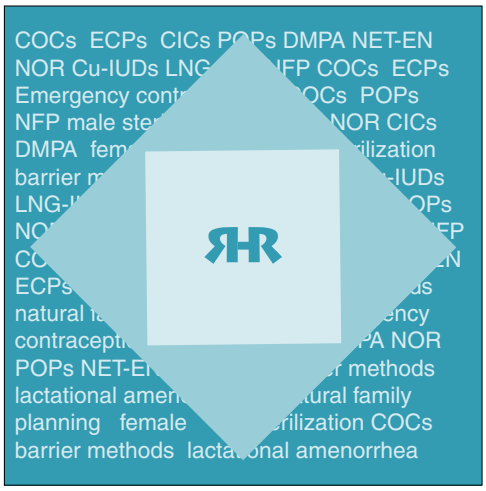
SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE

Second edition, 2004



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Representatives of 10 agencies and organizations, along with 19 other individuals, served as experts at the meeting that achieved consensus on these recommendations for contraceptive use. We would like to express our deep appreciation to all of them for contributing their time and expertise towards the consensus-building process.

The evidence on which the decisions in this document were based was in large part obtained from systematic reviews of the literature conducted and summarized by Dr KM Curtis, Dr ME Gaffield, Ms AP Mohllajee and Dr K Nanda. Dr Curtis, Ms Mohllajee and Dr Nanda also provided substantial support to the Secretariat. Dr H Peterson was overall coordinator of the project for the WHO Secretariat, which included Dr CE Chrisman, Ms K Church, Dr ME Gaffield, Dr C Huezo, Ms S Johnson, Ms G Lamptey, Dr E Marsh and Ms R Salem. Ms M Dunphy and Ms C Hamill were responsible for the design and layout of the publication. Ms M Ní Mhearáin was responsible for the cover design. We would like to express our deep appreciation to these individuals as well as to Drs L Edouard (United Nations Population Fund) and J Shelton (US Agency for International Development) for their strong support of this endeavour. We would also like to express our sincere appreciation to Dr Paul F.A.Van Look, Director, Department of Reproductive Health and Research, WHO, for his valuable support and detailed review of the publication.

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List of abbreviations

CIC	Combined injectable contraceptive
COC	Combined oral contraceptive
DMPA	Depot medroxyprogesterone acetate
ECP	Emergency contraceptive pill
HIV	Human immunodeficiency virus
IPPF	International Planned Parenthood Federation
IUD	Intrauterine device
LAM	Lactational amenorrhoea method
LNG IUD	Levonorgestrel-releasing IUD
NET-EN	Norethisterone enantate
NSAID	Nonsteroidal anti-inflammatory drug
PID	Pelvic inflammatory disease
POI	Progestogen-only injectable
POP	Progestogen-only pill
SDM	Standard days method
STI	Sexually transmitted infection
WHO	World Health Organization

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Executive summary

This document is one of two evidence-based cornerstones of the World Health Organization's (WHO) new initiative to develop and implement evidence-based guidelines for family planning. The first cornerstone, the Medical eligibility criteria for contraceptive use (third edition) published in 2004, provides guidance for who can use contraceptive methods safely. This document, the Selected practice recommendations for contraceptive use (second edition), provides guidance for how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. The recommendations contained in this document are the product of a process that culminated in an expert Working Group meeting held at the World Health Organization, Geneva, 13–16 April 2004. The meeting brought together 29 participants, including 10 agency representatives, from 15 countries to make selected practice recommendations for contraceptive use. The list of participants is provided at the end of the document. The recommendations were the expert Working Group's response to 33 specific questions selected by WHO, including 10 new questions for the second edition. These questions were selected based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from expert Working Group participants and family planning organizations/agencies.

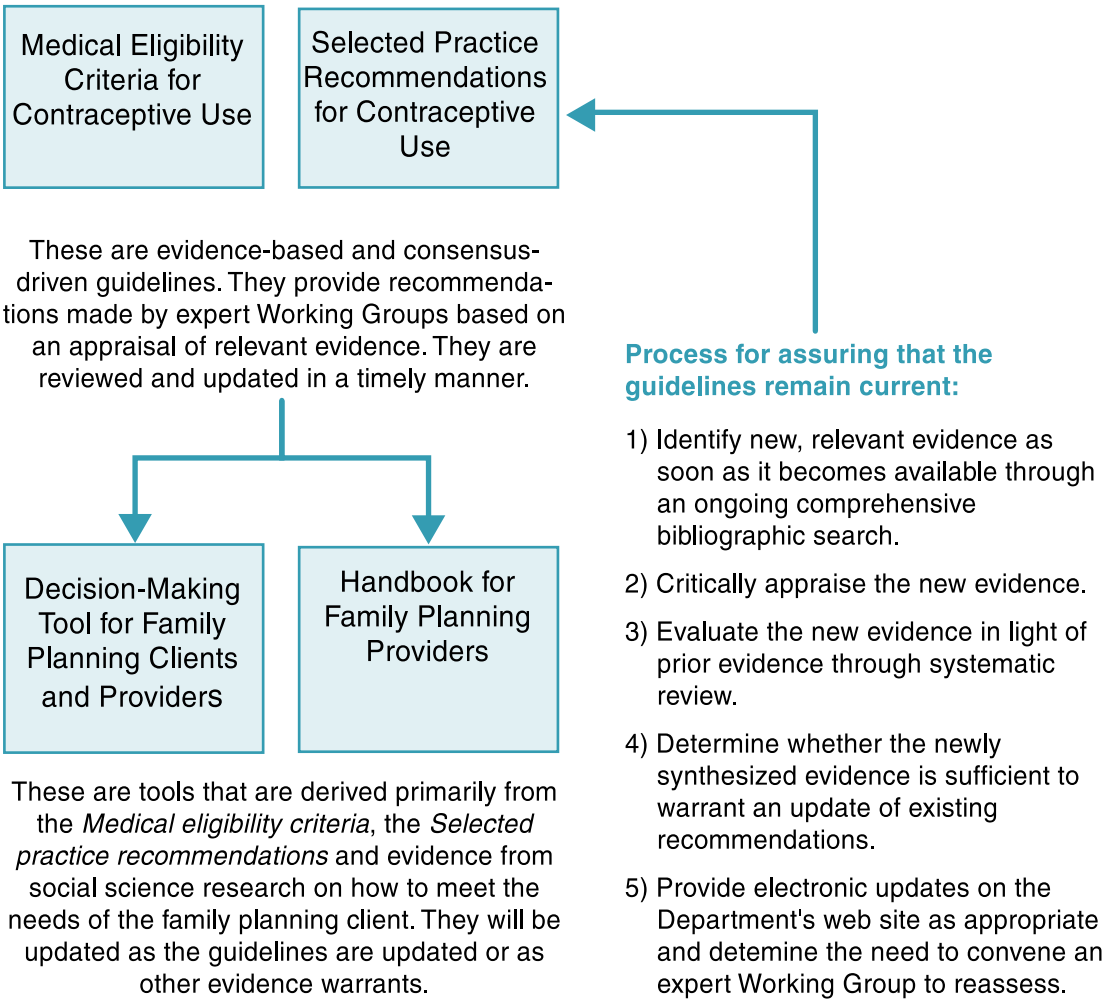
The document provides selected practice recommendations based on the best available evidence and is intended to be used by policy-makers, programme managers, and the scientific community. It aims to provide guidance to national family planning/reproductive health programmes in the preparation of guidelines for service delivery of contraceptives. The document covers the following family planning methods: combined oral contraceptives (COCs), combined injectable contraceptives (CICs), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel implants, emergency contraceptive pills (ECPs), copper-bearing intrauterine devices, levonorgestrel-releasing intrauterine devices (LNG IUDs), fertility awareness-based methods, and sterilization.

WHO will update and add to the recommendations in this document at appropriate intervals through expert Working Group meetings every three to four years and through input from its family planning Guidelines Steering Group on an as-needed basis. These recommendations will be made available on the WHO web site (www.who.int/reproductive-health). The web site will also provide additional information determined by WHO to be relevant to these recommendations, pending the next formal consensus expert Working Group meeting. Such updates may be particularly warranted for issues where the evidence base may change rapidly. WHO encourages research to address key unresolved issues for establishing selected recommendations for contraceptive use. WHO also invites comments and suggestions for improving this guidance.

Overview

In 1999, WHO reviewed its family planning guidance and determined that the creation of new evidence-based guidelines was warranted. Accordingly, WHO decided to expand its series of evidence-based family planning guidelines beginning with the second edition of the *Medical eligibility criteria for contraceptive use*, published in 2000. The first two cornerstones of this evidence-based series (Figure 1) are: the *Medical eligibility criteria for contraceptive use*, which provides guidance regarding "who" can use contraceptive methods safely, and this document, the *Selected practice recommendations for contraceptive use*, which provides guidance regarding "how" to safely and effectively use contraceptive methods. These two documents provide evidence-based guidance for choosing (the *Medical eligibility criteria for contraceptive use*) and for using (the *Selected practice recommendations for contraceptive use*) contraceptive methods. The third and fourth cornerstones, a decision-making tool for family planning clients and providers and a handbook for family planning providers, are being prepared as practical tools to improve the quality of family planning counselling and service delivery. These two tools incorporate the guidance contained in the *Medical eligibility criteria for contraceptive use* and the *Selected practice recommendations for contraceptive use*. All four cornerstones are best interpreted and used in a broader context of reproductive and sexual health care.

Figure 1. The four cornerstones of family planning guidance



Goal

The goal of this document is to provide policy- and decision-makers and the scientific community with a set of recommendations that can be used for developing or revising national guidelines on selected practice recommendations for contraceptive use.

This document addresses ongoing controversies and inconsistencies regarding how to maximize the effectiveness of contraceptive methods and how to manage their side-effects or other problems during use. The methods for which guidelines have been most inconsistent in the past include: combined oral contraceptives (COCs), combined injectable contraceptives (CICs), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel implants, emergency contraceptive pills (ECPs), copper-bearing intrauterine devices, levonorgestrel-releasing intrauterine devices (LNG IUDs), fertility awareness-based methods, and sterilization.

The document does not provide rigid guidelines but rather gives recommendations that provide a basis for rationalizing the provision and use of various contraceptives in view of the most up-to-date information available.

Because country situations and programme environments vary so greatly, it is inappropriate to set firm international guidelines on contraceptive use. However, it is expected that national programmes will use these guidance documents for updating or developing their own contraceptive guidelines in the light of their national health policies, needs, priorities and resources. The intent is to help improve access to, and quality of, family planning services. These improvements must be made within the context of users' informed choice and medical safety. Adaptation is not always an easy task and is best done by those well-acquainted with prevailing health conditions, behaviours, and cultures.

Background

Over the past 30 years, there have been significant advances in the development of new contraceptive technologies, including transitions from high-dose to low-dose combined oral contraceptives, and from inert to copper-bearing and levonorgestrel-releasing IUDs. In addition, combined injectable contraceptives, a combined hormonal patch and ring, and progestogen-only injectables and implants have been introduced. However, current policies and health care practices in some countries are based on scientific studies of contraceptive products that are no longer in wide use, on long-standing theoretical concerns that have never been substantiated, or on the personal preference or bias of service providers. These outdated policies or practices often result in limitations to both the quality of, and the access to, family planning services for clients. This document is intended to update the selected practice recommendations used in provision of contraceptives with a focus on hormonal contraceptives, IUDs, emergency contraception, fertility awareness-based methods, and sterilization.

Reproductive and sexual health care

> "Reproductive rights embrace certain human rights that are already recognized in national laws, international human rights documents and other relevant consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number and spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health." (para. 95, Beijing Platform for Action, 1995).

Reproductive and sexual health care including family planning services and information is recognized not only as a key intervention for improving the health of women and children but also as a human right. All individuals have the right to access, choice, and the benefits of scientific progress in the selection of family planning methods. A rights-based approach to the provision of contraceptives assumes a holistic view of clients, which includes taking into account clients' sexual and reproductive health care needs and considering all appropriate eligibility criteria and practice recommendations in helping clients choose and use a family planning method.

While this document primarily addresses selected practice recommendations for contraceptive use, medical eligibility criteria must be taken into account. In addition, social, behavioural, and other non-medical criteria, particularly client preference, must be considered. To provide contraceptive choices to clients in a way that respects and fulfils their human rights necessitates enabling clients to make informed choices for themselves. Women's choices, however, are often imposed or limited by direct or indirect social, economic and cultural factors. From the woman's point of view, choices are made in a particular time, societal and cultural context; choices are complex, multifactorial and subject to change. Decision-making for contraceptive methods usually requires the need to make trade-offs among the different methods, with advantages and disadvantages of specific contraceptive methods varying according to individual circumstances, perceptions, and interpretations.

Delivery of care in accordance with the client's human and reproductive rights is fundamental to quality of care. The development of international norms for medical eligibility criteria and practice recommendations for contraceptive use is only one aspect of improving the quality of reproductive health care. Many family planning programmes have included screening, treatment and follow-up procedures that reflect high standards of public health and clinical practice but should not be seen as eligibility requirements for specific contraceptive methods. These procedures include the screening and treatment of cervical cancer, anaemia and sexually transmitted infections (STIs), and the promotion of breastfeeding and cessation of smoking. Such procedures should be strongly encouraged if the human and material resources are available to carry them out, but they should not be seen as prerequisites for the acceptance and use of family planning methods when they are not necessary to establish eligibility for the use or continuation of a particular method.

Issues of service quality and access that affect method use

While this document chiefly addresses selected practice recommendations for contraceptive use, there are many other considerations in the appropriate provision of contraceptive methods, including the following service delivery criteria, which are universally relevant to the initiation and follow-up of all contraceptive method use.

a) Clients should be given adequate information in order to make an informed, voluntary choice of a contraceptive method. Information given to clients to help them make this choice should at least include: understanding of the relative effectiveness of the method; correct use of the method; how it works; common side-effects; health risks and benefits of the method; signs and symptoms that would necessitate a return to the clinic; information on return to fertility after discontinuing method use; and information on STI protection.

b) For those methods that require surgical approaches, insertion, fitting and/or removal by a trained health provider (sterilization, implants, IUDs, diaphragms, cervical caps), appropriately trained personnel in adequately equipped facilities must be available in order for those methods to be offered, and appropriate infection prevention procedures must be followed.

c) Adequate and appropriate equipment and supplies need to be maintained and held in stock (for example, contraceptive commodities, equipment and supplies for infection prevention procedures).

d) Service providers should be provided with guidelines (or client cards or other screening tools) to enable them to appropriately screen clients for conditions in which use of certain contraceptive methods would carry unacceptable health risks.

e) Service providers must be trained in providing family planning counselling to help clients make informed and voluntary decisions about their fertility. Counselling is a key element in quality of care and is also an important part of both initiation and follow-up visits and should respond to clients needs not only in contraception but also related to sexuality and the prevention of STIs, including infection with the human immunodeficiency virus (HIV).

Effectiveness of method

Contraceptive choice is in part dependent on the effectiveness of the contraceptive method in preventing unplanned pregnancy, which, in turn, is dependent for some methods not only on the protection afforded by the method itself, but also on how consistently and correctly it is used. Table 1 compares the percentage of women experiencing an unintended pregnancy during the first year of contraceptive method use when the method is used perfectly (consistently and correctly) and when it is used typically. Both consistent and correct use can vary greatly with such characteristics as age, income, users' desire to prevent or delay pregnancy, and culture. Methods that depend on consistent and correct use by clients have a wide range of effectiveness. Most men and women tend to be more effective users as they become more experienced with a method. However, programmatic aspects also have a profound effect on how effectively the method will be used.

Table 1. Percentage of women experiencing an unintended pregnancy during the first year of use and the percentage continuing use at the end of the first year. (United States of America).

Method (1)	% of women experiencing an unintended pregnancy within the first year of use: Typical use[1] (2)	Perfect use[2] (3)	% of women continuing use at one year[3] (4)
No method[4]	85	85	
Spermicides[5]	29	18	42
Withdrawal	27	4	43
Periodic abstinence	25		51
Calendar		9	
Ovulation method		3	
Sympto-thermal[6]		2	
Post-ovulation		1	
Cap[7]			
Parous women	32	26	46
Nulliparous women	16	9	57
Sponge			
Parous women	32	20	46
Nulliparous women	16	9	57
Diaphragm[7]	16	6	57
Condom[8]			
Female (Reality)	21	5	49
Male	15	2	53
Combined pill and minipill	8	0.3	68
Combined hormonal patch (Evra)	8	0.3	68
Combined hormonal ring (NuvaRing)	6	0.3	68
DMPA (Depo-Provera)	3	0.3	56
Combined injectable (Lunelle)	3	0.05	56
IUD			
ParaGard (copper T)	0.8	0.6	78
Mirena (LNG IUS)	0.1	0.1	81
LNG implants (Norplant, Norplant-2/Jadelle)	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

Emergency contraceptive pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.

Lactational amenorrhoea method: LAM is a highly effective, *temporary* method of contraception.[9]

Source: Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Stewart F, Nelson A, Cates W, Guest F, Kowal D. *Contraceptive Technology*. Eighteenth Revised Edition. New York, NY, Ardent Media, 2004.

Note: This table has been adapted from the source document by including generic as well as trade names and by modifying footnotes.

Notes:

[1] Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; see original source (Trussell J, 2004) cited above for the derivation of estimates for the other methods.

[2] Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason; see original source (Trussell J, 2004) cited above for the derivation of the estimates for each method.

[3] Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.

[4] The percentages becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

[5] Foams, creams, gels, vaginal suppositories, and vaginal film.

[6] Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory phase and basal body temperature in the post-ovulatory phase.

[7] With spermicidal cream or jelly.

[8] Without spermicides.

[9] However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

Special considerations

Return to fertility

The use of contraceptive methods, with the exception of male and female sterilization, does not result in an irreversible change in fertility. Return to fertility is immediate with all methods, with the exception of DMPA and NET-EN; the median delay in return to fertility with these methods is 10 and 6 months respectively from the date of the last injection, regardless of the duration of their use. Male and female sterilization should be regarded as permanent methods and all individuals and couples considering these methods should be counselled accordingly. No other methods result in permanent infertility.

STIs and contraception: dual protection

While the development of international norms for contraceptive provision is essential for quality of care in services, the social, cultural and behavioural context of each client must also be considered. In this regard, the problems of exposure to STIs, including HIV, deserve special consideration because of the equal importance of preventing pregnancy and preventing transmission of infection. When a risk of STI/HIV transmission exists, it is important that health care providers strongly recommend dual protection to all persons at significant risk, either through the simultaneous use of condoms with other methods or through the consistent and correct use of condoms alone for both pregnancy prevention and disease prevention. Women and men seeking contraceptive advice must always be reminded of the importance of condom use for preventing the transmission of STI/HIV and such use should be encouraged and facilitated where appropriate. Male latex condoms are proven to be highly effective against STI/HIV when used consistently and correctly.

Adolescents

In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices. Age alone does not constitute a medical reason for denying any method to adolescents. While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents (e.g. the use of progestogen-only injectables by those below 18 years), these concerns must be balanced against the advantages of avoiding pregnancy. It is clear that many of the same eligibility criteria that apply to older clients apply to young people. However, some conditions (e.g. cardiovascular disorders) that may limit use of some methods in older women do not generally affect young people since these conditions are rare in this age group. Social and behavioural issues should be important considerations in the choice of contraceptive methods by adolescents. For example, in some settings, adolescents are also at increased risk for STIs, including HIV. While adolescents may choose to use any one of the contraceptive methods available in their communities, in some cases, using methods that do not require a daily regimen may be more appropriate. Adolescents, married or unmarried, have also been shown to be less tolerant of side-effects and therefore have high discontinuation rates. Method choice may also be influenced by factors such as sporadic patterns of intercourse and the need to conceal sexual activity and contraceptive use. For instance, sexually active adolescents who are unmarried have very different needs from those who are married and want to postpone, space or limit pregnancy. Expanding the number of method choices offered can lead to improved satisfaction, increased acceptance and increased prevalence of contraceptive use. Proper education and counselling both before and at the time of method selection can help adolescents address their specific problems and make informed and voluntary decisions. Every effort should be made to prevent service and method cost from limiting the options available.

Clients with special needs

Medical eligibility criteria address contraceptive use by people with specific medical conditions. In addition, contraceptive provision to people with special needs requires further consideration. Individuals with a physical disability represent such a group. Decisions on appropriate contraception must take into account the nature of the disability, the expressed desires of the individual and the nature of the method. Decisions must be based on informed choice. Similar considerations should be given to individuals with mental disability or with serious psychiatric disease. Where the nature of the condition does not allow for informed choice, contraceptives should be provided only after full discussion with all parties including guardians or care-givers. The reproductive rights of the individual must be considered in any such decisions.

Table 2. List of questions proposed to the expert Working group

1. When can a woman start combined oral contraceptives (COCs)?
2. When can a woman start combined injectable contraceptives (CICs)?
3. When can a woman have repeat combined injectable contraceptive injections (CICs)?
4. When can a woman start progestogen-only pills (POPs)?
5. When can a woman start progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
6. When can a woman have repeat progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
7. When can a woman start using an implant?
8. How long can levonorgestrel implants be left in place?
9. When can a woman have a copper-bearing IUD inserted?
10. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
11. When can a woman have a levonorgestrel-releasing IUD (LNG IUD) inserted?
12. Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD (LNG IUD) insertion?
13. How can a woman take emergency contraceptive pills (ECPs)?
14. Can a woman receive an advance supply of emergency contraceptive pills (ECPs)?
15. When can a man rely on his vasectomy for contraception?
16. What can a Standard Days Method (SDM) user do if she has menstrual cycles outside the 26–32 day range?
17. What can a woman do if she misses combined oral contraceptives (COCs)?
18. What can a woman do if she misses progestogen-only pills (POPs)?
19. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives (COCs) or progestogen-only pills (POPs)?
20. What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills (ECPs)?
21. What can a woman do if she vomits after taking emergency contraceptive pills (ECPs)?
22. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable (POI) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
23. What can be done if a woman experiences menstrual abnormalities when using implants?

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

25. What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD (LNG IUD)?

26. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease (PID)?

27. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD) is diagnosed with pelvic inflammatory disease (PID)?

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

29. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD)is found to be pregnant?

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

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

32. What follow-up is appropriate for combined oral contraceptive (COCs), progestogen-only pill (POPs), implant and IUD users?

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

Method of work

This document is the product of a process that culminated in an expert Working Group meeting held at the World Health Organization, Geneva, 13–16 April 2004. The meeting brought together 29 participants from 15 countries to make selected practice recommendations for contraceptive use. (The list of participants is provided at the end of the document.) The expert Working Group was comprised of international family planning experts, including clinicians, epidemiologists, policy-makers, and programme managers. The expert Working Group also included experts in evidence identification and synthesis, as well as users of the guideline. A Guidelines Steering Group was established for this edition. All members of the expert Working Group were asked to declare conflicts of interests and none were declared.

The recommendations in this document are the expert Working Group's response to a review of 33 specific questions selected by WHO, based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from expert Working Group participants and family planning organizations/agencies. The list of questions that were posed to the expert Working Group is given in Table 2.

This document is a revision of the first edition of the Selected practice recommendations for contraceptive use published in 2002 following an expert Working Group meeting convened by WHO. That meeting was held in London, 3–6 October 2001, with the support of the International Planned Parenthood Federation (IPPF) to facilitate the participation of IPPF's International Medical Advisory Panel. The 2001 meeting brought together 33 participants from 16 countries to make selected practice recommendations based on the expert Working Group's response to 23 specific questions selected by WHO, based on the criteria noted above.

Using a system to identify new evidence on an ongoing basis (the Continuous Identification of Research Evidence or CIRE system, www.infoforhealth.org/cire/cire_pub.pl), WHO identified 7 recommendations from the first edition for which new evidence was available. WHO also decided to develop 10 new selected practice recommendations. Systematic reviews were conducted to appraise the complete body of evidence for these 17 recommendations.

The 2004 expert Working Group was charged with reviewing evidence obtained primarily from systematic reviews of literature published through February 2004. Whereas the review of the evidence for the first edition was limited to searches of MEDLINE and POPLINE from 1980 to 2000, additional bibliographic databases and years of publication were searched for the second edition, depending on the topic of the systematic review. Additional reports were identified from the reference lists in the articles obtained by the literature search. These systematic, comprehensive searches of the bibliographic databases yielded all primary studies that pertained to the relevant recommendation. Each article was reviewed by WHO to determine its relevance to the questions posed, the quality of the evidence provided, and whether the evidence was directly or indirectly applicable to answering the questions (Table 3). The evidence from individual articles was then synthesized in systematic reviews, which served as the basis for the expert Working Group's deliberations.

The purpose of the systematic reviews was to identify evidence to address the biomedical and behavioural components of the common clinical challenges represented by Questions 1–29. Questions 30–33 represented broader programmatic issues and were not addressed by the systematic reviews. The systematic reviews were provided to the expert Working Group prior to the meeting. In addition, individual members of the expert Working Group were asked to serve as resource persons for specific questions.

Where the expert Working Group had a systematic review of the evidence to consider as they made a recommendation, the evidence is cited in the reference list provided at the end of each recommendation. The recommendations for which no evidence is cited were based on expert

opinion and/or evidence obtained from sources other than systematic reviews. The first edition included 23 recommendations that are widely used globally. The Guidelines Steering Group, which convened on 13 April 2004, agreed with the Secretariat and proposed that the expert Working Group consider only those recommendations from the first edition for which there was new evidence or for which a compelling case had been made. The expert Working Group accepted this proposal on 14 April and, thus, the remainder of the expert Working Group meeting was focused on 7 current recommendations with new evidence and 10 new recommendations. The final 33 recommendations (23 recommendations from the previous edition and 10 new recommendations) were approved by all members of the Guidelines Steering Group and the expert Working Group at the completion of the meeting on 16 April 2004.

The 10 new recommendations for this second edition, together with any changes in the recommendations from the first edition, are listed in the summary of changes on page 16.

Table 3. Levels of evidence*

Recommendations were based on the following levels and categories of evidence:

Level I: Evidence obtained from at least one properly designed randomized controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Quality of evidence

Each study was also given a rating of good, fair, and poor based on grading the internal validity of a study.

* Harris RP et al. Methods Work Group, Third US Preventive Services Task Force. Current methods of the US Preventive Services Task Force: a review of the process. *American Journal of Preventive Medicine*, 2001, 20(Suppl. 3):21–35.

Types of evidence

Direct: The evidence was based on data directly addressing the question.

Indirect: The evidence was extrapolated from other relevant data.

How to use this document

The present document is intended to be used by policy-makers, family planning programme managers and the scientific community. It aims to provide guidance to national family planning/reproductive health programmes in the preparation of guidelines for service delivery of contraceptives. It should not be seen or used as the actual guidelines but rather as a reference.

The guidance in this document is intended for interpretation at country and programme levels in a manner that reflects the diversity of situations and settings in which contraceptives are provided.

The questions in this document are organized by four main topics related to how to safely and effectively use contraceptive methods, including initiation/continuation, incorrect use, problems during use, and programmatic issues. For each question, the expert Working Group's recommendations are provided for key specific situations, along with the "Comments" and "Key unresolved issues." Further, for questions addressed by the systematic reviews (Questions 1–29), the following information is also provided: 1) the phrasing of the question from which the literature

search terms were derived, 2) the level and quality of evidence and whether that evidence was directly or indirectly related to the question, and 3) the references identified by the systematic review and provided to the expert Working Group.

Each question results in recommendations that address what a woman can do in a specific situation. In some cases, subgroups of women are medically ineligible to follow the recommendations for that situation. In those circumstances, the document provides cautionary comments based on the *Medical eligibility criteria for contraceptive use, third edition*; these comments are indicated with an asterisk in italics, following the relevant condition, as additional guidance from the *Medical eligibility criteria for contraceptive use, third edition*.

Programmatic implications

Programmatic issues that need to be addressed include:

- informed choice
- elements of quality of care
- essential screening procedures for administering the methods
- provider training and skills
- referral and follow-up for contraceptive use as appropriate.

In the application of the selected practice recommendations to programmes, service delivery practices that are essential for the safe use of the contraceptive should be distinguished from practices that may be appropriate for good health care but are not related to use of the method. The promotion of good health care practices unrelated to safe contraception should be considered neither as a prerequisite nor as an obstacle to the provision of a contraceptive method, but as complementary to it.

As a next step, the selected recommendations need to be considered in light of country circumstances, so as to be applicable to providers at all levels of the service delivery system. Countries will need to determine how far and by what means it may be possible to extend their services to the more peripheral levels. This may involve upgrading both staff and facilities where feasible and affordable, or may require the extension of the skills of certain categories of health personnel or a modest addition of equipment and supplies and redeployment of space. It will also be necessary to address questions of misperceptions sometimes held by providers and users on the risks and side-effects of the methods and to look closely at the needs and perspectives of women and men in the context of informed choice.

Summary of changes from the first edition

Ten new recommendations were added in the second edition:

- How can a woman take emergency contraceptive pills?
- Can a woman receive an advance supply of emergency contraceptive pills?
- What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills?
- How long can levonorgestrel implants be left in place?
- When can a woman have a levonorgestrel-releasing IUD inserted?
- What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD?
- What should be done if a woman using a levonorgestrel-releasing IUD is diagnosed with pelvic inflammatory disease?
- What should be done if a woman using a levonorgestrel-releasing IUD is found to be pregnant?
- Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD insertion?
- When can a man rely on his vasectomy for contraception?

Of the 23 recommendations retained from the first edition, the guidance for management of missed contraceptive pills (Question 17 of this edition) underwent the most change and was simplified considerably. Limited changes were made to 11 questions (Questions 1, 2, 4, 5, 7, 9, 10, 22, 23, 28 and 30 of this edition); these were primarily in the form of additional guidance for women starting contraceptive methods postpartum and postabortion. The remaining 11 questions continue unchanged from the first edition. The format of the document has also been reorganized, so that recommendations are now grouped by type of question.

It is recognized that some of the selected practice recommendations in this report will need to be reviewed in the light of new research as it becomes available. At appropriate intervals, WHO will update and add to the selected practice recommendations in this document. These recommendations are available on WHO's reproductive health web site (www.who.int/reproductive-health). The web site will also provide additional information determined by WHO to be relevant to these practice recommendations, pending the next formal consensus expert Working Group meeting. WHO encourages research to address the key unresolved issues noted in this document.

Questions for which the expert Working Group provided recommendations

Initiation/continuation

1. When can a woman start combined oral contraceptives (COCs)?
2. When can a woman start combined injectable contraceptives (CICs)?
3. When can a woman have repeat combined injectable contraceptive injections (CICs)?
4. When can a woman start progestogen-only pills (POPs)?
5. When can a woman start progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
6. When can a woman have repeat progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
7. When can a woman start using an implant?
8. How long can levonorgestrel implants be left in place?
9. When can a woman have a copper-bearing IUD inserted?
10. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
11. When can a woman have a levonorgestrel-releasing IUD (LNG IUD) inserted?
12. Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD (LNG IUD) insertion?
13. How can a woman take emergency contraceptive pills (ECPs)?
14. Can a woman receive an advance supply of emergency contraceptive pills (ECPs)?
15. When can a man rely on his vasectomy for contraception?
16. What can a Standard Days Method (SDM) user do if she has menstrual cycles outside the 26–32 day range?

Incorrect use

17. What can a woman do if she misses combined oral contraceptives (COCs)?
18. What can a woman do if she misses progestogen-only pills (POPs)?

Problems during use

Vomiting and/or diarrhoea

19. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives (COCs) or progestogen-only pills (POPs)?
20. What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills (ECPs)?
21. What can a woman do if she vomits after taking emergency contraceptive pills (ECPs)?

Menstrual abnormalities

22. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable (POI) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

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

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

25. What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD (LNG IUD)?

Pelvic inflammatory disease

26. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease (PID)?

27. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD) is diagnosed with pelvic inflammatory disease (PID)?

Pregnancy

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

29. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD) is found to be pregnant?

Programmatic issues

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

31. How many pill packs [combined (COCs) or progestogen-only pills (POPs)] should be given at initial and return visits?

32. What follow-up is appropriate for combined oral contraceptive (COCs), progestogen-only pill (POPs), implant and IUD users?

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

Initiation/continuation

1. When can a woman start combined oral contraceptives (COCs)?
2. When can a woman start combined injectable contraceptives (CICs)?
3. When can a woman have repeat combined injectable contraceptive injections (CICs)?
4. When can a woman start progestogen-only pills (POPs)?
5. When can a woman start progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
6. When can a woman have repeat progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
7. When can a woman start using an implant?
8. How long can levonorgestrel implants be left in place?
9. When can a woman have a copper-bearing IUD inserted?
10. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
11. When can a woman have a levonorgestrel-releasing IUD (LNG IUD) inserted?
12. Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD (LNG IUD) insertion?
13. How can a woman take emergency contraceptive pills (ECPs)?
14. Can a woman receive an advance supply of emergency contraceptive pills (ECPs)?
15. When can a man rely on his vasectomy for contraception?
16. What can a Standard Days Method (SDM) user do if she has menstrual cycles outside the 26–32 day range?

1

When can a woman start combined oral contraceptives?

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

Note: The woman may be provided with COCs in advance with appropriate instructions on pill initiation, provided she is medically eligible.

Having menstrual cycles

- She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She also can 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.

Postpartum (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.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** 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.

Postpartum (non-breastfeeding)*

- If her menstrual cycles have not returned and she is 21 or more days postpartum, she can start COCs immediately, 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.
- If her menstrual cycles have returned, she can start COCs as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** It is highly unlikely that a woman will ovulate and be at risk of pregnancy during the first 21 days postpartum. However, for programmatic reasons, some contraceptive methods may be provided during this period. For women less than 21 days postpartum, use of COCs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Postabortion

- She can start COCs immediately postabortion. No additional contraceptive protection is needed.

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 nonhormonal 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 also can 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.

Switching from an IUD (including the levonorgestrel-releasing IUD)

- 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 also can 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 already has 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 effectiveness and compliance? **Level of evidence:** I, fair, indirect.

How does giving advance provision of COCs affect use, compliance, and continuation of COCs? **Level of evidence:** II-2, fair, direct.

References from systematic review

1. Killick S, Eyong E, Elstein M. Ovarian follicular development in oral contraceptive cycles. *Fertility and Sterility*, 1987, 48:409–413.

2. Lara-Torre E, Schroeder B. Adolescent compliance and side effects with Quick Start initiation of oral contraceptive pills. *Contraception*, 2002, 66:81–85.

3. Molloy BG et al. "Missed pill" conception: fact or fiction? *British Medical Journal* (Clinical Research Edition), 1985, 290:1474–1475.

4. Schwartz JL et al. Predicting risk of ovulation in new start oral contraceptive users. *Obstetrics and Gynecology*, 2002, 99:177–182.

5. Sitavarin S, Jaisamrarn U, Taneepanichskul S. A randomized trial on the impact of starting day on ovarian follicular activity in very low dose oral contraceptive pills users. *Journal of the Medical Association of Thailand*, 2003, 86:442–448.

6. Smith SK et al. The effect of deliberate omission of Trinordiol or Microgynon on the hypothalamo–pituitary–ovarian axis. *Contraception*, 1986, 34:513–522.

7. Stanback J, Qureshi ZP, Sekkade–Kigondu C. Advance provision of oral contraceptives to family planning clients in Kenya. *East African Medical Journal*, 2002, 79:257–258.

8. Taylor DR, Anthony FW, Dennis KJ. Suppression of ovarian function by Microgynon 30 in day 1 and day 5 "starters." *Contraception*, 1986, 33:463–471.

9. Westhoff C et al. Quick start: novel oral contraceptive initiation method. *Contraception*, 2002, 66:141–145.

10. Westhoff C et al. Bleeding patterns after immediate vs. conventional oral contraceptive initiation: a randomized, controlled trial. *Fertility and Sterility*, 2003, 79:322–329.

11. Yeshaya A et al. A delayed starting schedule of OCs: the effect on the incidence of breakthrough bleeding and compliance in women. *European Journal of Contraception and Reproductive Health Care*, 1996, 1:263–265.

12. Yeshaya A et al. Flexible starting schedule for oral contraception: effect on the incidence of breakthrough bleeding and compliance. *European Journal of Contraception and Reproductive Health Care*, 1998, 3:121–123.

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, 321:1259–1262.

2. Wilcox AJ et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception, 2001, 63:211–215.

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 use of COCs?

2

When can a woman start combined injectable contraceptives?

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

Notes:

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

If the woman cannot have the injection at the time of the consultation, arrangements can be made for her to have the injection through an appropriate service at a later date.

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 also can 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.

Postpartum (breastfeeding)*

- If she is more than 6 months postpartum and amenorrhoeic, she can have the first injection as advised for other amenorrhoeic women.

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

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** *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.*

Postpartum (non-breastfeeding)*

- If her menstrual cycles have not returned and she is 21 or more days postpartum, she can have the first injection immediately, 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.

- If her menstrual cycles have returned, she can have the first injection as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** *It is highly unlikely that a woman will ovulate and be at risk of pregnancy during the first 21 days postpartum. However, for programmatic reasons, some contraceptive methods may be provided during this period. For women less than 21 days postpartum, use of CICs is not usually recommended unless other more appropriate methods are not available or not acceptable.*

Postabortion

- She can have the first injection immediately postabortion. No additional contraceptive protection is needed.

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 nonhormonal 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 the levonorgestrel-releasing IUD)

- 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 a CIC 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 already has 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, good, indirect.

References from systematic review

1. Petta CA 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 and Sterility*, 2001, 75:744–748.

2. Petta CA et al. Delayed first injection of the once-a-month injectable contraceptive containing 25 mg medroxyprogesterone acetate and 5 mg estradiol-cypionate: effects on cervical mucus. *Contraception*, 2001, 64:363–368.

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, 321:1259–1262.

2. Wilcox AJ et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*, 2001, 63:211–215.

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?

3

When can a woman have repeat combined injectable contraceptive injections?

3. When can a woman have repeat combined injectable contraceptive (CIC) injections?

Note: These recommendations are based on information on CICs containing medroxyprogesterone acetate and estradiol cypionate (Cyclofem/Lunelle) but also apply to CICs 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, fair, indirect.

References from systematic review

1. Aedo AR et al. Pharmacokinetic and pharmacodynamic investigations with monthly injectable contraceptive preparations. *Contraception*, 1985, 31:453–469.
2. Bahamondes L et al. Return to fertility after discontinuation of the once a month injectable contraceptive Cyclofem. *Contraception*, 1997, 55:307–310.
3. Bassol S et al. A comparative study on the return to ovulation following chronic use of once-a-month injectable contraceptives. *Contraception*, 1995, 51:307–311.
4. 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, 36:441–457.

5. 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.

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?

4

When can a woman start progestogen-only pills?

4. When can a woman start progestogen-only pills (POPs)?

Note: She may be provided with POPs in advance with appropriate instructions on pill initiation, provided she is medically eligible.

Having menstrual cycles

- She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She also can 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.

Postpartum (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.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** 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.

Postpartum (non-breastfeeding)

- If she is less than 21 days postpartum, she can start POPs at any time. No additional contraceptive protection is needed.*
- If she is 21 or more days postpartum and her menstrual cycles have not returned, 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.
- If her menstrual cycles have returned, she can start POPs as advised for other women having menstrual cycles.

* It is highly unlikely that a woman will ovulate and be at risk of pregnancy during the first 21 days postpartum. However, for programmatic reasons, some contraceptive methods may be provided during this period.

Postabortion

- She can start POPs immediately postabortion. No additional contraceptive protection is needed.

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 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 nonhormonal 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 also can 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.

Switching from an IUD (including the levonorgestrel-releasing IUD)

- 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 also can 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 already has 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 effectiveness?

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, 321:1259–1262.

3. Wilcox et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*, 2001, 63:211–215.

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?

5

When can a woman start progestogen-only injectables — depot medroxyprogesterone acetate or norethisterone enantate?

5. When can a woman start progestogen-only injectables (POIs) — depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

Notes:

These recommendations are based on information on an injectable containing DMPA but apply also to NET-EN.

If the woman cannot have the injection at the time of the consultation, arrangements can be made for her to have the injection through an appropriate service at a later date.

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 also can 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.

Postpartum (breastfeeding)*

- If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have the 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 cycles have returned, she can have the first injection as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** 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.

Postpartum (non-breastfeeding)

- If she is less than 21 days postpartum, she can have the first injection at any time. No additional contraceptive protection is needed.*
- If she is 21 or more days postpartum and her menstrual cycles have not returned, 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.
- If her menstrual cycles have returned, she can have the first injection as advised for other women having menstrual cycles.

* It is highly unlikely that a woman will ovulate and be at risk of pregnancy during the first 21 days postpartum. However, for programmatic reasons, some contraceptive methods may be provided during this period.

Postabortion

- She can have the first injection immediately postabortion. No additional contraceptive protection is needed.

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 nonhormonal 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 the levonorgestrel-releasing IUD)

- 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 also can 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 already has 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 POIs to exert such an effect was uncertain.

Systematic review question

How does starting POIs on different days of the menstrual cycle affect contraceptive effectiveness? **Level of evidence:** II-1, good, indirect.

References from systematic review

1. Petta CA et al. Timing of onset of contraceptive effectiveness in Depo-Provera users: Part I. Changes in cervical mucus. *Fertility and Sterility*, 1998, 69:252–257.

2. Petta CA et al. Timing of onset of contraceptive effectiveness in Depo-Provera users. II. Effects on ovarian function. *Fertility and Sterility*, 1998, 70:817–820.

3. Siriwongse T et al. Effect of depo-medroxyprogesterone acetate on serum progesterone levels when administered on various cycle days. *Contraception*, 1982, 26:487–493.

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, 321:1259–1262.

2. Wilcox AJ et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*, 2001, 63:211–215.

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?

6

When can a woman have repeat progestogen-only injectables — depot medroxyprogesterone acetate or norethisterone enantate?

6. When can a woman have repeat progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (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 POIs to exert such an effect was uncertain.

Systematic review question

How soon after the last progestogen-only injection do ovulation and fertility return?
Level of evidence: II-3, fair, indirect.

References from systematic review

1. 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, 34:573–582.

2. Bassol S et al. Ovarian function following a single administration of depo-medroxy progesterone acetate (DMPA) at different doses. *Fertility and Sterility*, 1984, 42:216–222.

3. Fotherby K et al. A preliminary pharmacokinetic and pharmacodynamic evaluation of depot-medroxyprogesterone acetate and norethisterone oenanthate. *Fertility and Sterility*, 1980, 34:131–139.

4. Garza-Flores J et al. Return to ovulation following the use of long-acting injectable contraceptives: a comparative study. *Contraception*, 1985, 31:361–366.

5. Lan PT et al. Return of ovulation following a single injection of depo-medroxyprogesterone acetate: a pharmacokinetic and pharmacodynamic study. *Contraception*, 1984, 29:1–18.

6. Ortiz A et al. Serum medroxyprogesterone acetate (MPA) concentrations and ovarian function following intramuscular injection of Depo-MPA. *Journal of Clinical Endocrinology and Metabolism*, 1977, 44:32–38.

7. 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.

8. Saxena BN et al. Return of ovulation after the cessation of depot-medroxy progesterone acetate treatment in Thai women. *Journal of the Medical Association of Thailand*, 1980, 63:66–69.

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 POIs?

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

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

7

When can a woman start using an implant?

7. 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 also can 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.

Postpartum (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.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** 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.

Postpartum (non-breastfeeding)

- If she is less than 21 days postpartum, she can have the implant inserted at any time. No additional contraceptive protection is needed.*
- If she is 21 or more days postpartum and her menstrual cycles have not returned, 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.
- If her menstrual cycles have returned, she can have the implant inserted as advised for other women having menstrual cycles.

* It is highly unlikely that a woman will ovulate and be at risk of pregnancy during the first 21 days postpartum. However, for programmatic reasons, some contraceptive methods may be provided during this period.

Postabortion

- She can have the implant inserted immediately postabortion. No additional contraceptive protection is needed.

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 nonhormonal 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 the levonorgestrel-releasing IUD)

- 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 also can 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 already has 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, good, indirect.

References from systematic review

1. Brache V et al. Effect of preovulatory insertion of Norplant implants over luteinizing hormone secretion and follicular development. *Fertility and Sterility*, 1996, 65:1110–1114.

2. Brache V et al. Timing of onset of contraceptive effectiveness in Norplant implant users. II. Effect on the ovarian function in the first cycle of use. *Contraception*, 1999, 59:245–251.

3. Dunson TR et al. Timing of onset of contraceptive effectiveness in Norplant implant users. Part I. Changes in cervical mucus. *Fertility and Sterility*, 1998, 69:258–266.

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, 321:1259–1262.

2. Wilcox AJ et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*, 2001, 63:211–215.

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?

8

How long can levonorgestrel implants be left in place?

8. How long can levonorgestrel implants be left in place?

Note: These recommendations are based on information from, and relate to, approved levonorgestrel implants (Norplant and Jadelle). The product labelling for an etonogestrel implant (Implanon) states that the implant can be left in place for up to 3 years.

Norplant

For a woman weighing less than 70 kg

- A woman who weighs less than 70 kg at insertion and who continues to weigh less than 70 kg can have her implants left in place for up to 7 completed years.
- She should be counselled that increased weight (to > 70 kg) may lead to lower effectiveness of Norplant after 4 or 5 years (depending on the amount of weight gained).

For a woman weighing 70–79 kg

- A woman who weighs 70–79 kg at insertion should be advised that her implants will be less effective beyond the 5th year of use if her weight continues within the same range.
- She should return for a follow-up visit by the end of 4 years of use.
  - If she still weighs 70–79 kg, she and her provider should decide whether implants are left in place for up to 7 completed years.
  - If she weighs 80 kg or more at follow-up, she should seriously consider having her implants removed after 4 years of use because of their reduced effectiveness.

For a woman weighing 80 kg or more

- She should return for a follow-up visit by the end of 4 years of use. If she still weighs 80 kg or more, she should seriously consider having her implants removed after 4 years of use because of their reduced effectiveness.

Jadelle

She can have the implants left in place for up to 5 completed years, unless she weighs 80 kg or more. If she weighs 80 kg or more, she should seriously consider having her implants removed after 4 completed years of use because of their reduced effectiveness.

Comments

The expert Working Group reviewed published evidence that pregnancy among women using Norplant is rare through year 7 of use for women weighing less than 70 kg at insertion, and through year 4 of use for women weighing 70 kg or more at insertion. The contraceptive effectiveness decreases after year 4 for women weighing 70 kg or more at insertion, and is decreased substantially for women weighing 80 kg or more at insertion. The expert Working Group also reviewed unpublished data suggesting that women whose current weight is 70–79 kg have an increased risk of pregnancy after 5 years of use and that women whose current weight is 80 kg or more have a risk of pregnancy of approximately 6% in the 5th year of use. Based on these data, women weighing 70–79 kg during the 5th year of use should be aware of the reduced effectiveness of their implants if they choose to continue using them for a 6th or 7th year. Women weighing 80 kg or more should be strongly advised to consider having their implants removed after 4 years of use. The latest published pregnancy rates for years 5, 6, and 7 according to the weight at insertion are found in reference 3 below. While pregnancy rates are increased among women weighing 70–79 kg after year 5, the pregnancy rates in years 6 and 7 are no greater than those for several other contraceptive methods. Women using Norplant or Jadelle are much less likely to have an ectopic pregnancy than women using no contraception. However, in the unlikely event that pregnancy occurs, the chance that the pregnancy will be ectopic is increased.

A woman weighing 70–79 kg can have her Norplant taken out at any time before 7 years, if she is concerned about effectiveness beyond 5 years of use. At that point, she can have another set of implants inserted if desired. She, as for all women using implants, can also have her implant(s) removed at any time for any reason.

Systematic review question

Can levonorgestrel implants be left in place for longer than 5 years? **Level of evidence:** II-1, good, direct.

References from systematic review

1. Gu S et al. Effectiveness of Norplant implants through seven years: a large-scale study in China. *Contraception*, 1995, 52:99–103.

2. Nour El-Dine NM et al. Extension of use of the contraceptive implants, Norplant and levonorgestrel rods to seven years. *Egyptian Society of Obstetrics and Gynecology*, 2000, 26:377–393.

3. Sivin I et al. Prolonged effectiveness of Norplant® capsule implants: a 7-year study. *Contraception*, 2000, 61:187–194.

4. Sivin I et al. Levonorgestrel concentrations during 7 years of continuous use of Jadelle contraceptive implants. *Contraception*, 2001, 64:43–49.

5. Wan LS, Stiber A, Lam L. The levonorgestrel two-rod implant for long-acting contraception: 10 years of clinical experience. *Obstetrics and Gynecology*, 2003, 102:24–26.

Key unresolved issues

What are the effects of age and obesity on the effectiveness of Norplant during the 5th, 6th, and 7th years of use?

9

When can a woman have a copper-bearing IUD inserted?

9. When can a woman have a copper-bearing IUD inserted?

Having menstrual cycles

- She can have a copper-bearing IUD inserted at 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.

- She also can have the copper-bearing IUD 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.

Amenorrhoeic (non-postpartum)

- She can have a copper-bearing IUD inserted at any time, *if it can be determined that she is not pregnant*. No additional contraceptive protection is needed.

Postpartum and breastfeeding (including post-caesarean section)*

- If she is less than 48 hours postpartum, she can generally have a copper-bearing IUD inserted.

- If she is 4 or more weeks postpartum and amenorrhoeic, she can have a copper-bearing IUD inserted, if it is reasonably certain that she is not pregnant. No additional contraceptive protection is needed.

- If she is 4 or more weeks postpartum and her menstrual cycles have returned, she can have a copper-bearing IUD inserted as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** Women who have puerperal sepsis should not have a copper-bearing IUD inserted. For women 48 hours to less than 4 weeks postpartum, use of copper-bearing IUDs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Postpartum and non-breastfeeding (including post-caesarean section)*

- If she is less than 48 hours postpartum, she can generally have a copper-bearing IUD inserted.

- If she is 4 or more weeks postpartum and amenorrhoeic, she can have a copper-bearing IUD inserted, *if it can be determined that she is not pregnant.* No additional contraceptive protection is needed.

- If she is 4 or more weeks postpartum and her menstrual cycles have returned, she can have a copper-bearing IUD inserted as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition, 2004*.** Women who have puerperal sepsis should not have a copper-bearing IUD inserted. For women 48 hours to less than 4 weeks postpartum, use of copper-bearing IUDs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Postabortion*

- If she had a first-trimester abortion, she can have a copper-bearing IUD inserted immediately postabortion.

- If she had a second-trimester abortion, she can generally have a copper-bearing IUD inserted immediately postabortion.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition, 2004.*** Women should not have a copper-bearing IUD inserted immediately following septic abortion.

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.

For emergency contraception*

- She can have a copper-bearing IUD inserted within 5 days of unprotected intercourse as an emergency contraceptive.

- In addition, when the time of ovulation can be estimated, she can have a copper-bearing IUD inserted beyond 5 days after intercourse, as long as insertion does not occur more than 5 days after ovulation.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** Women who use the copper-bearing IUD for emergency contraception should be medically eligible for the insertion.

Comments

The expert Working Group determined that there is an acceptably low risk of ovulation up to day 7 of the menstrual cycle. Coupled with the 5–day emergency contraceptive effect of copper-bearing IUDs, the expert Working Group determined that the probability of an existing pregnancy is low before day 12 of the menstrual cycle.

The recommendation of the expert Working Group for insertion of copper-bearing IUDs does not apply to LNG IUDs because the emergency contraceptive effect of copper-bearing IUDs cannot be presumed to pertain. Thus, the use of the LNG IUD as an emergency contraceptive is not recommended. Further, there are theoretical concerns that in the event of pregnancy there may be added risks to the fetus due to hormonal exposure. Whether there is an increased risk of fetal abnormalities due to this exposure, however, is unknown.

As stated in the *Medical eligibility criteria for contraceptive use*, the IUD is not indicated during pregnancy and should not be used because of the risk of serious pelvic infection and septic spontaneous abortion. The expert Working Group recognized that the 6 criteria in question 33 ("How can a provider be reasonably sure that a woman is not pregnant?") will be helpful to the provider in determining whether women who are postpartum and breastfeeding may be pregnant. However, these criteria are not helpful in making this determination for women who are postpartum and non-breastfeeding or for women who are amenorrhoeic (non-postpartum). In those circumstances, other means to determine whether she is pregnant will need to be employed.

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, fair, indirect.

References from systematic review

1. Goldstuck ND. Pain response following insertion of a Gravigard (Copper-7) intrauterine contraceptive device in nulliparous women. *International Journal of Fertility*, 1981, 26:53–56.

2. Goldstuck ND, Matthews ML. A comparison of the actual and expected pain response following insertion of an intrauterine contraceptive device. *Clinical Reproduction and Fertility*, 1985, 3:65–71.

3. White MK et al. Intrauterine device termination rates and the menstrual cycle day of insertion. *Obstetrics and Gynecology*, 1980, 55:220–224.

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, 321:1259–1262.

2. Wilcox AJ et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception*, 2001, 63:211–215.

Key unresolved issues

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

10

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

10

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

Routine copper-bearing IUD insertion

- Prophylactic antibiotics are generally not recommended for copper-bearing IUD insertion. In settings of both high prevalence of cervical gonococcal and chlamydial infections and limited sexually transmitted infection (STI) screening, such prophylaxis may be considered.

- Counsel the copper-bearing IUD user to watch for symptoms of pelvic inflammatory disease (PID), especially during the first month.

Comments

The expert Working Group determined that prophylactic antibiotics for copper-bearing IUD insertion provide little, if any, benefit for women at low risk for STIs.

This recommendation applies to healthy women; women with health conditions (e.g. cardiac valve disorders) that warrant antibiotic prophylaxis for invasive procedures may also need antibiotic prophylaxis for copper-bearing IUD insertion.

Systematic review question

Does administration of prophylactic antibiotics decrease risk of infection during IUD insertion? **Level of evidence:** I, good, direct.

References from systematic review

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

Key unresolved issues

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

11

When can a woman have a levonorgestrel-releasing IUD inserted?

11

11. When can a woman have a levonorgestrel-releasing IUD (LNG IUD) inserted?

Having menstrual cycles

- She can have a LNG IUD inserted at any time within the first 7 days after the start of menstrual bleeding, at her convenience, not just during menstruation. No additional contraceptive protection is needed.

- She also can have a LNG IUD inserted at any other time during the menstrual cycle, at her convenience, 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 (non-postpartum)

- She can have the LNG IUD inserted at any time, *if it can be determined that she is not pregnant*. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Postpartum and breastfeeding (including post-caesarean section)*

- If she is 4 or more weeks postpartum and amenorrhoeic, she can have a LNG IUD inserted, if it is reasonably certain that she is not pregnant. No additional contraceptive protection is needed.

- If she is 4 or more weeks postpartum and her menstrual cycles have returned, she can have a LNG IUD inserted as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** Women who have puerperal sepsis should not have a LNG IUD inserted. For women less than 48 hours postpartum and women 48 hours to less than 4 weeks postpartum, use of LNG IUDs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Postpartum and non-breastfeeding (including post-caesarean section)*

- If she is 4 or more weeks postpartum and amenorrhoeic, she can have a LNG IUD inserted, *if it can be determined that she is not pregnant*. No additional contraceptive protection is needed.

- If she is 4 or more weeks postpartum and her menstrual cycles have returned, she can have a LNG IUD inserted as advised for other women having menstrual cycles.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** Women who have puerperal sepsis should not have a LNG IUD inserted. For women less than 48 hours postpartum and women 48 hours to less than 4 weeks postpartum, use of LNG IUDs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Postabortion*

- If she had a first-trimester abortion, she can have a LNG IUD inserted immediately postabortion.

- If she had a second-trimester abortion, she can generally have a LNG IUD inserted immediately postabortion.

* **Additional guidance from the *Medical eligibility criteria for contraceptive use. Third edition*, 2004.** Women should not have a LNG IUD inserted immediately following septic abortion.

Switching from another method

- If she is having menstrual cycles, she can have a LNG IUD inserted immediately, if it is reasonably certain that she is not pregnant. If she is amenorrhoeic, she can still have a LNG IUD inserted immediately, *if it can be determined that she is not pregnant*. There is no need to wait for her next menstrual period.
  - If she is within the first 7 days after the start of 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.
  - If her previous method was an injectable, she should have the LNG IUD inserted when the repeat injection would have been given. In that circumstance, no additional contraceptive protection is needed.

Comments

The expert Working Group determined that there is an acceptably low risk of ovulation up to day 7 of the menstrual cycle and that, therefore, the probability of an existing pregnancy is low before day 8.

The recommendation of the expert Working Group for insertion of copper-bearing IUDs does not apply to LNG IUDs because the emergency contraceptive effect of copper-bearing IUDs cannot be presumed to pertain. Thus, the use of the LNG IUD as an emergency contraceptive is not recommended. Further, there are theoretical concerns that in the event of pregnancy there may be added risks to the fetus due to hormonal exposure. Whether there is an increased risk of fetal abnormalities due to this exposure, however, is unknown.

As stated in the *Medical eligibility criteria for contraceptive use*, the IUD is not indicated during pregnancy and should not be used because of the risk of serious pelvic infection and septic spontaneous abortion. The expert Working Group recognized that the 6 criteria in question 33 ("How can a provider be reasonably sure that a woman is not pregnant?") will be helpful to the provider in determining whether women who are postpartum and breastfeeding may be pregnant. However, these criteria are not helpful in making this determination for women who are postpartum and non-breastfeeding or for women who are amenorrhoeic (non-postpartum). In those circumstances, other means to determine whether she is pregnant will need to be employed.

Systematic review question

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

References from systematic review

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Key unresolved issues

How quickly is protection reliably established by the LNG IUD?

What if any adverse effects are there on infants of breastfeeding mothers who initiate progestogen-only contraception less than 6 weeks postpartum?

12

Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD insertion?

12. Should prophylactic antibiotics be provided for levonorgestrel-releasing IUD (LNG IUD) insertion?

Routine LNG IUD insertion

- Prophylactic antibiotics are generally not recommended for LNG IUD insertion. In settings of both high prevalence of cervical gonococcal and chlamydial infections and limited sexually transmitted infection (STI) screening, such prophylaxis may be considered.

- Counsel the LNG IUD user to watch for symptoms of pelvic inflammatory disease (PID), especially during the first month.

Comments

The expert Working Group determined that prophylactic antibiotics for LNG IUD insertion provide little, if any, benefit for women at low risk for STIs.

This recommendation applies to healthy women; women with health conditions (e.g. cardiac valve disorders) that warrant antibiotic prophylaxis for invasive procedures may also need antibiotic prophylaxis for LNG IUD insertion.

These recommendations were based on evidence for the copper-bearing IUD.

Systematic review question

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

References from systematic review

No studies identified.

Other key references

See references from Question 10 ("Should prophylactic antibiotics be provided for copper-bearing IUD insertion?").

Key unresolved issues

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

13

How can a woman take emergency contraceptive pills?

13. How can a woman take emergency contraceptive pills (ECPs)?

Timing

- Ideally, she should take levonorgestrel-only or combined estrogen-progestogen ECPs as early as possible after unprotected intercourse, within 72 hours.
- She also can take levonorgestrel-only or combined estrogen-progestogen ECPs between 72 hours and 120 hours after unprotected intercourse. However, she should be advised that the effectiveness of ECPs is reduced the longer the interval between having unprotected intercourse and taking ECPs.

Regimens

- Preferably, she can take 1.50 mg of levonorgestrel in a single dose.
- Alternatively, she can take the levonorgestrel in 2 doses (1 dose of 0.75 mg of levonorgestrel, followed by a second dose of 0.75 mg of levonorgestrel 12 hours later).
- A third option is that she can take combined estrogen-progestogen ECPs in 2 doses (one dose of 100 µg of ethinylestradiol plus 0.50 mg of levonorgestrel, followed by a second dose of 100 µg of ethinylestradiol plus 0.50 mg of levonorgestrel 12 hours later).

Comments

The expert Working Group reviewed evidence that ECPs are most effective the sooner they are taken after unprotected intercourse, ideally within 72 hours. The evidence also indicated that ECPs are still effective between 72 hours and 120 hours but effectiveness is reduced, particularly after 96 hours. Effectiveness after 120 hours is unknown.

The expert Working Group considered evidence that levonorgestrel-only ECPs are preferable to combined estrogen-progestogen ECPs because they cause less nausea and vomiting.

The expert Working Group considered evidence that 1.50 mg of levonorgestrel (two 0.75 mg tablets) in a single dose is at least as effective as levonorgestrel in two doses (one dose of 0.75 mg of levonorgestrel, followed by a second dose of 0.75 mg of levonorgestrel 12 hours later). Programmes can provide either the single- or double-dose option, depending on available preparations. The expert Working Group, however, considered the single-dose option to be preferable to the double-dose option because of compliance considerations.

Systematic review questions

Can emergency contraceptive pills be taken later than 72 hours after unprotected intercourse? **Level of evidence:** II-2, good, direct.

Can emergency contraceptive pills be taken in a single dose? **Level of evidence:** I, good, direct.

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Key unresolved issues

What is the minimum effective dose of ECPs?

What is the decrease in effectiveness of ECPs with each day of delay beyond 72 hours after unprotected intercourse?

14

Can a woman receive an advance supply of emergency contraceptive pills?

14. Can a woman receive an advance supply of emergency contraceptive pills (ECPs)?

- She may receive an advance supply of ECPs to ensure that she will have them available when needed and can take them as soon as possible after unprotected intercourse.

Comments

The expert Working Group noted that an advance supply cannot be given in some countries, and, in those circumstances, an advance prescription may be given.

The expert Working Group reviewed evidence that a woman is more likely to use ECPs after unprotected intercourse if she has been given an advance supply and that providing an advance supply does not affect contraceptive use patterns, increase the frequency of ECP use, or increase the frequency of unprotected intercourse.

Systematic review question

Can emergency contraceptive pills be given to a woman in advance of when she might need them? **Level of evidence:** I, good, direct.

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Key unresolved issues

Does advance provision of ECPs result in differences in pregnancy rates and sexually transmitted infection rates?

15

When can a man rely on his vasectomy for contraception?

15. When can a man rely on his vasectomy for contraception?

- He should wait 3 months before relying on his vasectomy for contraception.
- During this period, he should resume sexual activity, but he or his partner will need to use additional contraceptive protection.
- Semen analysis, where available, can confirm contraceptive effectiveness after the 3–month waiting period.

Comments

The expert Working Group considered that vasectomy is highly effective when the procedure is properly performed and when the man waits for 3 months after the vasectomy before having unprotected intercourse. The expert Working Group reviewed evidence that a 3–month waiting period after vasectomy will be long enough for most men to be assured of vasectomy effectiveness but noted that semen analysis, where available, is the most reliable means to document vasectomy effectiveness.

The expert Working Group also reviewed evidence that having had 20 ejaculations after vasectomy (in the absence of a 3–month waiting period) is not a reliable determinant of vasectomy effectiveness. The man, however, should resume sexual activity (while using contraceptive protection) during the 3–month waiting period after his vasectomy in order to clear any remaining sperm from his semen.

Systematic review question

How many months or how many ejaculations after vasectomy are required to establish vasectomy success? **Level of evidence:** I, good, direct.

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Key unresolved issues

Is there a number of ejaculations after which the man can comfortably rely on his vasectomy for contraception?

How does vasectomy effectiveness vary by method of vas occlusion, especially in low-resource settings?

Can reliable tests be developed for low-resource settings for determining vasectomy effectiveness (including semen analysis)?

16

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

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

Note: 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, fair, direct.

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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?

Incorrect use

17. What can a woman do if she misses combined oral contraceptives (COCs)?

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

17

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

17. What can a woman do if she misses combined oral contraceptives (COCs)?

For 30–35 µg ethinylestradiol pills:

Missed 1 or 2 active (hormonal) pills or if she starts a pack 1 or 2 days late

- She should take an active (hormonal) pill as soon as possible* and then continue taking pills daily, 1 each day.
- She does not need any additional contraceptive protection.

Missed 3 or more active (hormonal) pills or if she starts a pack 3 or more days late

- She should take an active (hormonal) pill as soon as possible* and then continue taking pills daily, 1 each day.
- She should also use condoms or abstain from sex until she has taken active (hormonal) pills for 7 days in a row.
- If she missed the pills in the third week, she should finish the active (hormonal) pills in her current pack and start a new pack the next day. She should not take the 7 inactive pills.
- If she missed the pills in the first week and had unprotected sex, she may wish to consider the use of emergency contraception.

For 20 µg or less ethinylestradiol pills:

- If the woman misses 1 active (hormonal) pill or starts a pack 1 day late, she should follow the guidance above for "Missed 1 or 2 active (hormonal) pills or if she starts a pack 1 or 2 days late."
- If the woman misses 2 or more active (hormonal) pills or if she starts a pack 2 or more days late, she should follow the guidance above for "Missed 3 or more active (hormonal) pills or if she starts a pack 3 or more days late."

For both 30–***35 µg and 20 µg or less ethinylestradiol pills:***

Missed any inactive (nonhormonal) pills

- She should discard the missed inactive (nonhormonal) pill(s) and then continue taking pills daily, 1 each day.

* If a woman misses more than 1 active (hormonal) pill, she can take the first missed pill and then either continue taking the rest of the missed pills or discard them to stay on schedule.

Depending on when she remembers that she missed a pill(s), she may take 2 pills on the same day (one at the moment of remembering, and the other at the regular time) or even at the same time.

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. Women who frequently miss pills should consider an alternative contraceptive method.

The expert Working Group noted that the evidence for "missed pill" recommendations is primarily derived from studies of women using 30–35 µg ethinylestradiol pills.

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 four principles underlie the expert Working Group's recommendations:

- It is important to take an active (hormonal) pill as soon as possible when pills have been missed.
- 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. Based on data regarding ovulation, the expert Working Group determined that missing 3 or more active (hormonal) pills (2 or more for 20 µg or less ethinylestradiol pills) at any time during the cycle warrants additional precautions. The risk of pregnancy is greatest when active (hormonal) pills are missed at the beginning or at the end of the active pills, i.e. when the hormone-free interval is extended.
- Limited evidence on 20 µg ethinylestradiol pills suggests that there may be a higher risk of pregnancy when missing 20 µg ethinylestradiol pills than when missing 30–35 µg ethinylestradiol pills. Accordingly, the expert Working Group recommended a more cautious approach when missing 20 µg or less ethinylestradiol pills.
- Field experience from the first edition of the *Selected practice recommendations for contraceptive use* highlighted the need for simple "missed pill" recommendations.

Systematic review question

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

References from systematic review

1. Chowduhry V et al. “Escape” ovulation in women due to the missing of low-dose combination oral contraceptive pills. *Contraception*, 1980, 22:241–247.

2. Creinin MD et al. The effect of extending the pill-free interval on follicular activity: triphasic norgestimate/35 micro g ethinyl estradiol versus monophasic levonorgestrel/ 20 micro g ethinyl estradiol. *Contraception*, 2002, 66:147–152.

3. Elomaa K, Lahteenmaki P. Ovulatory potential of preovulatory sized follicles during oral contraceptive treatment. *Contraception*, 1999, 60:275–279.

4. Elomaa K et al. Omitting the first oral contraceptive pills of the cycle does not automatically lead to ovulation. *American Journal of Obstetrics and Gynecology*, 1998, 179:41–46.

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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, 43:149–159.

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Other key references

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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 µg 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?

18

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

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

Having menstrual cycles (including those who are breastfeeding) AND missed 1 or more pills by more than 3 hours

- She should:
  - Take 1 pill as soon as possible.
  - Continue taking the pills daily, 1 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 1 or more pills by more than 3 hours

- She should:
  - Take 1 pill as soon as possible.
  - Continue taking the pills daily, 1 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 back-up 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?

Problems during use

Vomiting and/or diarrhoea

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

20. What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills (ECPs)?

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

Menstrual abnormalities

22. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable (POI) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

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

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

25. What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD (LNG IUD)?

Pelvic inflammatory disease

26. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease (PID)?

27. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD) is diagnosed with pelvic inflammatory disease (PID)?

Pregnancy

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

29. What should be done if a woman using a levonorgestrel-releasing IUD (LNG IUD) is found to be pregnant?

19

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

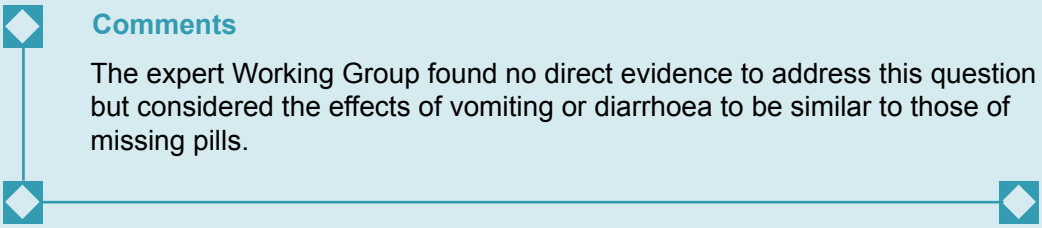
19. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives (COCs) or progestogen-only pills (POPs)?

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

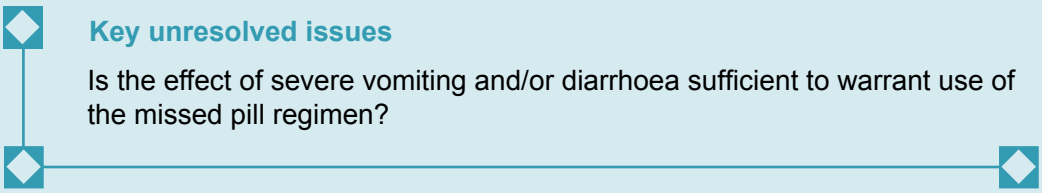
The expert Working Group found no direct evidence to address this question but considered the effects of vomiting or diarrhoea to be similar to those of missing pills.

Systematic review question

How does vomiting or diarrhoea during COC or POP use affect contraceptive effectiveness? **Level of evidence:** I, fair, indirect.

References from systematic review

1. Elomaa et al. 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?

What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills?

20. What can a woman do to prevent nausea and vomiting when taking emergency contraceptive pills (ECPs)?

- Levonorgestrel-only ECPs are preferable to combined estrogen-progestogen ECPs because they cause less nausea and vomiting.
- Routine use of anti-emetics before taking ECPs is not recommended. Pretreatment with certain anti-emetics can be considered depending on availability and clinical judgement.

Comments

The expert Working Group considered that many women will not experience nausea or vomiting when taking ECPs and that it is difficult to predict which women will experience nausea or vomiting. Although the expert Working Group did not recommend routine use of anti-emetics before taking ECPs, it noted that anti-emetics are effective in some women and can be offered when appropriate.

When providers are deciding whether to offer anti-emetics to women taking ECPs, they should consider the following:

- Nausea and vomiting are more likely to occur in women taking combined estrogen-progestogen ECPs than in women taking levonorgestrel-only ECPs.
- Evidence indicates that anti-emetics reduce the occurrence of nausea and vomiting in women taking combined estrogen-progestogen ECPs.
- Women who take anti-emetics may experience other side-effects from the anti-emetics.
- In some settings, availability of anti-emetics may be constrained.

From the limited evidence that the expert Working Group considered, it could not be established whether taking ECPs with food alters the risk of nausea or vomiting.

Systematic review question

What is the evidence regarding prevention of nausea and vomiting among women who take ECPs? **Level of evidence:** I, good, direct.

References from systematic review

1. Anonymous. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Task Force on Postovulatory Methods of Fertility Regulation. *Lancet*, 1998, 352:428–433.
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Key unresolved issues

What are the most effective regimens for preventing and treating nausea and vomiting associated with ECP use?

21

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

21. 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 she is taking combined estrogen-progestogen ECPs, 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 levonorgestrel-only ECPs are less likely to cause nausea and vomiting than are combined estrogen-progestogen ECPs.

The expert Working Group considered that 2 hours was sufficient for hormone absorption and that no action is required if a woman vomits after this time.

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?

22

What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable — depot medroxyprogesterone acetate and norethisterone enantate?

22. What can be done if a woman has menstrual abnormalities when using progestogen-only injectables (POIs) - depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (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 in 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 a sexually transmitted infection or pelvic inflammatory disease 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. In the interim, short-term treatment with ethinylestradiol may be helpful.
- 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 expert Working Group reviewed the limited available data regarding treatment and determined that treatment for light or heavy bleeding with estrogens or nonsteroidal anti-inflammatory drugs (NSAIDs) is likely to be of short-term or no benefit. For interim short-term treatment, when the bleeding is a health threat to the woman and she is discontinuing the injection, the expert Working Group determined that ethinylestradiol is modestly effective in decreasing the number of bleeding/spotting days.

Systematic review question

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

References from systematic review

1. Goldberg AB et al. Postabortion depot medroxyprogesterone acetate continuation rates: a randomized trial of cyclic estradiol. *Contraception*, 2002, 66:215–220.

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Key unresolved issues

What are the mechanisms underlying POI-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?

23

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

23. 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(s) 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 in 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 a sexually transmitted infection or pelvic inflammatory disease 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, nonhormonal and hormonal options are available:
  - Nonhormonal: nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Hormonal (if medically eligible): low-dose COCs or ethinylestradiol
- If she does not desire treatment, or the treatment is not effective, and she finds the bleeding unacceptable, the implant(s) 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, nonhormonal and hormonal options are available:
  - Nonhormonal: nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Hormonal (if medically eligible): 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(s) 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 expert Working Group reviewed the limited available data regarding treatment for light or heavy bleeding and determined that the following drugs are modestly effective:

- Nonhormonal drugs: nonsteroidal anti-inflammatory drugs (NSAIDs):
  - Ibuprofen
  - Mefenamic acid
- Hormonal drugs:
  - COCs
  - Ethinylestradiol

Systematic review question

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

References from systematic review

1. Alvarez-Sanchez F et al. Hormonal treatment for bleeding irregularities in Norplant implant users. *American Journal of Obstetrics and Gynecology*, 1996, 174:919–922.

2. Boonkasemsanti W et al. The effect of transdermal oestradiol on bleeding pattern, hormonal profiles and sex steroid receptor distribution in the endometrium of Norplant users. *Human Reproduction*, 1996, 11(Suppl 2):115–123.

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8. Subakir SB et al. Benefits of vitamin E supplementation to Norplant users--in vitro and in vivo studies. *Toxicology*, 2000, 148:173–178.

9. Witjaksono J et al. Oestrogen treatment for increased bleeding in Norplant users: preliminary results. *Human Reproduction*, 1996, 11(Suppl. 2):109–114.

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?

24

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

24

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

Spotting or light bleeding

- 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 nonsteroidal 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:
  - Nonsteroidal 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 expert Working 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, fair, direct.

References from systematic review

1. Anteby SO, Yarkoni S, Ever HP. The effect of a prostaglandin synthetase inhibitor, indomethacin, on excessive uterine bleeding. *Clinical and Experimental Obstetrics and Gynecology*, 1985, 12:60–63.

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8. Makarainen L, Ylikorkala O. Ibuprofen prevents IUCD-induced increases in menstrual blood loss. *British Journal of Obstetrics and Gynaecology*, 1986, 93:285–288.

9. Pedron N, Lozano M, Gallegos AJ. The effect of acetylsalicylic acid on menstrual blood loss in women with IUDs. *Contraception*, 1987, 36:295–303.

10. Randic L, Haller H. Ectopic pregnancy among past IUD users. *International Journal of Gynaecology and Obstetrics*, 1992, 38:299–304.

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14. Toppozada M et al. Management of uterine bleeding by PGs or their synthesis inhibitors. *Advances in Prostaglandin and Thromboxane Research*, 1980, 8:1459–1463.

15. Toppozada M et al. Control of IUD-induced bleeding by three nonsteroidal anti-inflammatory drugs. *Contraceptive Delivery Systems*, 1982, 3:117–125.

16. Yarkoni S, Anteby SO. Treatment of IUD related menorrhagia by indomethacin. *Clinical and Experimental Obstetrics and Gynecology*, 1984, 11:120–122.

17. Ylikorkala O, Kauppila A, Siljander M. Anti-prostaglandin therapy in prevention of side-effects of intrauterine contraceptive devices. *Lancet*, 1978, 2:393–395.

18. 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 and Gynaecology*, 1983, 90:78–83.

19. Wu S. Randomized multi-center study of baofuxin for treatment of bleeding side-effect induced by IUD. *Reproduction and Contraception*, 2004, 11:152–157.

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?

25

What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-releasing IUD?

25. What can be done if a woman experiences menstrual abnormalities when using a levonorgestrel-IUD (LNG IUD)?

Amenorrhoea

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

Spotting or light bleeding

- Spotting or light bleeding is common with LNG IUD use. It is not harmful and usually decreases over time.
- 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 LNG IUD and help her choose another method.

Heavier or longer menstrual bleeding than with normal menstrual periods

- Heavier and longer menstrual bleeding may occur during the first 3–6 months of LNG IUD use. Usually this is not harmful, and bleeding usually becomes lighter over time.
- 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 LNG 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 the risk of heavier or longer menstrual bleeding is concentrated in the first 3–6 months of LNG IUD use and decreases over time. No studies were available that assessed treatment alternatives.

Systematic review question

What is the evidence for effective treatment regimens for menstrual abnormalities during LNG IUD use?

References from systematic review

No studies identified.

Key unresolved issues

What are the mechanisms underlying LNG IUD associated bleeding abnormalities?

How can bleeding abnormalities associated with LNG IUD use best be treated?

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

26

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

26

26. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease (PID)?

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 sexually transmitted infections, 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, fair, direct.

References from systematic review

1. Altunyurt S, Demir N, Posaci C. A randomized controlled trial of coil removal prior to treatment of pelvic inflammatory disease. *European Journal of Obstetrics and Gynecology and Reproductive Biology*, 2003, 107:81–84.
2. 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, 15:143–149.
3. Söderberg G, Lindgren S. Influence of a intrauterine device on the course of an acute salpingitis. *Contraception*, 1981, 24:137–143.
4. Teisala K. Removal of an intrauterine device and the treatment of acute pelvic inflammatory disease. *Annals of Medicine*, 1989, 21:63–65.

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?

27

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

27

27. What should be done if a woman using a levonorgestrel-IUD (LNG IUD) is diagnosed with pelvic inflammatory disease (PID)?

Pelvic inflammatory disease (PID)

- Treat the PID using appropriate antibiotics.
- There is no need for removal of the LNG IUD if she wishes to continue its use.
- If she does not want to keep the LNG IUD, remove it after antibiotic treatment has been started.
- If the LNG 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 LNG IUD and continue antibiotics. If the LNG IUD is not removed, antibiotics should also be continued. In both circumstances, her health should be closely monitored.
- Provide comprehensive management for sexually transmitted infections, including counselling about condom use.

Comments

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

The recommendations were based on evidence for the copper-bearing IUD.

Systematic review question

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

References from systematic review

No studies identified.

Other key references

1. Altunyurt S, Demir N, Posaci C. A randomized controlled trial of coil removal prior to treatment of pelvic inflammatory disease. *European Journal of Obstetrics and Gynecology and Reproductive Biology*, 2003, 107:81–84.
2. 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, 15:143–149.
3. Söderberg G, Lindgren S. Influence of a intrauterine device on the course of an acute salpingitis. *Contraception*, 1981, 24:137–143.
4. Teisala K. Removal of an intrauterine device and the treatment of acute pelvic inflammatory disease. *Annals of Medicine*, 1989, 21:63–65.

Key unresolved issues

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

28

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

28

28. 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 an increased risk of first and second trimester miscarriage (including septic miscarriage that may be life-threatening) and of pre-term delivery if the IUD is left in place. The removal of the copper-bearing 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 first and second trimester miscarriage (including septic miscarriage that may be life-threatening) and of pre-term delivery if the copper-bearing IUD is left in place. 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 copper-bearing IUD.
- If the copper-bearing 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 copper-bearing 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 copper-bearing IUD. If the copper-bearing IUD is not located, this may suggest that an expulsion of the copper-bearing IUD has occurred.
- If ultrasound is not possible or if the copper-bearing 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 copper-bearing IUD improves pregnancy outcome if the IUD strings are visible or can be retrieved safely from the cervical canal, and that the risks of miscarriage, pre-term delivery and infection are substantial if the copper-bearing IUD is left in place.

Systematic review question

What are the risks of adverse events if the copper-bearing IUD is removed or kept in place?
Level of evidence: II-2, fair, direct.

References from systematic review

1. Alvior GT, Jr. Pregnancy outcome with removal of intrauterine device. *Obstetrics and Gynecology*, 1973, 41:894–896.

2. Dreishpoon IH. Complications of pregnancy with an intrauterine contraceptive device in situ. *American Journal of Obstetrics and Gynecology*, 1975, 121:412–413.

3. Fulcheri E, di Capua E, Ragni N. Pregnancy despite IUD: adverse effects on pregnancy evolution and fetus. *Contraception*, 2003, 68:35–38.

4. Kirkinen PS. Ultrasound-controlled removal of a dislocated intrauterine device in the first trimester of pregnancy: a report of 26 cases. *Ultrasound in Obstetrics and Gynecology*, 1992, 2:345–348.

5. Koetsawang S, Rachawat D, Piya-Anant M. Outcome of pregnancy in the presence of intrauterine device. *Acta Obstetricia et Gynecologica Scandinavica*, 1977, 56:479–482.

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7. Shalev J et al. Continuous sonographic monitoring of IUD extraction during pregnancy: preliminary report. *American Journal of Roentgenology*, 1982, 139:521–523.

8. 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: 265-270.

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11. Vessey MP et al. Outcome of pregnancy in women using an intrauterine device. *Lancet*, 1974, 1:495–498.

Key unresolved issues

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

29

What should be done if a woman using a levonorgestrel-releasing IUD is found to be pregnant?

29

29. What should be done if a woman using a levonorgestrel-IUD (LNG IUD) is found to be pregnant?

LNG IUD user is found to be pregnant

- Exclude ectopic pregnancy.
- Explain that she is at an increased risk of first and second trimester miscarriage (including septic miscarriage that may be life-threatening) and of pre-term delivery if the LNG IUD is left in place. The removal of the LNG 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 first and second trimester miscarriage (including septic miscarriage that may be life-threatening) and of pre-term delivery if the LNG IUD is left in place. 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 LNG IUD.
- If the LNG 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 LNG 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 LNG IUD. If the LNG IUD is not located, this may suggest that an expulsion of the LNG IUD has occurred.
- If ultrasound is not possible or if the LNG 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 LNG IUD improves pregnancy outcome if the IUD strings are visible or can be retrieved safely from the cervical canal, and that the risks of miscarriage, pre-term delivery and infection are substantial if the LNG IUD is left in place.

These recommendations were based on evidence for the copper-bearing IUD. In addition, the expert Working Group considered that there are theoretical concerns about hormonal exposure of the fetus. Whether there is an increased risk of fetal abnormalities due to this exposure, however, is unknown.

Systematic review question

What are the risks of adverse events if the LNG IUD is removed or kept in place?
Level of evidence: II-3, poor, indirect.

References from systematic review

1. Backman T et al. Pregnancy during the use of levonorgestrel intrauterine system. *American Journal of Obstetrics and Gynecology*, 2004, 190:50–54.

2. Fulcheri E, di Capua E, Ragni N. Pregnancy despite IUD: adverse effects on pregnancy evolution and fetus. *Contraception*, 2003, 68:35–38.

Key unresolved issues

Are there adverse fetal effects associated with in utero exposure to levonorgestrel with the LNG IUD?

Programmatic issues

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

31. How many pill packs [combined (COCs) or progestogen-only pills (POPs)] should be given at initial and return visits?

32. What follow-up is appropriate for combined oral contraceptive (COCs), progestogen-only pill (POPs), implant and IUD users?

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

30

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

30. 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, *Medical eligibility criteria for contraceptive use. Third edition,* 2004, 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:

* *The Medical eligibility criteria for contraceptive use. Third edition*, 2004, states that If a woman has a very high individual likelihood of exposure to gonorrhoea or chlamydial infection, she should generally not have an IUD inserted unless other methods are not available or not acceptable. If she has current purulent cervicitis or gonorrhoea or chlamydial infection, then she should not have an IUD inserted until these conditions are resolved and she is otherwise medically eligible.

† *The Medical eligibility criteria for contraceptive use. Third edition,* 2004, states that women at high risk of HIV infection should not use spermicides containing nonoxynol-9. Using diaphragms and cervical caps with nonoxynol-9 is not usually recommended for women at high risk of HIV infection unless other more appropriate methods are not available or not acceptable. 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§**

31

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

31. 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?

32

What follow-up is appropriate for combined oral contraceptive, progestogen-only pill, implant and IUD users?

32. What follow-up is appropriate for combined oral contraceptive (COC), progestogen-only pill (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 from 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?

33

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

33. 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 postabortion or miscarriage
- is fully or nearly fully breastfeeding, amenorrhoeic, and less then 6 months postpartum.

Expert Working Group Meeting to update the Selected Practice Recommendations for Contraceptive Use

Salle C, World Health Organization, Geneva, 13–16 April 2004

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