Missed Hormonal Contraceptives: New Recommendations

This committee opinion has been reviewed by the Social and Sexual Issues Committee and reviewed and approved by the Executive of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To provide evidence-based guidance for women and their health care providers on the management of missed or delayed hormonal contraceptive doses in order to prevent unintended pregnancy.

Evidence: Medline, PubMed, and the Cochrane Database were searched for articles published in English, from 1974 to 2007, about hormonal contraceptive methods that are available in Canada and that may be missed or delayed. Relevant publications and position papers from appropriate reproductive health and family planning organizations were also reviewed. The quality of evidence is rated using the criteria developed by the Canadian Task Force on Preventive Health Care.

Benefits, Harms, and Costs: This committee opinion will help health care providers offer clear information to women who have not been adherent in using hormonal contraception with the purpose of preventing unintended pregnancy.


Summary Statements

1. Instructions for what women should do when they miss hormonal contraception have been complex and women do not understand them correctly. (I)

2. The highest risk of ovulation occurs when the hormone-free interval is prolonged for more than seven days, either by delaying the start of combined hormonal contraceptives or by missing active hormone doses during the first or third weeks of combined oral contraceptives. (II)
Ovulation rarely occurs after seven consecutive days of combined oral contraceptive use. (II)

Recommendations

1. Health care providers should give clear, simple instructions, both written and oral, on missed hormonal contraceptive pills as part of contraceptive counselling. (III-A)

2. Health care providers should provide women with telephone/electronic resources for reference in the event of missed or delayed hormonal contraceptives. (III-A)

3. In order to avoid an increased risk of unintended pregnancy, the hormone-free interval should not exceed seven days in combined hormonal contraceptive users. (II-A)

4. Back-up contraception should be used after one missed dose in the first week of hormones until seven consecutive days of correct hormone use are established. In the case of missed combined hormonal contraceptives in the second or third week of hormones, the hormone-free interval should be eliminated for that cycle. (III-A)

5. Emergency contraception and back-up contraception may be required, and back-up contraception should be used. Health care professionals should counsel women in these situations on alternative methods of contraception that do not demand such stringent compliance. (III-A)

6. Back-up contraception should be used when three or more consecutive doses/days of combined hormonal contraceptives are missed in the second and third week until seven consecutive days of correct hormone use are established. For practical reasons, the scheduled hormone-free interval should be eliminated in these cases. (II-A)

7. Emergency contraception is rarely indicated for missed combined hormonal contraceptives in the second or third week of the cycle unless there are repeated omissions or failure to institute back-up contraception after the missed doses. In cases of repeated omissions of combined hormonal contraceptives, emergency contraception may be required, and back-up contraception should be used. Health care professionals should counsel women in these situations on alternative methods of contraception that do not demand such stringent compliance. (III-A)


INTRODUCTION

Despite the fact that Canadian women have access to a wide range of contraceptive options, unplanned pregnancies still occur.1 According to the 2006 Canadian Contraception Study, 50% of sexually active women in Canada use a hormonal contraceptive method. Oral contraceptives are the most popular method, used by 43.8% of women, followed by depot medroxyprogesterone acetate (Depo-Provera, 2.4%), the contraceptive patch (Evra, 1.2%), and the vaginal contraceptive ring (NuvaRing, 0.6%).2 Correct and consistent use of any contraceptive method is essential to its effectiveness, but adherence may vary significantly by contraceptive method. Hormonal contraceptives are nearly 100% effective with perfect use; however, typical failure rates in the range of 3% to 9% reflect the fact that adherence with daily, weekly, monthly, or even tri-monthly regimens is a problem. Women commonly fail to take hormonal contraception as directed. Up to 60% of COC users report irregular COC use, including missing pills or starting new pill packages late.3 North American studies have found that approximately 50% of women take one pill every day4 but that the percentage of women missing at least three pills a month can vary from 10% to 51%.5 In one survey conducted in 10 countries, nearly 75% of pill users forgot to take their daily pill when at home, and more than 25% said that they were more likely to forget to take their pill when on holiday.6

Although there are a number of guidelines for steps to take in the event of missed hormonal contraception, these instructions are often perceived as being too complex, because they vary for the type of pill, the number of pills missed, and the timing of the missed pill. Studies have found that although women may know what to do when one pill is missed, fewer women know what to do when two or more pills in a row are missed.7 Women in these studies reported that graphic instructions for missed pills were easier to understand than text-only instructions, and that simplified forms were easier to comprehend than more complex versions.8

The current guidelines for missed hormonal contraception and the relevant literature on contraceptive efficacy, ovulation inhibition, and mechanism of action of hormonal contraceptives were reviewed in order to provide simplified, written, evidence-based instructions to women and health care providers for dealing with missed hormonal contraception. Recognizing that hormonal contraceptives have multiple mechanisms of action, that there is no direct evidence assessing the impact of missed pills on the risk of unintended pregnancy, that there may be significant variation among users, and that there are no studies assessing the

ABBREVIATIONS

COC  combined oral contraceptive
CHC  combined hormonal contraception
DMPA  depot medroxyprogesterone acetate
DSG  desogestrel
EC  emergency contraception
EE  ethinyl estradiol
FSH  follicle stimulating hormone
HFI  hormone-free interval
HC  hormonal contraceptive
LNG  levonorgestrel
Patch  transdermal contraceptive patch
Ring  vaginal contraceptive ring
NG  norgestrel
NGM  norgestimate
OC  oral contraceptive
RCT  randomized controlled trial
WHO  World Health Organization
accuracy or efficacy of current guidelines, this document proposes new algorithms for advising women on what to do when hormonal contraception is missed. Recommendations are graded using the criteria developed by the Canadian Task Force on Preventive Health Care (Table).

**CURRENT RECOMMENDATIONS FOR MISSED HORMONAL CONTRACEPTION**

Although women often fail to take hormonal contraception consistently and correctly, there is no uniformity (and indeed some controversy) in the recommendations from various organizations and societies for counselling women on missed hormonal contraception and when to consider emergency contraception. For example, in the Netherlands alone, the Dutch College of General Practitioners, the Scientific Institute of Dutch Pharmacists, the Dutch Association of Obstetrics and Gynaecology, and the Dutch Expert Centre on Sexuality all give different recommendations on the use of the morning after pill in the event of a contraceptive pill being missed.9

In the 2004 Canadian Contraception Consensus, the Society of Obstetricians and Gynaecologists of Canada provided instructions for COC users in the event of missed pills.10 These stated that a woman may miss one pill; however, if two or more pills were missed in the first or second week of the pack, then back-up contraception should be used for seven days, and EC should be considered. If two or more pills were missed in the third week, a new pack of pills should be started immediately. If three or more pills were missed at any time, the woman should start a new pack immediately, consider EC, and use a back-up method. No differentiation was made between different types of pills.

In the same year, Hatcher, in Contraceptive Technology, suggested that in the first week of the CHC pill pack, missing from one to four pills was an indication to use a back-up method of contraception and consider emergency contraception.3 However, a woman could miss up to four pills in the second or third week of the pack without requiring emergency contraception or a back-up method of contraception. If two or more pills were missed in the third week, a new pack should be started in order to avoid extending the hormone-free interval. A missed pill was defined as taking a pill more than 24 hours after the last pill, or not at all. Again, no differentiation was made between pill types.

In 2004, the WHO published the Second Edition of Selected Practice Recommendations for Contraceptive Use, which contained recommendations for COC users and progestin-only pill users in the event of missed pills.11 These recommendations were based on systematic reviews of the relevant evidence by a working group of international family planning experts.12,13 Unlike previous recommendations and those of other organizations, they differentiated between CHC pills that contained 30–35 μg of ethinylestradiol and those that contained ≤ 20 μg of EE. The Working Group commented that the evidence for their recommendations was based primarily on studies of 30–35 μg EE
pills and that the more cautious recommendations for the 20 μg EE pills were based on limited evidence suggesting a possible higher risk of pregnancy when missing 20 μg EE pills. The main principles underlying their recommendations were the following: it is important to take an active (hormonal) pill as soon as possible when pills have been missed; the chance of pregnancy if pills are missed depends on how many pills are missed and when the pills are missed; the risk of pregnancy is greatest when the hormone-free interval is extended (i.e., pills are missed at the beginning or at the end of the active pills); seven days of continuous COC use are necessary to reliably prevent ovulation; missing three or more active pills at any time during the cycle (2 or more for ≤ 20 μg pills) warrants additional precautions.

The WHO recommendations allow a woman taking a 30–35 μg COC to miss up to two active hormonal pills or start a pack one or two days late without the need for back-up contraception or emergency contraception. Women taking a ≤ 20 μg COC could miss one active pill or start their pack one day late without requiring additional precautions. Women who missed three or more active 30–35 μg pills (or 2 or more active 20 μg pills) were advised to take an active pill as soon as possible, continue taking one pill daily, use a back-up method of contraception for seven days, and consider the use of emergency contraception. If the pills were missed in the third week, women should finish off the active pills and then start a new pack of pills right away, thus omitting the hormone-free interval. There was no definition given for what constituted a “missed pill.”

The WHO recommendations were endorsed by the Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit in the United Kingdom, who adapted them for use in developed countries. They presented their recommendations in table and flow chart formats to allow individual providers to use the most appropriate style of presentation in their own practice. The WHO recommendations for both missed COCs and missed progestin-only pills have also been endorsed by the International Planned Parenthood Federation.

The objective of the WHO was to provide an evidence-based yet simple and harmonized guide for missed pill taking, because previous rules were confusing, contradictory, too complex for some women, and probably overcautious in their advice about back-up contraception for much of the pill cycle. However, there have been criticisms of the WHO recommendations. Mansour and Fraser argued that given that many women are unsure of the dose of ethinyl estradiol in their pill, having two rules, one for 30–35 μg pills and one for ≤ 20 μg pills, would lead to confusion and that “one rule for all” would be better. They also raised the following concerns: there is no universally accepted definition of a “missed pill,” there is no strong evidence that it is safe to miss up to three 30–35 μg pills at the start of a new pack without using back-up contraception or EC, and the small studies done to detect ovulation after deliberate extension of the HFI were not powered to detect wide inter-individual variability. Guillebaud, a member of the WHO Expert Working Group, stated that the decision to have two schemes by dose was not well founded, given the limited evidence available and given that individual variation in ovarian activity appeared to be much greater than the effect of any dose. Thus he also suggested that in a developed country where fewer unintended pregnancies occur because women do not have access to reliable contraception or to information about its use, one rule for all would be more helpful and that more than one pill missed should trigger seven days of back-up contraception for all of the COCs. The Dutch organizations expressed concerns over the WHO recommendations in their 2007 guidelines for missed contraceptive pills and requested that the WHO initiate research to establish if its 2004 recommendations on forgetting more than one pill can be supported by better data. In the meantime, the Dutch consensus was that if only one pill is missed, no extra precautions are necessary. This is similar to the recommendations made by the American College of Obstetricians and Gynecologists (ACOG) in their 2006 patient information booklet. ACOG recommends that if more than one pill is missed, back-up contraception should be used for one week, regardless of the dose of pill or the timing in the cycle.

Given the contradictory recommendations that exist, providing women with clear simple instructions on what steps to take in the event of missed hormonal contraception may be a daunting task for health care providers. The SOGC Working Group reviewed the available evidence to help determine a simple approach to missed hormonal contraception that allows for the lowest number of pregnancies that could have been prevented if women had been given contraception and clear instructions for its use without unnecessary intervention with emergency contraception. While other guidelines have focused exclusively on oral contraceptives, this document includes all methods of hormonal contraception.

Evidence From Studies on Ovulation Suppression and Missed Hormonal Contraception

Most CHCs work primarily by suppressing ovulation. However, residual ovarian activity has been shown with most COCs, even 50 μg EE preparations, as demonstrated by increased levels of FSH, estradiol or progesterone, or ultrasonographic appearance of follicles or follicle-like structures. This is particularly true during the seven-day...
HFI with preparations containing older progestins (norethindrone acetate or norethindrone) and with very low dose COCs (≤ 20 µg EE). In one study, if ovarian activity was not detected during the first week of pill intake, it was unlikely to be found in week two or week three.

Studies have exposed women to dosing errors. These studies found that some form of ovarian activity or, occasionally, signs of ovulation (elevation of serum progesterone or appearance of a corpus luteum) could occur, especially with dosing errors in the first week of use. There was no evidence that omission of two pills during the second or third week of a pill pack resulted in ovulation.

Four studies examined the effects of oral contraceptives administered at defined stages of ovarian follicular development or at different days of the cycle. The risk of ovulation was higher when the diameter of a leading follicle was larger (> 10 mm) or when the pill was initiated later in the cycle (day 7 vs. day 1).

Adding estrogen during the HFI, decreasing or eliminating the HFI, starting the first pack of pills on cycle day one instead of day five, or regular use of the contraceptive patch appear to achieve more effective ovarian suppression. The vaginal contraceptive ring has also been reported to be highly effective in rapidly suppressing follicular development. One small randomized trial demonstrated that when the HFI was extended to allow follicular growth to 13 millimetres (day 11 median after ring removal), ovulation did not occur. In the same study, when the ring was used for only three days following a 7-day HFI, subsequent ovulation did not occur until 17 days after ring removal.

The limitations of these studies include small sample sizes that may not reflect variations in larger populations, lack of standard definitions for ovulation, and the fact that there was no direct evidence of how ovulation corresponds to the risk of unintended pregnancy. Although reduced ovarian suppression during hormonal contraceptive use may result in ovulation, other mechanisms of contraceptive action such as thickened cervical mucus and endometrial atrophy may help to offset the risk of unintended pregnancy. As with ovarian suppression, these other mechanisms of action are also influenced by the progestin used and its dose.

Small studies assessing the timing of DMPA injections found that DMPA injection up to day seven of the menstrual cycle reliably inhibits ovulation and that when DMPA was given after day seven, some women ovulated, although 90% had poor cervical mucus scores 24 hours after injection. Studies have also found a wide variation in the time between a woman’s last injection of DMPA and the resumption of ovulation, with a range of 15 to 49 weeks.

**Evidence From Studies on Pharmacokinetics of Hormonal Contraceptives**

The pharmacokinetic properties of contraceptive hormones will influence contraceptive efficacy when doses are missed, but evidence related to specific formulations is lacking. Although serum levels of hormones with longer half-lives remain stable for longer and theoretically should allow more leeway for dosing errors, other factors such as protein binding of hormones, the hormone dose (very low vs. low), and progestin potency are also important for maintaining effective hormone levels. At this time it is not possible to conclude whether some formulations are more tolerant of user error than others. As well, there is considerable evidence for large inter- and intra-individual variation as well as ethnic differences in the metabolism of contraceptive hormones, suggesting that the effect of missed doses is likely to be highly variable among women.

The pharmacokinetics of non-oral delivery systems are relevant to the risk for contraceptive failure when use is extended past the recommended time. The hormone reservoir in the contraceptive patch and ring maintain serum hormone concentrations in the therapeutic range past their recommended duration of use of 7 and 21 days, respectively. In a study of 12 women, serum concentrations of EE and norelgestromin (the active progestin metabolite in the patch) remained at ovulation inhibitory levels throughout at least nine days of wear, two days past the approved time for use. Likewise in a study of eight women using the vaginal ring, EE and etonogestrel slowly declined after peak levels were attained during the first week of use, falling below week one levels only after 30–35 days of wear.

**Evidence From Studies on Efficacy**

A woman’s adherence to her hormonal contraceptive regimen is a major determinant of its effectiveness. For some methods adherence is inherently more dependent on the action of the user; a woman using DMPA must act only once every three months to have perfect adherence, whereas a woman using oral contraceptives must take a pill every day for three weeks, remember to start a new cycle of pills at the end of the hormone-free interval, and repeat this for three pill cycles to achieve the same adherence. Methods that are more user-dependent demonstrate a larger difference in theoretical and actual contraceptive effectiveness. Failure rates for DMPA are 0.3% for perfect use and 3% to 6.7% for typical use, while failure rates for COCs are 0.3% with perfect use and 8% to 9% for actual use.

In studies of adherence to COC regimens, 15% to 47% of pill users report missing one pill per cycle and 22% report...
Women with no established pill-taking routine and poorer understanding of written information about the pill have been shown to have poorer adherence. Recently, age has not been shown to have a significant impact on COC adherence. A cohort study of 3316 women found that those using pills in a continuous 28-day cycle missed fewer pills in the vulnerable first week of the cycle than those using a 21-day regimen. In several randomized controlled trials, the contraceptive patch was found have better user adherence than COCs, although there was no significant difference in efficacy. However, in one cohort study in women at high risk for contraceptive failure, patch users had lower continuation and effectiveness rates than COC users. The vaginal ring, which requires only once-monthly insertion, was not used consistently during 11% to 15% of treatment cycles in controlled clinical trials. Studies of DMPA have shown that over one half of new users discontinue it by one year, and adherence to scheduled appointments is low, with 36% of users in a US clinic missing a regular injection appointment over one year of follow-up. Thus, the evidence indicates that regimen adherence is imperfect for all types of hormonal contraception, and strategies are needed to decrease the risk of contraceptive failure in circumstances of imperfect use.

**Box 1.** During the first week of use (week 1), delay in taking one pill ≥ 24 hours (i.e. missing one or more pills) increases the HFI and may allow ovulation during this week. Missing 1 active pill before ovulation is effectively inhibited (achieved after taking 1 active pill daily x 7 consecutive days) may also allow ovulation during this week. If intercourse occurred during the day of pill omission or in the 5 days prior, consider EC.

**Box 2.** Missing fewer than 3 pills in a row during week 2 or 3 is the same as having a short HFI after achieving effective inhibition of ovulation during the preceding week (1 pill daily x 7 consecutive days). Therefore, efficacy is not expected to be reduced, although breakthrough bleeding may occur. Eliminating the HFI may reduce the risk of unintended pregnancy when pills are missed in week 3. Eliminating the HFI when pills are missed in week 2 is proposed to simplify this algorithm.

**Box 3.** Missing 3 or more pills in a row during week 3 is likely to impair contraceptive effectiveness, because the HFI comes immediately after week 3. Eliminating the HFI and using a back-up method until 7 consecutive days of pills are taken should reduce the risk of unintended pregnancy. EC can be considered if unprotected intercourse has occurred during the interval of missed pills up until 7 consecutive pills have been taken. The same recommendation is proposed for week 2 to simplify the algorithm.
RECOMMENDATIONS CONCERNING MISSED HORMONAL CONTRACEPTIVES

Instructions for missed hormonal contraception need to be simple and easy to understand and remember. In addition, it is helpful if they are available in a printed graphic format that the woman can refer to in the event of missed contraception. Figures 1 to 5 show the proposed new recommendations.

The recommendations are based on the following assumptions:

1. A missed dose of combined hormonal contraceptive is defined as either taking (oral contraceptives) or initiating (contraceptive patch or ring) the COC 24 hours or more after the scheduled time.

2. The HFI should not exceed seven days.

3. Delaying the start of a CHC by 24 hours or more or missing one or more doses of CHC during week one may increase the risk of unintended pregnancy.

4. Ovulation is effectively inhibited after seven days of consecutive use of combined hormonal contraceptives.

5. Back-up contraception should be used for the first seven consecutive days of combined hormonal contraceptive use when a method is initiated, unless it is initiated on the first day of menses.

6. Eliminating the HFI when one or more days of CHCs are missed in week two or week three will reduce the risk of unplanned pregnancy.
7. Detachment of the contraceptive patch, expulsion of the vaginal contraceptive ring, or delayed removal or application/insertion of the contraceptive patch or vaginal ring are also considered as missed or incorrect use of a combined hormonal contraceptive method.

8. Ovulation inhibitory levels of hormones are maintained with extended wear of the contraceptive patch up to nine days and of the vaginal ring up to 28 days.

9. There is likely to be considerable inter-individual variation in metabolism of contraceptive hormones and thus variation among individual women in their susceptibility to contraceptive failure after missed CHC.

10. Recommendations for progestin-only methods are similar to previous recommendations.

11. Emergency contraception may be indicated in certain circumstances. It is important for women and their caregivers to have all the necessary information to make reasonable judgements about when EC is indicated. The concept of “when in doubt, use it” should be supported.

Extended or Continuous Combined Hormonal Contraception

The SOGC recently published guidelines on continuous or extended combined hormonal contraception.\textsuperscript{84} Extended use of combined hormonal contraception refers to the use of CHC with planned but less frequent hormone-free intervals, while continuous use refers to the uninterrupted use of CHC with no planned hormone-free-intervals. Many think
that continuous or extended CHC regimens have the potential to increase contraceptive efficacy and contraceptive adherence by removing the need to transition between packs of pills. Studies have found that reducing or eliminating the HFI achieves greater ovulation and follicular suppression, and this has led to the hypothesis that these regimens may be more forgiving of missed doses than the standard regimen. Nevertheless, most randomized controlled trials have found similar pregnancy rates between continuous/extended regimens and conventional 28-day cyclic regimens. Three randomized controlled trials found no statistical difference in adherence between continuous or extended regimens and 28-day regimens.

When CHC is taken continuously, the HFI is omitted. When there is no HFI, there is no rebound of the HPO axis and thus no signal to drive ovarian follicular growth. Therefore, it is logical that for extended/continuous CHC use, seven days would need to be missed before the recommendations for missed CHCs would apply.

Once a woman has used extended/continuous CHC for more than 21 days consecutively, she may miss up to seven days of her method. At no time should the HFI exceed seven days. If the HFI exceeds seven days, instructions would be the same as for cyclic users who have missed/delayed CHC in the first week of use. In general, when a woman resumes her extended/continuous regimen of CHC after a HFI, she should follow the recommendations that are provided to cyclic users for missed/delayed CHC during the first 21 consecutive days of its use.

Repeated Omission of Hormonal Contraceptives

As previously discussed, contraceptive effectiveness depends on consistent and correct use of a contraceptive method; however, adherence can be a challenge. Numerous studies have shown high rates of inconsistent or incorrect hormonal contraceptive use. In contrast to the commonly held belief that adherence will improve with time, a study of COC users found that in the first three months of COC use, women’s compliance did not improve and they actually became less consistent at taking their pills over time.

Providing advice to women who repeatedly miss their hormonal contraception is a counselling challenge. The recommendations for missed CHC are based on the assumption that seven consecutive days of hormonal contraception are required to reliably inhibit ovulation. However, women who repeatedly miss their CHCs may miss them at various times in their cycle and in varying quantities and thus may never use hormonal contraception for seven consecutive days. In this case, a more cautious approach is suggested. If the woman has not used her contraceptive method for seven days consecutively and has failed to use back-up contraception during these seven days or has missed her CHCs on a number of occasions within the same cycle, back-up contraception should be highly recommended until the
method has been used for at least seven consecutive days. EC may be required.

Women who frequently miss pills, forget to change their patch or ring, or are unable to return reliably for DMPA injections every three months should consider alternative methods of contraception that are less compliance demanding.

CONCLUSION

On the basis of the available scientific evidence, it is difficult to make simple recommendations on the steps to take after CHCs are missed or used improperly. The recommendations become more complex when the newer CHC delivery systems (the contraceptive patch and ring) are included. These recommendations attempt to balance the evidence with the practicalities of being easy to use. They are meant to guide health care providers in providing informed, appropriate counselling in situations of imperfect CHC use without undermining the efficacy of the contraceptive method or overusing EC. The most effective means of reducing the risk of unintended pregnancy remains the correct and consistent use of all contraceptive methods to optimize their efficacy.

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