

## Questions for which the Working Group provided recommendations

1. When can a woman start combined oral contraceptives?
2. What can a woman do if she misses combined oral contraceptives?
3. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills?
4. When can a woman start combined injectable contraceptives?
5. When can a woman have repeat combined injectable contraceptive injections?
6. When can a woman start progestogen-only pills?
7. What can a woman do if she misses progestogen-only pills?
8. What can a woman do if she vomits after taking emergency contraceptive pills?
9. When can a woman start progestogen-only injectables – Depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
10. When can a woman have repeat progestogen-only injectables – DMPA or NET-EN?
11. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?
12. When can a woman start using an implant?
13. What can be done if a woman experiences menstrual abnormalities when using implants?
14. When can a copper-bearing IUD be inserted?
15. What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?
16. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?
17. What should be done if a woman using a copper-bearing IUD is found to be pregnant?
18. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
19. What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?
20. What examinations or tests should be done routinely before providing a method of contraception?
21. How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?
22. What follow-up is appropriate for combined oral contraceptive, progestogen-only pill, implant and IUD users?
23. How can a provider be reasonably sure that a woman is not pregnant?





When can a woman start combined oral contraceptives?

## 1. When can a woman start combined oral contraceptives (COCs)?

### Having menstrual cycles

- ◆ She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- ◆ She can also start COCs at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Amenorrhoeic

- ◆ She can start COCs at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Breastfeeding\*

- ◆ If she is more than 6 months postpartum and amenorrhoeic, she can start COCs as advised for other amenorrhoeic women.
- ◆ If she is more than 6 months postpartum and her menstrual cycles have returned, she can start COCs as advised for other women having menstrual cycles.

\* Women less than 6 weeks postpartum who are primarily breastfeeding should not use COCs. For women who are more than 6 weeks but less than 6 months postpartum and are primarily breastfeeding, use of COCs is not usually recommended unless other more appropriate methods are not available or not acceptable.

### Switching from another hormonal method

- ◆ She can start COCs immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- ◆ If her previous method was an injectable, she should start COCs when the repeat injection would have been given. No additional contraceptive protection is needed.

### Switching from a non-hormonal method (other than the IUD)

- ◆ She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
  - ◆ She can also start immediately or at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.
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### Switching from an IUD (including hormonal)

- ◆ She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- ◆ She can also start at any other time, if it is reasonably certain that she is not pregnant.
  - ◇ If she has been sexually active in this menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
  - ◇ If she has *not* been sexually active in this menstrual cycle and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
  - ◇ If she is amenorrhoeic or has irregular bleeding, she can start COCs as advised for other amenorrhoeic women.



#### Comments

The expert working group considered the risk of ovulation within the first 5 days of menstruation to be acceptably low. Suppression of ovulation was considered to be less reliable when starting COCs after day 5. Seven days of continuous COC use was deemed necessary to reliably prevent ovulation.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.



## Systematic review question

How does starting COCs on different days of the menstrual cycle affect contraceptive efficacy and compliance? **Level of evidence:** II-1; indirect.

### References from systematic review

1. Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? *British Medical Journal Clinical Research Ed* 1985;290:1474-5.
2. Smith SK, Kirkman RJ, Arce BB, McNeilly AS, Loudon NB, Baird DT. The effect of deliberate omission of Trinordiol or Microgynon on the hypothalamo-pituitary-ovarian axis. *Contraception* 1986;34:513-22.
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4. Killick S, Eyong E, Elstein M. Ovarian follicular development in oral contraceptive cycles. *Fertility & Sterility* 1987;48:409-13.
5. Yeshaya A, Orvieto R, Kauschansky A, Dicker D, Dekel A, Bar-Hava I et al. A delayed starting schedule of OCs: the effect on the incidence of breakthrough bleeding and compliance in women. *European Journal of Contraception & Reproductive Health Care* 1996;1:263-5.
6. Yeshaya A, Orvieto R, Kaplan B, Dicker D, Bar-Hava I, Bar J. Flexible starting schedule for oral contraception: effect on the incidence of breakthrough bleeding and compliance. *European Journal of Contraception & Reproductive Health Care* 1998;3:121-3.

### Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

How quickly is protection reliably established by COCs?

Does starting each pill pack on a specific day of the week increase consistent, correct and continued use of COCs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during COC use?





What can a woman do if she misses combined oral contraceptives?

## 2. What can a woman do if she misses COCs?

### Missed any one active (hormonal) pill (Days 1–21)

- ◆ She should:
  - ◇ Take the missed pill as soon as possible.
  - ◇ Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
  - ◇ Continue taking the pills as usual, one each day.
- ◆ She does not need any additional contraceptive protection.

### Started a pack 2 or more days late

- ◆ She should:
  - ◇ Start the new pack that day. (If she has chosen to start her packs on a particular day of the week, she can discard the missed pills so that she stays on her schedule).
  - ◇ Continue taking the pills as usual, one each day.
  - ◇ Abstain from sex or use additional contraceptive protection for the next 7 days.
- ◆ She may wish to consider the use of emergency contraception if appropriate.

### Missed any 2–4 of the first 7 active (hormonal) pills of the pack (Days 1–7)

- ◆ She should:
  - ◇ Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
  - ◇ Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
  - ◇ Continue taking the pills as usual, one each day.
  - ◇ Abstain from sex or use additional contraceptive protection for the next 7 days.
- ◆ She may wish to consider the use of emergency contraception if appropriate.

### Missed any 2–4 of the middle 7 active (hormonal) pills in a pack (Days 8–14)

- ◆ She should:
    - ◇ Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
    - ◇ Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
    - ◇ Continue taking the pills as usual, one each day.
  - ◆ She does not need any additional contraceptive protection.
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### Missed any 2–4 of the last 7 active (hormonal) pills in a pack (Days 15–21)

- ◆ She should:
  - ◇ Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
  - ◇ Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
  - ◇ Continue taking the active pills as usual, one each day.
  - ◇ Discard the inactive pills and go straight to the next pack.
- ◆ She does not need any additional contraceptive protection.

### Missed 5 or more active (hormonal) pills in a row in any week (Days 1–21)

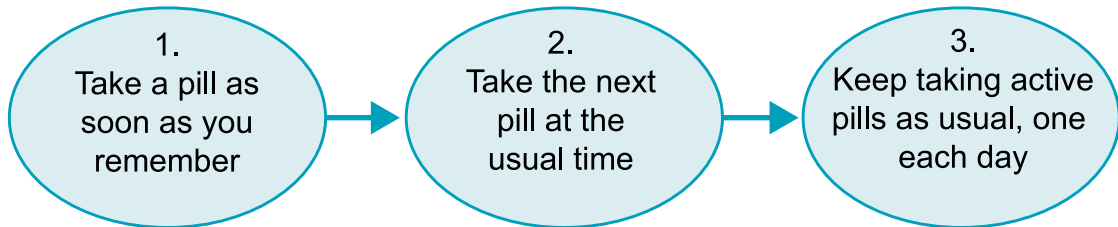
- ◆ She should:
  - ◇ Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
  - ◇ Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
  - ◇ Continue taking the active pills as usual, one each day.
  - ◇ Discard the inactive pills and go straight to the next pack.
  - ◇ Abstain from sex or use additional contraceptive protection for the next 7 days.
- ◆ She may wish to consider the use of emergency contraception if appropriate.

### Missed 1 or more inactive (non-hormonal) pills (Days 22–28 in 28-day pill packs)

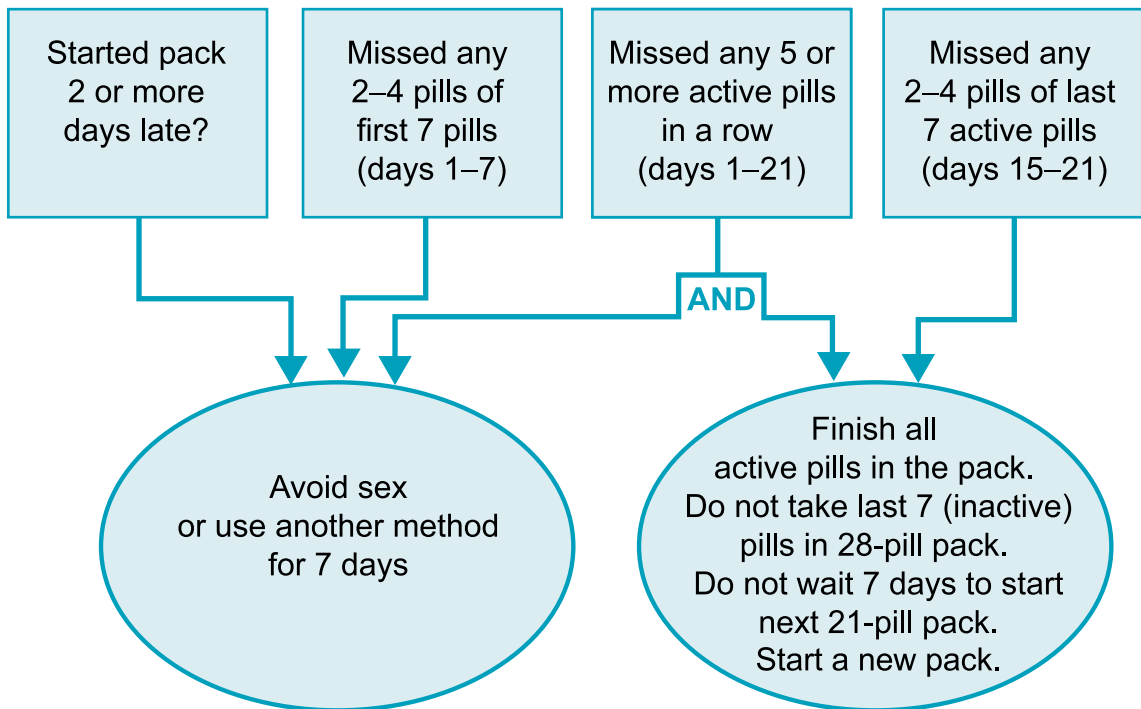
- ◆ She should:
    - ◇ Discard the missed inactive pill(s).
    - ◇ Continue taking the pills as usual, one each day.
    - ◇ Start a new pack as usual.
  - ◆ She does not need any additional contraceptive protection.
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# What to do if you miss one or more pills

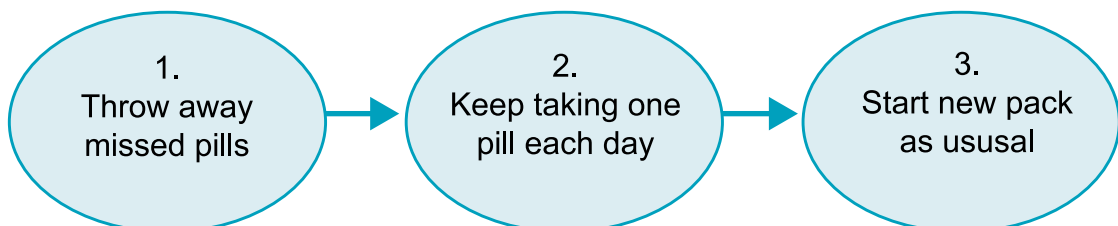
Every time you miss one or more active pills (days 1–21):



In these special cases, ALSO follow these special rules:



If you miss any of the 7 inactive pills (in a 28-pill pack only):





## Comments

The expert working group considered the inconsistent or incorrect use of pills to be a major reason for unintended pregnancy. Seven days of continuous COC use was deemed necessary to reliably prevent ovulation.

Many women (including those whose pill packs are marked with the days of the week) follow a pill-taking schedule that involves starting on a certain day of the week. When such a woman misses pills, it is necessary to discard the missed pills if she is to maintain her schedule. Other women may prefer not to discard missed pills, but they may have menses at other than expected intervals.

The following 3 principles underlie the expert working group's recommendations:

- 1) It is important to take an active pill as soon as possible when pills have been missed.
- 2) If pills are missed, the chance that pregnancy will occur depends not only on how many pills were missed, but also on *when* those pills were missed. The risk of pregnancy is greatest when pills are missed at the beginning or at the end of the active pills, i.e., the hormone-free interval is extended beyond the normal 7 days.
- 3) If pills are missed in the first week of the cycle (including starting late), or if many pills are missed (5 or more), the woman should abstain from sex or use additional contraceptive protection for the next 7 days.



## Systematic review question

What is the effect on contraceptive effectiveness when pills are missed on different days of the cycle? **Level of evidence:** I; indirect.

## References from systematic review

1. Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? *British Medical Journal Clinical Research Ed* 1985;290:1474-5.
2. van der Spuy ZM, Sohnius U, Pienaar CA, Schall R. Gonadotropin and estradiol secretion during the week of placebo therapy in oral contraceptive pill users. *Contraception* 1990;42:597-609.
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4. van Heusden AM, Fauser BC. Activity of the pituitary-ovarian axis in the pill-free interval during use of low-dose combined oral contraceptives. *Contraception* 1999;59:237-43.

5. Hamilton C.J., Hoogland H.J. Longitudinal ultrasonographic study of the ovarian suppressive activity of a low-dose triphasic oral contraceptive during correct and incorrect pill intake. *American Journal of Obstetrics & Gynecology* 1989;161:1159-62.
  6. Killick SR, Bancroft K, Oelbaum S, Morris J, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. *Advances in Contraception* 1990;6:33-40.
  7. Landgren BM, Diczfalusy E. Hormonal consequences of missing the pill during the first two days of three consecutive artificial cycles. *Contraception* 1984;29:437-46.
  8. Elomaa K, Rolland R, Brosens I, Moorrees M, Deprest J, Tuominen J et al. Omitting the first oral contraceptive pills of the cycle does not automatically lead to ovulation. *American Journal of Obstetrics & Gynecology* 1998;179:41-6.
  9. Landgren BM, Csemiczky G. The effect of follicular growth and luteal function of "missing the pill". A comparison between a monophasic and a triphasic combined oral contraceptive. *Contraception* 1991;43:149-59.
  10. Hedon B, Cristol P, Plauchut A, Vallon AM, Desachampst F, Taillant ML et al. Ovarian consequences of the transient interruption of combined oral contraceptives. *International Journal of Fertility* 1992;37:270-6.
  11. Letterie GS, Chow GE. Effect of "missed" pills on oral contraceptive effectiveness. *Obstetrics & Gynecology* 1992;79:979-82.
  12. Letterie GS. A regimen of oral contraceptives restricted to the periovulatory period may permit folliculogenesis but inhibit ovulation. *Contraception* 1998;57:39-44.
  13. Elomaa K, Lahteenmaki P. Ovulatory potential of preovulatory sized follicles during oral contraceptive treatment. *Contraception* 1999;60:275-9.
  14. Spona J, Elstein M, Feichtinger W, Sullivan H, Ludicke F, Muller U. Shorter pill-free interval in combined oral contraceptives decreases follicular development. *Contraception* 1996;54:71-7.
  15. Sullivan H, Furniss H, Spona J, Elstein M. Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60 microg) and ethinyl estradiol (15 microg) on ovarian activity. *Fertility & Sterility* 1999;72:115-20.
  16. Chowdhury V, Joshi UM, Gopalkrishna K, Betrabet S, Metha S, Saxena B. "Escape" ovulation in women due to the missing of low-dose combination oral contraceptive pills. *Contraception* 1980;22:241-7.
  17. Wang E, Shi S, Cekan SZ, Landgren BM, Diczfalusy E. Hormonal consequences of "missing the pill". *Contraception* 1982;26:545-66.
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  19. Morris SE, Grume GV, Cameron ED, Buckingham MS, Everitt JM, Elstein M. Studies on low dose oral contraceptives: plasma hormone changes in relation to deliberate pill ('Microgynon 30') omission. *Contraception* 1979;20:61-9.
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## Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

How do the number and timing of missed COCs affect the risk of pregnancy, and are there substantial variations among individuals or populations?

How well do COC users understand and follow pill-taking instructions, including use of back-up contraception after missed pills?

Would shortening the hormone-free interval significantly decrease pregnancy rates?

Are regimens for missed 30-35 mcg ethinylestradiol COCs appropriate for COCs with lower doses of estrogen, especially with regard to the need for back-up protection?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during COC use?

What are the most effective counselling and other communication strategies for maximizing consistent, correct and continued use of COCs?







What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills ?

### 3. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives (COCs) or progestogen-only pills (POPs)?

Vomiting (for any reason) within 2 hours after taking an active (hormonal) pill.

- ◆ She should take another active pill.

Severe vomiting or diarrhoea for more than 24 hours.

- ◆ She should continue taking pills (if she can) despite her discomfort.
- ◆ If severe vomiting or diarrhoea continues for 2 or more days, she should follow the procedures for missed pills.



#### Comments

The expert working group found no direct evidence to address this question but considered the effects of vomiting or diarrhoea to be similar to those of missing pills.



### Systematic review question

How does vomiting or diarrhoea during COC or POP use affect contraceptive effectiveness?

**Level of evidence:** I; indirect.

### References from systematic review

1. Elomaa K, Ranta S, Tuominen J, Lahteenmaki P. Charcoal treatment and risk of escape ovulation in oral contraceptive users. *Human Reproduction* 2001;16:76-81.



#### Key unresolved issues

Is the effect of severe vomiting and/or diarrhoea sufficient to warrant use of the missed pill regimen?





When can a woman start combined injectable contraceptives?

## 4. When can a woman start combined injectable contraceptives (CICs)?

Note: These recommendations are based on information on combined injectables containing medroxyprogesterone acetate and estradiol cypionate (Cyclofem/Lunelle) but also apply to combined injectables containing norethisterone enantate and estradiol valerate (Mesigyna).

### Having menstrual cycles

- ◆ She can have the first CIC injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- ◆ She can also have the first injection at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Amenorrhoeic

- ◆ She can have the first injection at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Breastfeeding\*

- ◆ If she is more than 6 months postpartum and amenorrhoeic, she can start CICs as advised for other amenorrhoeic women.
- ◆ If she is more than 6 months postpartum and her menstrual cycles have returned, she can have her first injection as advised for other women having menstrual cycles.

\* Women less than 6 weeks postpartum who are primarily breastfeeding should not use CICs. For women who are more than 6 weeks but less than 6 months postpartum and are primarily breastfeeding, use of CICs is not usually recommended unless other more appropriate methods are not available or not acceptable.

### Switching from another hormonal method

- ◆ She can have the first injection immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- ◆ If her previous method was another injectable, she should have the CIC injection when the repeat injection would have been given. No additional contraceptive protection is needed.

### Switching from a non-hormonal method (other than the IUD)

- ◆ She can have the first injection immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
  - ◆ If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.
  - ◆ If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.
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### Switching from an IUD (including hormonal)

- ◆ She can have the first injection within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- ◆ She can also start at any other time, if it is reasonably certain that she is not pregnant.
  - ◇ If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
  - ◇ If she has *not* been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- ◆ If she is amenorrhoeic or has irregular bleeding, she can have the injection as advised for other amenorrhoeic women.



#### Comments

The expert working group considered that an injection given up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.



## Systematic review question

How does starting CICs on different days of the menstrual cycle affect contraceptive effectiveness? **Level of evidence:** I; indirect.

### References from systematic review

1. Petta CA, Hays M, Brache V, Massai R, Hua Y, Alvarez Sanchez F et al. Delayed first injection of the once-a-month injectable contraceptive containing 25 mg of medroxyprogesterone acetate and 5 mg E(2) cypionate: effects on ovarian function. *Fertility & Sterility* 2001;75:744-8.

### Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.

### Key unresolved issues

How quickly is protection reliably established by CICs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during CIC use?





When can a woman have repeat combined injectable contraceptive injections?

## 5. When can a woman have repeat CIC injections?

Note: These recommendations are based on information on combined injectables containing medroxyprogesterone acetate and estradiol cypionate (Cyclofem/Lunelle) but also apply to combined injectables containing norethisterone enantate and estradiol valerate (Mesigyna).

### Reinjection interval

- ◆ Provide repeat CIC injections every 4 weeks.

### Early for an injection

- ◆ When the reinjection interval cannot be adhered to, the repeat injection can be given up to 7 days early but may disrupt bleeding patterns.

### Late for an injection

- ◆ When the reinjection interval cannot be adhered to, the repeat injection can be given up to 7 days late without requiring additional contraceptive protection.
- ◆ If she is more than 7 days late for an injection, she can have the injection, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days. She may wish to consider the use of emergency contraception if appropriate.



### Comments

The risk of ovulation was considered by the expert working group to be minimal during the early part of the second month after the last injection.



## Systematic review question

How soon after the last CIC injection do ovulation and fertility return?

**Level of evidence:** II-3; indirect.

### References from systematic review

1. Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Pharmacokinetic and pharmacodynamic investigations with monthly injectable contraceptive preparations. *Contraception* 1985;31:453-69.
2. Garza-Flores J. A multi-centered pharmacokinetic, pharmacodynamic study of once-a-month injectable contraceptives. I. Different doses of HRP112 and of DepoProvera. *Contraception* 1987;36:441-57.
3. Bassol S, Hernandez C, Nava MP, Trujillo AM, Luz de la Cruz D. A comparative study on the return to ovulation following chronic use of once-a-month injectable contraceptives. *Contraception* 1995;51:307-11.
4. Rahimy MH, Ryan KK. Lunelle monthly contraceptive injection (medroxyprogesterone acetate and estradiol cypionate injectable suspension): assessment of return of ovulation after three monthly injections in surgically sterile women. *Contraception* 1999;60:189-200.
5. Bahamondes L, Lavin P, Ojeda G, Petta CA, Diaz J, Maradiegue E et al. Return to fertility after discontinuation of the once a month injectable contraceptive Cyclofem. *Contraception* 1997;55:307-10.



### Key unresolved issues

What is the maximum time between injections that maintains effectiveness of CICs?

What are the most effective counselling and communication strategies for increasing adherence to CIC reinjection intervals?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during CIC use?







When can a woman start progestogen-only pills?

## 6. When can a woman start progestogen-only pills?

### Having menstrual cycles

- ◆ She can start progestogen-only pills (POPs) within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- ◆ She can also start POPs at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days.

### Amenorrhoeic

- ◆ She can start POPs at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 2 days.

### Breastfeeding\*

- ◆ If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can start POPs at any time. If she is fully or nearly fully breastfeeding no additional contraceptive protection is needed.
- ◆ If she is more than 6 weeks postpartum and her menstrual cycles have returned, she can start POPs as advised for other women having menstrual cycles.

\* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POPs is not usually recommended unless other more appropriate methods are not available or not acceptable.

### Switching from another hormonal method

- ◆ She can start POPs immediately, if she has been using her hormonal method consistently and correctly, or if it is otherwise reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- ◆ If her previous method was an injectable, she should start POPs when the repeat injection would have been given. No additional contraceptive protection is needed.

### Switching from a non-hormonal method (other than the IUD)

- ◆ She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
  - ◆ She can also start immediately or at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days.
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### Switching from an IUD (including hormonal)

- ◆ She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- ◆ She can also start at any other time, if it is reasonably certain that she is not pregnant.
  - ◇ If she has been sexually active in this menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
  - ◇ If she has *not* been sexually active in this menstrual cycle and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- ◆ If she is amenorrhoeic or has irregular bleeding, she can start POPs as advised for other amenorrhoeic women.



#### Comments

The expert working group considered the risk of ovulation when starting POPs within the first 5 days of menstruation to be acceptably low. Suppression of ovulation was considered to be less reliable when starting after day 5. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.



## Systematic review question

How does starting POPs on different days of the menstrual cycle affect contraceptive efficacy?

### References from systematic review

No studies identified.

### Other key references

1. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. *Contraception* 1994;50(6 Suppl 1):S1-195.
2. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
3. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

How quickly is protection reliably established by POPs?

Does starting each pill pack on a specific day of the week increase consistent, correct and continued use of POPs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POP use?





What can a woman do if she misses progestogen-only pills?

## 7. What can a woman do if she misses progestogen-only pills (POPs)?

### Having menstrual cycles (including those who are breastfeeding) AND missed one or more pills by more than 3 hours

- ◆ She should:
  - ◇ Take 1 pill as soon as possible.
  - ◇ Continue taking the pills as usual, one each day.
  - ◇ Abstain from sex or use additional contraceptive protection for the next 2 days.
- ◆ She may wish to consider the use of emergency contraception if appropriate.

### Breastfeeding and amenorrhoeic AND missed one or more pills by more than 3 hours

- ◆ She should:
  - ◇ Take 1 pill as soon as possible.
  - ◇ Continue taking the pills as usual, one each day.
- ◆ If she is less than 6 months postpartum, no additional contraceptive protection is needed.



### Comments

The expert working group considered the inconsistent or incorrect use of pills to be a major reason for unintended pregnancy and highlighted the importance of taking POPs at approximately the same time each day. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus.



## Systematic review question

What is the effect on contraceptive effectiveness when progestogen-only pills are missed on different days of the cycle?

## References from systematic review

No studies identified.

## Other key references

1. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. *Contraception* 1994;50(6 Suppl 1):S1-195.



### Key unresolved issues

How do the number and timing of missed POPs affect the risk of pregnancy?

When POPs are missed, is 48 hours of backup fully sufficient to re-establish contraceptive protection, and do requirements for back-up contraception vary depending on the number of missed pills?

How well do POP users understand and follow pill-taking instructions, including use of back-up contraception after missed pills?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POP use?

What are the most effective counselling and communication strategies for maximizing consistent, correct and continued use of POPs?







What can a woman do if she vomits after taking emergency contraceptive pills?

## 8. What can a woman do if she vomits after taking emergency contraceptive pills (ECPs)?

### Vomiting within 2 hours after taking a dose of pills

- ◆ She should take another ECP dose as soon as possible. If the ECPs are combined estrogen-progestogen pills (COCs), she may want to use an anti-emetic before taking the second dose.
- ◆ If vomiting continues, a repeat ECP dose can be given vaginally.



### Comments

The expert working group noted that progestogen-only ECPs are less likely to cause nausea and vomiting than are combined estrogen-progestogen ECPs.



## Systematic review question

How does vomiting or diarrhoea during ECP use affect contraceptive effectiveness?

### References from systematic review

No studies identified.



### Key unresolved issues

Does vomiting within 2 hours after taking ECPs result in a meaningful decrease in effectiveness?





When can a woman start progestogen-only injectables – DMPA or NET-EN?

## 9. When can a woman start progestogen-only injectables – DMPA or NET-EN?

Note: These recommendations are based on information on an injectable containing depot medroxyprogesterone acetate (DMPA) but apply also to norethisterone enantate (NET-EN).

### Having menstrual cycles

- ◆ She can have the first progestogen-only injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- ◆ She can also have the first injection at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Amenorrhoeic

- ◆ She can have the first injection at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Breastfeeding\*

- ◆ If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have her first injection at any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- ◆ If she is more than 6 weeks postpartum and her menstrual periods have returned, she can have her first injection as advised for other women having menstrual cycles.

\* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POIs is not usually recommended unless other more appropriate methods are not available or not acceptable.

### Switching from another hormonal method

- ◆ She can have the first injection immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- ◆ If her previous method was another injectable, she should have the progestogen-only injection when the repeat injection would have been given. No additional contraceptive protection is needed.

### Switching from a non-hormonal method (other than the IUD)

- ◆ She can have the first injection immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
    - ◇ If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.
    - ◇ If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.
-

### Switching from an IUD (including hormonal)

- ◆ She can have the first injection within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- ◆ She can also start at any other time, if it is reasonably certain that she is not pregnant.
  - ◇ If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
  - ◇ If she has *not* been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- ◆ If she is amenorrhoeic or has irregular bleeding, she can have the injection as advised for other amenorrhoeic women.



#### Comments

The expert working group considered that an injection given up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for progestogen-only injectables to exert such an effect was uncertain.



## Systematic review question

How does starting progestogen-only injectables on different days of the menstrual cycle affect contraceptive effectiveness? **Level of evidence:** II-1; indirect.

### References from systematic review

1. Siriwongse T, Snidvongs W, Tantayaporn P, Leepipatpaiboon S. Effect of depo-medroxyprogesterone acetate on serum progesterone levels when administered on various cycle days. *Contraception* 1982;26:487-93.
2. Petta CA, Faundes A, Dunson TR, Ramos M, DeLucio M, Faundes D et al. Timing of onset of contraceptive effectiveness in Depo-Provera users: Part I. Changes in cervical mucus. *Fertility & Sterility* 1998;69:252-7.
3. Petta CA, Faundes A, Dunson TR, Ramos M, DeLucio M, Faundes D et al. Timing of onset of contraceptive effectiveness in Depo-Provera users. II. Effects on ovarian function. *Fertility & Sterility* 1998; 70:817-20.

### Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.

### Key unresolved issues

How quickly is protection reliably established by injections of DMPA and NET-EN?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POI use?





When can a woman have repeat  
progestogen-only injectables – DMPA or NET-EN?

## 10. When can a woman have repeat progestogen-only injectables – DMPA or NET-EN ?

### Reinjection interval

- ◆ Provide repeat DMPA injections every 3 months.
- ◆ Provide repeat NET-EN injections every 2 months.

### Early for an injection

- ◆ The repeat injection for DMPA and NET-EN can be given up to 2 weeks early.

### Late for an injection

- ◆ The repeat injection for DMPA and NET-EN can be given up to 2 weeks late without requiring additional contraceptive protection.
- ◆ If she is more than 2 weeks late for a DMPA or NET-EN repeat injection, she can have the injection, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days. She may wish to consider the use of emergency contraception if appropriate.

### Switching between DMPA and NET-EN

- ◆ Using DMPA and NET-EN injections interchangeably is not recommended.
- ◆ If it becomes necessary to switch from one to the other, the switch should be made at the time the repeat injection would have been given.

### For a repeat POI when the previous injectable type and/or timing of injection is unknown

- ◆ She can have the injection if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- ◆ She may wish to consider the use of emergency contraception if appropriate.

#### ◆ Comments

The expert working group considered the risk of ovulation to be minimal within 2 weeks following the time for a repeat injection (3 months for DMPA and 2 months for NET-EN).

The mechanisms of action, the medical eligibility criteria, and the side-effects of DMPA and NET-EN are similar. Therefore it is safe to stop using one and start using the other.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for progestogen-only injectables to exert such an effect was uncertain.

## Systematic review question

How soon after the last injection of a progestogen-only injectable do ovulation and fertility return? **Level of evidence:** II-3; indirect.

### References from systematic review

1. Pardthaisong T. Return of fertility after the use of the injectable contraceptive Depo Provera: Updated data analysis. *Journal of Biosocial Science* 1984;16:23-34.
2. Anonymous. ICMR (Indian Council of Medical Research) Task Force on Hormonal Contraception. Return of fertility following discontinuation of an injectable contraceptive—norethisterone oenanthate (NET-EN) 200 mg dose. *Contraception* 1986;34:573-82.
3. Ortiz A, Hiroi M, Stanczyk FZ, Goebelsmann U, Mishell DR. Serum medroxyprogesterone acetate (MPA) concentrations and ovarian function following intramuscular injection of Depo-MPA. *Journal of Clinical Endocrinology and Metabolism* 1977;44:32-8.
4. Fotherby K, Saxena B, Shrimanker K, Hingorani V, Takker D, Diczfalusy E et al. A preliminary pharmacokinetic and pharmacodynamic evaluation of depot-medroxyprogesterone acetate and norethisterone oenanthate. *Fertility & Sterility* 1980;34:131-9.
5. Bassol S, Garza-Flores J, Cravioto MC, Diaz-Sanchez V, Fotherby K, Lichtenberg R et al. Ovarian function following a single administration of depo-medroxy progesterone acetate (DMPA) at different doses. *Fertility & Sterility* 1984;42:216-22.
6. Lan PT, Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Return of ovulation following a single injection of depo-medroxyprogesterone acetate: a pharmacokinetic and pharmacodynamic study. *Contraception* 1984;29:1-18.
7. Saxena BN, Dusitsin N, Tankeyoon M, Chaudhury RR. Return of ovulation after the cessation of depot-medroxy progesterone acetate treatment in Thai women. *Journal of the Medical Association of Thailand* 1980;63:66-9.
8. Garza-Flores J, Cardenas S, Rodriguez V, Cravioto MC, Diaz-Sanchez V. Return to ovulation following the use of long-acting injectable contraceptives: a comparative study. *Contraception* 1985;31:361-6.



### Key unresolved issues

How common is switching between DMPA and NET-EN and why does switching occur?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during use of progestogen-only injectables?

What is the maximum time between injections that maintains effectiveness of progestogen-only injectables?

What are the most effective counselling and other communication strategies for increasing adherence to reinjection intervals for progestogen-only injectables?







What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?

## 11. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?

### Amenorrhoea

- ◆ Amenorrhoea does not require any medical treatment. Counselling is sufficient.
- ◆ If she still finds amenorrhoea unacceptable, discontinue the injectable. Help her choose another method.

### Spotting or light bleeding

- ◆ Spotting or light bleeding is common during POI use, particularly in the first injection cycle, and is not harmful.
- ◆ In women with persistent spotting or bleeding, or women with bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
- ◆ If STI or pelvic inflammatory disease (PID) is diagnosed, she can continue her injections while receiving treatment, and be counselled on condom use.
- ◆ If no gynaecologic problems are found, and she finds the bleeding unacceptable, discontinue the injectable. Help her choose another method.

### Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

- ◆ Explain that heavy or prolonged bleeding is common in the first injection cycle.
- ◆ If heavy or prolonged bleeding persists, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
- ◆ If the bleeding becomes a threat to the health of the woman, or it is not acceptable to her, discontinue the injectable. Help her choose another method.
- ◆ To prevent anaemia, provide an iron supplement and/or encourage foods containing iron.



### Comments

The expert working group noted that menstrual abnormalities are common with use of POIs and that counselling about such abnormalities before initiation of POI use is essential to alleviate concerns and encourage continuation of the method.

The group reviewed the limited available data regarding treatment and determined that treatment for light or heavy bleeding with estrogens or non-steroidal anti-inflammatory drugs (NSAIDs) is likely to be of short-term or no benefit.



## Systematic review question

What is the evidence for effective treatment regimens for bleeding abnormalities during POI use? **Level of evidence:** I; direct.

### References from systematic review

1. Parker RA, McDaniel EB. The use of quinesterol for the control of vaginal bleeding irregularities caused by DMPA. *Contraception* 1980;22:1-7.
2. Sapire KE. A study of bleeding patterns with two injectable contraceptives given post-partum and the effect of two nonhormonal treatments. *Advances in Contraception* 1991;7:379-87.
3. Said S, Sadek W, Rocca M, Koetsawang S, Kirwat O, Piya-Anant M. Clinical evaluation of the therapeutic effectiveness of ethinyl oestradiol and oestrone sulphate on prolonged bleeding in women using depot medroxyprogesterone acetate for contraception. World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Long-acting Systemic Agents for Fertility Regulation. *Human Reproduction* 1996;11:1-13.



### Key unresolved issues

What are the mechanisms underlying progestogen-only injectable-associated bleeding abnormalities and how can they best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?







When can a woman start using an implant?

## 12. When can a woman start using an implant?

Note: These recommendations are based on information from, and relate to, approved levonorgestrel implants (Norplant and Jadelle). The extent to which they apply to etonogestrel implants is not known. The product labelling for an etonogestrel implant (Implanon) states that the implant should be inserted between days 1–5, but at the latest on day 5 of the woman's natural menstrual cycle.

### Having menstrual cycles

- ◆ She can have the implant inserted within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- ◆ She can also have the implant inserted at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Amenorrhoeic

- ◆ She can have the implant inserted at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Breastfeeding\*

- ◆ If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have the implant inserted at any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- ◆ If she is more than 6 weeks postpartum and her menstrual cycles have returned, she can have the implant inserted as advised for other women having menstrual cycles.

\* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of progestogen-only implants is not usually recommended unless other more appropriate methods are not available or not acceptable.

### Switching from another hormonal method

- ◆ The implant can be inserted immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
  - ◆ If her previous method was an injectable, she should have the implant inserted when the repeat injection would have been given. No additional contraceptive protection is needed.
-

### Switching from a non-hormonal method (other than the IUD)

- ◆ She can have the implant inserted immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
  - ◇ If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.
  - ◇ If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

### Switching from an IUD (including hormonal)

- ◆ She can have the implant inserted within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- ◆ She can also start at any other time, if it is reasonably certain that she is not pregnant.
  - ◇ If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
  - ◇ If she has *not* been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- ◆ If she is amenorrhoeic or has irregular bleeding, she can have the implant inserted as advised for other amenorrhoeic women.



#### Comments

The expert working group considered that an implant inserted up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for levonorgestrel implants to exert such an effect was uncertain.



## Systematic review question

How does starting implants on different days of the cycle affect contraceptive effectiveness?  
**Level of evidence:** II-3; indirect.

### References from systematic review

1. Brache V, Alvarez F, Faundes A, Cochon L, Thevenin F. Effect of preovulatory insertion of Norplant implants over luteinizing hormone secretion and follicular development. *Fertility & Sterility* 1996;65:1110-4.
2. Dunson TR, Blumenthal PD, Alvarez F, Brache V, Cochon L, Dalberth B et al. Timing of onset of contraceptive effectiveness in Norplant implant users. Part I. Changes in cervical mucus. *Fertility & Sterility* 1998;69:258-66.
3. Brache V, Blumenthal PD, Alvarez F, Dunson TR, Cochon L, Faundes A. Timing of onset of contraceptive effectiveness in Norplant implant users. II. Effect on the ovarian function in the first cycle of use. *Contraception* 1999;59:245-51.

### Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

How many days after the start of the menstrual cycle can etonogestrel implants be inserted and be effective during that cycle?

How quickly is protection reliably established by etonogestrel implants?

How quickly does fertility return once etonogestrel implants are removed?





What can be done if a woman experiences menstrual abnormalities when using implants?

### 13. What can be done if a woman experiences menstrual abnormalities when using implants?

Note: These recommendations are based on information from, and relate to, approved levonorgestrel implants (Norplant/Jadelle). The extent to which the treatment recommendations apply to etonogestrel implants (Implanon) is not known.

#### Amenorrhoea

- ◆ Amenorrhoea does not require any medical treatment. Counselling is sufficient.
- ◆ If she still finds amenorrhoea unacceptable, the implant should be removed. Help her choose another contraceptive method.

#### Spotting or light bleeding

- ◆ Spotting or light bleeding is common during implant use, particularly in the first year, and is not harmful.
- ◆ In women with persistent spotting or bleeding, or women with bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
- ◆ If STI or PID is diagnosed, she can continue using implants while receiving treatment and be counselled on condom use.
- ◆ If no gynaecologic problems are found, and she desires treatment, non-hormonal and hormonal options are available:
  - ◇ Non-hormonal: non-steroidal anti-inflammatory drugs (NSAIDs)
  - ◇ Hormonal (if medically appropriate): low-dose COCs or ethinylestradiol
- ◆ If she does not desire treatment or the treatment is not effective, and she finds the bleeding unacceptable, the implants should be removed. Help her choose another method.

#### Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

- ◆ Exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
  - ◆ If no gynaecologic problems are found, and she desires treatment, non-hormonal and hormonal options are available:
    - ◇ Non-hormonal: non-steroidal anti-inflammatory drugs (NSAIDs)
    - ◇ Hormonal (if medically appropriate): COCs or ethinylestradiol
  - ◆ If she does not desire treatment or the treatment is not effective, and the bleeding becomes a threat to her health or is not acceptable to her, the implant should be removed. Help her choose another method.
-



## Comments

The expert working group noted that menstrual abnormalities are common with use of implants and that counselling about such abnormalities before initiation of implant use is essential to alleviate concerns and encourage continuation of the method.

The group reviewed the limited available data regarding treatment for light or heavy bleeding and determined that the following regimens are modestly effective:

- ◆ Non-hormonal methods: non-steroidal anti-inflammatory drugs (NSAIDs):
  - ◇ Ibuprofen – 800 mg 3 times a day for 5 days
  - ◇ Mefenamic acid – 500 mg 2 times a day for 5 days
- ◆ Hormonal methods:
  - ◇ Low-dose COCs – 30 µg ethinylestradiol 150 µg levonorgestrel a day for 21 days
  - ◇ COCs – 50 µg ethinylestradiol 250 µg levonorgestrel a day for 21 days
  - ◇ Ethinylestradiol – 50 µg for 20 days



## Systematic review question

What is the evidence for effective treatment regimens for bleeding abnormalities during implant use? **Level of evidence:** I; direct.

## References from systematic review

1. Diaz S, Croxatto HB, Pavez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of Norplant implants. *Contraception* 1990;42:97-109.
  2. Alvarez-Sanchez F, Brache V, Thevenin F, Cochon L, Faundes A. Hormonal treatment for bleeding irregularities in Norplant implant users. *American Journal of Obstetrics & Gynecology* 1996;174:919-22.
  3. Witjaksono J, Lau TM, Affandi B, Rogers PA. Oestrogen treatment for increased bleeding in Norplant users: preliminary results. *Human Reproduction* 1996;11:109-14.
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4. Boonkasemsanti W, Reinprayoon D, Pruksananonda K, Niruttisard S, Triratanachat S, Leepipatpaiboon S et al. The effect of transdermal oestradiol on bleeding patterns, hormonal profiles and sex steroid receptor distribution in the endometrium of Norplant users. *Human Reproduction* 1996;11:115-23.
5. Cheng L, Zhu H, Wang A, Ren F, Chen J, Glasier A. Once a month administration of mifepristone improves bleeding patterns in women using subdermal contraceptive implants releasing levonorgestrel. *Human Reproduction* 2000;15:1969-72.
6. Subakir SB, Setiadi E, Affandi B, Pringgoutomo S, Freisleben HJ. Benefits of vitamin E supplementation to Norplant users – in vitro and in vivo studies. *Toxicology* 2000;148: 173-8.
7. Kaewrudee S, Taneepanichskul S, Jaisamraun U, Reinprayoon D. The effect of mefenamic acid on controlling irregular uterine bleeding secondary to Norplant use. *Contraception* 1999;60:25-30.



### Key unresolved issues

What are the mechanisms underlying etonogestrel and levonorgestrel implant-associated bleeding abnormalities and how can they best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?





When can a copper-bearing IUD be inserted?

## 14. When can a copper-bearing IUD be inserted?

### Having menstrual cycles

- ◆ A woman can have a copper-bearing IUD inserted any time within the first 12 days after the start of menstrual bleeding, at her convenience, not just during menstruation. No additional contraceptive protection is needed.
- ◆ The copper-bearing IUD can also be inserted at any other time during the menstrual cycle, at her convenience, if it is reasonably certain that she is not pregnant. No additional contraceptive protection is needed.

### Switching from another method

- ◆ She can have the copper-bearing IUD inserted immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period. No additional contraceptive protection is needed.



### Comments

The expert working group determined that the probability of an existing pregnancy is extremely low before day 12 of the menstrual cycle, based on the extremely low risk of ovulation before day 8 and the 5-day emergency contraceptive effect of copper-bearing IUDs.

The recommendation of the expert working group for copper-bearing IUDs does not apply to hormonal IUDs because the emergency contraceptive effect of copper-bearing IUDs cannot be presumed to apply to hormonal IUDs. Further, in the event of pregnancy there may be added risks to the fetus due to the hormonal exposure.



## Systematic review question

How does inserting an IUD on different days of the menstrual cycle affect contraceptive safety, effectiveness, and compliance? **Level of evidence:** II-3; indirect.

### References from systematic review

1. White MK, Ory HW, Rooks JB, Roach RW. Intrauterine device termination rates and the menstrual cycle day of insertion. *Obstetrics & Gynecology* 1980;55:220-4.
2. Goldstuck ND. Pain response following insertion of a Gravigard (Copper-7) intrauterine contraceptive device in nulliparous women. *International Journal of Fertility* 1981;26:53-6.
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### Other key references

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2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

How quickly is protection reliably established for hormonal, copper-bearing IUDs?







What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?

## 15. What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?

### Spotting or light bleeding between menstrual periods

- ◆ Spotting or light bleeding is common during the first 3–6 months of copper-bearing IUD use. It is not harmful and usually decreases over time.
- ◆ If she desires treatment, a short course of non-steroidal anti-inflammatory drugs (NSAIDs) may be given during the days of bleeding.
- ◆ In women with persistent spotting and bleeding, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
- ◆ If no gynaecologic problems are found, and she finds the bleeding unacceptable, remove the IUD and help her choose another method.

### Heavier or longer menstrual bleeding than with normal menstrual periods

- ◆ Heavier and longer menstrual bleeding is common during the first 3–6 months of copper-bearing IUD use. Usually this is not harmful, and bleeding usually becomes lighter over time.
- ◆ The following treatment may be offered during the days of menstrual bleeding:
  - ◇ Non-steroidal anti-inflammatory drugs (NSAIDs)
  - ◇ Tranexamic acid (a haemostatic agent)Aspirin should NOT be used.
- ◆ Exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.
- ◆ If the bleeding continues to be very heavy or prolonged, especially if there are clinical signs of anaemia, or if she finds the bleeding unacceptable, remove the IUD and help her choose another method.
- ◆ To prevent anaemia, provide an iron supplement and/or encourage foods containing iron.



### Comments

The expert working group noted that menstrual abnormalities are common in the first 3–6 months of IUD use and concluded that treatment during the days of bleeding can sometimes be effective. The group indicated that aspirin should not be used to treat IUD-related menstrual bleeding because it may worsen the problem.



## Systematic review question

What is the evidence for effective treatment regimens for menstrual abnormalities during IUD use? **Level of evidence:** I; direct.

### References from systematic review

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  2. Topozada M, El-Attar A, El-Ayyat MA, Khamis Y. Management of uterine bleeding by PGs or their synthesis inhibitors. *Advances in Prostaglandin and Thromboxane Research* 1980;8:1459-63.
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  4. Yarkoni S, Anteby SO. Treatment of IUD related menorrhagia by indomethacin. *Clinical & Experimental Obstetrics & Gynecology* 1984;11:120-2.
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  8. Ylikorkala O, Viinikka L. Comparison between antifibrinolytic and antiprostaglandin treatment in the reduction of increased menstrual blood loss in women with intrauterine contraceptive devices. *British Journal of Obstetrics & Gynaecology* 1983;90:78-83.
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## Key unresolved issues

What are the mechanisms underlying IUD-associated bleeding abnormalities and how do they vary among hormonal and copper-bearing devices?

How can bleeding abnormalities with hormonal and copper-bearing devices best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?





What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?

## 16. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?

### Pelvic inflammatory disease (PID)

- ◆ Treat the PID using appropriate antibiotics.
- ◆ There is no need for removal of the copper-bearing IUD if she wishes to continue its use.
- ◆ If she does not want to keep the IUD, remove it *after* antibiotic treatment has been started.
- ◆ If the IUD is removed, she can consider using emergency contraceptive pills if appropriate.
- ◆ If the infection does not improve, generally the course would be to remove the IUD and continue antibiotics. If the IUD is not removed, antibiotics should also be continued. In both circumstances, her health should be closely monitored.
- ◆ Provide comprehensive management for STIs, including counselling about condom use.

### Comments

The expert working group concluded that removing the IUD provides no additional benefit once PID is being treated with appropriate antibiotics.

### Systematic review question

Should the IUD be removed or left in place if the IUD user is diagnosed with PID?

**Level of evidence:** I; direct.

### References from systematic review

1. Larsson B, Wennergren M. Investigation of a copper-intrauterine device (Cu-IUD) for possible effect on frequency and healing of pelvic inflammatory disease. *Contraception* 1977;15:143-9.
2. Söderberg G, Lindgren S. Influence of a intrauterine device on the course of an acute salpingitis. *Contraception* 1981;24:137-43.
3. Teisala K. Removal of an intrauterine device and the treatment of acute pelvic inflammatory disease. *Annals of Medicine* 1989;21:63-5.

### Key unresolved issues

Are the clinical course of PID and the long-term sequelae of PID (infertility, ectopic pregnancy and chronic pain) influenced by the decision to remove or not remove an IUD once PID is diagnosed and appropriately treated?



What should be done if a woman using a copper-bearing IUD is found to be pregnant?

## 17. What should be done if a woman using a copper-bearing IUD is found to be pregnant?

### Copper-bearing IUD user is found to be pregnant

- ◆ Exclude ectopic pregnancy.
- ◆ Explain that she is at risk of second trimester miscarriage, pre-term delivery and infection if the IUD is left in place. The removal of the IUD reduces these risks, although the procedure itself entails a small risk of miscarriage.
  - ◇ If she does not want to continue the pregnancy, and if therapeutic termination of pregnancy is legally available, inform her accordingly.
  - ◇ If she wishes to continue the pregnancy, make clear to her the increased risks of miscarriage, pre-term delivery and infection. Advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

### The IUD strings are visible or can be retrieved safely from the cervical canal

- ◆ Advise her that it is best to remove the IUD.
- ◆ If the IUD is to be removed, remove it by pulling on the strings gently.
- ◆ Explain that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.
- ◆ If she chooses to keep the IUD, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

### The IUD strings are not visible and cannot be safely retrieved

- ◆ Where ultrasound is available, it may be useful in determining the location of the IUD. If the IUD is not located, this may suggest that an expulsion of the IUD has occurred.
- ◆ If ultrasound is not possible or if the IUD is determined by ultrasound to be inside the uterus, make clear the risks and advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.



#### Comments

The expert working group concluded that removing the IUD improves pregnancy outcome if the IUD strings are visible or can be retrieved safely from the cervical canal, and that the risk of miscarriage, pre-term delivery and infection is substantial if the IUD is left in place. The expert working group did not address the effects of hormonal IUDs during pregnancy, but there may be added risks to the fetus due to the hormonal exposure.



## Systematic review question

What are the risks of adverse events if the IUD is removed or kept in place?

**Level of evidence:** II-3; indirect.

### References from systematic review

1. Tatum HJ, Schmidt FH, Jain AK. Management and outcome of pregnancies associated with the Copper T intrauterine contraceptive device. *American Journal of Obstetrics and Gynecology* 1976;126:869-79.
2. Koetsawang S, Rachawat D, Piya-Anant M. Outcome of pregnancy in the presence of intrauterine device. *Acta Obstetrica & Gynecologica Scandinavica* 1977;56:479-82.
3. Skjeldestad FE, Hammervold R, Peterson DR. Outcomes of pregnancy with an IUD in situ—a population based case-control study. *Advances in Contraception* 1988;4:265-70.
4. Dreishpoon IH. Complications of pregnancy with an intrauterine contraceptive device in situ. *American Journal of Obstetrics and Gynecology* 1975;121:412-3.



### Key unresolved issues

What are the pregnancy outcomes for women who become pregnant with an IUD in place and how do these outcomes differ between women who do and do not have the IUD removed ?







Should prophylactic antibiotics be provided for  
copper-bearing IUD insertion?

## 18. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?

### Routine IUD insertion

- ◆ Prophylactic antibiotics are generally not recommended for IUD insertion. However, in settings of both high prevalence of STIs and limited STI screening, such prophylaxis may be considered.
- ◆ Counsel the IUD user to watch for symptoms of PID, especially during the first month.

#### ◆ Comments

The expert working group determined that prophylactic antibiotics for IUD insertion provide little, if any, benefit for women at low risk for STI.

### Systematic review question

Does administration of prophylactic antibiotics decrease risk of infection during IUD insertion?

**Level of evidence:** I; direct

### References from systematic review

1. Grimes DA, Schulz KF. Prophylactic antibiotics for intrauterine device insertion: a metaanalysis of the randomized controlled trials. *Contraception* 1999;60:57-63.

#### ◆ Key unresolved issues

Are prophylactic antibiotics for IUD insertion of any benefit in preventing PID in high STI prevalence settings?



What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?

## 19. What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?

Note: The Standard Days Method (SDM) is a fertility-awareness based method in which users must avoid unprotected intercourse on days 8–19 of the menstrual cycle.

### SDM users who have 2 or more cycles outside the 26–32 day range, within any one year of use

- ◆ Advise her that the method may not be appropriate for her because of a higher risk of pregnancy. Help her consider another method.

### Initial provision of SDM for women whose menstrual cycles are within the 26–32 day range

- ◆ Provide another method of contraception for protection on days 8–19 if she desires. Give supplies in advance.

### SDM users who have unprotected intercourse between days 8–19

- ◆ Consider the use of emergency contraception if appropriate.



#### Comments

The expert working group concluded that the probability of pregnancy is increased when the menstrual cycle is outside the 26–32 day range, even if unprotected intercourse is avoided between days 8–19.



## Systematic review question

What is the effectiveness of the Standard Days Method for women with cycles shorter or longer than 26–32 days? **Level of evidence:** II-3, direct

### References from systematic review

1. Arevalo M, Sinau I, Jennings V. A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning. *Contraception* 2000;60:357-60.

### Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. *British Medical Journal* 2000;321:1259-62.
2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001;63:211-5.



### Key unresolved issues

What are the most effective counselling and other communication strategies for maximizing consistent, correct and continued use of fertility awareness-based methods?







What examinations or tests should be done routinely before providing a method of contraception?

## 20. What examinations or tests should be done routinely before providing a method of contraception?

The examinations or tests noted apply to persons who are presumed to be healthy.

Those with known medical problems or other special conditions may need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. The WHO document, *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*, 2nd edition, 2000, may be useful in such circumstances.

The following classification was considered useful in differentiating the applicability of the various examinations or tests:

**Class A** = essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

**Class B** = contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context. The risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

**Class C** = does not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relationship of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use may be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions.

Notes to the table:

- \* A WHO consultation held in Geneva, 9–10 October 2001, concluded that women at high risk of HIV infection should not use products that contain nonoxynol-9. Such women should avoid spermicides containing nonoxynol-9 and nonoxynol-9 lubricated condoms. Condoms without nonoxynol-9 lubrication are effective and widely available. Women at high risk of HIV infection should also avoid using diaphragms and cervical caps to which nonoxynol-9 is added. The contraceptive effectiveness of diaphragms and cervical caps without nonoxynol-9 has been insufficiently studied and should be assumed to be less than that of diaphragms and cervical caps with nonoxynol-9.
  - \*\* It is desirable to have blood pressure measurements taken before initiation of COCs, CICs, POPs, POIs, and implants. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy morbidity and mortality risks are high, and hormonal methods are among the few methods widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.
  - \*\*\* For procedures performed using local anaesthesia.
-

Specific situation	Combined oral contraceptives	Combined injectable contraceptives	Progestogen-only pills	Progestogen-only injectables	Implants	IUDs	Condoms	Diaphragm/ Cervical cap	Spermicides	Female sterilization	Vasectomy
Breast examination by provider	C	C	C	C	C	C	C	C	C	C	N/A
Pelvic/genital examination	C	C	C	C	C	A	C	A	C	A	A
Cervical cancer screening	C	C	C	C	C	C	C	C	C	C	N/A
Routine laboratory tests	C	C	C	C	C	C	C	C	C	C	C
Haemoglobin test	C	C	C	C	C	B	C	C	C	B	C
STI risk assessment: medical history and physical examination	C	C	C	C	C	A	C*	C*	C*	C	C
STI/HIV screening: laboratory tests	C	C	C	C	C	B	C*	C*	C*	C	C
Blood pressure screening	**	**	**	**	**	C	C	C	C	A	C***





How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?

## 21. How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?

### Initial and return visits

- ◆ Provide up to one year's supply of pills, depending upon the woman's desires and anticipated use.
- ◆ Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.
- ◆ The re-supply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.

### ◆ Comments

The expert working group concluded that restricting the number of cycles of pills can result in unwanted discontinuation of the method and increased risk of pregnancy.

### ◆ Key unresolved issues

What are the effects of providing different numbers of pill packs at initial and return visits on the consistent and continued use of COCs and POPs?



What follow-up is appropriate for COC, POP, implant and IUD users?

## 22. What follow-up is appropriate for COC, POP, implant and IUD users?

These recommendations address the minimum frequency of follow-up recommended for safe and effective use of the method. The recommendations refer to general situations and may vary for different users and different contexts. For example, women with specific medical conditions may need more frequent follow-up visits.

These methods do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

### COCs

- ◆ An annual follow-up visit is recommended.
- ◆ There are added benefits to a 3-month follow-up contact after initiation.
- ◆ Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

### POPs (not breastfeeding)

- ◆ No annual follow-up visit is required, but a follow-up contact after initiation is recommended at about 3 months.
- ◆ Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

### POPs (breastfeeding)

- ◆ No routine follow-up visit is required.
- ◆ Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.
- ◆ Advise the woman that when she either ceases or significantly reduces frequency of breastfeeding, she should return for further contraceptive advice and counselling.

### Implants

- ◆ No routine follow-up visit is required.
  - ◆ Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.
  - ◆ Advise the woman to return when it is time to have the implants removed.
-

## IUDs

- ◆ A follow-up visit is recommended after the first menses or 3–6 weeks following insertion.
- ◆ Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.
- ◆ For devices that have a high rate of expulsion, more frequent follow-up than above may be indicated.
- ◆ Advise her to return when it is time to have the IUD removed.



### Comments

The expert working group concluded that follow-up visits or contacts should include, at a minimum, counselling to address issues such as side-effects or other problems, correct and consistent use of the method, and protection against STIs. Additional assessment may be appropriate, e.g., pelvic examination to check for IUD displacement.



### Key unresolved issues

Does having a 3-month follow-up visit or contact (versus no scheduled early return) after initiating COC and POP use increase consistent, correct and continued use?







How can a provider be reasonably sure that a woman is not pregnant?

### 23. How can a provider be reasonably sure that a woman is not pregnant ?

The diagnosis of pregnancy is important. The ability to make this diagnosis early in pregnancy will vary depending on resources and settings. Highly reliable biochemical pregnancy tests are often extremely useful, but not available in many areas. Pelvic examination, where feasible, is reliable at approximately 8–10 weeks since the first day of the last menstrual period.

The provider can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria:

- ◆ has not had intercourse since last normal menses
  - ◆ has been correctly and consistently using a reliable method of contraception
  - ◆ is within the first 7 days after normal menses
  - ◆ is within 4 weeks postpartum for non-lactating women
  - ◆ is within the first 7 days post-abortion or miscarriage
  - ◆ is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum.
-