiency virus (HIV); unfortunately, a prospective study of a nonoxynol-9 gel (COL-1492) did not demonstrate protection against HIV transmission in high-risk women.⁵ The search for suitable agents continues.

Condoms will continue to be a mainstay of contraception and strategies to prevent sexually transmitted infections (STIs). New condoms made from strong, thin polyurethane and other new polymers should provide better sensitivity and less potential for allergic reactions — which is one of the major concerns with currently available latex condoms. (See Chapter 8, “1. Condoms.”) These new condoms would also be less prone to degradation by lubricants.

Attempts to promote the *female condom* as a mainstream contraceptive have been relatively unsuccessful.⁶ It provides women with protection against STIs, but it has little aesthetic appeal and because of this will require refinement to become more popular.

INTRAUTERINE DEVICES

The perceived association of intrauterine devices (IUDs) with pelvic inflammatory disease (PID) has led to a steady reduction in IUD use in North America.⁷ This perception will be difficult to reverse, despite the realization that the risk of PID is associated only with insertion of the device.⁸ (See Chapter 7.) Nevertheless, the appeal of the IUD remains: it is highly effective, requires no maintenance, and now can be left in place for at least 5 years. The longer duration of placement reduces the risks of insertion (infection and perforation). The risk of expulsion may be reduced by new frameless and flexible devices which are fixed into the myometrium, and with these devices the potential for cramps and excess bleeding is also reduced.⁹

Hormone-releasing devices, particularly those releasing levonorgestrel (e.g., Mirena), provide reliable contraception with a dramatic reduction in menstrual bleeding.¹⁰ They offer potential for therapeutic applications beyond contraception. Despite this, *liability issues* (while not major concerns for modern IUDs) make industry cautious about becoming involved in this area of contraception. These concerns discourage companies from revising product labels containing highly conservative warnings about IUD use. This conservative product labeling discourages physicians from recommending use of an IUD.¹¹

HORMONAL CONTRACEPTION

FEMALE HORMONAL CONTRACEPTION

Developments in oral contraception have led to a steady reduction in the daily dose of both estrogen and progestin and the development of progestins with reduced metabolic impact. Third-generation progestins were introduced with the aim of reducing arterial disease in women,¹² but the large-scale acceptance of preparations containing these progestins has been affected by the controversy over whether or not they carry a higher risk of venous thrombosis than older preparations.¹³ (See Chapters 4 and 6.) This controversy has to some extent discouraged the release of new oral contraceptive preparations; but

several preparations containing new progestins (e.g., dienogest, drospirenone, chlormadinone acetate) are available in Europe and may be released in Canada in the future. The newer progestins carry individual potential metabolic advantages over currently available progestins.^{14,15}

It is unclear whether or not the dose of estrogen can be further reduced. The use of oral contraceptives by older women will likely continue to expand, particularly to control perimenopausal symptoms, and expansion of use into the postmenopausal years has great potential.

Most future advances in hormonal contraception for females will involve improvements in methods of administration. Once-a-month oral contraceptive preparations have been available for some time in China, using a powdered preparation at the time of menstruation to suppress ovulation in the subsequent cycle.¹⁶ Another approach, less successful, has been to administer a preparation that causes luteolysis and induction of menses. Mifepristone administered once per month has been proposed as an example of this kind of contraceptive; this would appeal to women having sporadic intercourse.¹⁷

Another approach in attempting to provide estrogen-free hormonal contraception has been to administer sequentially an antiprogestin (mifepristone) followed by a progestin (norgestrol acetate); this treatment combination results in inhibition of ovulation and the development of an irregular secretory endometrium. Use of this combination has reached the stage of phase II trials.¹⁸

Routes of hormone administration other than oral have potential for development. The use of *depot injections* such as Depo-Provera for contraception in Canada is a recent innovation by global standards, and its ultimate level of use in Canada is still unknown. Contraceptive *implants* releasing either estrogen and progestin or progestin alone are slow to develop, test, and market, and none are currently available in the Canadian market. (Sales of Norplant, the only implant to have been marketed in Canada, were discontinued in September 2002.) Second-generation implant systems (Implanon and Jadelle) have been developed to simplify insertion and removal, with use of 1 or 2 rods respectively in place of Norplant's 6. (See Chapter 5's section on progestin-only hormonal contraception.) Implanon releases etonogestrel for reliable contraception over a span of 2 years, while Jadelle releases levonorgestrel with reliable contraceptive effect over 3 years (and is under FDA review as a 5-year contraceptive).¹⁹ Another system undergoing trials releases a different progestin, nestorone, from silastic implants; this may be used safely in lactating mothers, since nestorone is rapidly metabolized after oral administration and has no apparent effect if ingested by a baby in breast milk.²⁰

Progestin implants and depot injections are, however, all associated with irregular menstrual bleeding and the potential for changes in weight and mood. Bleeding patterns tend to be more predictable and amenorrhea less common with use of

combined estrogen-progestin preparations such as Lunelle,²¹ although the inclusion of estrogen requires the same medical considerations as the use of combined oral contraceptives.

Future possibilities for administration of contraceptive steroids include the use of *injectable microspheres* containing both estrogen and progestin²² and further development of vaginal rings and transdermal patches delivering low doses of estrogen and progestin. Each of these would offer better control of vaginal bleeding and theoretically superior compliance.

MALE HORMONAL CONTRACEPTION

Regrettably, there does not appear to be a bright future for the development of reliable and acceptable means of contraception directed at suppression of sperm production. An agent which will easily, safely, and reliably suppress sperm production while leaving libido and erectile function intact has yet to be developed.

Weekly injections of testosterone will induce oligo- or azospermia after 3 months of treatment, but may be associated with acne, mood change, adverse lipoprotein changes, and delay in return of fertility.²³ The need for weekly injections and the potential for delay in return of fertility limit the appeal of this method. The addition of a progestin may allow the use of lower doses of testosterone, but the approach is not universally effective. Long-acting testosterone esters, delayed-release pellets of testosterone and implants of androgen or progestin are being explored as possible avenues for acceptable delivery of steroids.^{24,25}

An alternative approach in males is the use of a GnRH agonist to suppress testicular function combined with androgen therapy to maintain libido and male habitus and sexual characteristics. This has not proven as successful as hoped,²⁶ and the expense of such an approach makes it an impractical option.

IMMUNOLOGICAL APPROACHES

The idea of using the induction of antibodies to components of the reproductive process for contraception has been pursued for more than 30 years. While there have been promising achievements in animal and some human studies, there is a need for considerable refinement of the approach before it can become a practical option for widespread use. The ideal vaccine for contraception should be safe and reliable; furthermore, in order to be widely acceptable it should produce a long-lasting effect and should be reversible.

FEMALE IMMUNOLOGICAL APPROACHES

Research in immunocontraception is currently focused upon two areas of reproduction in the female: *fertilization and maternal recognition of pregnancy*. Producing a vaccine that will interfere with fertilization is limited by our understanding of the molecular mechanisms involved, but vaccines stimulating

production of antibodies to HCG have been under investigation for several decades.

Fertilization-limiting vaccines under investigation are directed either against sperm surface antigens or against the zona pellucida. The idea of inducing antibodies in women against sperm is an old one; in 1932, Baskin produced "temporary sterilization" in women by injecting them with their husband's sperm.²⁷ Investigations related to this approach did not continue. However, research to identify specific sperm surface antigens that could be the basis for a fertility-regulating vaccine in males or females has continued, and two of these (FA-1 and YLP(12)) show particular promise.²⁸ Sperm surface antibodies are able to affect sperm either before they leave the male or when they reach the female, but only a small proportion of the sperm generated in the male ever reach the site of fertilization in the female. Antibodies generated in the female therefore have to deal with significantly less sperm than do antibodies generated in the male. Thus antisperm vaccines appear to have more potential for effectiveness in females than in males.²⁹

The vaccines stimulating antibody production against the zona pellucida have the undesirable effect of causing oophoritis or ovarian failure through depletion of primordial follicles from the ovary.³⁰ Attempts to identify epitopes (specific antigenic determinants) that might allow a contraceptive effect of such a vaccine without causing pathological effects within the ovary are continuing.

Research carried out in India under the auspices of the World Health Organization (WHO) in the 1970s resulted in the development of a vaccine stimulating the production of antibodies to the β -subunit of the human chorionic gonadotropin (HCG) molecule (and, through linkage of antigens, coincidentally to *Clostridium tetani*).³¹ Because of potential cross-reactivity with LH, the WHO has sponsored research using an antibody to a 37-amino acid section of the β -HCG subunit in order to minimize the risk of autoimmune damage to pituitary cells.²⁹ These antibodies are only effective for a few months and thus require frequent repeat immunizations. However, there has been no evidence of autoimmune damage to pituitary cells, even where antibodies to the entire β -subunit of HCG are generated; but there has been some evidence of unexpected cross-reactivity against pancreatic and pituitary cells with antibodies raised against the carboxyl terminal of the β -subunit. Long-term studies will be needed to learn whether this finding is clinically significant.²⁹

There is political opposition to the development of β -HCG vaccines for contraception, since they could be considered abortifacient.³² The developers maintain that, in human studies, the length of the menstrual cycle has been unaffected by the development of anti- β -HCG antibodies, and that their effect occurs before the completion of implantation.³³ There is similarity to the concerns that have been expressed by some about the mode of action of intrauterine devices.

MALE IMMUNOLOGICAL APPROACHES

Developing antibodies against GnRH or FSH to suppress sperm production has been shown to be possible.³⁴ However, the use of suppressive therapy with androgens has been a more practical approach to the induction of reversible oligo- or azospermia, since it avoids the possibility of systemic immune reactions.

Raising antibodies to sperm surface proteins should allow sperm production to continue, but the sperm subsequently would either be immobilized or rendered incapable of fertilization. However, developing antibodies to sperm proteins carries a risk of stimulating testicular inflammation.²⁹ In addition, as described above, such antibodies would need to bind to the surface of considerably more sperm in the male genital tract than at the site of fertilization in the female. Nevertheless, the characterization of human sperm surface antigens is in its infancy,³⁵ and it may prove possible to develop vaccines generating immune responses in the epididymis or secondary sexual glands that are sufficient to have a contraceptive effect.

NEW APPROACHES TO CONTRACEPTION

ANTITESTICULAR AGENTS

Lonidamine is an indazole carboxylic acid compound used in cancer treatment. Its development as an antispermatic contraceptive compound in the early 1980s was abandoned because of renal damage, but recent derivatives have shown efficacy and reversibility as contraceptive agents in animal studies, without toxicity in either the liver or kidney.³⁶ They have no effect on the hypothalamic-pituitary-testicular axis; their effect in the testis arises from their ability to cause germ-cell loss from the seminiferous epithelium. Human studies of these compounds have yet to begin.³⁶

ANTI-IMPLANTATION STRATEGIES

Besides the generation of antibodies to β -HCG, strategies to stimulate interference with key steps in implantation are being explored. These key steps include angiogenesis and protection of the conceptus from immune responses.

Fumagillin is an anti-angiogenic agent that has shown some ability to prevent implantation when administered vaginally in monkey studies.³⁷ No human studies have been conducted, and appear unlikely to occur until further evidence of anti-angiogenic effectiveness is available.

The peptide pre-implantation factor (PIF) is one of the earliest known signals for the recognition of pregnancy; it appears to be produced even by 2-cell embryos.³⁸ Its exact role in implantation is unknown, but theoretically an analog of such a peptide could be used to interfere with maternal recognition of a conceptus, with consequent failure of implantation. Another fundamental requirement for the establishment of a pregnancy is the secretion of HLA-G antigens, produced primarily by

cytotrophoblasts at the fetal-maternal interface. These circulating antigens have a capacity analogous to that of membrane-bound structures to inhibit natural killer (NK) cells.³⁹ Interference with the production or action of the HLA-G antigens would result in the establishment of an immune response to the conceptus, involving NK cells.

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