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 1: Introduction
1. Family planning services should be provided with dignity and respect, based on individual differences and needs. (Grade A)
2. In order to enhance the quality of decision-making in family planning, health-care providers should be proactive in counselling and should provide accurate information. They should be approachable partners in a professional relationship. (Grade B)
3. Family planning counselling should include counselling on the decline in fertility that is associated with increasing female age. (Grade A)
4. Health-care providers should promote the use of latex condoms in combination with another method of contraception (dual protection). (Grade B)

Chapter 2: Contraceptive Care and Access
1. Comprehensive family planning services, including abortion services, should be freely available to all Canadians regardless of geographic location. These services should be confidential and respect an individual’s privacy. (Grade A)
2. Questions about sexuality should be incorporated into a general assessment. (Grade C)
3. Canadian women and men, with their health-care providers, should address both the prevention of unintended pregnancy and sexually transmitted infections (STIs). (Grade C)
4. Testing for STI and prevention counselling should not be restricted to young or high-risk individuals. (Grade B)
5. Women and men should receive practical information about a wide range of contraceptive methods so that they can select the method most appropriate to their needs and circumstances. (Grade C)
6. Health-care providers should assist women and men in developing the skills necessary to negotiate the use of contraception, as well as the correct and consistent use of a chosen method of contraception. (Grade C)

7. Health promotion, emergency contraception counselling, and the prevention of STIs, sexual violence, and cervical cancer should be integrated into contraceptive care. (Grade C)

8. The Government of Canada should enhance access to safe and effective products for Canadian women by accelerating the approval process through harmonization with the therapeutic guidelines of other developed countries. (Grade C)

9. The SOGC should work with groups that support initiatives in women's health to promote the accessibility of all forms of contraception in Canada. (Grade C)

10. Hormonal emergency contraception should be available without a prescription in pharmacies, family planning clinics, emergency rooms, walk-in clinics, and school health programs. (Grade B)

11. The Society of Obstetricians and Gynaecologists of Canada should continue the Contraception Awareness Project (CAP) to promote safer sex and effective contraception for Canadian women and men and to continue professional education for health-care providers who are active in this field. (Grade C)

12. The established program, which allows compassionate provision of oral contraceptives to patients in need in Canada, must be maintained. (Grade B)

Chapter 3: Emergency Contraception

1. Because the efficacy of hormonal emergency contraception may be higher if used sooner, it should be started as soon as possible after an act of unprotected intercourse. (Grade A)

2. Hormonal emergency contraception should be available without a prescription in pharmacies, family planning clinics, emergency rooms, walk-in clinics, and school health programs. (Grade B)

3. Users of emergency contraception should be evaluated for pregnancy if menses have not begun within 21 days following treatment. (Grade A)

4. Women and men of reproductive age should be counselled about emergency contraception. Women should be offered a prescription in advance of need. (Grade B)


<table>
<thead>
<tr>
<th>Table 1. Quality of Evidence Assessment&lt;sup&gt;2&lt;/sup&gt;</th>
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<tbody>
<tr>
<td>The quality of evidence reported in this document has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.</td>
</tr>
<tr>
<td>I: Evidence obtained from at least one properly randomized controlled trial.</td>
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<tr>
<td>I-1: Evidence from well-designed controlled trials without randomization.</td>
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<tr>
<td>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</td>
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<tr>
<td>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.</td>
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<tr>
<td>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</td>
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<table>
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<tr>
<th>Classification of Recommendations&lt;sup&gt;2&lt;/sup&gt;</th>
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<tr>
<td>Recommendations included in this document have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.</td>
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<tr>
<td>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health exam.</td>
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<tr>
<td>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health exam.</td>
</tr>
<tr>
<td>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</td>
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<tr>
<td>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</td>
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<tr>
<td>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</td>
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IMPACT OF FAMILY PLANNING DECISIONS

We live in an era of changing preferences for fertility control, family size, timing of establishing a family, and choice of occupation. The consequences of sexual risk-taking are increasingly significant. Canadians and their health-care providers are thus involved in fertility-related decisions that will fundamentally influence individual lives and society as a whole, well into the future. Family planning decisions affect and are influenced by emotional health, sexual attitudes and behaviours, gender equity, the quality of relationships, and respect between women and men. Family planning choices made today will affect not only the structure of the future population, but also the health, family size, responsibilities and social opportunities, and thus the quality of life of Canadians.

Physicians and other health-care professionals can contribute to the value of family planning decisions. Being proactive in counselling, providing accurate information, and being approachable partners in a professional relationship built on mutual respect, trust, open communication, and a sense of caring will ensure that good decisions are made. Training programs in Canada must maintain education in contraception and sexual health in their curricula, so that health-care providers will have the necessary skills to provide care in these areas.

TRENDS IN REPRODUCTIVE HEALTH AND CONTRACEPTIVE USE IN CANADA

Reproductive health in sexually active women and men involves the establishment of satisfying sexual relationships that are free of unwanted pregnancy, sexually transmitted infections, violence, and coercion. The risks of these events for individuals must be taken into account in the provision of care.

REPRODUCTIVE HEALTH

TRENDS IN BIRTHS AND THERAPEUTIC ABORTIONS

Over the past 40 years there has been a dramatic decline in the birth rate in Canadian women. The birth rate in 1997 was 44 per 1000 women aged 15 to 49, compared with 116 per 1000 women in 1959.3 The greatest decline in birth rate occurred in the 1960s with the introduction of a variety of birth control methods, but statistics from the 1990s continue to show a slow decline.4 One reason for this decline is that women are now older when they are having children.4 In 1997 the average age of first birth was 27 years, compared to 23 years in the 1960s.5 Although birth rates have declined dramatically in women under age 30, they have generally risen in women in their thirties over the last 15 years.5

As women delay childbearing until they are at an age when fecundity is declining, some face difficulties in conceiving. With increasing age, there is increased risk of aneuploidy, spontaneous abortion, and obstetrical complications such as diabetes and hypertension.6 Delayed childbearing is associated with an increased risk for neonatal morbidity largely due to an increase in the birth of preterm and low-birth-weight infants.7,8

Despite a steady decrease in the total pregnancy rate over the last 2 decades, the adolescent pregnancy rate has remained relatively steady. In 2000, the fertility rate for adolescents (number of pregnancies per 1000 women of reproductive age) in Canada was 17.3, compared with 33.9 for women aged 35 to 39 and 5.9 for women aged 40 to 44.3,5

The ratio of abortions per 100 live births rose from 28.6 in 1995 to 32.2 in 2000. The highest abortion rate (number of abortions per 1000 women) in 2000 in Canada was in the 20-to-24 age group, with a rate of 31.9 per 1000 women.3,5 The persistent use of abortion services indicates either that we are not meeting...

Figure 1. Data from Statistics Canada.3,5
the contraceptive needs of Canadian women, or that different approaches to the provision of contraception are required.

Relevant data from Statistics Canada in 2000 are shown in Figure 1.

TRENDS IN INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS

From January to December 2002, Statistics Canada reported 56,093 cases of chlamydia infection and 7,195 cases of gonorrhea.9 The highest risk for contracting chlamydia infection and gonorrhea is in 15 to 19 year olds.10 The 1998, age-specific incidence of hepatitis B remains highest among 25 to 29 year olds, with a male to female ratio of 5:2. The incidence of hepatitis B has continued to gradually decline with time.11

The number of positive human immunodeficiency virus (HIV) tests declined steadily in the late 1990s, although at the same time the number of positive HIV tests reported among heterosexuals increased. In 1999, 4190 Canadians were newly infected with HIV, similar to the number of newly reported cases in 1996. The cumulative total of HIV-positive tests reported in Canada up to June 2000 was 46,651.12

TRENDS IN DOMESTIC VIOLENCE

Effective use of a contraceptive method is difficult in situations where one partner is being victimized. Pregnancy is associated with both initiation and exacerbation of domestic violence, so contraceptive failure carries added risk for women in abusive or potentially abusive relationships.13 In Canada, the rate of spousal (including common-law partner) violence directed against women was reported in 1999 as 8%, a decline from the rate of 12% reported in 1993.14 However, in Aboriginal women, the reported rate of spousal violence in 1999 was 20%, compared to the reported rate of spousal violence in non-Aboriginal women of 7%.14

CONTRACEPTIVE USE

Canadian contraceptive use has changed over the past 20 years. Reliance on female sterilization has shown a linear decline across the past decade, while rates of male sterilization have stabilized in the same time.15-19 Oral contraceptive use has increased, so that it is now the contraceptive method most used in Canada; the use of intrauterine devices has greatly declined, and the use of condoms has increased15-19 (Table 2).

The Canadian Community Health Survey indicated that, of those individuals using condoms, only 41% reported always using them.20 Among Canadians aged 15 to 19 involved in a relationship of less than 12 months, the National Population Health Survey in 1996-97 found that 16% did not use a condom during their last intercourse, and 8% reported never using a condom.18 High-risk sexual behaviours occur across the age spectrum; of the survey population aged 15 to 49, 8% reported never using condoms, and 16% reported not using condoms at the last intercourse in a relationship of less than 12 months.21 Alcohol use poses a significant barrier to effective contraceptive use at all ages.

Very frequently we approach contraceptive practice with a focus only on preventing pregnancy rather than on family planning. Assist women to explore their plans for childbearing is an important part of family planning and contraceptive care. For a woman who wishes to have children in the future, contraceptive counselling includes providing specific information about how fertility declines with age (Table 3), so that she can make an informed choice about family planning.

MAJOR DETERMINANTS OF CONTRACEPTIVE CHOICE

An understanding of the social and psychological factors that drive contraceptive choice is essential for the creation of effective clinical and educational interventions to promote reproductive health in this area.23-26 Three activities, described here, appear to influence contraceptive use and other reproductive health behaviours significantly.27 In order to become an effective health-care professional and to be involved in shared contraceptive decision-making, clinicians should:

• share information
• enhance motivation, and
• help to develop behavioural skills

First, information about contraception and sexuality that is easy for the individual to understand and easy for the individual to act on is a prerequisite for contraceptive use.27-29 Information is easily exchanged verbally, or through brochures and other demonstration materials. This information, in order to be useful, needs to be:

| Table 2. Methods of Birth Control Currently Used By Women Who Have Had Intercourse19 |
|-----------------|------|
| Method          | %    |
| Oral contraceptives | 32  |
| Condom          | 21   |
| Sterilization, male | 15  |
| Sterilization, female | 8   |
| Withdrawal      | 6    |
| Injection (DMPA*) | 2   |
| Intracuterine device | 1   |
| Rhythm          | 2    |

*DMPA: depot-medroxyprogesterone acetate

| Table 3. Effect Of Age On Fertility22 |
|-----------------|------|
| Age When Beginning Attempts to Conceive | % of Women Remaining Childless |
| 20–24           | 6    |
| 25–29           | 9    |
| 30–34           | 15   |
| 35–39           | 30   |
| 40–44           | 64   |
Motivation will be affected by:

- personal attitudes about the use of contraception ("What do you think of this contraceptive method and its use?")
- social norms that are seen to support or to oppose contraceptive use ("What will people around you think of you using this contraceptive method?")
- personal factors modifying effective contraceptive use ("What could make you use your contraceptive method less effectively? What could you do to overcome these difficulties?")
- perceived vulnerability to, and perceived costs of, unwanted pregnancy ("How would you react if you got pregnant now? When do you want to get pregnant? Do you think you could get pregnant before you want to?")

Third, behavioural skills for using contraception are crucial determinants of whether even well-informed and well-motivated person will be capable of using contraception effectively over the long term.30,33

Contraceptive use requires an individual to perform a complicated series of intrapersonal and interpersonal acts that are rarely, if ever, directly taught or discussed. In order to be an effective user of contraception, an individual must be able to acquire and understand contraceptive information, anticipate sexual intercourse, talk with a partner about contraception, engage in such public acts as visiting a physician or a pharmacy to obtain contraception, and use contraception correctly and consistently over the long term.

Clinicians and educators need to be aware of the behavioural complexity of contraceptive use. They need to share, counsel, coach, teach, and problem solve so that individuals will be aware of their contraceptive behavior, be prepared to enact each of its steps skillfully, and be able to solve problems should the need arise. Strategies to reduce harm, including the concept of “dual protection” to reduce the risk of both unplanned pregnancy and sexually transmitted infection (STI), need to be addressed with each encounter.

The Society of Obstetricians and Gynaecologists of Canada provides easily accessible resources on contraception and sexual health:

- www.sexualityandu.ca (for health-care providers, educators, parents and consumers)
- www.sogc.org (for health-care providers to access clinical practice guidelines, has a contraception hotline, and lists answers to frequently asked questions)
- Sex Sense (an award-winning consumers’ guide to contraception and sexuality in paperback form)

**SUMMARY STATEMENTS**

1. Family planning is an important aspect of life and is a basic human right. Canadians have the right to the highest possible quality care related to their sexual and reproductive health as part of primary health care.
2. Both adults and adolescents face challenges when attempting to use contraception appropriately and consistently.
3. The provision of appropriate contraceptive services requires adequate training of care providers in the areas of contraception and sexual health. (Level II-2)
4. The consistent and correct use of latex condoms in combination with another method of contraception (dual protection) will provide maximal protection against unintended pregnancy and STI, including HIV infection. (Level III)

**RECOMMENDATIONS**

1. Family planning services should be provided with dignity and respect, based on individual differences and needs. (Grade A)
2. In order to enhance the quality of decision-making in family planning, health-care providers should be proactive in counselling and should provide accurate information. They should be approachable partners in a professional relationship. (Grade B)
3. Family planning counselling should include counselling on the decline in fertility that is associated with increasing female age. (Grade A)
4. Health-care providers should promote the use of latex condoms in combination with another method of contraception (dual protection). (Grade B)

**REFERENCES**

Chapter 2: Contraceptive Care and Access

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André Lalonde, MD, FRCS C 3
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2Toronto ON
3Ottawa ON

INTRODUCTION

The World Health Organization recognizes reproductive and sexual health care as a fundamental human right.1 The Platform for Action of the 1995 Beijing Conference affirms the following: … the basic right of all couples and individuals to decide freely and responsibly the number and spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health.2

Responsibility for ensuring these rights lies with government, the health-care system, and individual health-care providers. Specifically, governments must make safe and effective contraceptive methods available and accessible, and provide adequate funding for delivery of contraceptive and sexual health services. The health-care system must ensure that contraceptive and sexual health services meet the needs of the population. Finally, individual health-care providers must recognize contraceptive care as more than just the provision of a method of birth control. Health-care providers should not only ensure that individuals have information and access to the widest array of safe and effective methods of birth control, but also take into account their broader sexual and reproductive health-care needs in helping them to choose and use a contraceptive method. Those who actively collaborate in choosing a contraceptive are most likely to be satisfied with their method and are most likely to adhere to it over time.3

CONTRACEPTIVE CARE IN THE CONTEXT OF SEXUAL BEHAVIOR AND REPRODUCTIVE HEALTH

Choosing a contraceptive method, and having the desire and ability to take it up and continue to use contraception (contraceptive adherence) take place in the broader context of a person’s social circumstances, belief system, sexual behavior, and reproductive health needs. An integrated approach to contraceptive care that recognizes the relationship of these factors is therefore recommended in order to address their sexual health needs.4
CONTRACEPTIVE EFFECTIVENESS
A major factor influencing choice of a contraceptive method is the effectiveness of the method in preventing pregnancy. This is related to both the inherent efficacy of the method and how consistently and correctly it is used. Some methods such as sterilization are inherently very effective and are almost unaffected by user characteristics. Others, such as condoms, are inherently effective but in actual use are very dependent on the user for achieving their maximal effectiveness (Table 1). Health-care providers should address these differences in counselling.

INDIVIDUAL AND ENVIRONMENTAL DETERMINANTS OF CONTRACEPTIVE BEHAVIOR
An individual’s knowledge about contraception, their motivation to act on this knowledge, and their ability to act on it effectively will influence contraceptive choice and adherence to a contraceptive method over time. Supportive environmental factors such as ready access to health care, affordable contraception, and an agreeable partner are also critical to a person’s ability to use contraception effectively (Figure 1). Well-informed, well-motivated, and behaviourally skilled individuals in a supportive environment are the most likely to take up and adhere to effective and safe contraception. Information that is practical and relevant to contraceptive choice is central to a person’s ability to adopt a contraceptive method that meets her needs. Canadians have a limited awareness of their contraceptive options, and have suboptimal adherence to contraceptive methods. Health-care providers can help to address these challenges to effective contraceptive practice by providing information about

- the range of birth control options and their effectiveness
- specific characteristics of the method
- common side effects
- health risks and benefits
- how to use a chosen method correctly
- what to do if problems occur

Table 1. Effectiveness of Family Planning Methods*

<table>
<thead>
<tr>
<th>Effectiveness group</th>
<th>Family planning method</th>
<th>As commonly used</th>
<th>Used correctly and consistently</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always very effective</td>
<td>Vasectomy</td>
<td>0.2</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>DMPA</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>Female sterilization</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Cu-380 IUD (no longer available in Canada)</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Progestin-only oral contraceptives (during breastfeeding)</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Effective as commonly used; very effective when used correctly and consistently</td>
<td>Lactational amenorrhea method</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Combined oral contraceptives</td>
<td>6-8</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Progestin-only oral contraceptives (not during breastfeeding)</td>
<td>†</td>
<td>0.5†</td>
</tr>
<tr>
<td></td>
<td>Male condoms</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Coitus interruptus*</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Diaphragm with spermicide</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fertility awareness-based methods</td>
<td>20</td>
<td>1-9</td>
</tr>
<tr>
<td></td>
<td>Female condoms</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Spermicides</td>
<td>26</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Cervical Cap</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Nulliparous women</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parous women</td>
<td>40</td>
<td>26</td>
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</tbody>
</table>

| No Method | 85 | 85 |


Key

<table>
<thead>
<tr>
<th>0-1</th>
<th>2-9</th>
<th>Effective</th>
<th>10-30</th>
<th>Somewhat effective</th>
</tr>
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</table>
The individual must be able to discuss this matter preemptively with their partner or to adhere to a contraceptive regimen consistently over time.\textsuperscript{11-13} A person's social norms – that is, their perceptions about what is accepted or rejected by a partner, a parent, or other significant persons – also influence contraceptive choice and adherence.\textsuperscript{11-13} By considering the characteristics of a range of contraceptive methods, individuals can tailor the method they choose to their own attitudes and set of social expectations.

Specific behavioural skills are needed to acquire a contraceptive and use it correctly and consistently.\textsuperscript{4,11} The individual must first acknowledge the fact that he or she is (or soon will be) sexually active. Individuals must then formulate a contraceptive health agenda; this may involve acquiring and using a method of birth control, practising safer sex, and seeking reproductive health care such as regular cervical cancer screening. Once this agenda is set, the individual must actively seek information about contraception and related reproductive health issues, choose and obtain a method of contraception, negotiate its use with a partner, and use it correctly and consistently over time.

Contraception is a complex matter involving a number of tasks. Awareness of this on the part of health-care providers is the first step in assisting consumers to develop the behavioural skills required. Health-care providers should review with individuals how they can use these skills in situations when sexual activity is likely. For example, practising how to bring up condom use with a partner can help build the behavioural skills essential for practising safer sex. (“Tell him you want to have sex, and that he should put on a condom.”) Simple information about routines (“A lot of my patients take their pill every morning when they brush their teeth, and I give all of my patients a prescription for the ‘morning after pill,’ just in case.”) can build an individual’s confidence in their method and their ability to use it effectively.

Environmental factors may lessen the ability of even well-motivated individuals to use contraception effectively.\textsuperscript{8} Those who are in abusive or disempowered relationships, who cannot afford contraception, who have limited access to care, who are chemically dependent, and who have major competing life demands are unlikely to use contraception effectively, unless such environmental factors are addressed.\textsuperscript{8}

The assessment and discussion of environmental barriers to contraceptive choice (e.g., cost) or adherence (e.g., chemical dependency) are an important part of contraceptive counselling. For example, if a woman's environment requires an “invisible” method of contraception, injections of long-acting progestin or use of an intrauterine device with the strings cut short may represent a good user-method “fit.” Cost issues can often be circumvented if they are determined to be impediments as well. Finally, addressing issues such as physically abusive relationships in which contraception is not tolerated may take precedence over contraceptive management itself.

**THE RELATIONSHIP OF CONTRACEPTIVE PRACTICE TO SEXUAL BEHAVIOUR AND REPRODUCTIVE HEALTH**

Contraceptive choice and utilization can have direct effects on sexual activity and reproductive health status. For example, the provision of a non-barrier contraceptive can free a woman to initiate sexual activity without fear of pregnancy, but at the same time it puts her at risk of acquiring a sexually transmitted infection (STI) that can impair her fertility and overall health. The more sexual partners that young Canadian women report having, the more likely they are to be using oral contraception, the less likely they are to use condoms, and the more likely they are to have had an STI.\textsuperscript{14}

Given the interdependency of contraceptive use, sexual activity, and reproductive health, contraceptive care must address contraception in the broader context of each of these factors. When providing information for making a contraceptive choice appropriate to an individual's attitudes, preferences, and environmental constraints, health-care providers should also counsel about related sexual health concerns such as STIs, sexual function, relationship violence, cervical cancer screening, and hepatitis B vaccination.\textsuperscript{15} For example, a woman using

**Figure 1.** Individual and environmental determinants of contraceptive behavior: environmental factors.
a hormonal method of contraception who is in a new but monogamous relationship should be advised about the need for STI prevention, including dual protection (use of hormonal contraception plus condoms), mutual human immunodeficiency virus (HIV) antibody testing and mutual monogamy.

PUTTING AN INTEGRATED APPROACH TO CONTRACEPTIVE CARE INTO PRACTICE

To establish a “sexual health–friendly” environment, the following cues may be helpful.

Environmental cues such as posters, books, or brochures in the practice setting clearly establish that the health-care provider is an approachable and knowledgeable source for contraceptive and reproductive health care. These cues can encourage individuals to express contraceptive and reproductive health concerns even in visits not originally intended for this purpose.

Verbal cues can systematically address contraception and related sexual and reproductive health concerns. Health-care providers can use a script-like approach during routine history taking or sexual health–related visits. This might involve the following verbal cues from the health-care provider:

“Part of my job is to help look after your sexual and reproductive health. Do you mind if I ask a few questions in this area?

• Are you sexually active? With men, or with women, or both?
• What are you and your partner doing to prevent pregnancy?
• What are you and your partner doing to prevent sexually transmitted infection/HIV infection?
• Do you have any concerns or questions about sexual function?
• Do you have any concerns or questions about sexual or relationship violence?

You can always ask me questions about these issues.”

This approach to contraceptive care has a number of advantages. First, it can be used either in a visit for a general health assessment, or, with appropriate modification, in a visit for contraception or a sexual health concern. Second, it integrates a discussion of contraception, sexual activity, sexual function, and sexual or relationship violence. Third, this approach identifies the legitimacy of care in this area, and the approachable and non-judgemental nature of the clinician for ongoing sexual health care.

THE HEALTH-CARE PROVIDER AS AN INFORMATION RESOURCE

Practical information that is easy for the individual to understand and to translate into behaviour is the foundation of good contraceptive practice. This can be done through individual counselling, or through brochures, books, or Web sites such as:

www.sexualityandu.ca
www.plannedparenthood.org/health/
www.itsyoursexlife.com/
www.womenshealthmatters.ca

REFERRAL NETWORKS

A locally relevant referral map will help in making appropriate referrals for specialized care. This may include referral links to abortion providers, public health services, child protection services, domestic violence services and sex therapists. In addition, an office library with pamphlets, books, and a list of Web resources for patient use can support practical information needs.

CONTINUING EDUCATION

Knowledge in contraceptive care is frequently changing as new contraceptive technologies become available. Training programs for health-care professionals should include sexual health counselling. Health-care providers should assess their own skills and comfort level, and seek out continuing clinical education in contraceptive care and related areas. The Web site www.sexualityandu.ca, administered by the Society of Obstetricians and Gynaecologists of Canada (SOGC), contains current information for health-care providers and others. The SOGC also initiated and manages a Canada-wide Contraception Awareness Project (CAP) to promote safer sex and effective contraception for Canadian women and men. Information about this program is available at www.sogc.org (search for “contraception awareness”).

ACCESS TO CONTRACEPTION

There are significant barriers to the effective use of contraception. Some of these are related to the potential user, some are provider related, some are system related, and some are related to government and industry.

ISSUES RELATED TO CONTRACEPTIVE USERS

The knowledge and motivation of the contraceptive user is central to effective contraceptive practice. Potential users must first acknowledge their need for contraception. They must have enough information about contraception to choose a method, know how to obtain their chosen method if it is one that does not require a prescription, and know how to use it correctly. Alternatively, they need to know where and how to access a health-care provider for contraceptive counselling and sexual health assessment, so that a suitable method can be provided or prescribed. Teens are a particularly vulnerable group in this respect, as they are often reluctant to seek information and help for contraception from their family physician. School-based programs that provide information about contraception have been shown to reach this target group effectively.
ISSUES RELATED TO PROVIDERS
Other steps to contraceptive utilization are provider dependent. Providers must be knowledgeable about the variety of contraceptive methods available, and be able to provide them. Providers may be less likely to recommend use of a contraceptive method with which they are not familiar, such as the intrauterine device.

Health-care providers must also be approachable and accessible to the population in need of contraception. In times of doctor shortages and cutbacks in the funding of sexual health services by public health departments, there may not be a sufficient number of health-care providers to ensure that contraceptive services meet the needs of the population.

SYSTEM-RELATED ISSUES
Access to a contraceptive method can be impeded if the cost of the method is excessive, or if the delivery of the method is cumbersome or inconvenient. The cost of many contraceptive methods is out of reach for women with limited financial means. Both government and private insurance plans cover the costs of many birth control methods, but this is not uniform even for hormonal methods. Sexual health clinics and many university health services provide free or subsidized contraceptives but these services are not widely available to the population as a whole. The SOGC’s national Compassionate Oral Contraceptive Program ensures that access to contraception is not denied because of lack of funds. Information about this program is available at www.sogc.org (search for “contraception awareness”).

GOVERNMENT AND INDUSTRY-RELATED ISSUES
Canadian women deserve access to all safe and effective contraceptive methods. Nevertheless, contraceptive choice in Canada is restricted in comparison to the situation in many other countries. A comparison of the availability of new contraceptive products shows that Canadian women have access to only 17% of the newer methods available, compared to Denmark, where 61% of all newer products are approved, and the United States, where 44% are approved. The time for approval of new drugs in Canada is significantly longer than in the United States and Sweden. In this environment, sponsors may not submit applications for new hormonal contraceptives when there appears to be a low chance of successful approval.

In recent years, Canadian women have lost access to products that are approved because suppliers have withdrawn them from the Canadian market. Thus Canadian women no longer have access to the Gyne-T 380 IUD, Norplant, and the Lea Shield. The Canadian market is small for many of these products, and unfortunately decisions are made that are detrimental to the ability of Canadian women to choose a contraceptive that is most acceptable to them.

SUMMARY STATEMENTS

1. Sexuality is an important aspect of life and is expressed in a variety of ways.
2. Counselling about contraception and STI consists of tailoring information to individual needs, enhancing positive attitudes towards contraception, sexuality, and STI prevention; modifying barriers to effective use; and helping individuals to develop practical skills to use their contraceptive method consistently. (Level II-2)
3. All individuals in sexual relationships are at risk for acquiring STIs; individuals changing or establishing new relationships are especially at risk. (Level II-2)
4. Well-informed, well-motivated, and behaviourally skilled individuals are more likely to use safe contraceptive and STI prevention methods effectively and consistently. (Level II-2)
5. Canadian women and men have the right to access a wide range of contraceptive options.

RECOMMENDATIONS
1. Comprehensive family planning services, including abortion services, should be freely available to all Canadians regardless of geographic location. These services should be confidential and respect an individual’s privacy. (Grade A)
2. Questions about sexuality should be incorporated into a general assessment. (Grade C)
3. Canadian women and men, with their health-care providers, should address both the prevention of unintended pregnancy and STIs. (Grade B)
4. Testing for STI and prevention counselling should not be restricted to young or high-risk individuals. (Grade B)
5. Women and men should receive practical information about a wide range of contraceptive methods so that they can select the method most appropriate to their needs and circumstances. (Grade C)
6. Health-care providers should assist women and men in developing the skills necessary to negotiate the use of contraception, as well as the correct and consistent use of a chosen method of contraception. (Grade C)
7. Health promotion, emergency contraception counselling, and the prevention of STIs, sexual violence, and cervical cancer should be integrated into contraceptive care. (Grade C)
8. The Government of Canada should enhance access to safe and effective products for Canadian women by accelerating the approval process through harmonization with the therapeutic guidelines of other developed countries. (Grade C)
9. The SOGC should work with groups that support initiatives in women’s health to promote the accessibility of all forms of contraception in Canada. (Grade C)
10. Hormonal emergency contraception should be available without a prescription in pharmacies, family planning clinics, emergency rooms, walk-in clinics, and school health programs. (Grade B)

11. The SOGC should continue the Contraception Awareness Project (CAP) to promote safer sex and effective contraception for Canadian women and men and to continue professional education for health-care providers who are active in this field. (Grade C)

12. The established program, which allows compassionate provision of oral contraceptives to patients in need in Canada, must be maintained. (Grade B)

REFERENCES


CHAPTER 3: EMERGENCY CONTRACEPTION

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INTRODUCTION

Emergency contraception (EC) is any method of contraception which is used after intercourse and before the potential time of implantation. As these methods work prior to implantation, they are not abortifacients. Emergency contraception is a back-up method for occasional use, and should not be used as a regular method of birth control.

OPTIONS

There are 2 methods of emergency contraception: hormonal methods, which involve the use of emergency contraceptive pills (ECPs), and the post-coital insertion of a copper intrauterine device (IUD). Two hormonal preparations are used as ECPs in Canada: one contains only the progestin levonorgestrel, while the other is a combined preparation containing both ethinyl estradiol and levonorgestrel.

The levonorgestrel-only method, marketed as Plan B, was introduced into Canada in 2000 and is the only product approved by Health Canada for EC. The regimen consists of 2 doses of 750 µg levonorgestrel taken orally 12 hours apart.

In use since the 1970s, the Yuzpe method consists of the oral administration of 2 doses of 100 µg ethinyl estradiol (EE) and 500 µg levonorgestrel 12 hours apart. Ovral tablets (each containing 50 µg ethinyl estradiol and 250 µg levonorgestrel) are most commonly used to provide these doses. Other products can be substituted if they are more readily available (Table 1). Although they may not deliver an exactly equivalent dose, they are considered to offer equivalent efficacy.1

EFFECTIVENESS

The Yuzpe and levonorgestrel-only methods have been shown in randomized trials to reduce the risk of pregnancy by approximately 75 and 85% respectively.2,3 This does not mean that 25% of women using the Yuzpe method will become pregnant; it means that, if 100 women had unprotected intercourse once during the
second or third week of their menstrual cycle, 8 of them would be likely to become pregnant, but that only 2 would become pregnant (a reduction of 75%) after use of the Yuzpe method. A single dose of 1.5 mg of levonorgestrel appears to be as effective as the standard 2-dose levonorgestrel regimen. Although they have generally been used only up to 72 hours after intercourse, both hormonal methods of EC are effective when taken between 72 and 120 hours after unprotected intercourse. The effectiveness of EC has been shown to decline significantly with increasing delay between unprotected intercourse and the initiation of treatment: levonorgestrel EC prevented 95% of pregnancies when used within 24 hours of intercourse, 85% when used 25 to 48 hours after intercourse, and 58% when used 49 to 72 hours after intercourse. The corresponding figures for the Yuzpe method were 77%, 36%, and 31%. Although significant in several studies, this time-effect relationship was not seen in other studies.

A meta-analysis has demonstrated that the effectiveness of post-coital IUDs approaches 100%, significantly higher than the effectiveness of hormonal EC. Theoretically, EC could interfere with follicle maturation; the ovulatory process; cervical mucus; sperm migration; corpus luteum sufficiency; endometrial receptivity; fertilization; and zygote development, transport, and adhesion. The mechanism of action may differ not only with the different EC methods, but also within each method, depending upon when it is given relative to the time of both intercourse and ovulation.

### MECHANISM OF ACTION

Hormonal emergency contraception should be considered for any woman wishing to avoid pregnancy who presents within 5 days of unprotected or inadequately protected sexual intercourse. A post-coital IUD insertion can be considered up to 7 days after unprotected intercourse. Appropriate indications include the following situations:

- failure to use a contraceptive method
- condom breakage or leakage
- dislodgement of a diaphragm or cervical cap
- two or more missed birth control pills
- Depo-Provera injection over 1 week late
- ejaculation on the external genitalia
- mistimed fertility awareness
- sexual assault when the woman is not using reliable contraception

Because it is difficult to determine the infertile time of the cycle with certainty, EC should be provided to a woman who is concerned about her risk of pregnancy regardless of the cycle day of exposure. Although ECPs are not recommended as a regular form of contraception, repeat use poses no known health risks and should not be a reason for denying women access to treatment.

### CONTRAINDICATIONS

The only absolute contraindication to the use of emergency hormonal contraception is known pregnancy. The effect of ECP use in women already pregnant on the outcome of pregnancy is unknown, but pregnancies in which the fetus has been exposed to oral contraceptives (OCS) have shown no evidence of teratogenicity.

No substantial increased risk for developing venous thromboembolism has been found with combined hormonal EC. However, studies of safety have frequently excluded women who have contraindications to oral contraception. Since the levonorgestrel-only method carries no theoretical risk, it may be a preferred option for women with significant contraindications to estrogen – such as those with known thrombophilia, a history of stroke or heart attack, migraine headache with neurological symptoms, or smokers over age 35.

If insertion of an IUD is considered, a preexisting pregnancy must be excluded. This may require a sensitive urine pregnancy test or assay of serum human chorionic gonadotropin (hCG). There should be no history of recent pelvic inflammatory disease, low risk for sexually transmitted infection, and no evidence on examination of vaginal or cervical infection.

### SIDE EFFECTS

The common side effects of hormonal emergency contraception are gastrointestinal. The levonorgestrel method has a significantly lower incidence of nausea (23.1% versus 50.5%), vomiting (5.6% versus 18.8%), dizziness, and fatigue than the Yuzpe method. The antiemetic meclizine (available without prescription) has been shown to reduce the risk of nausea when taken orally in a dose of 50 mg 1 hour before the first dose of

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**Table 1. Ovral and Substitutions**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Pills per Dose</th>
<th>Ethinyl Estradiol (µg/dose)</th>
<th>Levonorgestrel (µg/dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovral</td>
<td>2</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>Alesse</td>
<td>5</td>
<td>100</td>
<td>500</td>
</tr>
<tr>
<td>Triphasil</td>
<td>4 yellow</td>
<td>120</td>
<td>500</td>
</tr>
<tr>
<td>Triquilar</td>
<td>4 yellow</td>
<td>120</td>
<td>500</td>
</tr>
<tr>
<td>Min-Ovral</td>
<td>4</td>
<td>120</td>
<td>600</td>
</tr>
</tbody>
</table>
the Yuzpe method, but its use increases the incidence of drowsiness.\textsuperscript{22} Less common side effects of both methods include headache, bloating, abdominal cramps, and spotting or bleeding.\textsuperscript{23} Most women will have menstrual bleeding within 3 weeks of taking ECPs.\textsuperscript{2}

Possible complications of post-coital IUD insertion include pelvic pain, abnormal bleeding, pelvic infection, perforation and expulsion.\textsuperscript{23}

MYTHS AND MISCONCEPTIONS

1. Emergency contraceptive pills cause a “mini-abortion.”

\textit{Fact:} Emergency contraceptive pills have no effect on an established pregnancy.\textsuperscript{19} They act prior to implantation and therefore are not abortifacients.\textsuperscript{15}

2. If emergency contraceptive pills are too easy to obtain, women will “abuse” them.

\textit{Fact:} Women who are supplied with emergency contraceptive pills in advance of need will use them appropriately and are not more likely to abandon regular forms of birth control.\textsuperscript{24-26}

3. Emergency contraceptive pills have high doses of hormones and are dangerous to use.

\textit{Fact:} The brief one-time dose of hormone in emergency contraceptive pills is extremely safe and can be used by virtually any woman who needs it.\textsuperscript{27}

PROVIDING EMERGENCY CONTRACEPTION

In order to determine whether EC is indicated, it must be determined that unprotected intercourse occurred within the time frame when EC is effective. The woman’s risk for having a preexisting pregnancy should be assessed by determining the timing and character of her last menstrual period. Rarely, a urine pregnancy test may be necessary to rule out pregnancy. A history of previous unprotected intercourse during the current cycle should not preclude the use of EC to lower risk related to unprotected intercourse within the therapeutic window for EC.

Health-care providers should also discuss broader sexual health concerns, such as whether the unprotected act was coerced, risks for sexually transmitted infections, and need for ongoing birth control. If nucleic acid amplification techniques are available to test for chlamydia, urine testing for chlamydia infection at the time of presentation for EC has been shown to detect most cases. It should be considered for high-risk groups (e.g., women under age 30) when reliable follow-up cannot be guaranteed.\textsuperscript{28}

Women should be informed about the potential side effects of EC, and should be advised that hormonal EC will not prevent pregnancy resulting from unprotected intercourse in the days or weeks following treatment. A barrier method such as the condom can be used for the remainder of the current menstrual cycle, and a regular contraceptive method can be initiated at the beginning of the next cycle if the woman desires. A woman who wishes to begin using OCs may be provided with a prescription to start with her next period or the next day following the use of ECPs.\textsuperscript{29} She should use a condom until she has taken the oral contraceptive pill for 7 consecutive days.

To maximize effective use of EC, women should have it readily available when needed. Visits for periodic health examinations or reproductive health concerns give an opportunity for health-care providers to offer a woman a prescription for EC in advance of need.

FOLLOW-UP

Women should be advised to have a pregnancy test if they do not experience normal menstrual bleeding by 21 days after treatment (28 days if she began using OCs after taking ECPs). If indicated, a follow-up appointment can be made to discuss contraception issues or to test for sexually transmitted infections.

TROUBLESHOOTING

Women who experience nausea or vomiting after taking hormonal EC should be advised to take an antiemetic such as meclizine or dimenhydrinate. Using the levonorgestrel-only method as a single-dose regimen (1.5 mg orally) obviates the need for a second dose if nausea occurs, and may be preferred for this reason.

If it is likely that a woman may forget to take her second dose of the 2-dose regimen, the single-dose levonorgestrel regimen should be recommended. If the second dose is forgotten, it can be taken up to 24 hours after the first without significant change in pharmacokinetics compared to the 12-hour dosing schedule.\textsuperscript{30}

DRUG INTERACTIONS

Although theoretically the serum concentrations of the ECP hormones are affected by the use of drugs such as rifampicin and certain anticonvulsants, the efficacy of ECPs in this situation is uncertain. A case report of a woman taking warfarin who used the levonorgestrel-only ECP described a subsequent significant increase in anticoagulant effect.\textsuperscript{31}

SUMMARY STATEMENTS

1. Women who have had unprotected intercourse and wish to prevent pregnancy can be offered use of hormonal emergency contraception up to 5 days after intercourse, (Level II-2) or insertion of a copper IUD up to 7 days after intercourse, to reduce the risk of pregnancy. (Level II-2)
REFERENCES


Please note: The CPD Quiz including objectives and questions will appear at the end of the third part.
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 4: Combined Hormonal Contraception
1. A range of hormonal contraceptives should be available to ensure that the individual receives the preparation most suited for her needs. (Grade C)
2. Women using oral contraceptives should be counselled that antibiotic use does not appear to affect combined OC efficacy (except for griseofulvin and rifampicin). (Grade B)

Chapter 5: Progestin-Only Hormonal Contraception
1. 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)
2. Progestin-only methods should be considered as contraceptive options for women with a past history of venous thromboembolism (VTE), or for women who are at a higher risk of myocardial infarction or stroke. In women with a proven thrombophilia, progestin-only preparations should be used with caution. (Grade B)
3. Young women who use depot medroxyprogesterone acetate (DMPA) should be counselled about dietary and lifestyle factors that will affect their peak bone mass, such as smoking, exercise, and calcium intake. (Grade A)

Chapter 6: Special Considerations for Hormonal Contraception
1. All women who smoke should be counselled to stop. Women over 35 who smoke should be advised not to use combined oral contraceptives (OCs). (Grade A)
The oral contraceptive pill (combined OC) was first introduced in 1960. Since then it has undergone many modifications and has been used by millions of women worldwide. In Canada, 18% of women aged 15 to 49 use the combined OC. Of Canadian women who use contraception, 32% use the combined OC as their method of birth control.2

The combined OC preparations available in Canada are shown in Table 1. Formulations may be monophasic (each tablet contains a fixed amount of estrogen and progestin); biphasic (each tablet contains a fixed amount of estrogen, while the amount of progestin increases in the second half of the cycle); or triphasic (the amount of estrogen may be fixed or variable, while the amount of progestin increases in 3 equal phases). Biphasic and triphasic formulations were initially developed with the intent of lowering the total steroid content of combined OCs.3

Two types of estrogen are used in combined OCs: ethinyl estradiol and mestranol. Mestranol is a “prodrug” that is converted in vivo to ethinyl estradiol.4 Several different progestins, of varying degrees of progestational potency, are used in combined OCs. The progestins may also have estrogenic, antiestrogenic, or androgenic activity. The “potencies” attributed to different combined OC preparations are based on pharmacological experimental models. These include the mouse uterine weight assay for estrogenic activity, demonstration of glycogen vacuoles in human endometrium for progestogenic activity, and the rat ventral prostate assay for androgenic activity.5,6 However, there is no clear clinical or epidemiological evidence that compares the relative potencies of currently available combined OCs. The many variables that affect the potency of combined OCs (including dosage, bioavailability, protein binding, receptor binding affinity, and interindividual variability) make it difficult to extrapolate the results of isolated experiments to provide clinically relevant information in humans.4

Progestins can be classified according to their chemical structure as an estrane (norethindrone, ethynodiol diacetate) or as a gonane (levonorgestrel, desogestrel, norgestimate). In general, the gonane progestins appear to be more potent than the estrane derivatives (smaller doses can be used), but otherwise differences between the estrane and gonane compounds are difficult to characterize.7,8 Progestins have also been classified according to the sequence of their development (first, second, or third generation), but the definitions of first, second, or third generation progestins are not universally accepted. Newer progestins (norgestimate and desogestrel) have been shown to have little or no androgenic activity.7,8 These progestins, when administered in combination with ethinyl estradiol, produce a net estrogen-dominant effect, which may partly explain the effects seen on hepatic proteins (increased levels of sex hormone-binding globulin), lipid metabolism (increased levels of triglycerides and high-density lipoprotein-cholesterol), and on haemostatic variables (increased levels of fibrinogen, plasminogen, and Factor VII).7,8

**EFFICACY**

The combined OC is a highly effective method of reversible contraception. With perfect use, the combined OC is 99.9% effective in preventing pregnancy.9 However, typical user failure rates range from 3 to 8%.10,11

Poor patient compliance is a major factor in limiting effectiveness. In one study, the proportion of women who reported
missing no pills (53 to 59%) was much higher than the proportion recorded electronically (19 to 33%). According to the electronic devices, 30% of women missed 3 or more pills in the first cycle of combined OC use. Another study found that 47% of women miss 1 or more pills and 22% miss 2 or more pills per cycle.

The effect of body weight on the efficacy of the combined OC is controversial. A retrospective cohort study found that women weighing 70.5 kg or more had a significantly increased risk of combined OC failure compared with women of lower body weight. The relative risk of failure was 2.6 among low-dose combined OC users and 4.5 among very-low-dose combined OC users. However, a large cohort study failed to find evidence of any influence of body weight on the risk of accidental pregnancy in combined OC users. Further studies are required before recommendations can be made.

**MECHANISM OF ACTION**

The combined OC’s multiple mechanisms of action may contribute to its high efficacy. Its main mechanism of action is to suppress gonadotropin secretion, thereby inhibiting ovulation. Other mechanisms of action include:

- Development of endometrial atrophy, making the endometrium unreceptive to implantation;
- Production of viscous cervical mucus that impedes sperm transport;
- Possible effect on secretion and peristalsis within the fallopian tube, which interferes with ovum and sperm transport.

**INDICATIONS**

In the absence of contraindications, use of the combined OC may be considered for any woman seeking a reliable, reversible, coitally-independent method of contraception. It is particularly suited for women who wish to take advantage of its non-contraceptive benefits.

The use of condoms is still recommended in combined OC users for protection against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV).

**CONTRAINDICATIONS**

The World Health Organization (WHO) has developed a list of absolute and relative contraindications to the use of combined OCs, based on the available evidence of risks.

**ABSOLUTE CONTRAINDICATIONS**

- < 6 weeks postpartum if breastfeeding
- Smoker over the age of 35 (≥ 15 cigarettes per day)
- Hypertension (systolic ≥ 160 mm Hg or diastolic ≥ 100 mm Hg)

<table>
<thead>
<tr>
<th>Table 1. Composition of Various Combination Hormonal Contraceptives</th>
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<tbody>
<tr>
<td><strong>Type</strong></td>
</tr>
<tr>
<td><strong>Combination Monophasic</strong></td>
</tr>
<tr>
<td>Ethinyl estradiol / desogestrel</td>
</tr>
<tr>
<td>Ethinyl estradiol / ethynodiol diacetate</td>
</tr>
<tr>
<td>Ethinyl estradiol / levonorgestrel</td>
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<td>Ethinyl estradiol / norelgestromin</td>
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<tr>
<td>Ethinyl estradiol / norethindrone</td>
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<tr>
<td>Ethinyl estradiol / norethindrone acetate</td>
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<tr>
<td>Ethinyl estradiol / norgestimate</td>
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<tr>
<td>Ethinyl estradiol / norgestrel</td>
</tr>
<tr>
<td>Mestranol / norethindrone</td>
</tr>
<tr>
<td>Ethinyl estradiol / cyproterone acetate</td>
</tr>
<tr>
<td><strong>Biphasic</strong></td>
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<td><strong>Triphasic</strong></td>
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<td>Ethinyl estradiol / norethindrone</td>
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<tr>
<td>Ethinyl estradiol / norgestimate</td>
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<tr>
<td>Ethinyl estradiol / levonorgestrel</td>
</tr>
</tbody>
</table>

*indicated for severe acne, should not be prescribed solely for its contraceptive properties
• current or past history of venous thromboembolism (VTE)
• ischemic heart disease
• history of cerebrovascular accident
• complicated valvular heart disease (pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)
• migraine headache with focal neurological symptoms
• breast cancer (current)
• diabetes with retinopathy/nephropathy/neuropathy
• severe cirrhosis
• liver tumour (adenoma or hepatoma)

RELATIVE CONTRAINDICATIONS
• smoker over the age of 35 (< 15 cigarettes per day)
• adequately controlled hypertension
• hypertension (systolic 140–159mm Hg, diastolic 90–99mm Hg)
• migraine headache over the age of 35
• currently symptomatic gallbladder disease
• mild cirrhosis
• history of combined OC-related cholestasis
• users of medications that may interfere with combined OC metabolism

NON-CON Traceptive BENEFITS
In addition to providing effective contraception, the combined OC has a number of non-contraceptive benefits that may make it an attractive option for many women. These include
• cycle regulation
• decreased menstrual flow19,20
• increased bone mineral density21-24
• decreased dysmenorrhea19,25-27
• decreased peri-menopausal symptoms28,29
• decreased acne30-36
• decreased hirsutism37
• decreased endometrial cancer38-42
• decreased ovarian cancer43-48
• decreased risk of fibroid49,50
• possibly fewer ovarian cysts51
• possibly fewer cases of benign breast disease52
• possibly less colorectal carcinoma53-55
• decreased incidence of salpingitis56,57
• decreased incidence or severity of moliminal symptoms58

SIDE-EFFECTS
Some combined OC users will experience minor side-effects, most commonly during the first 3 cycles.59 These side-effects may lead to discontinuation of the combined OC. Reassurance and adequate counselling about expected common side-effects can help to prevent unnecessary discontinuation and enhance compliance.60-61 The most common reason patients discontinue combined OC use is abnormal menstrual bleeding, followed by nausea, weight gain, mood changes, breast tenderness, and headache.60

1. IRREGULAR BLEEDING
Unexpected bleeding occurs in 10 to 30% of women in the first month of combined OC use62-64, and is a common reason for discontinuing use of combined OCs.65-67 The actual incidence of breakthrough bleeding or spotting is difficult to know as it is defined in various ways in different studies. It does appear that breakthrough bleeding or spotting in women beginning combined OC use improves with time.68-70 The likelihood of irregular bleeding is greater during the first 3 cycles of combined OC use, although rates at 3 months do not differ significantly from rates at 1 month.69-70 Randomized trials have compared the rates of irregular bleeding between 2 or 3 products, but no single comprehensive study has compared the rates of irregular bleeding in all of the existing combined OC formulations. Amenorrhea occurs in approximately 2 to 3% of cycles.62

2. BREAST TENDERNESS AND NAUSEA
Breast tenderness and nausea may occur, but generally improve with time.71 These symptoms may occur less often in women who use combined OCs containing smaller amounts of estrogen.59

3. WEIGHT GAIN
Although weight gain is often thought to be a side-effect of the combined OC,72 placebo-controlled trials have failed to show any association between low-dose combined OCs and weight gain.73-76 Studies comparing the combined OC to other contraceptive methods have also failed to show a significant OC-associated weight gain.

4. MOOD CHANGES
Although women may report depression and mood changes while taking the combined OC, placebo-controlled trials have not demonstrated a significantly increased risk of mood changes in combined OC users compared to placebo users.73

RISKS

1. VENOUS THROMBOEMBOLISM
The rates of venous thromboembolism in combined OC users are 3- to 4-fold higher than among non-users.77 The absolute risk of VTE in combined OC users is 1 to 1.5 per 10 000 users per year of use. The risk of VTE during the first year of use appears to be higher than that in subsequent years of use.78-79 (See chapter 6: Special Considerations for more information.)
2. MYOCARDIAL INFARCTION
In women taking a combined OC containing more than 50 µg of ethinyl estradiol, myocardial infarction rates increase 3-fold.80-81 However, a number of recent studies have found no significant increase in the risk of myocardial infarction with preparations containing less than 50 µg of ethinyl estradiol, irrespective of age.82-85 (See chapter 6: Special Considerations for more information.)

3. STROKE
A significantly increased risk of stroke is seen in users of combined OCs that contain more than 50 µg of ethinyl estradiol.86 Although some studies of low-dose combined OCs report no increase in the risk of stroke,87-88 others have reported an increased risk of up to 2-fold.89-92 Smoking and hypertension are major risk factors for stroke.93 Combined OC users with hypertension are at an increased risk of stroke relative to users without hypertension.94 A meta-analysis published in 2000 reported an odds ratio of 1.93 (95% confidence interval [CI], 1.35–2.74) for current combined OC preparations in studies that controlled for smoking and hypertension.95 (See chapter 6: Special Considerations for more information.)

4. GALLBLADDER DISEASE
Combined OC use increases the secretion of cholic acid in bile, potentially leading to a higher incidence of gallstone formation.96 However, there does not appear to be a significantly increased risk of gallstone formation in combined OC users.97,98

5. BREAST CANCER
Despite numerous studies, the risk of breast cancer in combined OC users is still controversial. A case-control study published in 1986 showed no association between the use of the combined OC and the risk of breast cancer.99 The best data available until recently were the results of a large meta-analysis published in 1996.100 The results of this study suggested that there was a small but significant increase in risk of breast cancer in women who were currently taking the combined OC (relative risk [RR], 1.24; 95% CI, 1.15–1.33) and in the first 10 years after discontinuing it. There did not appear to be a significant excess risk of having breast cancer diagnosed 10 or more years after stopping the combined OC.100 To put this into perspective, the cumulative likelihood of breast cancer up to the age of 35 in Canadian women is approximately 2 per 1000 women.101 If these 1000 women were using combined OCs, and if the associated breast cancer risk was 1.5-fold higher, they would experience 3 cases of breast cancer by the age of 35 rather than 2 cases. It is unclear whether the small increase in breast cancer risk associated with combined OC use is related to the OC itself or to delaying the first full-term birth.

In a more recent study of over 9000 women between the ages of 35 and 64, there was no significant association between the use of the combined OC and breast cancer.102 Among current combined OC users, the relative risk was 1.0 (95% CI 0.8–1.3), and among former users the relative risk was 0.9 (95% CI 0.8–1.0). The risk did not increase with longer periods of use, with different dosages of estrogen, or with different progestin components. The risk of breast cancer was not increased in women with a family history of breast cancer who used the combined OC, or in women who started using the combined OC at an earlier age.

It is possible that women who carry the BRCA1 gene or BRCA2 gene mutations may be at a higher risk of breast cancer than other women when using combined OCs.103-105

6. CERVICAL CANCER
Although human papillomavirus (HPV) is known to be linked to cervical cancer, many studies did not take this into account when studying combined OC use and the risk of cervical neoplasia. One study suggests that long-term combined OC use may increase the risk of cervical cancer in women who are HPV positive but not in women who are HPV negative.106 A systematic review of 28 studies of women with cervical cancer also found that increasing the duration of combined OC use was associated with an increased risk of cervical cancer.107 The data, although limited, suggested that the relative risk of cervical cancer may decrease after use of combined OCs ceases. Infection with HPV, the major risk factor for cervical cancer,108 is related to sexual behaviour, and sexual behaviour may differ between combined OC users and non-users. A long-term study published in 2002 concluded that, in a well-screened population of HPV-positive women followed for 10 years, combined OC use did not increase the risk of cervical cancer.109 The specific role that combined OCs play in the development of cervical cancer remains uncertain.

MYTHS AND MISCONCEPTIONS
Numerous myths and misconceptions exist concerning the combined OC.

1. The combined OC causes cancer.
Fact: The combined OC reduces the risks of ovarian and endometrial cancer. The risk of ovarian cancer is reduced by at least half in women who use combined OCs.43-48,110 A meta-analysis of 20 studies of combined OC use indicated that the risk of ovarian cancer decreased with increasing duration of OC use, reducing by 10 to 12% after 1 year of use and by approximately 50% after 5 years of use.45 This reduction in risk persists for 10 to 20 years after combined OC use has been discontinued. The reduced risk of ovarian cancer in combined OC users has also been noted in women who have a pathogenic mutation in the BRCA1 or BRCA2 gene, a mutation that increases their lifetime risk of developing ovarian cancer.48,111 The combined OC is associated with a
50% overall reduction in the risk of endometrial cancer and the protective effect persists long after the combined OC is discontinued. The combined OC may also have a protective effect against colorectal cancer. There appears to be either no increase or a very slight increase in the risk of breast cancer in current combined OC users.

2. Women on the combined OC should have periodic pill breaks.

Fact: This is unnecessary. Pill breaks place a woman at risk for unintended pregnancy and cycle irregularity.

3. The combined OC affects future fertility.

Fact: Fertility is restored within 1 to 3 months after stopping the combined OC.

4. The combined OC causes birth defects if a woman becomes pregnant while taking it.

Fact: There is no evidence that the combined OC causes birth defects if it is taken inadvertently during pregnancy.

5. The combined OC must be stopped in all women over 35 years old.

Fact: Healthy, non-smoking women may continue to use the combined OC until menopause.

6. The combined OC causes acne.

Fact: Acne improves in women using the combined OC due to a decrease in circulating free androgen. Although all combined OCs will result in an improvement of acne, 2 combined OCs in Canada have received official labelling for the treatment of acne; these 2 OCs contain ethinyl estradiol in combination with either levonorgestrel or norgestimate. The combination pill with cyproterone acetate is indicated for the treatment of severe acne and is also a contraceptive.

INITIATION

1. PATIENT ASSESSMENT

Before prescribing a combined OC, a thorough history should be taken, including potential contraindications, smoking history, and medications. The physical examination should include a blood pressure measurement. A pelvic examination, although an important aspect of well-woman care, is not mandatory before providing combined OCs. The pelvic examination may be postponed until a follow-up visit. Negotiating the pelvic examination may be particularly important with adolescents.

No routine laboratory screening is required. Assessing the cholesterol-lipoprotein profile and carbohydrate metabolism should follow the Guidelines from the Canadian Periodic Health Examination. Routine screening for thrombophilies is not recommended.

2. COUNSELLING

Adequate counselling prior to initiation of combined OCs may help to improve compliance (regular use) and adherence (continuation). Counselling with regard to combined OC use should include the following:

- information on potential side-effects
- non-contraceptive benefits of the combined OC
- addressing common myths and misconceptions
- discussing risks and warning signs, including when to seek medical care
- discussing what to do if pills are missed
- emphasizing dual protection (the combined OC with condom use to prevent STIs and HIV infection)
- information about emergency contraception in the event of missed pills

3. PRESCRIPTION

- The choice of a combined OC, for first-time users, should take into account the prescriber’s clinical judgment and the preferences of the user. A low-dose preparation (≤ 35 µg of ethinyl estradiol) is preferred. The preparation of choice for the combined OC user is the one that provides effective contraception, acceptable cycle control, and the least side-effects for that individual.
- Various start dates for the combined OC are used. Conventionally, the combined OC is started during the first 5 days of the menstrual cycle or on the first Sunday after menses begin. If the combined OC is started within the first 5 days of the menstrual cycle, a backup method of contraception is not necessary for prevention of pregnancy, provided that no pills have been missed. Another alternative is the Quick Start method, where a combined OC user takes her first pill in the health-care provider’s office after ruling out pregnancy. A back-up method of contraception should be used for the first week after combined OC initiation if the Quick Start method is used. This method, with its simple starting instructions, improves compliance, particularly in adolescents, and is not associated with an increase in the incidence of breakthrough bleeding or other side-effects.
- Women who use a 21-day preparation should be cautioned never to exceed the 7 day pill-free interval between packs.
- The health-care provider may discuss emergency contraception (EC) as well as providing an EC prescription in advance of need.
- Dual protection with condoms should be re-emphasized.
- A follow-up visit should be scheduled to review the combined OC users’ experience, satisfaction, and compliance, as well as to perform a blood pressure check. If indicated, a pelvic examination can be performed at the follow-up visit.

Combined OC prescribers should take steps to reduce long-term costs, and improve follow-up and oral contraceptive tracking, by eliminating indiscriminate “free sampling.” Initiation
of therapy with a single sample pack, for immediate protection and for demonstration purposes, should be accompanied by a prescription. For patients who are unable to pay for their medications and are not covered by a private insurance plan or government assistance, health-care providers can apply to the National Compassionate Oral Contraceptive Program on their behalf. This program ensures that access to contraception is not denied on the basis of lack of funds. (Go to http://sogc.medical.org/forms/pdfs/factSheetCompassion_e.pdf for more information about the program. Go to http://www.sogc.org/forms/pdfs/compassionform%5Fe.pdf to access the application form.)

CONTINUOUS USE OF COMBINED ORAL CONTRACEPTIVE PILLS

The use of combined oral contraceptive pill on a continuous basis was first studied in 1977, using 50 µg ethinyl estradiol pills.119 When given in a continuous fashion, the combined OC may have a number of advantages including decreased incidence of pelvic pain, headaches, bloating/swelling, and breast tenderness for women who experience these symptoms during the pill-free interval120; improved control over symptoms of endometriosis121 and polycystic ovary syndrome122; and greater convenience due to fewer withdrawal bleeds per year. Disadvantages of giving the combined OC in a continuous fashion include little information on long-term safety (although there are long-term data for comparable total estrogenic fashion include little information on long-term safety (although there are long-term data for comparable total estrogenic

VAGINAL ADMINISTRATION OF COMBINED ORAL CONTRACEPTIVES

Six clinical trials have evaluated the administration of combined OCs given vaginally.130-136 Theoretical advantages in administering the combined OC vaginally include avoiding the “first pass” metabolism by the liver, which may help to decrease side-effects and improve tolerance. The largest study of this method of administration involved 1055 women and resulted in pregnancy rates of 2.78% at one year with use of a preparation containing 50 µg ethinyl estradiol with 250 µg levonorgestrel (1 Ovral tablet daily), and 4.54% at one year with use of a preparation containing 30 µg ethinyl estradiol with 150 µg desogestrel (1 Orthocept or 1 Marvelon tablet daily). No significant difference in pregnancy rates was reported between these two products when administered vaginally.132 Failure rates in this study were not compared to those seen with oral administration of combined OCs.

TROUBLESHOOTING

I. BREAKTHROUGH BLEEDING

The rates of irregular bleeding reported by women in clinical trials of combined OCs vary widely.59,68,137-138 Bleeding rates at 3 months do not appear to differ significantly from those at 1 month; therefore, new users of a combined OC should be encouraged to continue with the expectation that any irregular bleeding will subside, rather than switching to another combined OC. An improvement in bleeding patterns is usually seen over time, so that reassurance and a reminder of the usually transient nature of irregular bleeding is essential. A Pap smear, STI testing, or a pregnancy test may be performed if indicated.

If the bleeding persists after the third cycle of use, or has a new onset, other causes of bleeding must be ruled out. Possible reasons for irregular bleeding while taking the combined OC include irregular pill taking, smoking, uterine or cervical pathology, malabsorption, pregnancy, use of concomitant medications (e.g. anticonvulsants, rifampin, herbal medicines), and infection.141 Health-care providers should rule out these
potential causes of irregular bleeding. The patient should be
asked about the duration of pill use, dosage, timing, missed pills,
symptoms of pregnancy, diarrhea or vomiting in the last cycle,
dyspareunia, vaginal bleeding after intercourse, smoking, and
the use of other medication. New onset of irregular bleeding
in a long-term combined OC user may be a marker for chlamy-
dia infection (up to 29% of these women may have a positive
chlamydia test), so that these women should be screened for
Chlamydia infection.

Several empirical regimens have been used to manage break-
through bleeding once other causes have been eliminated,
although there is no reliable evidence to support them. In the
case of persistent or new onset bleeding, a short course of oral
estrogen may be helpful, such as 1.25 mg of conjugated estro-
gen or 2 mg of estradiol-17β daily for 7 days. If no improve-
ment is seen, a therapeutic trial of another combined OC may
be indicated. It may be useful to offer a combined OC contain-
ing a different type of progestin, such as switching from a
preparation that contains a gonane progestin to one that con-
tains an estrane progestin (or vice versa). There is no combined
OC preparation that is less likely than others to cause break-
through bleeding. Consistent pill use, dual protection, and
smoking cessation should be emphasized.

2. MISSED PILLS
Missing pills at the beginning or end of the 21-day cycle has the
effect of lengthening the hormone-free interval. If the hormone-
free interval exceeds 7 days, the risk of ovulation and possible
conception is increased. Forgetting tablets in the second or third
week of the 21-day cycle is unlikely to increase the risk of ovu-
lation if the hormone-free interval does not exceed 7 days.

3. AMENORRHEA
Amenorrhea occurs in 2 to 3% of combined OC users. Preg-
nancy should first be ruled out in any OC user who develops
amenorrhea. Amenorrhea in women taking combined OCs is
not dangerous, and many women readily accept the absence of
withdrawal bleeding. If amenorrhea is unacceptable, adding
exogenous estrogen (e.g., 0.625–1.25 mg conjugated estrogens
or 1–2 mg of 17β estradiol) for 10 days per cycle will often
result in resumption of bleeding. Switching to another
preparation may be effective. There is usually no indication to
switch to a pill containing 50 µg ethinyl estradiol.

4. CHLOASMA
Chloasma, a darkening of facial skin pigmentation, may occur
during OC use. If chloasma occurs, changing to another pill
will not help. The hyperpigmentation may never completely
disappear. The use of sunscreen may help to prevent further
pigmentation.

5. BREAST TENDERNESS (MASTALGIA) AND
GALACTORRHEA
Mastalgia often resolves after several cycles of combined OC
use. Decreasing caffeine intake may be helpful in reducing
mastalgia. Decreasing the estrogen content of the combined
OC may also be helpful. The presence of galactorrhea during
combined OC use is rare and is an indication for perform-
ing a serum prolactin assay.

6. NAUSEA
Nausea is a common side effect during the first cycles of com-
bined OC use, and usually decreases with time. However, nau-
sea or vomiting may occur when a woman takes 2 pills at the
same time. Taking the pills a few hours apart may be helpful in
this case. Taking the pill with food or at bedtime will often con-
trol the nausea. A lower estrogen dose may improve the nau-
sea. If nausea occurs in a long-time pill user, pregnancy
must be ruled out.

7. PREGNANCY
If pregnancy occurs in a woman taking a combined OC, she
should stop taking the pill immediately. She should be informed
that there is no increased risk of birth defects as a result of inad-
vertent combined OC use during pregnancy.

DRUG INTERACTIONS
Ethinyl estradiol is metabolized at several different sites. First, it
is sulphated in the intestinal wall, then it is hydroxylated in the
cytochrome P450-3A4 pathway of the liver, after which it is con-
jugated with glucuronides and passes into the enterohepatic

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**Instructions Regarding Missed Pills**

- If you miss 1 pill, take it as soon as you remember. This may mean taking 2 pills in 1 day.
- If you miss 2 pills in a row during the first 2 weeks of the pack, take 2 pills on the day you remember and 2 on
  the following day. Use a backup method of contraception if you have sex in the 7 days after you miss the pills.
- If you have had unprotected intercourse after missing a pill, use emergency contraception.
- If you miss 2 pills in a row in the third week of the pack, throw out the remainder of the pack and start a new
  pack the day you remember. You may not have a period this month. If you had unprotected intercourse after
  missing a pill, use emergency contraception.
- If you miss 3 pills in a row, throw out the remainder of the pack and start a new pack on the day you remember.
- If you had unprotected intercourse after missing a pill, use emergency contraception. Use a backup method of
  contraception if you have intercourse in the first 7 days of the new pack. You may not have a period this month.
These processes may vary between women and may be affected by other medications. Drug interactions may occur via alterations in absorption, serum protein binding, receptor binding or in hepatic metabolism. The clinical significance of many of the interactions is questionable. It has been suggested that less than 5% of drug interactions with combined OCs result in pregnancy. Nevertheless, due to the widespread use of combined OCs, health-care professionals must be aware of concurrent medication use and the potential for drug interactions.

Evidence from a single pharmacokinetic interaction study suggests that a woman taking the anticonvulsant phenytoin or carbamazepine should use a combined OC preparation containing 50 µg ethinyl estradiol, rather than a lower-dose preparation. Monitoring of phenytoin concentrations is important because combined OCs may inhibit their metabolism.

Whether or not antibiotic use has an effect on the efficacy of combined OCs has been a matter of controversy. A significant pharmacokinetic interaction between combined OCs and antibiotics, apart from rifampicin and griseofulvin, has not been proven. It has been suggested that if an interaction does exist, it is likely that it occurs in a small number of predisposed individuals. It is not possible at this time to predict who is at risk for potential interaction.

Table 2 shows significant drug interactions with combined OCs. Some medications may result in contraceptive failure if used concomitantly with combined OCs. Some medications may increase the activity of the combined OC, resulting in increased estrogenic side-effects. Oral contraceptives may also decrease the clearance of other medications, thereby increasing their activity. Other drug interactions may occur but are not included in the table because of a lack of scientific documentation or questionable clinical significance.

**THE TRANSDERMAL CONTRACEPTIVE PATCH**

**INTRODUCTION**

The contraceptive patch was approved for use in Canada in 2002 and became available for use in January of 2004. The contraceptive patch delivers 150 µg of norelgestromin (the primary active metabolite of norgestimate) and 20 µg of ethinyl estradiol daily to the systemic circulation. These doses cannot be compared to the doses of estrogen and progestin in a combined oral contraceptive. One patch is applied weekly for 3 consecutive weeks, followed by 1 patch-free week. The patch is placed on 1 of 4 sites: the buttocks, outer upper arm, lower abdomen or upper torso, excluding the breast.

**EFFICACY**

Overall, studies have found that the Pearl Index with perfect use of the contraceptive patch is 0.7 (95% CI, 0.31–1.10), while with typical use the Pearl Index is 0.88 (95% CI, 0.44–1.33). A subgroup of women weighing more than 90 kg may have an increased risk of pregnancy while using the patch. In one study, 4 of the 6 pregnancies that occurred were in women weighing at least 90 kg; in a pooled analysis, 5 of the 15 pregnancies that occurred in patch users were in women weighing more than 90 kg. The contraceptive efficacy of other methods of hormonal contraception, including the combined OC, progestin implants, and the vaginal contraceptive ring, may also be influenced by body weight.

**MECHANISM OF ACTION**

The mechanism of action is similar to that of the combined OC. The contraceptive patch suppresses follicular development and inhibits ovulation. Other mechanisms of action may include the development of endometrial atrophy making the endometrium unreceptive to implantation and cervical mucus changes that impede sperm transport.

**INDICATIONS**

In the absence of contraindications, the contraceptive patch may be considered for any woman seeking a reliable, reversible, coitally independent method of contraception. It may be especially

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<table>
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<tr>
<th>Medications Whose Action May Cause Contraceptive Failure</th>
<th>Medications Which May Increase OC Activity</th>
<th>Medications Whose Clearance Can Be Decreased by OCs</th>
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<tr>
<td>Carbamazepine</td>
<td>Acetaminophen</td>
<td>Amitriptyline</td>
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<tr>
<td>Griseofulvin</td>
<td>Erythromycin</td>
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<td>Oxcarbazepine</td>
<td>Fluoxetine</td>
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<td>Phenobarbital</td>
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<td>Phenytoin</td>
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<td>Primidone</td>
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<td>Rifampin</td>
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<td>Ritonavir</td>
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<td>St. John’s Wort</td>
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<td>Topiramate</td>
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suited for women seeking a less compliance-demanding method of contraception.

The use of condoms is still recommended in contraceptive patch users for protection against STIs and HIV.

**CONTRAINDICATIONS**

Contraindications to use of the contraceptive patch are similar to those for the combined oral contraceptive pill. These include current or past history of venous thromboembolism; cerebrovascular or coronary disease; complicated valvular heart disease; severe hypertension; diabetes with end-organ involvement; headaches with focal neurological symptoms; known or suspected breast cancer; undiagnosed genital bleeding; hepatic adenomas or carcinomas; acute or chronic hepatocellular disease with abnormal liver functions; and known or suspected pregnancy. Although not an absolute contraindication, women with a body weight of greater than or equal to 90 kg may find that the contraceptive patch is less effective than in women with lower body weights.153

**NON-CONTRACEPTIVE BENEFITS**

Cycle control has been shown to be comparable to that seen with the combined OC.138,152-153 Although non-contraceptive benefits are assumed to be similar to those seen with the combined OC, these potential benefits have not been assessed in studies to date.

**SIDE EFFECTS**

With the exception of application site reactions, the side-effects experienced by contraceptive patch users are similar to those experienced by combined OC users.

1. **IRREGULAR BLEEDING/SPOTTING**

Overall, the incidence of breakthrough bleeding and spotting is similar to that seen with combined OC users; although for cycles 1 and 2, patch users have significantly higher rates of spotting (18.3% of patch users compared to 11.4% of combined OC users).138 Subsequent cycles showed no significant difference between patch users and combined OC users. The incidence of breakthrough bleeding or spotting tends to decrease with time.138,152-153 Amenorrhea with the contraceptive patch is rare.152

2. **BREAST SYMPTOMS AND HEADACHE**

Breast symptoms (including discomfort, engorgement, or pain) and headache are the most common side effects reported with patch use in pooled analysis (22% and 21% of users).156 Breast symptoms are more common with the patch than with the combined OC in the first 2 cycles of patch use; but by cycle 3, there is no significant difference between the 2 groups. Most reported breast symptoms are either mild or moderate (86%) and tend to decrease with continued patch use, down to 0% of patients at 13 months.138 Only 1.9% of patients discontinued patch use due to breast symptoms.156 Headaches led to patch discontinuation in 1.1% of study patients.156

**RISKS**

The risks are assumed to be the same as those known for the combined OC.

**MYTHS AND MISCONCEPTIONS**

1. The patch won’t stay on during exercise; in hot, humid weather; while swimming; or while in the shower.

*Fact:* The patch has excellent adhesive properties under a wide range of conditions and climates (including bathing, sauna and whirlpool use, treadmill activity, or cool-water immersion).157 In clinical trials, approximately 1.9% of patches required replacement due to complete detachment.138,152 Over time, the incidence of patch detachment may decrease as the patch user becomes more familiar with the application technique. Despite the fact that detachment is rare, patch users should be advised to check daily to ensure that their patch is adequately attached.

2. Women are more likely to be compliant with the patch if they are older.

*Fact:* In a randomized, controlled study comparing patch users to combined OC users, a significantly higher proportion of patch users had perfect compliance when compared to the combined OC users (88.2% versus 77.7%).138 Compliance was improved across all of the age groups in comparison to the combined OC, but especially in the younger women (aged 18–24). Perfect compliance rates in younger women using the patch were 88% versus 68% to 74% perfect compliance rates for the combined OC group.

3. Because of the transdermal delivery system, the patch will have less effect on the lipid profile than the combined oral contraceptive pill.

*Fact:* An increase in serum total cholesterol and triglyceride levels is seen in users of both the patch and the combined OC.138,156

4. Because the patch is a hormonal method of contraception, women who use the patch will gain weight.

*Fact:* There does not appear to be an association between the
contraceptive patch and weight gain when investigated and compared to placebo. In a pooled analysis of patch users, 78.5% of patients remained within 5% of their baseline weight while using the contraceptive patch.

**INITIATION**

A “first-day start,” when the patch is applied on the first day of menses, is recommended. This will be the “Patch Change Day.” If the patch is applied after the first day of menses, a backup method of contraception should be used for 1 week. A new patch is applied weekly for 3 weeks including the week in which the patch is started; week 4 is patch-free. Withdrawal bleeding usually occurs during the patch-free week. It is recommended that the patch always be applied on the same day, e.g. on a Monday.

The patch should be applied to clean, dry, healthy, intact skin. The patch may be applied at 1 of 4 sites: the buttock; the abdomen; the upper outer arm; or the upper torso, but not directly to the breast. These 4 sites are therapeutically equivalent. Patch users should be advised to check daily that their patch is adhering well.

A follow-up appointment should be made to assess the patch users’ satisfaction with the method, to discuss any side-effects, to ensure that it is being used correctly, and to answer questions. If indicated, a pelvic examination can be performed at the follow-up visit.

**SWITCHING FROM THE COMBINED OC TO THE CONTRACEPTIVE PATCH**

The contraceptive patch should be applied on the first day of withdrawal bleeding. If the patch is started after the first day of withdrawal bleeding, a backup method of contraception should be used for 7 days. If more than 5 days have elapsed since the last hormone-containing pill was taken, a backup method of contraception should be used for the first 7 days of patch use.

Alternatively, the patch can be applied on the day after the last hormonal pill is taken. In this case, there would be no hormone-free interval. Back-up contraception would not be needed in this case and the patient would not experience a menstrual bleed in that month.

**SWITCHING FROM DEPOT-MEDROXYPROGESTERONE ACETATE (DMPA) TO THE CONTRACEPTIVE PATCH**

The first contraceptive patch should be applied on the day that the next DMPA injection would be due. If given at this time, backup contraception is not required.

**TROUBLESHOOTING**

**1. PATCH PARTIALLY OR COMPLETELY DETACHES**

If the patch has either partially or completely detached for less than 24 hours, the woman should attempt to reattach the patch. If this is not successful, a new patch should be applied. The patch change day would remain the same. If the patch has been completely or partially detached for more than 24 hours or the timing is uncertain, a new patch should be applied and a new cycle started. Back-up contraception should be used for 1 week.

**2. PATCH APPLICATION, CHANGE, OR REMOVAL IS FORGOTTEN**

If the patch user forgets to apply the patch in week 1, the patch user should apply a new patch as soon as she remembers. Back-up contraception is recommended for 1 week. The patch user then has a new patch change day; although if she prefers to keep the same patch change day, that is an acceptable option.

If the patch user forgets to change the patch in week 2 or 3, the recommended course of action depends on how late the user is in changing the patch. The patch can maintain target hormonal serum concentrations through 9 full days of use. For this reason, if the patch user is less than 48 hours late in changing her patch, she should change it immediately; she will not require backup contraception. The patch change day does not change. If however, she is more than 48 hours late in changing her patch, a new 4 week cycle should be started immediately by applying a new patch. She will have a new patch change day and will need to use backup contraception for 1 week.

If the patch user forgets to remove the patch in week 4, the old patch should be removed as soon as it is remembered. The next patch is applied on the usual patch change day. Back-up contraception is not required if there is less than a 7 day patch-free interval. The patch-free interval should never exceed 7 days.

**3. CHANGING THE PATCH-CHANGE DAY**

A new cycle should be started by placing the first patch of the new cycle on the new desired patch change day during the patch-free week. The patch-free interval should not exceed 7 days.

**DRUG INTERACTIONS**

Pharmacokinetic studies have shown no significant interaction between tetracycline and the contraceptive patch. Other drug interactions have not been specifically studied and, at this time, drug interactions that are reported with the combined OC are assumed also to occur with the contraceptive patch.

**THE VAGINAL CONTRACEPTIVE RING**

**INTRODUCTION**

The vaginal contraceptive ring (NuvaRing) was approved by the US Food and Drug Administration (FDA) in 2001 and
became available in the US market in 2003. It has been submitted for approval in Canada. It is a flexible, nearly transparent ring that is 54 mm in outer diameter and 4 mm in cross-sectional diameter. The ring releases a constant rate of 15 µg of ethinyl estradiol and 0.120 mg of the progestin etonogestrel per day.\textsuperscript{161} Etonogestrel is the active metabolite of desogestrel. Each ring is used for 1 cycle and then removed. A cycle consists of 3 weeks of continuous ring use followed by a 1 week ring-free interval.

**Efficacy**

In several thousand cycles of use, the Pearl Index — with perfect use of the vaginal ring — is between 0.4 and 0.77,\textsuperscript{162,163} while the overall Pearl Index is between 0.65 and 1.18.\textsuperscript{162,163} Knowing that compliance may affect contraceptive efficacy, compliance rates were calculated in studies. Perfect compliance is seen in 85.6 to 91% of contraceptive ring users.\textsuperscript{162,163}

**Mechanism of Action**

The mechanism of action is similar to that of the combined OC. The vaginal contraceptive ring suppresses follicular development and inhibits ovulation.\textsuperscript{164,165} Other mechanisms of action may include the development of endometrial atrophy making the endometrium un receptive to implantation and cervical mucus changes that impede sperm transport.\textsuperscript{166}

**Indications**

In the absence of contraindications, the vaginal contraceptive ring can be considered for any woman seeking a reliable, reversible, coitally independent method of contraception. It may be particularly suited for women who prefer a method of contraception that does not require daily attention.

The use of condoms is still recommended in vaginal contraceptive ring users for protection against STIs and HIV.

**Contraindications**

Contraindications to use of the vaginal ring are similar to those for the combined OC. These include: pregnancy or suspected pregnancy; current or past venous thromboembolism; cerebrovascular or coronary artery disease; complicated valvular heart disease; severe hypertension; diabetes with end-organ involvement; headaches with focal neurological symptoms; known or suspected carcinoma of the breast, endometrium, or cervix; unexplained vaginal bleeding; or an allergic reaction to any of the components of the rings.

Relative contraindications include uterovaginal prolapse or vaginal stenosis if they prevent retention of the ring.

**Non-contraceptive Benefits**

Although assumed to be similar for those seen with the combined OC, no studies have specifically addressed non-contraceptive benefits of the vaginal contraceptive ring.

**Side-effects**

Side-effects are similar to those seen for the combined OC, although certain side-effects are obviously specific to the vaginal ring.

1. **Irregular bleeding**

Irregular bleeding occurs in up to 6.4% of cycles and usually consists of spotting.\textsuperscript{162} Unlike other contraceptive methods, irregular bleeding does not appear to be significantly higher in the first cycles of ring use. When compared to the combined OC, the vaginal ring has significantly less irregular bleeding, most notably in the first cycle of use.\textsuperscript{167} Withdrawal bleeding occurs in the majority of cycles.\textsuperscript{162}

2. **Hormonal Side-effects**

Headache (11.8%), nausea (4.5%), and breast tenderness (2.8%) are the most common reported hormonal side-effects occurring in ring users.\textsuperscript{162}

3. **Vaginal Symptoms**

Vaginitis is the most commonly reported local side-effect, occurring in 13.7% of users, although only 5.3% of cases were felt to be treatment-related.\textsuperscript{162} Treatment-related leukorrhea occurs in approximately 5% of women.\textsuperscript{162} Although women or their partners may be aware of the device, only 1 to 2.5% of ring users discontinued the ring due to foreign body sensation, coital problems, or expulsion. Vaginal symptoms of discharge and irritation led to discontinuation in about 1 to 2% of women.\textsuperscript{162}

**Risks**

The risks are felt to be the same as for oral contraceptives.\textsuperscript{162}

**Initiation**

The ring is used vaginally. The first ring cycle is started between day 1 and day 5 of the menstrual cycle. The ring is inserted and left in place for 3 weeks and then removed for 1 week. Withdrawal bleeding usually occurs during the ring-free interval.\textsuperscript{163} The ring-free interval should be no longer than 7 days. To switch from the combined OC to the vaginal ring, the ring should be inserted no later than 7 days after the last combined OC tablet. To switch from a progestin-only pill, the vaginal ring is inserted the day after the last pill is taken.
When switching from an injectable contraceptive method, the ring is inserted on the day when the next injection would be due.

**TROUBLESHOOTING**

If the ring is expelled and has been out of the vagina for less than 3 hours, the user should rinse the ring in lukewarm water and reinsert it. Back-up contraception is not required. If the ring is lost, a new ring should be inserted. If it is out of the vagina for longer than 3 hours, a back-up method of contraception should be used for 7 days.

If the ring remains in the vagina for more than 3 weeks (but less than 4 weeks total), it is still effective in preventing pregnancy. The ring should be removed and a new ring inserted after a 1-week ring-free break. If however, the ring has been left in place for more than 4 weeks, it may no longer provide adequate protection against pregnancy. Consideration should be given to the use of emergency contraception and a backup method of contraception should be used until a new ring has been in place for at least 7 days.

**DRUG INTERACTIONS**

In one study, vaginal spermicide use was not found to have any short-term or long-term effects on the efficacy of the vaginal ring. Vaginally administered miconazole was not found to have a significant effect on serum concentrations of ethinyl estradiol or etonogestrel. For more information about spermicides please refer to chapter 8. Until further research is available, other drug interactions are considered similar to those seen with combined OCs.

**COMBINED INJECTABLE CONTRACEPTION**

A monthly injectable contraceptive composed of 5 mg estradiol cypionate and 25 mg medroxyprogesterone acetate (Lunelle) was approved by the FDA in October 2000 for use in the United States. As of January 2004, it has not been submitted for approval in Canada. It is administered by intramuscular injection, with no more than 33 days between injections. In a study of 782 American women followed over 1 year, there were no pregnancies. Its mechanism of action is primarily by inhibition of ovulation. It has the same indications and contraindications as combined oral contraceptive pills. This method should be considered for women who have difficulty remembering to take daily pills, who want monthly predictable bleeding, or have enteric absorption problems (e.g., inflammatory bowel disease).

When compared with DMPA, the combined monthly injectable has more frequent injections (every 28 ± 5 days), and faster return to ovulation. The first normal ovulatory cycle occurs 63 to 112 days following the last injection after 3 monthly injections of Lunelle. The vaginal bleeding with this method is due to estrogen withdrawal, and usually occurs 3 weeks (day 22) after the injection.

When compared with combined OCs, the combined monthly injectable has less breakthrough bleeding, a greater incidence of amenorrhea (14.6% during at least 1 cycle over 1 year, compared with 3.3% for OC users \( p \leq 0.01 \)), better inhibition of ovarian follicular activity than a 20 µg ethinyl estradiol pill, and a weight gain of about 4 pounds over 1 year.

**SUMMARY STATEMENTS**

1. To date, no single low-dose combined oral contraceptive
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CHAPTER 5: PROGESTIN-ONLY HORMONAL CONTRACEPTION

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INTRODUCTION

Progestin-only contraception may be provided in injectable form, as oral medication, or as an implant. Currently, only the injectable and the oral forms are available in Canada.

INJECTABLE PROGESTIN

Depot medroxyprogesterone acetate (DMPA) has been used as a contraceptive agent since 1967 and is extensively used by millions of women in over 90 countries. It was approved for contraceptive use in Canada in 1997. Approximately 2% of Canadian women use DMPA for birth control.1

Efficacy

DMPA is a highly effective form of contraception, with a failure rate of less than 0.3% per year.2,6

Mechanism of Action

DMPA works primarily by inhibiting the secretion of pituitary gonadotropins, thereby suppressing ovulation.7 It increases the viscosity of cervical mucus8 and induces endometrial atrophy.2

Indications

In the absence of contraindications, DMPA may be considered for any woman seeking a reliable, reversible, coitally independent method of contraception. It does not require daily attention and therefore may be more suitable for women who have difficulty complying with other birth control methods. It may be used by women who require an estrogen-free method of contraception or for those who wish to take advantage of its non-contraceptive benefits. It may be suitable for the following women:

- women with known contraindications or sensitivity to estrogen
- women over the age of 35 who smoke
- women with migraine headaches
- women who are breastfeeding
- women with endometriosis
- women with sickle cell disease
- women taking anti-convulsant medications

The use of condoms is still recommended in DMPA users for protection against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection.

Contraindications

The World Health Organization (WHO) has developed a list of absolute and relative contraindications to the use of DMPA based on the available evidence of risks.6 Absolute contraindications include pregnancy (known or suspected), unexplained vaginal bleeding, and current diagnosis of breast cancer. Relative contraindications include severe cirrhosis, active viral hepatitis, and benign hepatic adenoma.

Non-contraceptive Benefits

DMPA use is a reliable method of contraception, and it also has a number of non-contraceptive benefits. These include

- amenorrhea with subsequent reduction in dysmenorrhea and anemia (The rate of amenorrhea is 55 to 60% at 12 months and 68% at 24 months.)3,9,11
- reduced risk of endometrial cancer12
- reduction in symptoms associated with endometriosis,13,14 premenstrual syndrome, and chronic pelvic pain15
• decreased incidence of seizures\textsuperscript{16}
• possible reduced risk of pelvic inflammatory disease\textsuperscript{17,18}
• possible decreased incidence of sickle cell crisis\textsuperscript{19}

SIDE EFFECTS

1. MENSTRUAL CYCLE DISTURBANCE
The most common side effect associated with DMPA use is the disruption of menstrual patterns. Irregular bleeding or unwanted amenorrhea may lead to discontinuation of DMPA.\textsuperscript{9} In large studies of DMPA users, unpredictable bleeding was common in the first few months of use but decreased in amount and frequency with time. Abnormally heavy or prolonged bleeding occurred in only 1 to 2\% of users.\textsuperscript{3,20} At 12 months, 55 to 60\% of DMPA users are amenorrheic, and by 24 months up to 68\% are amenorrheic.\textsuperscript{3,9-11,20}

2. HORMONAL SIDE EFFECTS
Reported hormonal side effects with use of DMPA include headache, acne, decreased libido, nausea, and breast tenderness. Headache is the most common non-bleeding side effect reported by DMPA users, occurring in approximately 17\% of DMPA users.\textsuperscript{3,21} Migraine headaches do not constitute a contraindication to DMPA use.\textsuperscript{6}

3. WEIGHT GAIN
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).\textsuperscript{9} Other studies have failed to find an effect of DMPA on weight.\textsuperscript{22-24} Weight gain associated with DMPA use is thought to be due to appetite stimulation\textsuperscript{25} and a possible mild anabolic effect. The product monograph suggests the following average weight gains in DMPA users: 2.5 kg in the first year of use, 3.7 kg after the second year of use, and 6.3 kg after the fourth year of use. DMPA users should be given counselling regarding healthy eating and exercise.

4. MOOD EFFECTS
Although mood changes have been reported in DMPA users\textsuperscript{3} and may lead to discontinuation of DMPA, prospective studies do not appear to demonstrate an increase in depressive symptoms in DMPA users.\textsuperscript{26-27} This suggests that depression is not a contraindication for DMPA use. Further studies are required to determine if there is a causal link.

RISKS

1. DELAYED RETURN OF FERTILITY
Although DMPA is a reversible contraceptive method, there may be a delay in the resumption of ovulation. DMPA users have an average 9-month delay before restoration of full fertility after the last injection.\textsuperscript{7,28,29} The rate of conception 10 months after the last DMPA injection is 50\%, and approximately 90\% by 24 months.\textsuperscript{7}

2. REDUCTION IN BONE MINERAL DENSITY (BMD)
Although some cross-sectional studies have demonstrated no adverse effect of DMPA on bone mineral density,\textsuperscript{30,31} the majority of studies report a decrease in BMD in DMPA users.\textsuperscript{32-37} Prospective studies have found a mean loss of BMD at the lumbar spine of between 0.87\% and 3.52\%.\textsuperscript{35,36,37} Although a decrease in BMD has been observed, it does not appear to induce osteoporosis. Furthermore, two cross-sectional studies of past DMPA users\textsuperscript{38,39} did not demonstrate a measurable difference in BMD compared with controls, suggesting that there is an improvement in BMD after DMPA is discontinued. A prospective cohort study\textsuperscript{36} reported a substantial recovery of BMD once DMPA was discontinued. One randomized, double-blind controlled trial suggested that supplemental oral estrogen may attenuate the negative effects of DMPA on BMD.\textsuperscript{40} Larger, long-term prospective studies in current and past users of DMPA are required to evaluate BMD changes further.

3. VENOUS THROMBOEMBOLISM (VTE), CARDIOVASCULAR DISEASE, STROKE
When used in standard contraceptive doses, DMPA does not appear to increase the risk of VTE,\textsuperscript{41,42} but only limited data are available. DMPA users do not appear to have an increased risk of cardiovascular disease, stroke, or myocardial infarction.\textsuperscript{41}

MYTHS AND MISCONCEPTIONS

1. DMPA administered inadvertently during pregnancy is associated with birth defects.
\textit{Fact:} There is no evidence that fetuses exposed to DMPA \textit{in utero} are at an increased risk of congenital anomalies.\textsuperscript{43,44}

2. All DMPA users will gain weight.
\textit{Fact:} Although DMPA users may gain weight, a significant percentage of patients will not gain weight while using DMPA.\textsuperscript{9} Dietary counselling is advised.

3. DMPA should not be given to breastfeeding women.
\textit{Fact:} DMPA has been shown to be an effective method of postpartum contraception that has little or no effect on breast milk production or on infant development.\textsuperscript{43,45-48}

4. DMPA causes cancer.
\textit{Fact:} DMPA is associated with a decreased risk of endometrial cancer.\textsuperscript{12} There does not appear to be an increased risk of ovarian cancer\textsuperscript{49} or breast cancer.\textsuperscript{50,52} Studies suggest either a slight or no increase in the risk of cervical cancer.\textsuperscript{52,56}

INITIATION

It is best to administer DMPA during the first 5 days of menses.
in order to avoid inadvertent injection during pregnancy. If the woman is switching from using a combined oral contraceptive (OC) to DMPA, DMPA should be given within the first 5 days of stopping the combined OC. DMPA is given as a 150 mg intramuscular injection every 12 weeks. The injection may be given in the deltoid or gluteus maximus muscles. If given within the first 5 days of the menstrual cycle, contraceptive effect is achieved within 24 hours of injection. However, DMPA can be given at any time during the menstrual cycle if pregnancy or the possibility of pregnancy can be definitely ruled out. If given after the first 5 days of the menstrual cycle, the woman should be advised to use a backup method of birth control for at least 1 week.

**FOLLOW UP**

Follow-up visits should be scheduled every 12 weeks for repeat injections. These follow-up visits allow for an assessment of bleeding patterns and other potential side effects, an assessment of patient satisfaction, and an opportunity to reinforce the issue of condom use for protection against STIs and HIV infection.

**TROUBLESHOOTING**

1. **MENSTRUAL CYCLE DISTURBANCE**

If irregular bleeding persists after the first 6 months of use, underlying causes of abnormal vaginal bleeding should be ruled out. Once this has been done, management options include:
   - increasing the DMPA dose to between 225 and 300 mg IM for 2 to 3 injections.
   - decreasing the interval between doses.
   - supplemental estrogen therapy, such as 0.625 mg of conjugated equine estrogen by mouth for 28 days, or 1 to 2 mg of estradiol-17β given by mouth for 28 days. Alternatively, supplemental estrogen therapy can be given transdermally in the form of a 50 µg or 100 µg estradiol-17β patch for a total of 25 days.
   - administration of non-steroidal anti-inflammatory agents, such as ibuprofen 400 to 800 mg twice daily for a total of 10 days.
   - adding a combined oral contraceptive pill for 1 to 3 months.

2. **LATE INJECTION**

If it has been less than 14 weeks since a woman’s last injection, the next DMPA injection can be given. If it has been 14 or more weeks since her last injection, but she has not had intercourse within the last 10 days and she has a negative serum assay for βHCG, the DMPA injection can be given. A backup method of contraception should be used for 2 weeks. If she has had intercourse within the last 10 days, the DMPA injection can be given if the serum assay for βHCG is negative, although she must continue to use a backup method of birth control and have a repeat serum assay for βHCG performed in 2 weeks (the serum assay for βHCG will not be positive until at least 8 days post-conception). DMPA is not teratogenic if given inadvertently during pregnancy.

**DRUG INTERACTIONS**

Few medications will interact with DMPA. Aminoglutethimide and nevirapine have been shown to decrease the effectiveness of DMPA.

**ORAL PROGESTIN: PROGESTIN-ONLY PILL**

Although not as well known or widely used as combined oral contraceptives, progestin-only pills (POPs) used for contraception are very safe and highly effective when used as directed. POPs are also known as “mini-pills.” In Canada, the POP is supplied in packages of 28 tablets, each containing 0.35 mg of norethindrone (Micronor).

**Efficacy**

With perfect use, the POP has a failure rate of approximately 0.5%. Maximal effectiveness depends on consistent pill-taking. With typical use, the failure rate is between 5 and 10%. The failure rate appears to be lower in motivated women.

**Mechanism of Action**

The chief mechanism of action in preventing pregnancy is through alterations in the cervical mucus. POPs reduce the volume of mucus, increase its viscosity, and alter its molecular structure, resulting in little or no sperm penetration. In addition, sperm motility is impaired, making fertilization unlikely. Ovulation may be suppressed or partially suppressed. Forty percent of women using progestin-only contraceptives continue to ovulate. Endometrial changes, reducing the potential for implantation, may occur. For maximal effectiveness, the POP must be taken at the same time every day.

**Indications**

In the absence of contraindications, the POP may be considered for any woman seeking a reliable, reversible, coitally independent method of contraception. It may be used by women who require an estrogen-free method of contraception. For this reason, it may be suitable for women over age 35 who smoke, women who experience migraine headaches with neurological symptoms, women who have unwanted side effects with use of combined oral contraceptives, or women who are breastfeeding.

The use of condoms is recommended for POP users to...
protect against sexually transmitted infections and infection with the human immunodeficiency virus.

**CONTRAINDICATIONS**

The World Health Organization has developed a list of absolute and relative contraindications to the use of POPs based on the available evidence of risk. Absolute contraindications include pregnancy and current breast cancer. Relative contraindications include active viral hepatitis and liver tumours.

**NON-CONTRACEPTIVE BENEFITS**

In addition to providing an effective method of contraception, the POP may decrease menstrual flow. Up to 10% of users will develop amenorrhea. Menstrual cramping and premenstrual symptoms may decrease.

**SIDE EFFECTS**

1. **IRREGULAR BLEEDING**
   Irregular bleeding is the most frequently cited reason for discontinuation of the POP. Spotting occurs in approximately 12% of users in the first month, but this usually decreases to less than 3% at 18 months. Forty percent of long-term users continue to have regular cycles while using the POP.

2. **HORMONAL SIDE EFFECTS**
   Hormonal side effects such as headache, bloating, acne, and breast tenderness occur less commonly.

**RISKS**

Use of POPs is not associated with any major morbidity. Given in contraceptive doses, the POP does not appear to increase the risk of VTE, stroke, or myocardial infarction.

**MYTHS AND MISCONCEPTIONS**

1. The POP can only be used by women who are breastfeeding.
   *Fact:* Although the POP is safe to use in breastfeeding women, it can be considered for any women seeking a reliable, reversible contraceptive method.

2. The POP is not an effective method of birth control.
   *Fact:* When used as directed, the POP is a safe and effective method of birth control with a failure rate of approximately 0.5%.

**INITIATION**

The POP is usually started on the first day of the menstrual cycle, although it may be started at any time during the menstrual cycle as long as pregnancy can be excluded. A pill containing the active hormone norethindrone is taken every day. There is no pill-free interval. A backup method of birth control should be used for the first 7 days. Contraceptive reliability requires regular pill-taking at the same time each day (within 3 hours). Sperm penetration tests have shown that sperm permeability through cervical mucus increases if the interval between POPs is longer than 24 hours.

**POSTPARTUM**

There is a theoretical concern that progestins administered within the first 72 hours after delivery may 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 breast-feeding when progestin-only contraceptive methods were used within the first 72 hours postpartum.

**FOLLOW UP**

A follow-up visit should be scheduled. This allows for an assessment of bleeding patterns, an assessment of patient satisfaction, and an opportunity to reinforce the issue of condom use for protection against STIs and HIV. After this visit, a POP user should continue annual well-woman care as for any sexually active woman.

**TROUBLESHOOTING**

1. **IRREGULAR BLEEDING**
   Irregular bleeding is a common side effect of the POP. Pregnancy, infection, and genital pathology should be ruled out. Once this has been done, treatment options include the use of a non-steroidal anti-inflammatory agent for up to 10 days, switching to a low-dose combined oral contraceptive pill, or adding a short course of supplemental estrogen. Supplemental estrogen therapy can be given orally as 0.625 mg of conjugated equine estrogen for 28 days or 1 to 2 mg of micronized estradiol-17β given for 28 days, or it may be given transdermally in the form of a 50 µg or 100 µg estradiol-17β patch for a total of 25 days.

   The use of anti-progestogenic agents has shown some success in the management of irregular bleeding associated with progestin-only contraceptive methods. These agents, such as mifepristone, are not currently available in Canada.

2. **MISSED PILL**
   If a pill is missed, it should be taken as soon as possible. The next pill should be taken at the regular time, even if it means that 2 pills will be taken at the same time. If the pill use is delayed by more than 3 hours, a backup method of birth control should be used for the next 48 hours. If 2 or more pills in a row have been missed, then the individual must take 2 pills
per day for 2 days and use a backup method of birth control for 48 hours.

In the event of a missed or late pill, the use of emergency contraception may be considered if appropriate. The healthcare provider may choose to provide an advance prescription for emergency contraception for use in these circumstances.

**DRUG INTERACTIONS**

Drug interactions with POPs are less well-known than are those for combined oral contraceptives. The progestins used in POPs are metabolized by the cytochrome P-450 enzyme system, and any medication that will induce this system (such as certain anticonvulsants) may accelerate the metabolism of the POP and reduce its contraceptive effectiveness.

**PROGESTIN IMPLANTS**

At one time, the 6-rod progestin implant called Norplant was available in Canada. Norplant was a highly effective 5-year method of reversible contraception with a failure rate of 0.1% per year.64 Levonorgestrel was released from the 6 rods, thereby suppressing ovulation, inducing endometrial atrophy, and rendering cervical mucus impermeable to sperm. Norplant was removed from the market in Canada in September 2000 because a lower-than-expected hormonal release rate was noted from several lots and there was a concern that contraceptive efficacy may have been affected.65 In July 2002, health-care professionals were informed that there did not appear to be a higher failure rate from these lots, and women were advised that they did not need to continue to use backup contraception. At the same time, the company that manufactured Norplant stated that it had no plans to reintroduce Norplant to the Canadian or US markets.66 For those women who currently have Norplant in place, studies suggest that it remains effective in women who weigh less than 70 kg for up to 7 years (Pearl Indices less than 2 per 100 women-years).67,68

New progestin-only implants with fewer rods have been developed and may become available in Canada in the future. An implant system with fewer rods will have the advantage of greater ease of insertion and removal. However, thorough training in insertion and removal of these implants is still extremely important to avoid injury to blood vessels, skin, and nerves.

The following chart compares the characteristics of 2 of the newer devices with the 6-rod Norplant system:

Implanon, which contains etonogestrel as its active ingredient, differs from Norplant models because it appears to consistently inhibit ovulation until the beginning of the third year of use.69 This appears to translate into higher amenorrhea rates compared with levonorgestrel rod implant systems.71 The failure rate for Implanon is quite low, with no reported pregnancy in a database that followed 70 000 cycles of use.72 Any pregnancies that have been reported with this method were felt to have occurred before it was inserted.73 Pregnancies with Norplant (and Norplant-2) are felt to be lower than female sterilization for the first 5 years after insertion.74,75 Prolonged and irregular vaginal bleeding are major reasons for discontinuation of implant methods in all implant users and hence careful preinsertion counselling is essential.74

**SUMMARY STATEMENTS**

1. Depot injections of medroxyprogesterone acetate (DMPA) and progestin implants are the most effective hormonal methods of contraception, and are appropriate contraceptive choices for Canadian women. (Level II-1)
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)
3. The use of progestins given at contraceptive doses does not appear to increase the risk of VTE, myocardial infarction, or stroke. (Level II-2)
4. Progestin-only preparations may be appropriate contraceptive choices for women who have a past history of VTE. Whether the use of progestin-only preparations in women with a proven thrombophilia alters the risk of VTE is not known. (Level III)
5. The use of DMPA in healthy young women is associated with a decrease in bone mineral density that appears to be reversible. There is no evidence that use of DMPA causes osteoporosis. (Level II-1)

**RECOMMENDATIONS**

1. 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)

2. Progestin-only methods should be considered as contraceptive options for women with a past history of VTE, or for women who are at a higher risk of myocardial infarction or stroke. In women with a proven thrombophilia, progestin-only preparations should be used with caution. (Grade B)

3. Young women who use DMPA should be counselled about dietary and lifestyle factors that will affect their peak bone mass, such as smoking, exercise, and calcium intake. (Grade A)

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CHAPTER 6: SPECIAL CONSIDERATIONS FOR HORMONAL CONTRACEPTION

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INTRODUCTION

In this chapter cardiovascular disease risk and the use of hormonal contraception is discussed. The possible use or non-use
of hormonal contraceptives in women with pre-existing medical conditions is also addressed.

VENOUS THROMBOEMBOLISM, MYOCARDIAL INFARCTION, AND STROKE IN USERS OF COMBINED AND PROGESTIN-ONLY HORMONAL CONTRACEPTION

VENOUS THROMBOEMBOLISM AND COMBINED HORMONAL CONTRACEPTION

Venous thromboembolism (deep vein thrombosis and pulmonary embolism) has been recognized as a complication of the use of combined oral contraceptives (OCs) since their introduction. Most studies dealing with the risk of thrombosis associated with contraception are observational in design, leading to level II evidence. Observational data are reported as point estimates, which measure the magnitude or strength of the association. Point estimates are expressed in cohort studies as the relative risk (risk of the disease in the exposed group divided by risk of the disease in the unexposed group) and in case-control studies as the odds ratio (odds of exposure in the case group divided by odds of exposure in the control group). A point estimate of 1.0 or close to 1.0 indicates that there is no association between the exposure and the outcome. Results are significant if the confidence interval does not overlap 1.0. The absolute risk is the variable of relevance for clinical decisions. When the absolute risk is not available, an estimate can be obtained by multiplying the baseline incidence in the population of interest by the relative risk or odds ratio associated with the risk factor of interest. The attributable risk is the difference between the baseline incidence and the incidence in patients exposed to the risk factor of interest.

The incidence of venous thromboembolism (VTE) is approximately 10 per 10 000 per year in adults. Among healthy non-pregnant women who do not use combined OCs, the incidence is approximately 0.3 per 10 000 per year at age 20 to 24 and increases to approximately 0.6 per 10 000 per year at age 40 to 44. The risk increases exponentially thereafter. The incidence of VTE during pregnancy and the puerperium is approximately 13 per 10 000 deliveries. The case-fatality rate of VTE is 1 to 2%.

Venous thromboembolic rates are 3- to 4-fold higher among users of current combined OC preparations than among non-users. This translates into an absolute risk of 1 to 1.5 per 10 000 women per year of use. The risk of VTE during the first year of use has been shown consistently to be much higher than the risk during subsequent use.

The risk of VTE has been attributed to the estrogen content of combined OCs. This risk has declined as the estrogen content of OCs has declined, although this effect was not significant in 1 study. Reductions in the content of ethinyl estradiol below 50 µg have not been associated with a further decrease in thromboembolic risk.

As the risk profile improved, small differences between preparations of combined OCs have emerged. A variety of progestogens are currently used in combined oral contraceptives. They are grouped as second-generation progestogens (principally levonorgestrel) and third-generation progestogens (desogestrel and gestodene). Norgestimate is partly converted to levonorgestrel and has been included variably with one or the other group. In 1995, the risk of VTE was reported to be about 2-fold higher in users of combined OCs containing third-generation progestogens than in users of second-generation progestogens. This unexpected finding led to a prolonged controversy over its validity, because of multiple potential biases including the effect of duration of use. A recent metanalysis of studies published since 1995 has shown an overall adjusted odds ratio of 1.7 (95% confidence interval [CI], 1.4–2.0) for VTE risk in users of third- versus second-generation oral contraceptives. Seven of twenty-seven potentially relevant studies were included in the final analysis. The authors calculated an excess risk of thromboembolic events of 1.5 per 10 000 per year with use of third-generation oral contraceptives. The findings could not be explained by several potential biases. This represents level II-2 evidence. The increase in risk continues to be viewed with caution, both because its validity remains questionable and because the strength of the association is small, translating into small absolute increases in risk (or attributable risk).

Initial data suggested that the risk of VTE in users of combined oral contraceptives containing cyproterone acetate may be increased compared to users of oral contraceptives containing second-generation progestogens. A major flaw in the design of this study was the lack of adjustment for duration of use. Other studies have not found an increase in risk. In a recent best-evidence synthesis on 6 controlled epidemiological studies, Spitzer found a comparable attributable risk of VTE for conventional OCs and OCs containing cyproterone. Furthermore, preparations containing cyproterone are often prescribed for women with severe acne or hirsutism, with or without polycystic ovary syndrome. These women may have inherent differences in thromboembolic risk.

Underlying biologic predisposition to thrombosis (thrombophilia) compounds the effect of combined OCs on the risk of VTE. This effect is greater with severe thrombophilias (deficiency of physiologic inhibitors of coagulation, such as antithrombin, protein C or protein S; and homozygous or combined thrombophilias) than with milder thrombophilias (heterozygous factor V Leiden, heterozygous prothrombin gene mutation). Heterozygous factor V Leiden increases the risk of VTE 5- to 7-fold, and heterozygous prothrombin gene mutation 2- to 3-fold. These mild thrombophilias are found in 5 to 10% of the Caucasian population. Women with...
heterozygous factor V Leiden who do not use combined OCs have an incidence of VTE of 5.7 per 10,000 per year. When women with heterozygous factor V Leiden who use combined OCs have a 30-fold increase in VTE risk when compared to non-users. This translates into an absolute risk of 28.5 per 10,000 per year.25

Testing for underlying thrombophilias is generally considered indicated in women with a personal or family history of VTE. Screening in asymptomatic women is not recommended. It has been estimated that more than 20,000 women would need to be screened and counselled to prevent 1 episode of venous thrombosis, and two million women would need to be screened and counselled to prevent 1 death from pulmonary embolism.27 The value of these strategies needs to be tested in prospective studies.

Women with known severe thrombophilias should not use combined OCs. Women with milder thrombophilias should probably also avoid combined OCs, but this is less certain.

A history of VTE puts women at risk of recurrence.28 Because of this, combined OCs are generally considered contraindicated in women with previous VTE, especially if the thromboembolic episode was idiopathic or there is underlying thrombophilia. Use of combined OCs can probably be considered in selected women with previous VTE if the thromboembolic episode was associated with a transient risk factor and there is no underlying thrombophilia. Active VTE is considered an absolute contraindication to use of combined OCs.

Adequate counselling should be ensured when prescribing combined OCs to women with an increased risk of VTE.

Cerebral vein thrombosis is also increased in users of combined OCs compared to non-users, and the risk is compounded by underlying thrombophilias.29 The baseline risk of cerebral venous thrombosis is extremely low (estimated incidence, 0.04 per 10,000 per year).29

MYOCARDIAL INFARCTION AND COMBINED HORMONAL CONTRACEPTION

Myocardial infarction (MI) is a rare disorder among young women. The baseline incidence in women with no risk factors who do not use combined OCs is estimated at 0.001 per 10,000 women per year at age 20 to 24.5 The incidence rises steeply from age 35 upward.50 At age 40 to 44, the baseline incidence is 0.2 per 10,000 per year.5 The case-fatality rate is about 30%,5,50 with a similar disability rate.

In users of combined OCs with an ethinyl estradiol content of more than 50 µg, MI rates are increased approximately 3-fold.5,31 Both smoking and age over 35 compound this risk.51-32 Because of the very low baseline incidence of MI in women younger than 35, the compounding effect of combined OC use becomes clinically significant chiefly in women over 35 who smoke.51

Several recent studies have found no significant increase in the risk of MI with use of combined OCs containing less than 50 µg ethinyl estradiol, regardless of age.33-36 Because the number of women over age 35 included in these studies is small, the safety of combined OC use in women over 35 needs to be interpreted with caution.

Smoking is a prominent risk factor for MI; the relative risk of MI in women who smoke is approximately 1.5-31 All women should be counselled to stop smoking, regardless of contraceptive choice. In one study,35 no increase in risk with the use of combined OCs was found in women smoking less than 25 cigarettes per day. A non-significant increase in risk with the use of combined OCs was found in heavy smokers (odds ratio [OR], 2.5; 95% CI, 0.9-7.5). Combined OC use had a compounding effect with heavy smoking, with an odds ratio of 32 (95% CI, 12-81) in heavy smokers when compared to non-smoking non-users. Thus, age and smoking are the major risk factors for MI in women who consider using combined OCs. Because of the potential for combined OCs to compound the effects of age and smoking, it is prudent to avoid their use in women over 35 who smoke heavily.

Some studies suggest that the risk of MI is not increased in users of combined OCs containing third-generation progestogens, and increased about 2-fold in users of second-generation progestogens.37-39 It is also suggested that the case-fatality rate is lower with use of third-generation combined OCs.39 A meta-analysis of recent studies suggests that the risk of MI is in fact lower with use of third- than with second-generation combined OCs, with an odds ratio of 0.62 (95% CI, 0.38-0.99).40 If these findings are valid, use of third-generation combined OCs may carry less risk of death and disability than second-generation OCs because of the higher fatality and disability rate associated with MI than that associated with venous thromboembolic disease.41-42 It is too early, however, to recommend preferential prescribing of second- or third-generation contraceptives based on different cardiovascular profiles. Differential prescribing according to age or underlying clinical risk is also not recommended. Further research is necessary to determine the true comparative global risk profile of these contraceptive preparations.

Combined OC users with hypertension are at increased risk of MI, compared to users without hypertension.31 Use of combined OCs should be avoided in women with uncontrolled hypertension, but they may probably be used safely in women with documented hypertension if the blood pressure is controlled by medication and followed closely. Women with hypertension who use combined OCs have a higher risk of poor control of blood pressure with medication.43

A family history of premature atherosclerotic events may warrant evaluation of the lipid profile before prescribing combined OCs. Hereditary thrombophilia does not influence the risk of MI.37 Screening for thrombophilic abnormalities is therefore not indicated solely because of a family history of MI.
STROKE AND COMBINED HORMONAL CONTRACEPTION

The baseline incidence of ischemic stroke in women who do not use combined OCs is estimated at 0.06 per 10,000 women per year at age 20 to 24. At age 35 upward, the incidence is 0.16 per 10,000 per year. The case-fatality rate of ischemic stroke is about 25%, with a 30% disability rate.

A significantly increased risk of stroke is observed in users of combined OCs with a high estrogen content. With current preparations, the risk has been found not to be increased in some studies. An increase in risk up to 2-fold was found in other studies. A recent meta-analysis reported an odds ratio for stroke of 1.93 (95% CI, 1.35–2.74) in users of current preparations, after controlling for smoking and hypertension.

The risk of stroke with use of third-generation combined OCs appears similar to that with second-generation combined OCs, although some data suggest a lower risk. Smoking is a major risk factor for stroke, with an approximate doubling of the risk overall as well as in women who use combined OCs.

Hypertension is a major risk factor for stroke. Combined OC users with hypertension are at increased risk of stroke, compared with users without hypertension. Use of combined OCs should be avoided in women with uncontrolled hypertension, but they can be probably be used safely in women with documented hypertension if the blood pressure is controlled by medication and followed closely. Women with hypertension who use combined OCs have a higher risk of poor control with medication.

MIGRAINE AND COMBINED HORMONAL CONTRACEPTION

Women taking combined OCs may notice an increase or a decrease in the severity of their headaches. Tension headaches are not related to combined OC use. Migraine headache is associated with an approximately 3-fold increase in risk of ischemic stroke. The risk of stroke is considered higher in women who have migraine with aura (relative risk approximately 6 compared with women without migraine), although not all studies report a difference. The risk of stroke is further increased by the presence of hypertension, smoking, and the use of combined OCs.

Migraine is not considered a contraindication to the use of combined OCs in the absence of aura or other risk factors. Combined OC use is generally considered contraindicated in patients with migraine aura, although visual scintillations lasting less than 1 hour are considered acceptable by some authors. New-onset headache or worsening headache require discontinuation of combined OCs and re-evaluation of the patient. Headache that occurs repeatedly in the pill-free week may be prevented by continuous use.

A small increase in the risk of hemorrhagic stroke with combined OC use has been found in developing countries but nowhere else.

VENOUS THROMBOEMBOLISM AND PROGESTIN-ONLY HORMONAL CONTRACEPTION

Progestins do not appear to increase the risk of VTE in contraceptive doses, but only limited data are available and 1 study found an increased risk even when adjusting for the indication for use.

Progestin-only contraception is presently used as an alternative to combined OC use in women at heightened risk of VTE. The safety of this strategy needs to be tested in prospective studies. No data exist for emergency contraception, but the benefits far outweigh the potential risks.

MYOCARDIAL INFARCTION, STROKE, AND PROGESTIN-ONLY HORMONAL CONTRACEPTION

The use of progestin preparations is not associated with an increase in the risk of MI or stroke, even in therapeutic indications. Women at heightened risk of MI or stroke, including women with atypical migraine, can use progestin-only contraception as well as progestin-only emergency contraception.

HORMONAL CONTRACEPTION IN WOMEN WITH PRE-EXISTING CONDITIONS

It is important to balance the risks of pregnancy with the risks of oral contraceptives in women with pre-existing conditions.

HYPERLIPIDEMIA

The presence of hypertriglyceridemia increases the risk of pancreatitis and is a relative contraindication to the use of combined OCs.

DIABETES MELLITUS

Early combined OC formulations impaired glucose metabolism by increasing peripheral insulin resistance. Currently available products have no appreciable effect on carbohydrate metabolism. There is no evidence that use of combined OCs worsens the course of type 1 or 2 diabetes mellitus in the absence of vascular disease. Effective prevention of pregnancy outweighs the small risk of complicating vascular disease in diabetic women who are otherwise healthy, and whose diabetes is well controlled.

LIVER AND GALLBLADDER DISEASE

Combined OC use increases the secretion of cholic acid in bile. Women using combined OCs have a small increase in the risk of symptomatic gallstones. Combined OCs should not be used in women with active liver disease, or in women with known benign or malignant liver tumours.
INFLAMMATORY BOWEL DISEASE
There may be a modest association between the use of combined OCs and the development of inflammatory bowel disease. Combined OCs have been reported to increase the risk of relapse of inflammatory bowel disease in some studies, but not all. Combined OCs may be absorbed inadequately in the presence of chronic inflammation or active diarrhea.

SYSTEMIC LUPUS ERYTHEMATOSUS
Combined OCs are generally not prescribed to women with systemic lupus erythematosus because estrogen can exacerbate the disease. However, their use may be considered in selected cases, in the absence of active nephritis or antiphospholipid antibodies.

SICKLE CELL DISEASE
Women with sickle cell disease are at increased risk of stroke. However, the risk of pregnancy is high in these women, and effective prevention of pregnancy is essential. Despite a paucity of data, the general consensus is that combined OCs can be used. In one study, women randomized to use of depot-medroxyprogesterone acetate (DMPA) or combined OC, reported a more marked improvement in painful crises with the use of DMPA (70% reduction) than with OC (54.5% reduction). Control women had a 50% reduction of crises.

Yoong found some form of cyclical crises in 58% of women and concluded that DMPA should be considered in severe cases.

EPILEPSY
Combined OCs can be used safely in women with epilepsy. Some drugs reduce the efficacy of combined OCs. In this case, the use of combined OCs containing more than 35 µg of ethinyl estradiol may be warranted.

It is recommended that injections of DMPA be given every 10 weeks rather than every 12 weeks in women who are receiving antiepileptic drugs that induce hepatic microsomial enzymes.

ELECTIVE SURGERY
Whether women should discontinue OC use 4 weeks before elective surgery is controversial. The decision must take into account the risk of an unwanted pregnancy during this period of time. Discontinuation should be considered before surgery associated with a high risk of thrombosis, such as surgery for malignancy or surgery followed by prolonged immobilization. Standard recommendations for antithrombotic prophylaxis should be adhered to. Patients in whom OC are continued should be considered for antithrombotic prophylaxis.

MIGRAINE
Please refer to paragraph migraine and combined hormonal contraception.

SUMMARY STATEMENTS
1. The risk of myocardial infarction and stroke is increased significantly with smoking and may be slightly increased with the use of combined OCs. Because cardiovascular disease increases rapidly in women aged over 35, and because risk factors have a compounding effect, the use of combined OCs in smokers significantly increases the cardiovascular risk over the age of 35. (Level II-2)
2. Whether women should discontinue low-dose combined OC use before elective surgery is controversial. The decision must take into account the risk of unwanted pregnancy and the risk of post-operative thromboembolic events. (Level III)
3. The association between antibiotic use and contraceptive failure is based on isolated case reports only. Pharmacologic and cohort studies do not support an effect of antibiotics on combined OC-induced ovulation suppression or contraceptive failure. (Level II-2)

RECOMMENDATIONS
1. All women who smoke should be counselled to stop. Women over 35 who smoke should be advised not to use combined OCs. (Grade A)
2. Women using combined OCs who are undergoing major surgery or surgery that will be followed by prolonged periods of immobility should receive peri-operative antithrombotic prophylaxis. (Grade A) Consideration may be given to discontinuing low-dose combined OCs 4 weeks prior to elective surgery. A reliable contraceptive method (e.g., progestin-only contraception) should be substituted when combined OCs are withdrawn. (Grade C)

REFERENCES


CHAPTER 7: INTRAUTERINE DEVICES

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INTRODUCTION

Worldwide, over 100 million women have used the intrauterine contraceptive device (IUD). However, in North America less than 1% of women use this highly effective method of contraception. In Canada, 2 copper IUDs (Nova-T and Flexi-T 300) and a levonorgestrel-releasing device (Mirena) are currently available.

Mirena is also referred to as a levonorgestrel-releasing intrauterine system (LNG-IUS).

EFFICACY

Intrauterine devices are highly effective methods of reversible contraception. In a large trial, the failure rate of a copper IUD (Nova-T) was 1.26 per 100 women-years (WY) and the rate of ectopic pregnancy was 0.25 per 100 WY. The failure rate of the levonorgestrel-releasing intrauterine system was 0.09 per 100 WY and the ectopic pregnancy rate was 0.02 per 100 WY.1

Although the product monograph for the Nova-T copper IUD suggests that it be replaced every 30 months, clinical trials have shown that it is effective for 5 years.1,2 The Flexi-T 300 copper IUD and the LNG-IUS should be replaced every 5 years.
MECHANISM OF ACTION

Intrauterine devices have multiple mechanisms of action. The chief mechanism of action of all IUDs appears to be the prevention of fertilization. If fertilization does occur, IUDs also appear to have post-fertilization effects, including the potential inhibition of implantation.

The copper-bearing IUDs consist of a vertical stem with a silver-cored copper wire wound around it. The presence of a foreign body and of copper in the endometrial cavity causes biochemical and morphological changes in the endometrium. These changes adversely affect sperm transport so that fertilization rarely occurs. The copper ions also have a direct effect on sperm motility, reducing the ability of sperm to penetrate cervical mucus. Ovulation is not affected in users of the copper IUD.

The levonorgestrel-releasing intrauterine system consists of a small polyethylene T-shaped frame with a cylindrical reservoir containing levonorgestrel on its vertical arm. This cylinder slowly releases hormone through a rate-limiting membrane. The LNG-IUS produces a weak foreign body reaction and endometrial changes that include endometrial decidualization and glandular atrophy. Endometrial estrogen and progesterone receptors are suppressed. Cervical mucus may become thickened, creating a barrier to sperm penetration. Ovulation may be inhibited in some women.

INDICATIONS

In the absence of contraindications, the IUD may be considered for any woman seeking a reliable, reversible, coitally independent method of contraception. It is particularly suited for women seeking long-term birth control or a method requiring less compliance. Women who have contraindications or sensitivities to estrogen, or women who are breastfeeding, may be good candidates for use of an IUD.

The copper IUD, in appropriately selected patients, may be used for postcoital contraception in women presenting up to 7 days after an act of unprotected intercourse.

The LNG-IUS has been shown to decrease menstrual flow and cramping, and therefore has been used in women with menorrhagia and dysmenorrhea. It should not be used for postcoital contraception.

CONTRAINDICATIONS

The World Health Organization (WHO) has developed a list of absolute and relative contraindications to use of an IUD.

ABSOLUTE CONTRAINDICATIONS
- pregnancy
- current, recurrent, or recent (within past 3 months) pelvic inflammatory disease (PID) or sexually transmitted infection (STI)
- puerperal sepsis
- immediate post-septic abortion
- severely distorted uterine cavity
- unexplained vaginal bleeding
- cervical or endometrial cancer
- malignant trophoblastic disease
- copper allergy (for copper IUDs)
- breast cancer (for LNG-IUS)

RELATIVE CONTRAINDICATIONS
- risk factor for STIs or human immunodeficiency virus (HIV)
- impaired response to infection
  - in HIV-positive women
  - in women undergoing corticosteroid therapy
- from 48 hours to 4 weeks postpartum
- ovarian cancer
- benign gestational trophoblastic disease

NON-CONTRACEPTIVE BENEFITS

Intrauterine devices are used primarily for contraception, but they also provide a number of non-contraceptive health benefits.

Case-control studies provide some evidence that use of non-medicated or copper IUDs reduces the risk of endometrial cancer. This protective effect is not related to the duration or timing of use, and its mechanism is not well understood.

Menorrhagia responds favourably to use of the LNG-IUS, with reported reductions in menstrual blood loss of 74 to 97% and favourable effects on hemoglobin levels. In 2 studies of women scheduled to undergo hysterectomy for menorrhagia, 64 to 80% of women randomized preoperatively to LNG-IUS insertion subsequently cancelled their hysterectomy, compared with 9 to 14% of women randomized to receive other medical treatments.

Dysmenorrhea may also improve in LNG-IUS users.

A randomized controlled study found that use of the LNG-IUS protects against endometrial hyperplasia in women on tamoxifen. Small reports support a beneficial effect in the treatment of fibroid-related menorrhagia.

Comparison of IUD and LNG-IUS Devices

<table>
<thead>
<tr>
<th>Type of Device</th>
<th>Failure rate per 100 woman-years</th>
<th>Ectopic rate per 100 woman-years</th>
<th>Duration of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper IUD (Nova-T)</td>
<td>1.26</td>
<td>0.25</td>
<td>5 years</td>
</tr>
<tr>
<td>LNG-IUS</td>
<td>0.09</td>
<td>0.02</td>
<td>5 years</td>
</tr>
</tbody>
</table>
SIDE EFFECTS

1. BLEEDING
Irregular menstrual bleeding or an increase in the amount of bleeding are the most common side effects of IUDs in the first months after insertion. Menstrual blood loss in users of copper IUDs increases by up to 65% over non-users. Use of non-steroidal anti-inflammatory agents (NSAIDs) or tranexamic acid may help to decrease the amount of menstrual blood loss. The average number of days of spotting or bleeding appears to decrease over time. Users of copper IUDs have an average of 13 days of bleeding or spotting in the first month after insertion, decreasing to an average of 6 days at 12 months after insertion. The cumulative termination rates for bleeding problems after 5 years of use are up to 20% for copper IUDs. By contrast, users of the LNG-IUS experience a reduction in menstrual blood loss of between 74% and 97%. Women using the LNG-IUS have an average of 16 days of bleeding or spotting at 1 month after insertion, and this decreases to an average of 4 days by 12 months after insertion. The cumulative termination rates for bleeding problems after 5 years of use are up to 14% for the LNG-IUS. Between 16 and 35% of LNG-IUS users will become amenorrheic after one year of use. Since information received in advance will improve user satisfaction, patients should be carefully counselled regarding potential menstrual changes prior to IUD insertion.

2. PAIN OR DYSMENORREA
Up to 6% of copper IUD and LNG-IUS users will have discontinued use at 5 years because of pain. Pain may be a physiological response to the presence of the device, but the possibility of infection, malposition of the device (including perforation), and pregnancy should be excluded. The LNG-IUS has been associated with a decrease in menstrual pain.

3. HORMONAL
The LNG-IUS appears to exert some systemic hormonal effects, even though the daily dose of levonorgestrel is extremely low. Hormonal side effects include depression, acne, headache, and breast tenderness. Most studies report a low incidence of such adverse effects, which appear to be maximal at 3 months after insertion and then decrease. Although weight gain has been reported as a side effect of LNG-IUS use, a large trial reported no significant difference in weight gain over 5 years in LNG-IUS users and copper IUD users.

4. FUNCTIONAL OVARIAN CYSTS
Functional ovarian cysts have been reported in up to 30% of LNG-IUS users. Since these cysts usually resolve spontaneously, they should be managed expectantly.

RISKS

1. UTERINE PERFORATION
Uterine perforation is a rare complication of IUD insertion, occurring at a rate of 0.6 to 1.6 per 1000 insertions. All uterine perforations, either partial or complete, occur or are initiated at the time of IUD insertion. Risk factors for perforation include postpartum insertion, an inexperienced operator, and a uterus that is immobile, extremely antverted or extremely retroverted.

2. INFECTION
Methodological flaws in early observational research exaggerated the risk of PID associated with IUD use. Evidence from large cohort studies, case-control studies, and randomized controlled trials indicates that any risk of genital tract infection after the first month of IUD use is small. There appears to be an inverse relation between the risk of infection and the time since IUD insertion. The Women's Health Study data showed a relative risk of PID of 3.8 in the first month after insertion, reaching baseline risk after 4 months. Investigations by the World Health Organization found the risk to be highest in the first 20 days following insertion. Although insertion of an IUD contaminates the endometrial cavity with bacteria, the cavity becomes sterile soon afterwards. Exposure to STIs, and not the use of the IUD itself, is responsible for PID occurring after the first month of use.

It remains unclear whether the risk of PID is reduced in users of the LNG-IUS compared to users of the copper IUDs. IUD users should continue to use condoms for protection against STIs.

3. EXPULSION
Expulsion of the IUD is most common in the first year of use (2–10% of users). The 5-year cumulative expulsion rate for the copper IUD is 6.7% and for the LNG-IUS is 5.8%. Risk factors for expulsion include insertion immediately postpartum, nulliparity, and previous IUD expulsion. A woman who has expelled one IUD has a 30% chance of expelling a subsequent device.

4. FAILURE
If a woman becomes pregnant with an IUD in situ, the possibility of ectopic pregnancy must be excluded.

The risk of spontaneous abortion is increased in women who continue a pregnancy with an IUD in place. The UK Family Planning Research Network study found that 75% of pregnancies aborted if a copper IUD was left in situ, but that early removal virtually eliminated the risk of septic abortion. If the IUD was removed, 89% of women had a live birth, compared to 25% of women who left the IUD in place. Although the risk of spontaneous abortion appears to be normalized after IUD removal, the risk of preterm delivery remains higher.
MYTHS AND MISCONCEPTIONS

1. Nulliparous women cannot use IUDs.
   
   **Fact:** Nulliparity is not a contraindication to IUD use. In carefully selected nulliparous women, IUDs may be successfully used.

2. IUDs increase the risk of ectopic pregnancy.
   
   **Fact:** IUDs do not increase the risk of ectopic pregnancy. Because IUDs work primarily by preventing fertilization, IUD users have a lower risk of ectopic pregnancy than women who are not using any form of birth control (0.02–0.25/100 WY versus 0.12–0.5/100 WY). However, in women who conceive with an IUD in place, the diagnosis of ectopic pregnancy should be excluded.

3. IUDs increase the risk of infertility.
   
   **Fact:** IUDs do not increase the risk of infertility. Women who discontinue use of an IUD in order to conceive are able to conceive at the same rate as women who have never used an IUD. Copper IUD use is not associated with an increase in tubal factor infertility in nulliparous women.

4. IUDs increase the long-term risk of PID.
   
   **Fact:** The incidence of PID among IUD users is less than 2 episodes per 1000 years of use, similar to that of the general population. The increase in risk of PID associated with IUD use appears to be related only to the insertion process. After the first month of use, the risk of infection is not significantly higher than in women without IUDs.

5. IUDs are not effective contraceptives.
   
   **Fact:** IUDs are a highly effective method of birth control. In fact, in long-term users of IUDs, the failure rate approaches that of tubal ligation.

   The LNG-IUS appears to be as effective as tubal ligation.

INITIATION

Prior to insertion, informed consent should be obtained and the patient should be aware of the risks, benefits, and alternative methods of contraception. Patients should be counselled regarding the potential side effects associated with the IUD of choice, particularly alterations in the menstrual cycle. Patients should also be reminded that the IUD does not protect against STIs or HIV.

The IUD can be inserted at any time during the menstrual cycle once pregnancy or the possibility of pregnancy can be excluded. Although the advantages of inserting the IUD during or shortly after menses include ruling out pregnancy and the masking of insertion-related bleeding, there is no evidence to support the common practice of inserting the IUD only during menses. In fact, infection and expulsion rates may be higher when inserted during menses. The IUD can be removed and replaced at the same time on any day of the menstrual cycle.

Postpartum women may be candidates for immediate IUD insertion (within 10–15 minutes after delivery of the placenta).

These women are at higher risk of expulsion and uterine perforation. In most circumstances, it is best to wait to insert the IUD until the uterus is completely involuted, usually at 4 to 6 weeks postpartum. Women should wait until 6 weeks post-partum to have the LNG-IUS inserted. An IUD can be safely inserted immediately after a first trimester pregnancy termination.

The cost-effectiveness of screening for gonorrhea and chlamydia infection prior to IUD insertion is unclear. The cervix should be carefully inspected prior to IUD insertion, and, if there is any evidence of mucopurulent discharge or pelvic tenderness, cervical swabs should be performed and IUD insertion delayed until the results are known.

ANTIBIOTIC PROPHYLAXIS

A Cochrane Collaboration review concluded that neither doxycycline nor azithromycin before IUD insertion conferred benefit.

According to the American Health Association’s 1997 guidelines for prevention of bacterial endocarditis (SBE), antibiotic prophylaxis is not necessary prior to IUD insertion if there is no obvious infection. However, in the presence of infection, removal of an IUD requires SBE antibiotic prophylaxis.

FOLLOW UP

A follow-up visit should be scheduled post-insertion. This allows for the exclusion of infection, an assessment of bleeding patterns, an assessment of patient and partner satisfaction, and an opportunity to reinforce the issue of condom use for protection against STIs and HIV. After this visit, an IUD user should continue annual well-woman care as for any sexually active woman.

An IUD user should be instructed to contact her healthcare provider if any of the following occur:

- she cannot feel the IUD’s threads
- she or her partner can feel the lower end of the IUD
- she thinks she is pregnant
- she experiences persistent abdominal pain, fever, or unusual vaginal discharge
- she or her partner feel pain or discomfort during intercourse
- she experiences a sudden change in her menstrual periods
- she wishes to have the device removed or wishes to conceive

Troubleshooting

1. LOST STRINGS

If an IUD user is unable to palpate the IUD strings, a speculum exam should be performed. If the strings are not seen in the cervical os, the device may have been expelled, may have perforated the uterine wall, or the strings may have been drawn up into the cervical canal. Pregnancy should be excluded. Once pregnancy is excluded, the cervical canal should be explored (with a cotton swab, cytobrush, forceps, or similar instrument).
to see if the strings can be found. If the strings cannot be found, ultrasound is the preferred method to identify the location of the IUD. If the device is seen within the uterus, it can be left in situ. If the device is not identified within the uterus or the pelvis, a plain x-ray of the abdomen should be performed to determine whether the device has perforated the uterine wall. Both the LNG-IUS and the copper IUD are radio-opaque.

2. PREGNANCY WITH AN IUD IN PLACE
Once the diagnosis of an ectopic pregnancy has been excluded, the woman should be asked about her wishes for the pregnancy. If she wishes to terminate the pregnancy, the device should be left in place until the procedure. If she wishes to continue with the pregnancy, the IUD should be removed if possible. If the strings are visible, gentle traction is applied to remove the device. If the strings are not visible, gentle exploration of the cervical canal is performed. If no strings are found, the possibility of perforation must be considered. This is best excluded by pelvic ultrasound. Despite reports of successful hysteroscopic IUD removal during the first trimester, if the device remains in the uterus then usually no attempt is made to remove it. Note should be made of recovery of the IUD at the time of delivery.

3. AMENORRHEA OR DELAYED MENSES
Pregnancy must be excluded. Once pregnancy has been excluded, investigation should be as for a woman without an IUD. Up to 35% of LNG-IUS users may experience amenorrhea. If proper positioning of the LNG-IUS is confirmed, it is unnecessary to perform repeated pregnancy tests. If the IUD user is post-menopausal, the device should be removed.

4. PAIN AND ABNORMAL BLEEDING
Increased menstrual bleeding with or without an increase in menstrual cramping may occur in IUD users. In the event of partial expulsion or perforation, the device should be removed and consideration given to inserting another IUD. In the first few months after insertion, pain and spotting can also occur between menses. Once partial expulsion, perforation, pregnancy, and infection are ruled out, treatment with NSAIDs may be helpful in treating these symptoms. The number of days of bleeding or spotting usually decreases over time. If pain or bleeding persists or worsens, removing the IUD must be considered.

IUD users should be informed about potential changes in bleeding patterns, as well as signs and symptoms of infection prior to IUD insertion.

5. DIFFICULTY REMOVING THE IUD
Grasping the string with a ring forceps and exerting gentle traction can usually accomplish removal of an IUD. If the strings cannot be seen, manoeuvres such as those described above can be used to assist in localizing the strings. If further manoeuvres are needed, a paracervical block may be considered. A uterine sound can be passed into the endometrial cavity to localize the IUD. Cervical dilation may be required. Once localized, the IUD can be subsequently grasped with a small grasping instrument directed towards it. If removal is not easily performed, direct visualization of the IUD with ultrasound or hysteroscopy may be required. Occasionally general anesthetic may be needed to carry out IUD removal.

6. STI IDENTIFIED WITH IUD IN PLACE
Appropriate antibiotic therapy should be initiated for an IUD user (and her sexual contacts) found to have chlamydial or gonococcal cervicitis. If there is a suggestion of PID, the device should be removed after pre-treating the woman with antibiotics. She should be counselled regarding the use of barrier contraceptive methods for STI prevention.

7. ACTINOMYCOSIS ON PAP SMEAR
Actinomyces is considered a commensal vaginal organism but may be associated with frank infection. Up to 20% of cervical smears in long-term copper IUD users show evidence of Actinomyces, although this finding is only noted in up to 3% of LNG-IUS users. However, when cultures are performed, only 40% of women with Actinomycetes-like organisms found on Pap smears are shown to be colonized. Removal of the device in women with Actinomyces on their Pap smear may not be necessary. In the asymptomatic woman, it is reasonable to leave the IUD in place, follow her with annual Pap smears and pelvic examinations, and warn her of potential symptoms of PID. If the decision is made to treat, antibiotic therapy with penicillin G, tetracycline, or doxycycline may be given. If the woman is symptomatic, the IUD should be removed after antibiotic preloading. If the infection is severe, she should be hospitalized, treated for PID, and investigated for possible abscess.

SUMMARY STATEMENTS
1. In women who are at low risk of acquiring STIs, the use of an intrauterine device may be an excellent contraceptive option. Efficacy rates for the levonorgestrel-releasing intrauterine system approach those of surgical sterilization; it is therefore an excellent alternative to surgical sterilization for women who seek long-term contraception. (Level II-2)
2. The copper IUDs (Nova-T and Flexi-T 300) and the LNG-IUS (Mirena) provide effective contraception for 5 years. (Level I)
3. The risk of genital tract infection after the first month of IUD use is small. There appears to be an inverse relation between risk of infection and time since IUD insertion. Although the relative risk of pelvic inflammatory disease (PID) in the first month after insertion is increased slightly, the absolute risk is still low. Exposure to sexually transmitted infections, and
not the use of the IUD itself, is responsible for PID occurring after the first month of use. (Level II-2)
4. Both types of IUDs provide excellent contraceptive efficacy (Level I). In addition, the copper IUD may decrease the risk of endometrial cancer (Level II-2); the levonorgestrel-releasing IUS may provide an acceptable alternative to hysterectomy, by decreasing menorrhagia and increasing hemoglobin concentrations. (Level I)

RECOMMENDATIONS
1. Health-care professionals providing family planning services should be familiar with the use of the intrauterine device (IUD). (Grade A)
2. Appropriately trained personnel in adequately equipped facilities should be available in order to ensure that women have access to the IUD if they desire this method of contraception. (Grade A)

REFERENCES
35. Tietze C. Evaluation of intrauterine devices: ninth progress report of the


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.

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)


CHAPTER 8: BARRIER METHODS

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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 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. Laboratory tests have shown the passage of viruses, including hepatitis B, herpes simplex, and HIV, through small pores on the surface of lambskin condoms. 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.

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.

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. Some men may complain of decreased sensation or loss of erection.

RISKS

Technical problems with condom use (occurrence of an unrecognized leak, slippage) are more common when men are not used to the method. 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.

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.

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. Unpackaged condoms exposed to ultraviolet light are weakened by 80% to 90% within 8 to 10 hours. 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. 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 healthcare 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.

“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. 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. 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. 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. 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

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**Table 1.** Lubricants and Products that are Safe or Unsafe to Use with Condoms

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

**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
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.)

Table 3. How to Talk About Condoms with a Partner

<table>
<thead>
<tr>
<th>If the partner says …</th>
<th>You can say …</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I’m on the pill. You don’t need a condom.”</td>
<td>“I want to use it anyway. We will be protected from infections we may not realize we have.”</td>
</tr>
<tr>
<td>“Condoms aren’t romantic.”</td>
<td>“What’s more romantic than making love and protecting each other’s health at the same time?”</td>
</tr>
<tr>
<td>“I know I’m clean of disease. I haven’t had sex with anyone in ‘X’ months.”</td>
<td>“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.”</td>
</tr>
<tr>
<td>“I can’t feel a thing when I use a condom. It’s like wearing a raincoat in a shower.”</td>
<td>“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.”</td>
</tr>
<tr>
<td>“I don’t stay hard when I put on a condom.”</td>
<td>“I can do something about that.”</td>
</tr>
<tr>
<td>“Putting it on interrupts everything and destroys the romantic atmosphere.”</td>
<td>“Not if I help put it on.” OR “We can make it erotic together.”</td>
</tr>
<tr>
<td>“But I love you.”</td>
<td>“Then, if you love me, you’ll help me protect myself.”</td>
</tr>
<tr>
<td>“I guess you don’t really love me.”</td>
<td>“I do, but I’m not risking my future to prove it.”</td>
</tr>
<tr>
<td>“Just this once.”</td>
<td>“Once is all it takes.”</td>
</tr>
<tr>
<td>“You carry a condom around with you? You were planning on having sex?”</td>
<td>“I always carry condoms because I care about myself and I care about us.”</td>
</tr>
<tr>
<td>“I won’t have sex with you if you insist on using a condom.”</td>
<td>“OK. Let’s put it off until we can agree. Let’s satisfy each other without intercourse.”</td>
</tr>
<tr>
<td>“I don’t have a condom with me.”</td>
<td>“I do.”</td>
</tr>
</tbody>
</table>

REFERENCES


### 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.⁶⁻⁷

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 impervious 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 Disadvantages of the female condom include
• the need to practice 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

REFERENCES

Diaphragms are available in a variety of sizes and types. 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, dysplasia, gonorrhea, pelvic inflammatory disease, and tubal infertility.

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

A diaphragm can be inserted up to 6 hours before intercourse. 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. 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, 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. 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*.

**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.

**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. Of these, the use of a spermicide may be a more important cause.

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

**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.

**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.

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

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**Table 4. Fitting for a Diaphragm**

<table>
<thead>
<tr>
<th>The correct diaphragm size can be estimated by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• inserting the index and middle fingers into the vagina until the posterior wall is reached (by middle finger);</td>
</tr>
<tr>
<td>• marking the point at which the index finger touches the pubic bone with the tip of the thumb; and</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
</tbody>
</table>
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. For some women, having recurrent UTIs may be a contraindication to diaphragm use.

REFERENCES

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

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

REFERENCES


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 impregnated 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.5 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
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 bleeding

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

**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.

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.

**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.

**REFERENCES**


**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.
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>
<thead>
<tr>
<th>Table 8. How to Use Spermicides</th>
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<tbody>
<tr>
<td>- Read and follow the package instructions.</td>
</tr>
<tr>
<td>- Insert spermicide high in the vagina to cover the cervix.</td>
</tr>
<tr>
<td>- Use the appropriate amount of spermicide.</td>
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<tr>
<td>- Wait the recommended time between insertion and intercourse.</td>
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<tr>
<td>- Insert an additional application of spermicide with every act of intercourse.</td>
</tr>
<tr>
<td>- Do not douche for at least 6 hours after intercourse.</td>
</tr>
<tr>
<td>- Always have additional supply of spermicides.</td>
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</tbody>
</table>

**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 I)

**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)

REFERENCES


CHAPTER 9: NATURAL FAMILY PLANNING METHODS

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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 spinbarkeit) as ovulation approaches. After ovulation, the mucus becomes viscous, 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.

**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.

**Standard Day Method**

This method defines menstrual cycle days 8 to 19 as the fertile window. 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.

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. An independent prospective study showed a method failure rate of 6.2%, although others consider it to be higher. 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. 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
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. Since the pregnancy rate increases in women whose infants are receiving supplementary food, 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. Incorporating this information into family planning programs generally would greatly benefit women.

**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 each month.
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.

**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*. 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.

**REFERENCES**

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. 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.

EFFICACY

It is difficult to accurately assess the effectiveness of this method because data are lacking. 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.

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.

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. In HIV-infected men, the pre-ejaculate may contain HIV-infected cells. 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.

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.

REFERENCES


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 gonorrhea, syphilis, hepatitis B, herpes simplex virus, and chlamydia by mouth-to-genital 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)

REFERENCES


CHAPTER 10: STERILIZATION

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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

1. 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 Fallope 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 of 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

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 niti-nol 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
quinacrine pellets or erythromycin tablets for tubal occlusion. 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. 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. When the person has a mental disability, it is even more difficult for the physician to determine their capacity to provide informed consent. Contraceptive sterilization of an incompetent, mentally disabled person is illegal.

**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 likelihood of expressing regret, requesting information about reversal of sterilization, and obtaining reversal, increase over the years following sterilization. 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. 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. 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. 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.*

**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. Potential complications include the following:

- anaesthesia-related risks
- wound infection
- bruising
- haematoma 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

MENTRUAL 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.\textsuperscript{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.\textsuperscript{26}

**2. VASECTOMY**

**Efficacy**

Pregnancy rates following vasectomy vary from 0% to 2.2% with any occlusion method.\textsuperscript{35,36} No carefully controlled studies have compared the different occlusion methods.\textsuperscript{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.\textsuperscript{37,38} Recanalization occurs in up to 2.6% of cases within 3 months after vasectomy.\textsuperscript{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.\textsuperscript{35,36}

Use of an electrocoagulation technique,\textsuperscript{40,41} fascial interposition,\textsuperscript{41,43} removing a larger piece of vas,\textsuperscript{40} and experience on the part of the physician\textsuperscript{44} 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.\textsuperscript{45,46}

**Mechanism of Action**

There are 2 principal techniques for vasectomy:

- **Conventional vasectomy**\textsuperscript{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.

- **No-scalpel vasectomy**\textsuperscript{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.\textsuperscript{38}

Other approaches to male sterilization involve percutaneous chemical occlusion of the vas,\textsuperscript{48} or use of silver, silicone rubber–silver, or tantalum ring clips — the latter of which is compatible with reversible vasectomy.\textsuperscript{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 anesthetics, 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 vasectomy\textsuperscript{38} and the use of suturing clips\textsuperscript{49}:

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

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Table 2. Probability of Pregnancy Following Reversal of Tubal Ligation\textsuperscript{23}

<table>
<thead>
<tr>
<th>Technique</th>
<th>Pregnancy Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clip</td>
<td>90</td>
</tr>
<tr>
<td>Ring</td>
<td>76–80</td>
</tr>
<tr>
<td>Pomeroy</td>
<td>67</td>
</tr>
<tr>
<td>Monopolar cautery</td>
<td>52</td>
</tr>
</tbody>
</table>
disposes to recanalisation and may cause significant pain with palpation or during intercourse and ejaculation

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

**RARE COMPLICATIONS**

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

**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,\(^\text{57}\) and that antibodies may persist for as long as 10 years after surgery.\(^\text{58}\) However, several studies\(^\text{53,57,58}\) did not report any other laboratory abnormalities, nor immunological diseases of any kind.\(^\text{57,59,60}\)

**CARDIOVASCULAR DISEASES**

Following the identification of a marked increase of atherosclerosis in vasectomized cynomolgus monkeys fed high-cholesterol diets,\(^\text{61,62}\) several large studies (more than 4000 men with observation over 20 years)\(^\text{59,60,63}\) 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.\(^\text{59,60,63-68}\) 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.\(^\text{36,58}\)

**TESTICULAR CANCER**

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

**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,\(^\text{36,74-76}\) while in large cohort studies the relative risks varied from 0.8 to 2.1.\(^\text{36,77}\) 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.\(^\text{36}\)

   To date, there is no obvious biological mechanism for a relationship between vasectomy and prostatic cancer,\(^\text{75,76}\) 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.\(^\text{79}\)

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.\(^\text{44}\)

If the semen analysis shows the presence of non-motile spermatozoa, one year or more after surgery, a cautious assurance of sterilization can be given;\(^\text{36}\) annual semen tests may be undertaken for additional reassurance.\(^\text{42}\)
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)

REFERENCES


<table>
<thead>
<tr>
<th>Time Since Vasectomy</th>
<th>Sperm in the Semen (%)</th>
<th>Pregnancy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 years</td>
<td>97</td>
<td>76</td>
</tr>
<tr>
<td>3 to 8 years</td>
<td>88</td>
<td>53</td>
</tr>
<tr>
<td>9 to 14 years</td>
<td>79</td>
<td>44</td>
</tr>
<tr>
<td>More than 14 years</td>
<td>71</td>
<td>30</td>
</tr>
</tbody>
</table>


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

Most contraceptive options are open to women in peri-
menopause. This section will discuss some of the considerations
for perimenopausal women, but the details of the methods are
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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 inter-
mittent 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. Non-
contraceptive benefits may be especially helpful in this age
group. Low-dose OCs containing 20 to 35 µg of ethinyl estra-
diol 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. Important additional benefits of such treatment
include a decrease in the risk of ovarian cancer and endome-
trial cancer, reduced dysmenorrhea and menorrhagia, and
a lower risk of functional ovarian cysts. There is a decreased
risk of hereditary cancers. Longer duration of use is associat-
ed with decreased risk. The risk of colorectal cancer may also be
reduced with OC use.

Women taking a combined OC may experience a return of
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osly; this may have a number of advantages, including a
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and breast tenderness for women who experience these symp-
toms during the hormone-free interval.

INTRAUTERINE DEVICE

The intrauterine device (IUD) is an effective method of con-
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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-oper-
atively to LNG-IUS insertion subsequently cancelled their hys-
terectomy, compared with 9% to 14% of women randomized

CHAPTER 11: CONTRACEPTION —
MEETING SPECIAL NEEDS

Nathalie Fleming, MD, FRCSC, Margaret Morris, MD, FRSCS,
Helen Pymar, MD, MPH, FRCSC, Thirza Smith, MD, FRSCS

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. While women over the
age of 40 may have difficulty in conceiving, most are still fer-
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Pregnancy in perimenopause is associated with increased
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terectomy, compared with 9% to 14% of women randomized
to receive other medical treatments.\textsuperscript{19,20} Dysmenorrhea may also improve in LNG-IUS users.\textsuperscript{21}

**PROGESTIN-ONLY METHODS**

The use of depot medroxyprogesterone acetate or the progesterin-only pill are methods that can be used for contraception in perimenopause. These methods may be associated with amenorrhea\textsuperscript{22} or irregular vaginal bleeding.\textsuperscript{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.\textsuperscript{25} Menstrual abnormalities are not usually worsened after tubal ligation,\textsuperscript{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)

**REFERENCES**


7. Casper RF, Dodin S, Reid RL; Study Investigators. The effect of 20 µg ethinyl estradiol/1 mg norethindrone acetate (Minestrin), a low-dose oral contraceptive, on vaginal bleeding patterns, hot flashes, and quality of life in symptomatic perimenopausal women. Menopause 1997;4:139–47.


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.

LACTATIONAL 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)

REFERENCES


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ethisterone (NET) and levonorgestrel (LNG) from a single tablet into the infant’s circulation through the mother’s milk. Contraception 1987;35:517–22.

5. Truitt ST, Frazer AB, Grimes DA, Gallo ME; Schulz KF. Combined 


7. Halderman LD, Nelson AL. Impact of early postpartum administration of progestin-only hormonal contraceptives compared with 


3. POSTABORTION 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. 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)

REFERENCES


5. El-Tagy A, Sakr E, Sokal D, Issa A. Safety and acceptability of post-abortal

Table 1. Recommended Initiation of Contraceptive Options After Abortion

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

REFERENCES

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)

REFERENCES

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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. 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.

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.

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. 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.

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. 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. This perception will be difficult to reverse, despite the realization that the risk of PID is associated only with insertion of the device. (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.

Hormone-releasing devices, particularly those releasing levonorgestrel (e.g., Mirena), provide reliable contraception with a dramatic reduction in menstrual bleeding. 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.

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, 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. (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, drosiprenone, 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.

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. 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.

Another approach in attempting to provide estrogen-free hormonal contraception has been to administer sequentially an anti-progestin (mifepristone) followed by a progestin (norgestrel 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.

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). 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.

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, 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 progestin 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. 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.

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, 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 immuncontraception 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. 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. 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.

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. 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 antibodies to the β-subunit of the HCG molecule (and, through linkage of antibodies to Clostridium tetani). 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. 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.

There is political opposition to the development of β-HCG vaccines for contraception, since they could be considered abortifacient. 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. 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. 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. 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, 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 antispermatogenic contraceptive compound in the early 1980s was abandoned because of renal damage, but recent derivatives have shown efficacy 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.

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. No human studies have been conducted, and appear unlikely to occur until further evidence of anti- nidatory 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. 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. 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.

REFERENCES