World Health Organization

Selected practice recommendations for contraceptive use

Third edition 2016

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Department of Reproductive Health and Research

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Acronyms and abbreviations

CDC	Centers for Disease Control and Prevention (United States of America)
CIC	combined injectable contraceptive
CIRE	Continuous Identification of Research Evidence
COC	combined oral contraceptive
CRPD	United Nations Convention on the Rights of Persons with Disabilities
Cu-IUD	copper-bearing intrauterine device
CVR	combined contraceptive vaginal ring
DMPA	depot medroxyprogesterone acetate
DMPA-IM	DMPA, administered intramuscularly
DMPA-SC	DMPA, administered subcutaneously
EC	emergency contraception
ECP	emergency contraceptive pill
ETG	etonogestrel
FAB	fertility awareness-based (method)
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IM	intramuscular
IUD	intrauterine device
LNG	levonorgestrel
LNG-ECP	levonorgestrel emergency contraceptive pill
LNG-IUD	levonorgestrel-releasing intrauterine device
MEC	*Medical eligibility criteria for contraceptive use* (WHO publication)
NET-EN	norethisterone enanthate
NIH	National Institutes of Health (United States of America)
NSAID	nonsteroidal anti-inflammatory drug
PICO	population, intervention, comparator, outcome
PID	pelvic inflammatory disease
POC	progestogen-only contraceptive
POI	progestogen-only injectable
POP	progestogen-only pill
SDM	Standard Days Method®
SI(II)	Sino-implant (II)®
SPR	*Selected practice recommendations for contraceptive use* (WHO publication)
STI	sexually transmitted infection
UPA	ulipristal acetate
UPA-ECP	ulipristal acetate emergency contraceptive pill
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

Introduction

This document is part of the process for improving the quality of care in family planning. Specifically, it is one of two evidence-based cornerstones (guidance documents) of the World Health Organization's (WHO's) initiative to develop and implement family planning guidelines for national programmes. The first cornerstone, the *Medical eligibility criteria for contraceptive use* (MEC, now in its fifth edition)[1], provides thorough information and guidance on the safety of various contraceptive methods for use in the context of specific health conditions and characteristics. This document, *Selected practice recommendations for contraceptive use, third edition* (SPR third edition), is the second cornerstone; it provides guidance for how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. For recommendations issued in the SPR, safety considerations include common barriers to safe, correct and consistent use of contraception and the benefits of preventing unintended or unwanted pregnancy. There are two other cornerstone documents aimed at guiding health-care providers in applying the recommendations in the MEC and SPR: *Decision-making tool for family planning clients and providers*[2] and *Family planning: a global handbook for providers*.[3] Figure 1 illustrates how each of these four WHO documents is targeted to a particular audience and addresses a unique, yet complementary aspect of family planning.

Family planning is essential to promoting the well-being and autonomy of women, their families and their communities. Quality of care in family planning is paramount for ensuring progress towards achieving high standards of health for all. As defined in the WHO publication, *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations*,[4] elements of quality of care in family planning include: choice among a wide range of contraceptive methods; evidence-based information on the effectiveness, risks and benefits of different methods; technically competent, trained health workers; provider–user relationships based on respect for informed choice, privacy and confidentiality; and the appropriate constellation of services that are available in the same locality. This document contributes to improving the quality of care in family planning by presenting evidence-based guidance on the safe provision of contraceptive methods for both women and men.

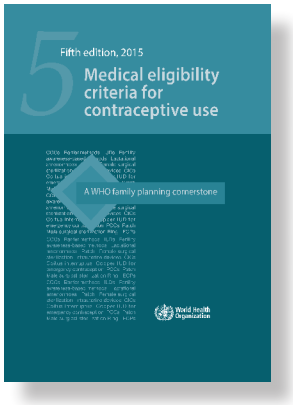
This third edition of the SPR has two components, published separately. This main document, the SPR third edition, contains the new, updated and reaffirmed contraceptive provision recommendations and describes how to apply them. Meanwhile, the SPR Web annex, *Development of updated guidance for the third edition*, contains supplementary material that explains how the recommendations were developed.[5]

The SPR third edition includes guidance on the following family planning methods for women and men: copper-bearing intrauterine devices (Cu-IUDs), levonorgestrel-releasing IUDs (LNG-IUDs), levonorgestrel (LNG) and etonogestrel (ETG) implants, depot medroxyprogesterone acetate (DMPA)

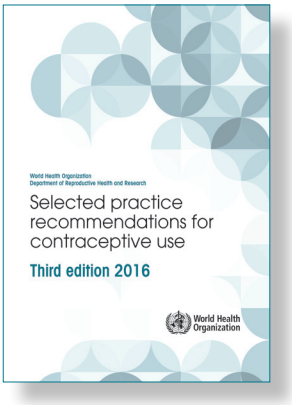
[1] Published in 2015. Available at: http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/
[2] Published in 2005. Available at: http://www.who.int/reproductivehealth/publications/family_planning/9241593229index/en/
[3] Published in 2011. Available at: http://www.who.int/reproductivehealth/publications/family_planning/9780978856304/en/
[4] Published in 2014. Available at: http://who.int/reproductivehealth/publications/family_planning/human-rights-contraception/en/
[5] Available at: www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/

Figure 1. The four cornerstones of family planning guidance

Target audience: Policy makers and programme managers



Medical eligibility criteria for contraceptive use
Guidance on *who* can use contraceptive methods safely



Selected practice recommendations for contraceptive use
Guidance on *how* to use contraceptive methods safely and effectively

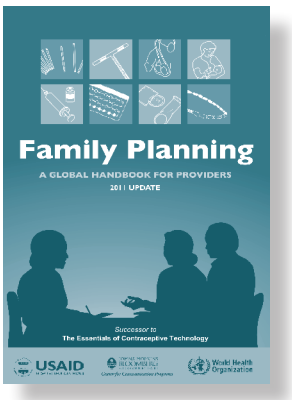
These are evidence-based guidance and consensus-driven guidelines. They provide recommendations made by expert working groups based on an appraisal of relevant evidence. They are reviewed and updated in a timely manner.

Process for assuring that the guidelines remain current:

1. Identify new, relevant evidence as soon as it becomes available through an ongoing comprehensive bibliographic search.
2. Critically appraise the new evidence.
3. Evaluate the new evidence in light of prior evidence.
4. Determine whether the newly synthesized evidence is sufficient to warrant an update of existing recommendations.
5. Provide electronic updates on WHO's reproductive health web site (www.who.int/reproductivehealth) as appropriate and determine the need to convene an expert working group to reassess guidelines formally.

Target audience: Providers of contraceptive counselling and services

Decision-making tool for family planning clients and providers



Family planning: a global handbook for providers

These are tools that incorporate the *Medical eligibility criteria*, the *Selected practice recommendations* and other consensus recommendations on how to meet the needs of the family planning client. They will be updated as the guidelines are updated or as other evidence warrants.

administered intramuscularly or subcutaneously, norethisterone enanthate (NET-EN), progestogen-only pills (POPs), low-dose (≤ 35 µg ethinyl estradiol) combined[1] oral contraceptive pills (COCs), the combined contraceptive transdermal patch (the patch), the combined contraceptive vaginal ring (CVR), combined injectable contraceptives (CICs), emergency contraceptive pills (ECPs), Cu-IUD for emergency contraception, Standard Days Method® (SDM) (a fertility awareness-based method), and male sterilization (vasectomy). It covers the following topics: method initiation/continuation, incorrect use, problems during use (vomiting and/or diarrhoea, menstrual abnormalities, pelvic inflammatory disease, pregnancy) and programmatic issues.

Target audience

The intended audience for this publication includes policy-makers and family planning programme managers at the national level. The SPR is not meant to serve as the actual guidelines for national family planning and reproductive health programmes, but rather as a reference in the preparation of guidelines for delivery of contraceptive services. 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. Policy-makers and family planning programme managers can use this guidance to develop their own national standards and protocols. While it is unlikely that the recommendations in this document would change during this process, it is very likely that their application at country level will vary. In particular, the level of clinical knowledge and experience of various types of providers and the resources available at the service-delivery point will have to be taken into consideration.

Guideline development methods

The Guideline Development Group (GDG), convened by WHO, consisted of 68 individuals representing a wide range of stakeholders. Their mandate was to review and, where appropriate, revise the guidance in the second edition of the SPR (2004) and the 2008 SPR update. GDG meetings were held on 14–15 May 2013, 9–12 March 2014 and 24–25 September 2014.

For this revision process, the GDG prioritized the review of 19 topics related to the inclusion in the third edition of five new contraceptive methods:

- a 2-rod levonorgestrel-containing implant – Sino-implant (II)®
- subcutaneously administered DMPA
- the patch
- the CVR, and
- ulipristal acetate ECPs (UPA-ECPs);

and one additional question:

- When can a woman resume or start regular contraception after using emergency contraception?

The recommendations in this document are based on the latest clinical and epidemiological data summarized in 14 systematic reviews. When no direct evidence was identified, indirect evidence was considered, such as extrapolation from evidence relating to similar contraceptive methods or evidence for proxy measures of clinical outcomes. For example, evidence on COCs was considered for recommendations for the patch and the CVR, evidence for one type of levonorgestrel implant was considered for another type of levonorgestrel implant, and markers of ovulation were used as a proxy measure for risk for pregnancy. An additional systematic review on the values and preferences

[1] "Combined" refers to a combination of ethinyl estradiol and a progestogen.

of contraceptive users was prepared to inform the development of the recommendations issued in these updated guidelines.

The GDG considered the overall quality of the available scientific evidence, paying particular attention to the strength and consistency of the data, according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evidence review.[1] To formulate recommendations, the GDG considered the GRADE evidence profiles, any indirect evidence, the benefits of preventing unintended pregnancy, and an approach towards patient values and preferences that prioritized the availability of a wide range of contraceptive options and the removal of unnecessary medical barriers, thus facilitating access to contraceptive services. In this updated edition of the SPR, the GDG classified recommendations on reviewed topics as "strong" or "conditional". Because the target audience for this document is policy-makers, a "strong" recommendation is one that can be adopted as policy in most situations, while a "conditional" recommendation will require substantial debate and involvement of various stakeholders before becoming policy.[2]

In the SPR third edition, the majority of recommendations are provided in narrative form; however, for recommendations on which examinations and tests should be offered for the safe provision of a contraceptive method, an A-B-C classification scale is applied. This scale was defined by the expert group that developed the first edition of the SPR in 2001, and has been used by national programmes ever since. To avoid unnecessary confusion among users of the guideline, the A-B-C classification has been retained for recommendations related to examinations and tests. The GDG followed the same process when formulating recommendations for examinations and tests as was done for other recommendations (e.g. developing clinical questions according to the PICO format, conducting systematic reviews, preparing GRADE evidence tables, and formulating recommendations based upon these elements while considering the benefits and potential harms of applying the recommendations, and women's values and preferences).

The Continuous Identification of Research Evidence (CIRE) system was created by WHO and its partners in 2002 to continuously and systematically identify newly published evidence that is relevant to WHO's family planning guidelines. When applicable, systematic reviews are updated to determine whether WHO recommendations remain consistent with the overall body of evidence. In many instances, either no new evidence has been identified since the publication of the last edition of the SPR and the 2008 update, or evidence emerging since those publications simply confirms previous research findings. Therefore, in many cases, the recommendations that were previously published were reviewed and confirmed by the GDG with no changes made.

Through consensus, the GDG arrived at the new recommendations (see Table 1) and upheld the majority of the existing recommendations. Consensus was achieved through discussion, debate and expert consultation with final agreement among all members of the GDG.

WHO will initiate a review of all the recommendations in this document in four years. In the interim, WHO will continue to monitor the body of evidence informing these recommendations and will convene additional consultations, as needed, should new evidence necessitate reconsideration of existing recommendations. Such updates may be particularly warranted for issues where the evidence base may change rapidly. These interim recommendations will be made available on WHO's

[1] Further information is available at the website of the GRADE working group: http://www.gradeworkinggroup.org

[2] The definitions for "strong" and "conditional" recommendations are based on guidance provided in the WHO Handbook for Guideline Development, available at http://www.who.int/kms/guidelines_review_committee/en/

web pages for sexual and reproductive health.[1] WHO encourages research to address key unresolved issues related to the safe and effective use of contraceptives. WHO also invites comments and suggestions for improving this guidance.

Summary of reviewed recommendations

Nineteen topics (encompassing over 75 recommendations) were reviewed by the GDG during the revision of the SPR to develop this third edition. These new recommendations are summarized in Table 1. The GRADE approach was applied to assess the quality of the available evidence and provided the basis for formulation of the recommendations. For some topics, multiple outcomes of interest and/or contraceptive methods were examined; for these topics, a range of GRADE assessments is presented. An explanation of the process followed to select and prioritize these 19 topics is described in the SPR Web annex: Development of updated guidance for the third edition.[2] All other recommendations were confirmed by the GDG and did not undergo formal review for the third edition of the SPR (these confirmed recommendations are not included here in Table 1, but can be found in the main text).

[1] Available at: http://www.who.int/reproductivehealth/topics/family_planning/en/
[2] Available at: www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/

Table 1: New topics reviewed for the SPR third edition

New clinical recommendations	GRADE assessment of quality of evidence	Strength of recommendation[a]
1. Levonorgestrel (LNG) implant: Sino-implant (II)®		
1.1 A woman can start Sino-implant (II), or SI(II), within 7 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also provided for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.	No direct evidence	Strong
1.2 It is desirable to have blood pressure measurements taken before initiation of SI(II). Women should not be denied use of SI(II) simply because their blood pressure cannot be measured.	No direct evidence	Strong
1.3 Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, sexually transmitted infection (STI) risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of SI(II).	No direct evidence	Strong
1.4 The product labelling for SI(II) states that the implant can be left in place for up to 4 years.	Low	Strong
1.5 No routine follow-up is required after initiating SI(II).	No direct evidence	Strong
2. Progestogen-only injectable contraceptive: DMPA administered subcutaneously (DMPA-SC)		
2.1 A woman can start DMPA-SC within 7 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also provided for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.	No direct evidence	Strong
2.2 It is desirable to have blood pressure measurements taken before initiation of DMPA-SC. Women should not be denied use of DMPA-SC simply because their blood pressure cannot be measured.	No direct evidence	Strong
2.3 Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, STI risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of DMPA-SC.	No direct evidence	Strong
2.4 Provide repeat DMPA-SC injections every 3 months. Recommendations are also provided for early and late injections.	Very low	Strong
3. Combined hormonal contraceptives (CHCs): the combined contraceptive patch and the combined contraceptive vaginal ring (CVR)		
3.1 A woman can start the patch or CVR within 5 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also provided for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.	Patch – Range: Moderate to low CVR – No direct evidence	Strong
3.2 It is desirable to have blood pressure measurements taken before initiation of the patch or CVR. Women should not be denied use of the patch or CVR simply because their blood pressure cannot be measured.	No direct evidence	Strong
3.3 Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, STI risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of the patch and CVR.	No direct evidence	Strong
3.4 A woman may need to take action if she has a dosing error with the patch or CVR. Recommendations are provided for management of the extension of the patch-free interval, unscheduled detachment of the patch, extended use of the patch, extension of the CVR-free interval, unscheduled removal of the CVR, and extended use of the CVR.	Patch: No direct evidence CVR: Very low	Strong
3.5 An annual follow-up visit is recommended after initiating the patch or CVR.	No direct evidence	Strong
4a. Emergency contraceptive pills (ECPs): ulipristal acetate (UPA-ECPs), LNG-only (LNG-ECPs) or combined estrogen–progestogen (combined ECPs)		
4.1 A woman should take a dose of UPA-ECP as early as possible after intercourse within 120 hours.	Low	Strong
4.2 LNG-ECPs or UPA-ECPs are preferable to combined 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.	Range: Moderate to low	Strong
4.3 If the woman vomits within 3 hours after taking a dose of UPA-ECP, she should take another dose as soon as possible.	No direct evidence	Strong
4b. Resumption or initiation of regular contraception after using emergency contraception		
4.4 Following administration of LNG-ECPs or combined ECPs, a woman may resume her contraceptive method, or start any contraceptive method immediately, including a copper-bearing intrauterine device (Cu-IUD).	No direct evidence	Strong
4.5 Following administration of UPA-ECPs, the woman may resume or start any progestogen-containing method (either combined hormonal contraceptives or progestogen-only contraceptives) on the 6th day after taking UPA. She can have an LNG-IUD inserted immediately if it can be determined that she is not pregnant. She can have the Cu-IUD inserted immediately.	No direct evidence	Conditional

[a] Strong recommendation: one that can be adopted as policy in most situations; conditional recommendation: policy-making will require substantial debate and involvement of various stakeholders.

1 Background

The *Selected practice recommendations for contraceptive use* (SPR) provides guidance regarding "how" to use contraceptive methods safely and effectively. The goal of the document is to improve access to, and quality of, family planning services by providing policy-makers, decision-makers and programme managers with recommendations that can be used for developing or revising national guidelines on the provision of all hormonal contraceptives, intrauterine devices, barrier methods, fertility awareness-based methods, male and female sterilization, and emergency contraception. This document does not provide rigid guidelines but 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.

1.1 Reproductive and sexual health care as a human right

The Programme of Action of the 1994 International Conference on Population and Development (ICPD) defines reproductive health as: "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes" *(1)*. The Programme of Action also states that the purpose of sexual health "is the enhancement of life and personal relations, and not merely counselling and care related to reproduction and sexually transmitted diseases". Recognizing the importance of agreements made at the ICPD and other international conferences and summits, the 1995 Beijing Declaration and Platform for Action defines reproductive rights in the following way:

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 (2).

Among the Millennium Development Goals (MDGs) agreed by states in 2001, target 5b called for universal access to reproductive health by 2015. At the end of that period, it has been reported that global contraceptive prevalence is 64% (41% in low-income countries) and global unmet need for family planning is 12% (22% in low-income countries) *(3)*. Now, among the new Sustainable Development Goals (SDGs), targets 3.7 and 5.6 call for universal access to sexual and reproductive health-care services and sexual and reproductive health and reproductive rights, respectively, by 2030. Reproductive and sexual health care, including family planning services and information, is recognized not only as a key intervention for improving the health of men, women and children, but also as a human right. International and regional human rights treaties, national constitutions and laws provide guarantees specifically relating to access to contraceptive information and services. These include the guarantee that states should ensure timely and affordable access to good quality sexual and reproductive health information and services, including contraception, which should be delivered in a way that ensures fully informed

decision-making, respects dignity, autonomy, privacy and confidentiality, and is sensitive to individuals' needs and perspectives in a client–provider partnership *(4)*. 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 when helping clients choose and use a family planning method safely.

Evidence shows that the respect, protection and fulfilment of human rights contribute to positive health outcomes. The provision of contraceptive information and services that respect individual privacy, confidentiality and informed choice, along with a wide range of safe contraceptive methods, increases people's satisfaction and their continued use of contraception *(5–8)*.

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 these 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 since they are not necessary to establish eligibility for the use or continuation of a particular method.

1.2 Contraceptive choice

While this document primarily addresses specific contraceptive practices, considerations of social, behavioural and other non-medical criteria – particularly client preference – must also be taken into account. 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 taken away from them or limited by direct or indirect social, economic and cultural factors. From a women's point of view, her choices are made at a particular time, in a particular societal and cultural context; choices are complex, multifactorial and subject to change. Decision-making for contraceptive methods usually requires making trade-offs among the advantages and disadvantages of different methods, and these vary according to individual circumstances, perceptions and interpretations. Factors to consider when choosing a particular contraceptive method include the characteristics of the potential user, the baseline risk of disease, the adverse effects profile of different products, cost, availability and patient preferences.

This document does not provide recommendations about which specific product or brand to use after selecting a particular type of contraceptive method. Instead it provides guidance on "how" to use contraceptive methods safely and effectively. Decisions about what methods to use should take into account client eligibility to use various contraceptive methods (please refer to the *Medical eligibility criteria for contraceptive use, fifth edition*, 2015, also known as the MEC) *(9)*, as well as clinical judgement and user preferences.

1.2.1 Issues of service quality and access that affect method use and choice

While this document chiefly addresses selected practice recommendations, 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:

- Clients should be given adequate information to help them make an informed, voluntary choice of a contraceptive method. The following information should be provided about each contraceptive method:
  - relative effectiveness
  - correct usage
  - how it works
  - common side-effects
  - health risks and benefits
  - signs and symptoms that would necessitate a return to the clinic
  - return to fertility after discontinuation
  - STI protection.

  Information should be presented using language and formats that can be easily understood and accessed by the client.
- Women who frequently experience user errors and women who anticipate experiencing user errors with user-dependent methods (e.g. oral contraceptive pills, the combined contraceptive transdermal patch [the patch], the combined contraceptive vaginal ring [CVR] or barrier methods) should be counselled regarding alternative contraceptive methods that are less dependent on the user to be effective (e.g. sterilization, intrauterine device [IUD], implant or injectable contraceptive).
- In order to offer methods that require surgical approaches, insertion, fitting and/or removal by a trained health-care provider (i.e. sterilization, implant, IUD, diaphragm, cervical cap), appropriately trained personnel in adequately equipped and accessible facilities must be available, and appropriate infection prevention procedures must be followed.
- Adequate and appropriate equipment and supplies need to be maintained and held in stock (e.g. contraceptive commodities and supplies for infection prevention procedures).
- Service providers should be provided with guidelines, client cards and/or other screening tools.

1.3 Effectiveness of methods

Contraceptive choice is in part dependent on the effectiveness of the contraceptive method in preventing unplanned pregnancy, which is in turn (for some methods) dependent not only on the protection afforded by the method itself, but also on how consistently and correctly it is used. Table 1.1 compares the percentage of women experiencing an unintended pregnancy during the first year of contraceptive use when the method is used perfectly (consistently and correctly) and when it is used typically (assuming occasional non-use and/or incorrect use). Consistent and correct usage can both vary greatly with client characteristics such as age, income, desire to prevent or delay pregnancy, and culture. Methods that depend on consistent and correct usage by clients (e.g. condoms and pills) have a wide range of effectiveness. Most men and women tend to be more effective users as they become more experienced with a method. Programmatic aspects, however, such as availability and cost of services and quality of counselling, also have a profound effect on how effectively (consistently and correctly) the method will be used.

1.4 Return to fertility

Among contraceptive methods, only male and female sterilization are regarded as permanent (no possibility of future childbearing). All individuals and couples considering these methods should be counselled accordingly. No other methods result in permanent infertility.

All other methods are reversible, usually with prompt return to fertility upon method discontinuation, with the exception

Table 1.1 Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception, and the percentage continuing use at the end of the first year, United States

	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at one year[c]
Method (1)	Typical use[a] (2)	Perfect use[b] (3)	(4)
No method[d]	85	85	
Spermicides[e]	28	18	42
Fertility awareness-based methods	24		47
Standard Days Method®[f]	—	5	—
TwoDay Method®[f]		4	
Ovulation Method[f]		3	
Sympto-thermal method		0.4	
Withdrawal	22	4	46
Sponge			36
Parous women	24	20	
Nulliparous women	12	9	
Condom[g]			
Female	21	5	41
Male	18	2	43
Diaphragm[h]	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Evra patch	9	0.3	67
NuvaRing®	9	0.3	67
Depo-Provera	6	0.2	56
Intrauterine contraceptives			
ParaGard® (copper T)	0.8	0.6	78
Mirena® (levonorgestrel)	0.2	0.2	80
Implanon®	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

Emergency contraceptives: Emergency contraceptive pills or insertion of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.[i]

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

[a] 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 and the diaphragm are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth corrected for underreporting of abortion.

[b] 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.

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

[d] 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.

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

[f] The Ovulation Method and TwoDay Method® are based on evaluation of cervical mucus. The Standard Days Method® avoids intercourse on cycle days 8–19. The sympto-thermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

[g] Without spermicides.

[h] With spermicidal cream or jelly.

[i] Plan B One-Step®, ella® and Next Choice One Dose® are the only dedicated products specifically marketed for emergency contraception in the United States at the time of writing. The label for Plan B One-Step (one dose is one white pill) says to take the pill within 72 hours after unprotected intercourse. Research has shown that all of the brands listed here are effective when used within 120 hours after unprotected sex. The label for Next Choice One Dose (one dose is one peach pill) says to take one pill within 72 hours after unprotected intercourse. The United States Food and Drug Administration has in addition declared the following 19 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel® (one dose is two white pills), Nordette® (one dose is four light-orange pills), Cryselle®, Levora®, Low-Ogestrel®, Lo/Ovral®, or Quasence® (one dose is four white pills), Jolessa®, Portia®, Seasonale® or Trivora® (one dose is four pink pills), Seasonique® (one dose is four light-blue-green pills), Enpresse® (one dose is four orange pills), Lessina® (one dose is five pink pills), Aviane® or LoSeasonique® (one dose is five orange pills), Lutera® or Sronyx® (one dose is five white pills), and Lybrel® (one dose is six yellow pills).

[j] 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.

Source: Trussell, 2011 *(10)*.

of injectable contraceptives depot medroxyprogesterone acetate (DMPA) and norethisterone enanthate (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.

1.5 Sexually transmitted infections and contraception: dual protection

In addition to the imperative of international norms for contraceptive provision to assure 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 infections among sexually active clients of reproductive age. When there is a risk of transmission of HIV and other STIs, such as in the context of high prevalence rates of HIV and other STIs in the geographic area or individual risk behaviour (e.g. multiple sexual partners without use of condoms), it is important that health-care providers offer information on safer sexual practices to prevent transmission and 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 prevention of both pregnancy and STIs, including HIV. Women and men seeking contraceptive advice must always be reminded of the importance of condom use for preventing the transmission of HIV/STIs and such use should be encouraged and facilitated where appropriate. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

2 Methods

This document, *Selected practice recommendations for contraceptive use, third edition*, builds upon a process initiated in 2000. Since the publication of the first edition of the SPR in 2002, several revisions have been undertaken. For interested readers, the methods used to develop the recommendations issued in this third edition are described in the accompanying SPR Web annex of supplementary material: *Development of updated guidance for the third edition*.[1] A brief summary of the methods used to develop the SPR guidance since the publication of the first edition is provided here.

The first edition of the SPR was published in 2002 after a multidisciplinary group of experts assembled to discuss newly published evidence pertaining to the topics addressed in the guidelines. In November 2002, the World Health Organization (WHO) established the Continuous Identification of Research Evidence (CIRE) system *(11)*, to systematically and continuously monitor the evidence supporting the recommendations in this guideline on an ongoing basis. In the CIRE system, as new evidence emerges, the articles are screened for relevance. When applicable, systematic reviews are updated to alert WHO as to whether its recommendations remain consistent with the overall body of evidence or not. WHO uses CIRE to ensure the SPR guidance remains current between GDG meetings and to identify topics that need to be addressed when a formal guideline revision occurs.

In preparation for the current third edition, a Guideline Development Group (GDG) was convened in 2013 to prioritize topics to be reviewed and updated (please refer to the acknowledgements section for a list of GDG members and the SPR Web annex, Appendix 2, for a summary of the GDG members' declarations of interests). The GDG prioritized the review of 19 topics related to the inclusion in the third edition of five new contraceptive methods:

- a 2-rod levonorgestrel-containing implant – Sino-implant (II)® (see section 7.3.1)
- subcutaneously-administered depot medroxyprogesterone acetate (DMPA-SC) (see section 7.3.2)
- the combined contraceptive transdermal patch (see section 7.4.1)
- the combined contraceptive vaginal ring (CVR) (see section 7.4.1), and
- ulipristal acetate emergency contraceptive pills (UPA-ECPs) (see section 7.5.1);

and one additional question:

- When can a woman resume or start regular contraception after using emergency contraception? (see section 7.5.2).

The GDG created questions using the PICO format (i.e. questions with specified populations, interventions, comparators and outcomes) to guide the systematic reviews and the preparation of Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence tables.[2] In many cases, either no new evidence was identified or new evidence confirmed prior findings. Thus, for many topics, prior recommendations were simply reaffirmed. In this third edition of the SPR, the GRADE approach was used to classify

[1] Available at: www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/

[2] Further information is available at the website of the GRADE working group: http://www.gradeworkinggroup.org

recommendations on reviewed topics as "strong" or "conditional". Because the target audience for this document is primarily policy-makers, a "strong" recommendation is one that can be adopted as policy in most situations, while a "conditional" recommendation will require substantial debate and involvement of various stakeholders before becoming policy *(12)*.

In this document, recommendations are presented in narrative form for readers accustomed to the format of previous SPR editions. For the recommendations on examinations and tests prior to initiating use of each contraceptive method, an A-B-C classification is employed to define whether various procedures are necessary for the safe provision of the method. The recommendation categories for examinations and tests (i.e. the use of Class A, B and C) were defined by the expert group that developed the first edition of the SPR in 2001. They were applied in 2001 to alert programme managers and policy-makers of whether or not a particular test or examination is mandatory prior to providing a contraceptive method. Often, examinations and tests are mandated when, in fact, they are not necessary. In developing the recommendations for these examinations and tests, the GDG followed the same rigorous process of evidence review as was done for other recommendations in this edition.

The GDG endorsed an approach to patient preferences and values that prioritized the availability of a wide range of contraceptive options and the removal of unnecessary medical barriers. Because the focus of this guidance is on the safe provision of contraceptive methods, once counselling and shared decision-making for a contraceptive method has taken place, and since costs vary widely throughout different regions and settings, opportunity costs were not formally assessed during the formulation of these recommendations.

Through consensus, the GDG arrived at new and revised recommendations and upheld the majority of the existing recommendations. Consensus was achieved through discussion, debate and expert consultation, with final agreement among all the members of the GDG. For each recommendation, the Chair asked GDG members whether they agreed with the recommendation; any disagreement was documented. All GDG members agreed with all of the recommendations in the guideline.

3 How to use this document

This document is not meant to serve as the actual guidelines for national family planning and reproductive health programmes, but rather as a reference in the preparation of guidelines for delivery of contraceptive services. 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. While it is unlikely that the recommendations in this document would change during this process, it is very likely that their application at country level will vary. In particular, the level of clinical knowledge and experience of various types of providers and the resources available at the service-delivery point will have to be taken into consideration.

Recommendations are presented in section 7 in sub-sections by type of contraceptive method: intrauterine devices (IUDs); progestogen-only contraceptives (POCs); combined hormonal contraceptives (CHCs); emergency contraception (EC); Standard Days Method® (SDM); and male sterilization. In these method sub-sections, recommendations are presented for: timing of initiation; examinations and tests needed before initiation; continuation, discontinuation and switching methods; management of problems during usage, such as side-effects or dosing errors; and appropriate follow-up. In addition, remarks and information on underlying principles are provided when needed, as well as lists of all relevant references. The SPR third edition contains information on the recommendations which are based upon a review of the summarized epidemiological and clinical data, considerations of benefits and harms, patient values and preferences, and the quality of the evidence. Details on this process are presented in the SPR Web annex: *Development of updated guidance for the third edition*.[1]

3.1 Classification of examinations and tests before initiation of contraceptive methods

Regarding examinations and tests that may be considered before initiation of contraceptives, the following classification was used in differentiating the applicability of the various examinations and tests:

Class A = The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B = The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available.

Class C = The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

The examinations or tests that are considered for each type of contraceptive in section 7 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 confirmed as appropriate candidates for a particular contraceptive method. The SPR's partner document, *Medical eligibility*

[1] Available at: www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/

criteria for contraceptive use, fifth edition (MEC, published in 2015), may be useful in such circumstances *(9)*.

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.

3.2 Contraceptive eligibility

Within this revised third edition of the SPR, references to the MEC categories for contraceptive eligibility (categories 1–4) are often included. Box 1 lists these categories and their basic definitions.

Box 1: MEC categories for contraceptive eligibility

Category 1	A condition for which there is no restriction for the use of the contraceptive method
Category 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
Category 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method
Category 4	A condition which represents an unacceptable health risk if the contraceptive method is used

For further information, please refer to: *Medical eligibility criteria for contraceptive use, fifth edition*, WHO, 2015 *(9)*.

4 Programmatic implications

The following issues need to be addressed when applying the recommendations in this document to programmes:

- 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.

Service-delivery practices that are essential for the safe use of particular contraceptive methods 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 first step, the recommendations need to be considered in light of the country context, 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 it may require a modest addition of equipment and supplies, and redeployment of space. It will also be necessary to address misperceptions sometimes held by providers and users about the risks and side-effects of particular methods, and to look closely at the needs and perspectives of women and men during the process of facilitating an informed choice.

Adaptation of global guidelines to national programmes is not always an easy task and is best done by those well acquainted with prevailing local health conditions, behaviours and culture. These improvements must be made within the context of users' informed choices and medical safety.

4.1 Introducing guidelines into national programmes

When introducing this guidance on the selected practice recommendations for contraceptive use into a national programme for sexual and reproductive health care, it is important to consider that this material is not simply a document that must be distributed, but rather it contains health-care practices that must be introduced to providers through a well-planned process of adaptation and implementation.

Guidance for countries on the introduction of sexual and reproductive health guidelines is available in the document, *Introducing WHO's sexual and reproductive health guidelines and tools into national programmes (13)*. That publication is designed for use by policy-makers, programme managers and other health-care professionals embarking on a process to introduce evidence-based practices in sexual and reproductive health into their national or local programmes. Within the document, six overarching principles are recommended for the effective adaptation and implementation of WHO guidance on sexual and reproductive health into national programmes. These principles include: building consensus; building on what exists; identifying possible barriers and facilitating factors;

ensuring that adaptations are evidence-based; planning scale-up from the beginning; and implementing a range of interventions to change provider practices.

To introduce this third edition of *Selected practice recommendations for contraceptive use*, WHO suggests that countries or local authorities follow a six-step process:

- plan for advocacy
- conduct a situation analysis
- adapt the guidance to fit a country's needs, circumstances and context
- design an implementation strategy
- pilot-test an evaluation
- implement advocacy and scale-up.

This process may vary depending upon whether the guidance is being introduced for the first time or is being used to update existing service-delivery guidelines. Throughout these steps, WHO stresses the importance that the process for introducing guidance be collaborative and participatory to foster ownership and buy-in among policy-makers, professional bodies and other national experts.

5 Clients with special needs

5.1 People with disabilities

According to United Nations Convention on the Rights of Persons with Disabilities (CRPD, 2006), people with disabilities must have access, on an equal basis with others, to all forms of sexual and reproductive health care (Article 25) as part of the general right to marry, found a family and retain their fertility (Article 23) *(12)*. Health-care professionals often fail to offer sexual and reproductive health services to people with disabilities, based on the common misconception that they are not sexually active *(14)*. Provision of contraceptive services to people with disabilities may, however, require decisions regarding appropriate contraception considering the preferences of the individual, the nature of the disability and the specifics of different contraceptive methods.

For example, some barrier methods may be difficult to use for those with limited manual dexterity; combined oral contraceptives may not be an appropriate method for women with impaired circulation or immobile extremities, even in the absence of known thrombogenic mutations, because of concerns about an increased risk of deep vein thrombosis (DVT); and other methods will be preferable for individuals with intellectual or mental health disabilities who have difficulty remembering to take daily medications. For women who have difficulty with menstrual hygiene, the impact of the contraceptive method on menstrual cycles should also be considered.

In all instances, medical decisions must be based upon informed choice, based on adequate sexual and reproductive health education. When the nature of the disability makes it more challenging to discern the will and preferences of the individual, contraceptives should only be provided in a manner consistent with Article 12 of CRPD. Specifically, in such cases a process of supported decision-making should be instituted in which individuals who are trusted by the individual with the disability (or disabilities), personal ombudsman and other support persons jointly participate with the individual in reaching a decision that is, to the greatest extent possible, consistent with the will and preference of that individual. Given the history of involuntary sterilization of persons with disabilities, often as a technique for menstrual management in institutions *(14)*, it is especially important to ensure that decisions about sterilization are only made with the full and informed consent of the individual, either alone or with support, free from coercion.

5.2 Adolescents

Adolescents in many countries lack adequate access to contraceptive information and services that are necessary to protect their sexual and reproductive health and rights. There is an urgent need to implement programmes that both meet the contraceptive needs of adolescents and remove barriers to services. In general, adolescents are eligible to use all the same methods of contraception as adults, 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 about the use of certain contraceptive methods by adolescents (e.g. the use of progestogen-only injectable contraceptives by those below 18 years), these concerns must be balanced against the advantages of preventing

unintended pregnancy. To help determine if adolescents with certain medical conditions or characteristics can safely use particular contraceptive methods, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition (9).*

Political and cultural factors may affect adolescents' ability to access contraceptive information and services. For example, where contraceptive services are available, adolescents (unmarried ones, in particular) may not be able to obtain them because of restrictive laws and policies. Even if adolescents are able to obtain contraceptive services, they may not do so because of fear that their confidentiality will not be respected, or that health workers may be judgemental. All adolescents, regardless of marital status, have a right to privacy and confidentiality in health matters, including reproductive health care. Appropriate sexual and reproductive health services, including contraception, should be available and accessible to all adolescents without necessarily requiring parental or guardian authorization by law, policy or practice.

Social and behavioural issues should also be key considerations in the choice of contraceptive methods by adolescents. For example, in some settings, adolescents are also at increased risk for sexually transmitted infections, 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 convenient. 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 meet their particular needs and make informed and voluntary decisions. Every effort should be made to prevent the costs of services and/or methods from limiting the options available.

References for sections 1–5

1. Programme of Action of the International Conference on Population and Development. In: Report of the International Conference on Population and Development (Cairo, 5–13 September 1994). Cairo: United Nations; 1994: para. 7.2 (A/CONF.171/13, http://www.un.org/popin/icpd/conference/offeng/poa.html, accessed 8 July 2016).
2. Beijing Declaration and Platform for Action. In: Report of the Fourth World Conference on Women (Beijing, 4–15 September, 1995). Beijing: United Nations; 1995: para. 95 (A/CONF.177/20; http://www.un.org/esa/gopher-data/conf/fwcw/off/a--20.en, accessed 8 July 2016).
3. Chapter 4: Health service coverage. In: World health statistics 2015. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/topics/mdgs/health-service-coverage2015.pdf, accessed 8 July 2016).
4. Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/102539/1/9789241506748_eng.pdf, accessed 8 July 2016).
5. Koenig MA. The impact of quality of care on contraceptive use: evidence from longitudinal data from rural Bangladesh. Baltimore (MD): Johns Hopkins University; 2003.
6. Arends-Kuenning M, Kessy FL. The impact of demand factors, quality of care and access to facilities on contraceptive use in Tanzania. J Biosoc Sci. 2007;39(1):1–26. doi:10.1017/S0021932005001045.
7. RamaRao S, Lacuest M, Costello M, Pangolibay B, Jones H. The link between quality of care and contraceptive use. Int Fam Plann Perspect. 2003;29(2):76–83. doi:10.1363/ifpp.29.076.03.
8. Sanogo D, RamaRao S, Johnes H, N'diaye P, M'bow B, Diop CB. Improving quality of care and use of contraceptives in Senegal. Afr J Reprod Health. 2003;7(2):57–73.
9. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
10. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, editors. Contraceptive technology: twentieth revised edition. New York (NY): Ardent Media; 2011.

11. WHO handbook for guideline development, second edition. Geneva: World Health Organization; 2014 (http://www.who.int/kms/handbook_2nd_ed.pdf, accessed 8 July 2016).
12. United Nations Convention on the Rights of Persons with Disabilities. Resolution adopted by the United Nations General Assembly. New York (NY): United Nations; 2006 (A/RES/61/106; http://www.un-documents.net/a61r106.htm, accessed 8 July 2016).
13. Introducing WHO's sexual and reproductive health guidelines and tools into national programmes: principles and processes of adaptation and implementation. Geneva: World Health Organization; 2007 (http://whqlibdoc.who.int/hq/2007/WHO_RHR_07.9_eng.pdf, accessed 8 July 2016).
14. World report on disability 2011. Geneva: World Health Organization; 2011 (http://www.who.int/disabilities/world_report/2011/report/en/, accessed 8 July 2016).

6

Summary of changes within the *Selected practice recommendations for contraceptive use, third edition*

Five new contraceptive methods were added in this edition:

- Sino-Implant (II)® – a 2-rod implant, each rod containing 75 mg of levonorgestrel
- subcutaneously administered depot medroxyprogerone acetate (DMPA-SC)
- combined hormonal transdermal contraceptive patch
- combined contraceptive vaginal ring (CVR)
- ulipristal acetate emergency contraceptive pills (UPA-ECPs).

One new question was considered in this edition:

- When can a woman resume or start regular contraception after using emergency contraception?

7 Recommendations

7.1 How can a health-care provider be reasonably certain 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.

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

7.2 Intrauterine devices

Intrauterine devices (IUDs) are long-acting methods of contraception. This section provides recommendations on copper-bearing IUDs (Cu-IUD) and levonorgestrel-releasing IUDs (LNG-IUD).

IUDs can generally be used by most women including adolescents and nulliparous women. To help determine if women with certain medical conditions or characteristics can safely use IUDs, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition* (MEC) *(1)*.

IUDs do not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

7.2.1 Copper-bearing IUDs (Cu-IUD) and levonorgestrel-releasing IUDs (LNG-IUD)

Initiation of Cu-IUD

Having menstrual cycles

- Within 12 days after the start of menstrual bleeding: A Cu-IUD can be inserted at the woman's convenience, not just during menstruation. No additional contraceptive protection is needed.
- More than 12 days since the start of menstrual bleeding: A Cu-IUD can be inserted at the woman's convenience if it is reasonably certain that she is not pregnant. No additional contraceptive protection is needed.

Amenorrhoeic (non-postpartum)

- A Cu-IUD can be inserted at any time if it can be determined that the woman is not

pregnant. No additional contraceptive protection is needed.

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

- Within 48 hours after delivery: A Cu-IUD can be inserted, including immediately after delivery of the placenta.
  - If the delivery is by caesarean section, the Cu-IUD can be placed after delivery of the placenta, before closing the uterus.
- 48 hours to less than 4 weeks postpartum: Use of Cu-IUDs is not usually recommended unless other more appropriate methods are not available or not acceptable (MEC category 3).
- 4 or more weeks postpartum and amenorrhoeic:
  - Breastfeeding: A Cu-IUD can be inserted if it is reasonably certain that the woman is not pregnant. No additional contraceptive protection is needed.
  - Non-breastfeeding: A Cu-IUD can be inserted if it can be determined that the woman is not pregnant. No additional contraceptive protection is needed.
- 4 or more weeks postpartum and menstrual cycles have returned: A Cu-IUD can be inserted as advised for other women having menstrual cycles.
- Women who have puerperal sepsis should not have a Cu-IUD inserted (MEC category 4).

Post-abortion

- A Cu-IUD can be inserted immediately after a first-trimester abortion.
- A Cu-IUD can generally be inserted immediately after a second-trimester abortion.
- A Cu-IUD should not be inserted immediately following septic abortion (MEC category 4).

Switching from another method

- A Cu-IUD can be inserted immediately if it is reasonably certain the woman is not pregnant; there is no need to wait for her next menstrual period. No additional contraceptive protection is needed.

For emergency contraception

- A Cu-IUD can be inserted within 5 days of unprotected intercourse as an emergency contraceptive.
- In addition, when the time of ovulation can be estimated, a Cu-IUD can be inserted beyond 5 days after intercourse, as long as insertion does not occur more than 5 days after ovulation.
- Women who use the Cu-IUD for emergency contraception should be medically eligible for the insertion *(1)*.

Initiation of LNG-IUD

Having menstrual cycles

- Within 7 days after the start of menstrual bleeding: An LNG-IUD can be inserted at the woman's convenience, not just during menstruation. No additional contraceptive protection is needed.
- More than 7 days since the start of menstrual bleeding: An LNG-IUD can be inserted at the woman's convenience if it is reasonably certain she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic (non-postpartum)

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

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

- Within 48 hours after delivery: An LNG-IUD can generally be inserted, including immediately after the delivery of the placenta.
  - If the delivery is by caesarean section, the LNG-IUD can be placed after delivery of the placenta, before closing the uterus.
- 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 (MEC category 3).

- 4 or more weeks postpartum and amenorrhoeic:
  - Breastfeeding: An LNG-IUD can be inserted if it is reasonably certain that the woman is not pregnant. No additional contraception is needed.
  - Non-breastfeeding: An LNG-IUD can be inserted if it can be determined that the woman is not pregnant. No additional contraceptive protection is needed.
- 4 or more weeks postpartum and menstrual cycles have returned: An LNG-IUD can be inserted as advised for other women having menstrual cycles.
- Women who have puerperal sepsis should not have an LNG-IUD inserted (MEC category 4).

Post-abortion

- An LNG-IUD can be inserted immediately after a first-trimester abortion.
- An LNG-IUD can generally be inserted immediately after a second-trimester abortion.
- An LNG-IUD should not be inserted immediately following septic abortion (MEC category 4).

Switching from another method

- If a woman is having menstrual cycles, an LNG-IUD can be inserted immediately if it is reasonably certain the woman is not pregnant; there is no need to wait until her next menstrual period. If the woman is amenorrhoeic, an LNG-IUD can be inserted immediately if it can be determined that she is not pregnant; there is no need to wait for her next menstrual period.
  - Within 7 days after the start of menstrual bleeding: An LNG-IUD can be inserted. No additional contraceptive protection is needed.
  - More than 7 days since the start of menstrual bleeding: An LNG-IUD can be inserted. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- If the woman's previous method was an injectable contraceptive, the LNG-IUD should be inserted when the repeat injection would have been given. No additional contraceptive protection is needed.

Remarks *(See references 2–4)*

The Guideline Development Group (GDG) determined that there is an acceptably low risk of ovulation up to day 7 of the menstrual cycle and that the probability of an existing pregnancy is therefore low before day 8.

The recommendations of the GDG for insertion of Cu-IUDs for the purposes of emergency contraception do not apply to LNG-IUDs because the safety and effectiveness of LNG-IUD use for emergency contraception is unknown. 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 MEC, 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 GDG recognized that the checklist of six criteria will be helpful to the provider in determining whether a woman who is postpartum and breastfeeding may be pregnant (see section 7.1: How can a health-care provider be reasonably certain that a woman is not pregnant?). However, for a woman who is postpartum and non-breastfeeding, or one who is amenorrhoeic (non-postpartum), these six criteria do not apply and other means should be used to determine whether she is pregnant.

Examinations and tests before providing Cu-IUD or LNG-IUD *(5, 6)*

In healthy women, the only examinations and tests that are essential and mandatory before IUD insertion include a pelvic/genital examination and STI risk assessment. When available, a haemoglobin test and STI/HIV screening will also contribute substantially to safe and effective use. Please see the table and notes below for further information.

Examination or test	Cu-IUD and LNG-IUD*
Breast examination by provider	C
Pelvic/genital examination	A
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	B
STI risk assessment: medical history and physical examination	A‡
STI/HIV screening: laboratory tests	B‡
Blood pressure screening	C

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ The *Medical eligibility criteria for contraceptive use, fifth edition*, states: "IUD insertion may further increase the risk of PID [pelvic inflammatory disease] among women at increased risk of STIs, although limited evidence suggests that this risk is low. Current algorithms for determining increased risk of STIs have poor predictive value. Risk of STIs varies by individual behaviour and local STI prevalence. Therefore, while many women at increased risk of STIs can generally have an IUD inserted, some women at increased risk (very high individual likelihood) of STIs should generally not have an IUD inserted until appropriate testing and treatment occur" *(1)*.

Use of prophylactic antibiotics at the time of IUD insertion

Routine IUD insertion (Cu-IUD or LNG-IUD)

- Prophylactic antibiotics are generally not recommended for IUD insertion. In settings of both high prevalence of cervical gonococcal and chlamydial infections and limited STI screening, such prophylaxis may be considered.
- The IUD user should be counselled to watch for symptoms of pelvic inflammatory disease (PID), especially during the first month of use.

Remarks *(See reference 7)*

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

These recommendations apply to healthy women; women with health conditions that warrant antibiotic prophylaxis for invasive procedures (e.g. women with cardiac valve disorders) may also need antibiotic prophylaxis for IUD insertion.

As no evidence was identified for the provision of prophylactic antibiotics prior to insertion of the LNG-IUD, these recommendations were based on evidence for the Cu-IUD.

Management of menstrual abnormalities for Cu-IUD users

Spotting or light bleeding

- Spotting or light bleeding is common during the first 3–6 months of Cu-IUD use. It is not harmful and usually decreases over time.
- If a woman 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, gynaecologic problems should be excluded when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer the woman for care.
- If no gynaecologic problems are found, and the woman finds the bleeding unacceptable, remove the IUD and help her choose another method.

Heavier or longer menstrual bleeding than with normal menstrual periods

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

Remarks *(See reference 8)*

The GDG 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 GDG indicated that aspirin should not be used to treat IUD-related menstrual bleeding because it may worsen the problem.

Management of menstrual abnormalities for LNG-IUD users

Amenorrhoea

- Amenorrhoea does not require any medical treatment. Counselling is sufficient.
- If a woman finds amenorrhoea unacceptable, remove the LNG-IUD and 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, gynaecologic problems should be excluded when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer the woman for care.
- If no gynaecologic problems are found and the woman 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 or longer menstrual bleeding may occur during the first 3–6 months of LNG-IUD use. Usually this is not harmful, and bleeding typically becomes lighter over time.
- Gynaecologic problems should be excluded when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer the woman for care.
- If the bleeding continues to be very heavy or prolonged, especially if there are clinical signs of anaemia, or if the woman finds the bleeding unacceptable, remove the LNG-IUD and help her choose another method.
- To prevent anaemia, provide an iron supplement and/or encourage her to eat foods containing iron.

Remarks

The GDG 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.

Management of IUDs when a Cu-IUD or LNG-IUD user is found to have pelvic inflammatory disease (PID)

- Treat the PID using appropriate antibiotics.
- There is no need to remove the IUD if the woman 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, consider using emergency contraceptive pills and/or other contraceptive method(s), if appropriate.
- If the infection does not improve, consider removing the IUD while continuing antibiotics. If the IUD is not removed, antibiotics should still be continued. In both circumstances, the woman's health should be closely monitored.
- Provide comprehensive management for STIs, including counselling about condom use.

Remarks *(See reference 9)*

The GDG concluded that removing the IUD provides no additional benefit once PID is being treated with appropriate antibiotics. As no evidence was identified for the LNG-IUD, the recommendations were based solely upon evidence for the Cu-IUD.

Management of the IUD when a Cu-IUD or LNG-IUD user is found to be pregnant

- Exclude ectopic pregnancy.
- Explain to the woman that she is at an increased risk of first- and second-trimester miscarriage (including septic miscarriage that may be life-threatening) and of preterm delivery if the IUD is left in place. The removal of the IUD reduces these risks, although the procedure itself entails a small risk of miscarriage.
  - If she does not want to continue the pregnancy and if therapeutic termination of pregnancy is legally available, inform her accordingly.

– If she understands and accepts the risks mentioned above and she wishes to continue the pregnancy, proceed according to the instructions below.

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

- Advise the woman that it is best to remove the IUD.
- If the IUD is to be removed, remove it by pulling on the strings gently.
- Whether the IUD is removed or kept, 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 the IUD cannot be safely retrieved

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

Remarks *(See reference 10)*

The GDG concluded that removing the IUD improves pregnancy outcome if the IUD strings are visible or can be retrieved safely from the cervical canal, and that the risks of miscarriage, preterm delivery and infection are substantial if the IUD is left in place. These recommendations were based on evidence for the Cu-IUD. In addition, the GDG considered that there are theoretical concerns about fetal exposure to hormones in women found to be pregnant with an LNG-IUD in place. Whether there is an increased risk of fetal abnormalities due to this exposure, however, is unknown.

Appropriate follow-up after insertion of a Cu-IUD or LNG-IUD

These recommendations address the minimum frequency of follow-up recommended for safe and effective use of IUDs. They 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.

- A follow-up visit is recommended after the first menses or 3–6 weeks following insertion.
- Women should be advised to return at any time to discuss side-effects or other problems, or if they want to change methods.
- Women should be advised to return when it is time for IUD removal.

Remarks *(See reference 11)*

The GDG 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.

References for intrauterine devices (IUDs)

1. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
2. Whiteman MK, Tyler CP, Folger SG, Gaffield ME, Curtis KM. When can a woman have an intrauterine device inserted? A systematic review. Contraception. 2013;87(5):666–73. doi:10.1016/j.contraception.2012.08.015.
3. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ. 2000;321(7271):1259–62.
4. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception. 2001;63(4):211–5.
5. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM. Laboratory screening prior to initiating contraception: a systematic review. Contraception. 2013;87(5):645–9. doi:10.1016/j.contraception.2012.08.009.

6. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM et al. Hemoglobin measurement prior to initiating copper intrauterine devices: a systematic review. Contraception. 2013;87(5):639–44. doi:10.1016/j.contraception.2012.08.008.
7. Grimes DA, Schulz KF. Prophylactic antibiotics for intrauterine device insertion: a metaanalysis of the randomized controlled trials. Contraception. 1999;60(2):57–63.
8. Godfrey EM, Whiteman MK, Curtis KM. Treatment of bleeding irregularities in women with copper-containing IUDs: a systematic review. Contraception. 2013;87(5):549–66. doi:10.1016/j.contraception.2012.08.005.
9. Tepper NK, Steenland MW, Gaffield ME, Marchbanks PA, Curtis KM. Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review. Contraception. 2013;87(5):655–60. doi:10.1016/j.contraception.2012.08.011.
10. Brahmi D, Steenland MW, Renner RM, Gaffield ME, Curtis KM. Pregnancy outcomes with an IUD in situ: a systematic review. Contraception. 2012;85(2):131–9. doi:10.1016/j.contraception.2011.06.010.
11. Steenland MW, Lauren B, Zapata LB, Brahmi D, Marchbanks PA, Curtis KM. The effect of follow-up visits or contacts after contraceptive initiation on method continuation and correct use. Contraception. 2013;87(5):625–30. doi:10.1016/j.contraception.2012.09.018.

7.3 Progestogen-only contraceptives

Progestogen-only contraceptives (POCs) include progestogen-only implants, progestogen-only injectable contraceptives (POIs) and progestogen-only pills (POPs), and they are presented separately in that order within this section.

POCs can be safely used by most women. To help determine if women with a particular medical condition or characteristic can safely use POCs, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition* (MEC) *(1)*.

POCs do not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

7.3.1 Progestogen-only implants

Progestogen-only implants are a type of long-acting contraception.

The various types of progestogen-only implants that are considered here are the following.

- Levonorgestrel (LNG): The LNG-containing implants are Norplant, Jadelle and Sino-implant (II)[1].
  - Norplant is a 6-rod implant, each rod containing 36 mg of LNG (no longer in production).
  - Jadelle is a 2-rod implant, each rod containing 75 mg of LNG.
  - Sino-implant (II) is a 2-rod implant, each rod containing 75 mg of LNG.[2]
- Etonogestrel (ETG): The ETG-containing implants are Implanon® and Nexplanon®. Both consist of a single-rod implant containing 68 mg of ETG.

Initiation of implants

These recommendations are based on information from, and relate to, approved levonorgestrel (LNG) implants, Norplant® and Jadelle® (Norplant has been discontinued). Limited evidence exists for the Sino-implant (II)®. The extent to which the recommendations apply to etonogestrel (ETG) implants is not known.

NEW recommendation 1.1

A woman can start Sino-implant (II), or SI(II), within 7 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.

Having menstrual cycles

- Within 7 days after the start of menstrual bleeding: The implant can be inserted. No additional contraceptive protection is needed.
- More than 7 days since the start of menstrual bleeding: The implant can be inserted if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

[1] New contraceptive method for the third edition.
[2] New contraceptive method for the third edition.

Amenorrhoeic (non-postpartum)

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

Postpartum (breastfeeding)

- Less than 6 weeks postpartum: An implant can generally be inserted (MEC category 2).
- 6 weeks to 6 months postpartum and amenorrhoeic: An implant can be inserted. If the woman is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- More than 6 weeks postpartum and menstrual cycles have returned: The implant can be inserted as advised for other women having menstrual cycles.

Postpartum (non-breastfeeding)

- Less than 21 days postpartum: An implant can be inserted (MEC category 1). No additional contraceptive protection is needed. 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 (i.e. depending on national, regional and/or local programme protocols), some contraceptive methods may be provided during this period.
- 21 or more days postpartum and menstrual cycles have not returned: An implant can be inserted if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- Menstrual cycles have returned: An implant can be inserted as advised for other women having menstrual cycles.

Post-abortion

- The implant can be inserted immediately post-abortion. No additional contraceptive protection is needed.

Switching from another hormonal method

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

Switching from a nonhormonal method (other than the IUD)

- The implant can be inserted immediately if it is reasonably certain that the woman is not pregnant; there is no need to wait for her next menstrual period.
  - Within 7 days of the start of her menstrual bleeding: No additional contraceptive protection is needed.
  - More than 7 days since the start of menstrual bleeding: She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

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

- Within 7 days after the start of menstrual bleeding: An implant can be inserted. No additional contraceptive protection is needed. The IUD can be removed at that time.
- More than 7 days since the start of menstrual bleeding: The implant can be inserted if it is reasonably certain that the woman is not pregnant.
  - Sexually active in this menstrual cycle and more than 7 days since the start of menstrual bleeding: It is recommended that the IUD be removed at the time of her next menstrual period.
  - Not sexually active in this menstrual cycle and more than 7 days since the start of menstrual bleeding: 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 the woman is amenorrhoeic or has irregular bleeding, the implant can be inserted as advised for other amenorrhoeic women.

Remarks *(See references 2–7, 34)*

The Guideline Development Group (GDG) 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.

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

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

Examinations and tests needed before initiation of implants

In healthy women, no examinations or tests are essential or mandatory before initiating progestogen-only implants. However, there is special consideration for blood pressure screening; it is desirable to have blood pressure measurements taken before initiation of implants. It is important to note that in settings where blood pressure measurements are unavailable, women should not be denied use of implants simply because their blood pressure cannot be measured.

Examination or test	Implants*
Breast examination by provider	C
Pelvic/genital examination	C
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ It is desirable to have blood pressure measurements taken before initiation of implants. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy-related morbidity and mortality risks are high, and hormonal methods are among the few methods that are widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

NEW recommendation 1.2

It is desirable to have blood pressure measurements taken before initiation of SI(II). Women should not be denied use of SI(II) simply because their blood pressure cannot be measured.

NEW recommendation 1.3

Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, STI risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of SI(II).

Remarks *(See references 35–37)*

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

Continuation of LNG-releasing implants (duration of use)

These recommendations are based on information from, and relate to, approved LNG implants, Norplant and Jadelle (Norplant has been discontinued). The product labelling for an ETG implant (Implanon) states that the implant can be left in place for up to three years. The product labelling for Sino-implant (II)[1] states that the implant can be left in place for up to four years.

Norplant

Global production of Norplant was discontinued in 2008. Though originally approved for up to five years of use, 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. Women with Norplant in place who have exceeded this time frame may wish to have the implants removed due to increasing risk of pregnancy.

Jadelle

For a woman weighing less than 80 kg

- She can have the implants left in place for up to five completed years.

For a woman weighing 80 kg or more

- She should seriously consider having her implants removed after four completed years of use because of their reduced effectiveness.

Remarks *(See reference 41)*

The GDG 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. Women weighing 70–79 kg during the fifth year of use should be aware of the reduced effectiveness of their implants if they choose to continue using them for a sixth or seventh year, although the pregnancy rates in years 6 and 7 are no greater than those for several other contraceptive methods. Women weighing 80 kg or more should be strongly advised to consider having their implants removed after four years of use, as their risk of pregnancy is approximately 6% in the fifth year of use. Regarding the duration of use of Sino-implant (II)†, the GDG agreed that the evidence supports the product labelling for four years duration of continuous use. 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.

NEW recommendation 1.4

The product labelling for SI(II) states that the implant can be left in place for up to four years.

Management of menstrual abnormalities for implant users

These recommendations are based on information from, and relate to, approved LNG implants, Norplant and Jadelle. The extent to which the treatment recommendations apply to Sino-implant (II) and ETG implants (Implanon) is not known.

Amenorrhoea

- Amenorrhoea does not require any medical treatment. Counselling is sufficient.
- If a woman 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 the woman for care.

[1] New recommendation for the third edition.

- If an STI or pelvic inflammatory disease is diagnosed, the woman can continue using implants while receiving treatment and be counselled on condom use.
- If no gynaecologic problems are found and the woman desires treatment, nonhormonal and hormonal options are available:
  – nonhormonal: nonsteroidal anti-inflammatory drugs (NSAIDs)
  – hormonal (if medically eligible): low-dose COCs or ethinyl estradiol.
- If the woman 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 the woman for care.
- If no gynaecologic problems are found and the woman desires treatment, nonhormonal and hormonal options are available:
  – nonhormonal: NSAIDs
  – hormonal (if medically eligible): COCs or ethinyl estradiol.
- If the woman 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.

Remarks *(See references 8–19)*

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

- Nonhormonal drugs: NSAIDs
  – ibuprofen
  – mefenamic acid
- Hormonal drugs
  – COCs
  – ethinyl estradiol.

Appropriate follow-up after initiation of implants

These recommendations address the minimum frequency of follow-up recommended for safe and effective use of implants. 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.

NEW recommendation 1.5

No routine follow-up is required after initiating SI(II).

Implants

- No routine follow-up visit is required.
- Women should be advised to return at any time to discuss side-effects or other problems, or if she wants to change the method.
- Women should be advised to return when it is time to have the implant(s) removed.

Remarks *(See references 38–40)*

The GDG 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.

7.3.2 Progestogen-only injectable contraceptives (POIs)

These injectable contraceptives include depot medroxyprogesterone acetate (DMPA) and norethisterone enanthate (NET-EN).

Three formulations are considered here:

1. DMPA-IM = 150 mg of DMPA given intramuscularly
2. DMPA-SC = 104 mg of DMPA given subcutaneously[1]
3. NET-EN = 200 mg of NET-EN given intramuscularly.

[1] New recommendation for the third edition.

Of note, DMPA-SC efficacy is likely maintained when administered in the upper arm, which may be acceptable to women in addition to subcutaneous injection in the abdomen or thigh *(20)*.

Initiation of POIs

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

NEW recommendation 2.1

A woman can start DMPA-SC within 7 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.

Having menstrual cycles

- Within 7 days after the start of menstrual bleeding: The first POI injection can be given. No additional contraceptive protection is needed.
- More than 7 days since the start of menstrual bleeding: The first POI injection can be given if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

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

Postpartum (breastfeeding)

- 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 (MEC category 3).
- 6 weeks to 6 months postpartum and amenorrhoeic: The first POI injection can be given. If the woman is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- More than 6 weeks postpartum and menstrual cycles have returned: The first injection can be given as advised for other women having menstrual cycles.

Postpartum (non-breastfeeding)

- Less than 21 days postpartum: The first POI injection can be given. No additional contraceptive protection is needed. 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 (i.e. depending on national, regional and/or local programme protocols), some contraceptive methods may be provided during this period.
- 21 or more days postpartum and menstrual cycles have not returned: The first injection can be given if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- Menstrual cycles have returned: The first injection can be given as advised for other women having menstrual cycles.

Post-abortion

- The first injection can be given immediately post-abortion. No additional contraceptive protection is needed.

Switching from another hormonal method

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

Switching from a nonhormonal method (other than the IUD)

- The first injection can be given immediately if it is reasonably certain that the woman is not pregnant; there is no need to wait for her next menstrual period.
  - Within 7 days of the start of menstrual bleeding: No additional contraceptive protection is needed.

– 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 LNG-IUD)

- Within 7 days after the start of menstrual bleeding: The first injection can be given. No additional contraceptive protection is needed. The IUD can be removed at that time.
- More than 7 days since the start of menstrual bleeding: The first injection can be given if it is reasonably certain that the woman is not pregnant.
  – Sexually active in this menstrual cycle and more than 7 days since the start of menstrual bleeding: It is recommended that the IUD be removed at the time of her next menstrual period.
  – Not sexually active in this menstrual cycle and more than 7 days since the start of menstrual bleeding: 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 the woman is amenorrhoeic or has irregular bleeding, she can have the injection as advised for other amenorrhoeic women.

Remarks *(See references 5, 6, 20, 21)*

The GDG 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.

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

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

In their review of the evidence, the GDG noted that DMPA-SC efficacy is maintained when administered in the upper arm, which may be acceptable to women in addition to subcutaneous injection in the abdomen or thigh.

Examinations and tests needed before initiation of POIs

In healthy women, no examinations or tests are essential or mandatory before initiating POIs. However, there is special consideration for blood pressure screening; it is desirable to have blood pressure measurements taken before initiation of POIs. It is important to note that in settings where blood pressure measurements are unavailable, women should not be denied use of POIs simply because their blood pressure cannot be measured.

Examination or test	POIs*
Breast examination by provider	C
Pelvic/genital examination	C
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ It is desirable to have blood pressure measurements taken before initiation of POIs. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy-related morbidity and mortality risks are high, and hormonal methods are among the few methods that are widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

NEW recommendation 2.2

It is desirable to have blood pressure measurements taken before initiation of DMPA-SC. Women should not be denied use of DMPA-SC simply because their blood pressure cannot be measured.

NEW recommendation 2.3

Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, STI risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of DMPA-SC.

Remarks *(See references 35–37)*

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

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.

Timing for repeat POIs (reinjection) for continuation of method

Reinjection interval

- Repeat DMPA injections should be provided every three months.
- Repeat NET-EN injections should be provided every two months.

NEW recommendation 2.4

Provide repeat DMPA-SC injections every three months. Recommendations are also available for early and late injections.

Early for an injection

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

Late for an injection

- The repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection. The repeat NET-EN injection can be given up to 2 weeks late without requiring additional contraceptive protection.
- If the woman is more than 4 weeks late for a repeat DMPA injection or more than 2 weeks late for a repeat NET-EN injection, the injection can be given 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 for a woman 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 contraceptive type and/or timing of injection is unknown

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

Remarks *(See references 20, 22)*

The GDG considered the risk of ovulation to be minimal within 4 weeks following the scheduled time for repeat DMPA injection (three months) and 2 weeks following the scheduled time for repeat NET-EN injection (two months).

DMPA injections should be administered every three months. While the repeat DMPA injection can be given up to four weeks late without requiring additional contraceptive protection, this does not mean that the regular DMPA injection interval can be extended by four weeks.

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.

In their review of the evidence, the GDG noted that DMPA-SC efficacy is maintained when administered in the upper arm, which may be acceptable to women in addition to subcutaneous injection in the abdomen or thigh.

Management of menstrual abnormalities during use of POIs

These recommendations refer to DMPA-IM and NET-EN formulations; it may be that treatment will be the same among women using DMPA-SC.

Amenorrhoea

- Amenorrhoea does not require any medical treatment. Counselling is sufficient.
- If the woman still finds amenorrhoea unacceptable, discontinue the injectable contraceptive and 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 the woman for care.
- If an STI or pelvic inflammatory disease is diagnosed, the woman 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, short-term treatment with NSAIDs may be helpful. If she decides to discontinue the injectable contraceptive, 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 the woman for care.
- If the bleeding becomes a threat to the health of the woman or it is not acceptable to her, discontinue the injectable contraceptive. Help her choose another method. In the interim, short-term treatment with either ethinyl estradiol or NSAIDs may be helpful.
- To prevent anaemia, provide an iron supplement and/or encourage her to eat foods containing iron.

Remarks *(See references 23–30)*

The GDG 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 GDG reviewed the limited available data on treatment options for light or heavy bleeding and determined that the following drugs may be helpful for short-term treatment (i.e. 5–7 days):

For spotting or light bleeding:

- NSAIDs
  - mefenamic acid
  - valdecoxib.

For heavy or prolonged bleeding:

- NSAIDs
  - mefenamic acid
  - valdecoxib
- hormonal drugs
  - ethinyl estradiol.

7.3.3 Progestogen-only pills (POPs)

POPs contain only a progestogen and no estrogen.

Initiation of progestogen-only pills (POPs)

POPs may be provided to a woman in advance with appropriate instructions on pill initiation, provided she is medically eligible.

Having menstrual cycles

- Within 5 days after the start of menstrual bleeding: POPs can be initiated. No additional contraceptive protection is needed.
- More than 5 days since the start of menstrual bleeding: POPs can be initiated if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 2 days.

Amenorrhoeic

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

Postpartum (breastfeeding)

- Less than 6 weeks postpartum: POPs can generally be initiated (MEC category 2). If the woman is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- 6 weeks to 6 months postpartum and amenorrhoeic: POPs can be initiated. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.
- More than 6 weeks postpartum and menstrual cycles have returned: POPs can be initiated as advised for other women having menstrual cycles (MEC category 1).

Postpartum (non-breastfeeding)

- Less than 21 days postpartum: POPs can be initiated. No additional contraceptive protection is needed. 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 (i.e. depending on national, regional and/or local programme protocols), some contraceptive methods may be provided during this period.
- 21 or more days postpartum and menstrual cycles have not returned: POPs can be initiated if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 2 days.
- Menstrual cycles have returned: POPs can be initiated as advised for other women having menstrual cycles.

Post-abortion

- POPs can be initiated immediately post-abortion. No additional contraceptive protection is needed.

Switching from another hormonal method

- POPs can be initiated immediately if the woman 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 the woman's previous method was an injectable contraceptive, POPs can be initiated when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a nonhormonal method (other than the IUD)

- Within 5 days after the start of menstrual bleeding: POPs can be initiated. No additional contraceptive protection is needed.
- More than 5 days since the start of menstrual bleeding: POPs can be initiated if it is reasonably certain that the woman is not pregnant. 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)

- Within 5 days after the start of menstrual bleeding: POPs can be initiated. No additional contraceptive protection is needed. The IUD can be removed at that time.
- More than 5 days since the start of menstrual bleeding: POPs can be initiated if it is reasonably certain that the woman is not pregnant.
  - Sexually active in this menstrual cycle: It is recommended that the IUD be removed at the time of her next menstrual period.
  - Not sexually active in this menstrual cycle: 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 the woman is amenorrhoeic or has irregular bleeding, POPs can be initiated as advised for other amenorrhoeic women.

Remarks *(See references 5, 6, 31)*

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

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

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

Examinations and tests needed before initiation of POPs

In healthy women, no examinations or tests are essential or mandatory before initiating POPs. However, there is special consideration for blood pressure screening; it is desirable to have blood pressure measurements taken before initiation of POPs. It is important to note that in settings where blood pressure measurements are unavailable, women should not be denied use of POPs simply because their blood pressure cannot be measured.

Examination or test	POPs*
Breast examination by provider	C
Pelvic/genital examination	C
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ It is desirable to have blood pressure measurements taken before initiation of POPs. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy-related morbidity and mortality risks are high, and hormonal methods are among the few methods that are widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

Remarks

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

These classifications focus on the relationship of the exams or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these exams or tests in other circumstances. For example, some of the exams 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.

Number of POP pill packs that should be provided at initial and return visits

Initial and return visits

- Provide up to one year's supply of pills, depending on the woman's preference 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.

Remarks

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

Management of vomiting and/or severe diarrhoea while using POPs

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

- The woman should take another active pill.

Severe vomiting or diarrhoea for more than 24 hours

- The woman 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.

Remarks *(See reference 32)*

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

Management of missed POPs

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

- The woman should take 1 pill as soon as possible and then continue taking the pills daily, 1 each day. She should also 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

- The woman should take 1 pill as soon as possible and then continue taking the pills daily, 1 each day. If she is less than six months postpartum, no additional contraceptive protection is needed.

Remarks *(See references 31, 33)*

The GDG 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.

Existing guidance is provided for situations when a user misses 1 or more pills by more than 3 hours. For women taking the 75 µg desogestrel-containing pill, the existing guidance for both women having menstrual cycles and those who are breastfeeding and amenorrhoeic applies when 1 or more pills have been missed by more than 12 hours.

Appropriate follow-up after initiation of POPs

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

POPs (not breastfeeding)

- No annual follow-up visit is required, but a follow-up contact after initiation is recommended at about three 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.

Remarks

The GDG 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.

References for progestogen-only contraceptives (POCs)

1. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
2. Brache V, Alvarez F, Faundes A, Cochon L, Thevenin F. Effect of preovulatory insertion of Norplant implants over luteinizing hormone secretion and follicular development. Fertil Steril. 1996;65:1110–4.
3. Brache V, Blumenthal P, Alvarez F, Dunson T, Cochon L, Faundes A. Timing of onset of contraceptive effectiveness in Norplant implant users. Part II. Effect on the ovarian function in the first cycle of use. Contraception. 1999;59(4):245–51.
4. Dunson TR, Blumenthal PD, Alvarez F, Brache V, Cochon L, Dalberth B et al. Timing of onset of contraceptive effectiveness in Norplant implant users. Part I. Changes in cervical mucus. Fertil Steril. 1998;69(2):258–66.
5. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ. 2000;321(7271):1259–62.
6. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception. 2001;63(4):211–5.
7. Zheng S, Wu X, Fan B. Serum concentrations of levonorgestrel, estradiol and progesterone in women using China-made long-acting levonorgestrel subdermal implant (Sino-Implant) during the first year. Reprod Contracept. 1993;13:172–8.
8. Alvarez-Sánchez F, Brache V, Thevenin F, Cochon L, Faundes A. Hormonal treatment for bleeding irregularities in Norplant implant users. Am J Obstet Gynecol. 1996;174:919–22.
9. Boonkasemsanti W, Reinprayoon D, Pruksananonda K, Niruttisard S, Triratanachat S, Leepipatpaiboon S, Wannakrairot P. The effect of transdermal oestradiol on bleeding pattern, hormonal profiles and sex steroid receptor distribution in the endometrium of Norplant users. Hum Reprod. 1996;11(Suppl 2):115–23.
10. Cheng L, Zhu H, Wang A, Ren F, Chen J, Glasier A. Once a month administration of mifepristone improves bleeding patterns in women using subdermal contraceptive implants releasing levonorgestrel. Hum Reprod. 2000;15(9):1969–72.
11. d'Arcangues C, Piaggio G, Brache V, Ben Aissa R, Hazelden C, Massai R et al.; on behalf of the Study Group on Progestogen-induced Vaginal Bleeding Disturbances. Effectiveness and acceptability of vitamin E and low-dose aspirin, alone or in combination, on Norplant-induced prolonged bleeding. Contraception. 2004;70(6):451–62. doi:10.1016/j.contraception.2004.05.012.
12. Diaz S, Croxatto HB, Pavez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of Norplant implants. Contraception. 1990;42:97–109.
13. Glasier AF, Wang H, Davie JE, Kelly RW, Critchley HO. Administration of an antiprogesterone up-regulates estrogen receptors in the endometrium of women using Norplant: a pilot study. Fertil Steril. 2002;77(2):366–72. doi:10.1016/S0015-0282(01)02997-1.
14. Kaewrudee S, Taneepanichskul S, Jaisamraun U, Reinprayoon D. The effect of mefenamic acid on controlling irregular uterine bleeding secondary to Norplant use. Contraception. 1999;60:25–30.
15. Subakir SB, Setiadi E, Affandi B, Pringgoutomo S, Freisleben HJ. Benefits of vitamin E supplementation to Norplant users – in vitro and in vivo studies. Toxicology. 2000;148:173–8.
16. Witjaksono J, Lau TM, Affandi B, Rogers PAW. Oestrogen treatment for increased bleeding in Norplant users: preliminary results. Hum Reprod. 1996;11(Suppl. 2):109–14.
17. Han L, Fan H, Gong Q, Xie Z, Meng F, Hong Y et al. The effects of three types of long-acting subcutaneous implants on menstrual blood loss. Chinese J Fam Plann. 1998;6:250–3.
18. Qi L, Liu J, Yu L, Ye L, Sun L, Liu K. Multicenter clinical study of two Sino-subdermal implants. Chinese J Fam Plann. 2002;79:87–95.
19. Du M, Zheng H, Guo W. Five-year clinical observation of China-made type II levonorgestrel subdermal implant (Sino-implant). Chinese J Fam Plann. 1996;4:201–3.
20. Halpern V, Combes SL, Dorflinger LJ, Weiner DH, Archer DF. Pharmacokinetics of subcutaneous depot medroxyprogesterone acetate injected in the upper arm. Contraception. 2014;89(1):31–5. doi:10.1016/j.contraception.2013.07.002.
21. Kapp N, Gaffield ME. Initiation of progestogen-only injectables on different days of the menstrual cycle and its effect on contraceptive effectiveness and compliance: a systematic review. Contraception. 2013;87(5):576–82. doi:10.1016/j.contraception.2012.08.017.

22. Paulen ME, Curtis KM. When can a woman have repeat progestogen-only injectables – depot medroxyprogesterone acetate or norethisterone enantate? Contraception. 2009;80(4):391–408. doi:10.1016/j.contraception.2009.03.023.
23. Goldberg AB, Cardenas LH, Hubbard AE, Darney PD. Post-abortion depot medroxyprogesterone acetate continuation rates: a randomized trial of cyclic estradiol. Contraception. 2002;66(4):215–20.
24. Harel Z, Biro F, Kollar L, Riggs S, Flanagan P, Vaz R. Supplementation with vitamin C and/or vitamin B(6) in the prevention of Depo-Provera side effects in adolescents. J Pediatr Adolesc Gynecol. 2002;15(3):153–8.
25. Jain JK, Nicosia AF, Nucatola DL, Lu JJ, Kuo J, Felix JC. Mifepristone for the prevention of breakthrough bleeding in new starters of depo-medroxyprogesterone acetate. Steroids. 2003;68(10–13):1115–9.
26. Parker RA, McDaniel EB. The use of quinesterol for the control of vaginal bleeding irregularities caused by DMPA. Contraception. 1980;22(1):1–7.
27. Said S, Sadek W, Rocca M, Koetsawang S, Kirwat O, Piya-Anant M et al. Clinical evaluation of the therapeutic effectiveness of ethinyl oestradiol and oestrone sulphate on prolonged bleeding in women using depot medroxyprogesterone acetate for contraception. World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Long-acting Systemic Agents for Fertility Regulation. Hum Reprod. 1996;11(Suppl 2):1–13.
28. Sapire KE. A study of bleeding patterns with two injectable contraceptives given postpartum and the effect of two non-hormonal treatments. Adv Contracept. 1991;7(4):379–87.
29. Nathirojanakun P, Taneepanichskul S, Sappakitkumjorn N. Efficacy of a selective COX-2 inhibitor for controlling irregular uterine bleeding in DMPA users. Contraception. 2006;73(6):584–7. doi:10.1016/j.contraception.2005.09.013.
30. Tantiwattanakul P, Taneepanichskul S. Effect of mefenamic acid on controlling irregular uterine bleeding in DMPA users. Contraception. 2004;70(4):277–9. doi:10.1016/j.contraception.2004.04.003.
31. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception. 1994;50(6 Suppl 1):S1–195.
32. Elomaa K, Ranta S, Tuominen J, Lähteenmäki P. Charcoal treatment and risk of escape ovulation in oral contraceptive users. Hum Reprod. 2001;16(1):76–81.
33. Korver T, Klipping C, Heger-Mahn D, Duijkers I, van Osta G, Dieben T. Maintenance of ovulation inhibition with the 75-µg desogestrel-only contraceptive pill (Cerazette®) after scheduled 12-h delays in tablet intake. Contraception. 2005;71(1):8–13. doi:10.1016/j.contraception.2004.07.016.
34. Phillips SJ, Zhang Wen. When can a woman start Sino-implant (II)? Systematic review. unpublished.
35. Tepper NK, Curtis KM, Steenland MW, Marchbanks PA. Blood pressure measurement prior to initiating hormonal contraception: a systematic review. Contraception. 2013;87(5):631–8. doi:10.1016/j.contraception.2012.08.025.
36. Tepper NK, Curtis KM, Steenland MW, Marchbanks PA. Physical examination prior to initiating hormonal contraception: a systematic review. Contraception. 2013;87(5):650–4. doi:10.1016/j.contraception.2012.08.010.
37. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM. Laboratory screening prior to initiating contraception: a systematic review. Contraception. 2013;87(5):645–9. doi:10.1016/j.contraception.2012.08.009.
38. Steenland MW, Zapata LB, Brahmi D, Marchbanks P, Curtis KM. Appropriate follow up to detect potential adverse events after initiation of select contraceptive methods: a systematic review. Contraception. 2013;87(5):611–24. doi:10.1016/j.contraception.2012.09.017.
39. Steenland MW, Zapata LB, Brahmi D, Marchbanks PA, Curtis KM. The effect of follow-up visits or contacts after contraceptive initiation on method continuation and correct use. Contraception. 2013;87(5):625–30. doi:10.1016/j.contraception.2012.09.018.
40. Brindis CD, Geierstanger SP, Wilcox N, McCarter V, Hubbard A. Evaluation of a peer provider reproductive health service model for adolescents. Perspect Sex Reprod Health. 2005;37(2):85–91. doi:10.1363/psrh.37.085.05.
41. Phillips SJ, Steyn PS, Zhang W, Curtis KM. How long may the Sino-implant (II) be left in place? (unpublished)

7.4 Combined hormonal contraceptives

Combined hormonal contraceptives (CHCs) refer to contraceptive products that contain an estrogen combined with a progestogen. This section gives recommendations for the use of various CHCs, including combined oral contraceptives (COCs), the combined contraceptive patch (the patch), the combined contraceptive vaginal ring (CVR) and combined injectable contraceptives (CICs). In this section, COCs, the patch and the CVR will be addressed first, followed by CICs.

CHCs can be safely used by most women. To help determine if women with certain medical conditions or characteristics can safely use CHCs, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition* (MEC) *(1)*.

CHCs do not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and

consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

7.4.1 Combined oral contraceptives (COCs), the combined contraceptive patch and the combined contraceptive vaginal ring (CVR)

The recommendations on COCs in this guidance refer to low-dose COCs containing ≤ 35 µg ethinyl estradiol, combined with a progestogen. Recommendations in this guidance are the same for all COC formulations, irrespective of their progestogen content.

The patch releases 20 µg of ethinyl estradiol and 150 µg of norelgestromin daily.†

The CVR releases 15 µg of ethinyl estradiol and 120 µg of etonogestrel daily.†

COCs, the patch and the CVR are typically dosed with 21–24 consecutive days of hormone followed by 4–7 hormone-free days. However, dosing regimens that have fewer or no hormone-free days are also used.

Initiation of COCs, the patch[1] and the CVR[1]

A woman may be provided with COCs, patches or CVRs in advance with appropriate instructions on initiation, provided she is medically eligible.

Having menstrual cycles

- Within 5 days after the start of menstrual bleeding: COCs, the patch and the CVR can be initiated. No additional contraceptive protection is needed.
- More than 5 days since the start of menstrual bleeding: COCs, the patch and the CVR can be initiated if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

NEW recommendation 3.1

A woman can start the patch or CVR within 5 days after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are: amenorrhoeic, postpartum, post-abortion, switching from another method.

Amenorrhoeic

- COCs, the patch and the CVR can be initiated at any time if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Postpartum (breastfeeding)

- Less than 6 weeks postpartum and primarily breastfeeding: The woman should not use COCs, the patch or the CVR (MEC category 4).
- 6 weeks to 6 months postpartum and primarily breastfeeding: Use of COCs, the patch or the CVR is generally not recommended unless other more appropriate methods are not available or not acceptable (MEC category 3).
- More than 6 months postpartum and amenorrhoeic: COCs, the patch and the CVR can be initiated as advised for other amenorrhoeic women.
- More than 6 months postpartum and menstrual cycles have returned: COCs, the patch and the CVR can be initiated as advised for other women having menstrual cycles.

Postpartum (non-breastfeeding)

- Less than 21 days postpartum: Use of COCs, the patch or the CVR is generally not recommended unless other more appropriate methods are not available or not acceptable (MEC category 3). 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 (i.e. depending on national, regional and/or local programme protocols), some contraceptive methods may be provided during this period.
- 21 or more days postpartum: For women with no other risk factors for venous thromboembolism, COCs, the patch and the CVR can generally be initiated (MEC category 2).

[1] New recommendation for the third edition.

- Medically eligible and menstrual cycles have not returned: COCs, the patch and the CVR can be initiated immediately if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- Medically eligible and menstrual cycles have returned: COCs, the patch and the CVR can be initiated as advised for other women having menstrual cycles.

Post-abortion

- COCs, the patch and the CVR can be initiated immediately post-abortion. No additional contraceptive protection is needed.

Switching from another hormonal method

- If the woman has been using her hormonal method consistently and correctly or if it is reasonably certain that she is not pregnant, COCs, the patch and the CVR can be initiated immediately; there is no need to wait for her next menstrual period.
- If a woman's previous method was an injectable contraceptive, COCs, the patch or the CVR should be initiated when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a nonhormonal method (other than the IUD)

- Within 5 days after the start of menstrual bleeding: COCs, the patch and the CVR can be initiated. No additional contraceptive protection is needed.
- More than 5 days since the start of menstrual bleeding: COCs, the patch and the CVR can be initiated immediately if it is reasonably certain that the woman is not pregnant. 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)

- Within 5 days after the start of menstrual bleeding: COCs, the patch and the CVR can be initiated. No additional contraceptive protection is needed. The IUD can be removed at that time.
- More than 5 days since the start of menstrual bleeding: COCs, the patch and the CVR can be initiated if it is reasonably certain that the woman is not pregnant.
  - Sexually active in this menstrual cycle: It is recommended that the IUD be removed at the time of her next menstrual period.
  - Not sexually active in this menstrual cycle: 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 the woman is amenorrhoeic or has irregular bleeding, COCs, the patch or the CVR can be initiated as advised for other amenorrhoeic women.

Remarks *(See references 2–4)*

The Guideline Development Group (GDG) 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.

Recommendations for when to start COCs, the patch and the CVR are based primarily on evidence from COCs and on limited evidence on the patch and CVR. Pending further evidence, the GDG concluded that the evidence available on when to start COCs applies to the patch and CVR.

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

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

Examinations and tests needed before initiation of COCs, the patch[1] and the CVR[1]

In healthy women, no examinations or tests are essential or mandatory before initiating COCs, the patch or the CVR. However, there is special consideration for blood pressure screening; it is desirable to have blood pressure measurements taken before initiation of COCs, the patch and the CVR. It is important to note that in settings where blood pressure measurements are unavailable, women should not be denied use of COCs, the patch or the CVR simply because their blood pressure cannot be measured.

Examination or test	COCs, patch, CVR*
Breast examination by provider	C
Pelvic/genital examination	C
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ It is desirable to have blood pressure measurements taken before initiation of COCs, the patch and the CVR. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy-related morbidity and mortality risks are high, and hormonal methods are among the few methods that are widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

NEW recommendation 3.2

It is desirable to have blood pressure measurements taken before initiation of the patch or CVR. Women should not be denied use of the patch or CVR simply because their blood pressure cannot be measured.

NEW recommendation 3.3

Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, haemoglobin test, STI risk assessment (medical history and physical examination) and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of the patch and CVR.

[1] New recommendation for the third edition.

Number of COC pill packs that should be provided at initial and return visits

Initial and return visits

- Provide up to one year's supply of pills, depending on the woman's preference 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.

Remarks *(See references 35–37)*

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

Management of vomiting and/or severe diarrhoea while using COCs

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

- The woman should take another active pill.

Severe vomiting or diarrhoea for more than 24 hours

- The woman 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.

Remarks *(See reference 5)*

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

Management of missed COCs

For pills containing 30–35 µg ethinyl estradiol

Missed 1 or 2 active (hormonal) pills in a row, or starts a pack 1 or 2 days late:

- The woman should take an active (hormonal) pill as soon as possible and then continue taking pills daily, 1 each day.
  - If the woman misses 2 or more active (hormonal) pills in a row, she can take the first missed pill and then either continue taking the rest of the missed pills (1 each day) or discard them to stay on schedule.
  - Depending on when the woman remembers that she missed the 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.
- No additional contraceptive protection is needed.

Missed 3 or more active (hormonal) pills in a row, or starts a pack 3 or more days late:

- The woman should take an active (hormonal) pill as soon as possible and then continue taking pills daily, 1 each day.
  - If the woman misses 2 or more active (hormonal) pills in a row, she can take the first missed pill and then either continue taking the rest of the missed pills (1 each day) or discard them to stay on schedule.
  - Depending on when the woman remembers that she missed the 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.
- The woman should also use condoms or abstain from sex until she has taken active (hormonal) pills for 7 days in a row.
- If the woman 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 the woman missed the pills in the first week and had unprotected sex, she may wish to consider the use of emergency contraception.

For pills containing up to 20 µg of ethinyl estradiol

Missed 1 active (hormonal) pill or starts a pack 1 day late:

- The woman should follow the guidance above for "Missed 1 or 2 active (hormonal) pills in a row, or starts a pack 1 or 2 days late".

Missed 2 or more active (hormonal) pills in a row, or starts a pack 2 or more days late:

- The woman should follow the guidance above for "Missed 3 or more active (hormonal) pills in a row, or starts a pack 3 or more days late".

For pills containing up to 20 µg or 30–35 µg of ethinyl estradiol

Missed any inactive (nonhormonal) pills:

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

Management of dosing errors during patch use[1]

NEW recommendation 3.4

A woman may need to take action if she has a dosing error with the patch or CVR. Recommendations are provided for management of the extension of the patch-free interval, unscheduled detachment of the patch, extended use of the patch, extension of the CVR-free interval, unscheduled removal of the CVR, and extended use of the CVR.

Extension of the patch-free interval (i.e. forgetting to apply a new patch after the 7-day patch-free interval)

- If the patch-free interval is extended for ≤ 48 hours (i.e. if the total patch-free interval is > 7 days and ≤ 9 days), a new patch should be applied as soon as possible. The woman should keep the same patch change day, meaning that she should start/change the patch on the scheduled patch start/change day as she would without a dosing error. No additional contraceptive protection is needed.

1 New recommendation for the third edition.

- If the patch-free interval is extended for > 48 hours (i.e. if the total patch-free interval is > 9 days), a new patch should be applied as soon as possible. The woman should keep the same patch change day. She should also use condoms or abstain from sex until she has worn a patch for 7 days in a row. If unprotected sexual intercourse occurred during the previous 5 days, she may wish to consider emergency contraception.

Unscheduled detachment of the patch

- If the patch becomes detached for ≤ 48 hours, a new patch should be applied as soon as possible (if detachment occurs < 24 hours after the patch was applied, the woman can try to reapply the same patch or replace with a new patch). The woman should keep the same patch change day. No additional contraceptive protection is needed.
- If the patch becomes detached for > 48 hours, a new patch should be applied as soon as possible. The woman should keep the same patch change day.
  - The woman should also use condoms or abstain from sex until she has worn a patch for 7 days in a row.
  - If the unscheduled detachment occurred during the third week of patch use, the woman should omit the patch-free week by finishing the third week of patch use and starting a new patch immediately. If she is unable to start a new patch immediately after the third week of patch use, she should also use condoms or abstain from sex until she has worn a patch for 7 days in a row.
  - If the unscheduled detachment occurred during the first week of patch use and unprotected sexual intercourse occurred during the previous 5 days, the woman may wish to consider emergency contraception.

Extended use of the patch

- If patch removal and reapplication is delayed by ≤ 48 hours (i.e. if patch use is extended from 7 to ≤ 9 days) during weeks 1–3 of patch use, a new patch should be applied as soon as possible. The woman should keep the same patch change day. No additional contraceptive protection is needed.
- If patch removal and reapplication is delayed by > 48 hours (i.e. if patch use is extended from 7 to > 9 days) during weeks 2–3 of patch use, while a woman is using the first or second patch of her cycle, the patch should be removed or replaced as soon as possible. She should keep the same patch change day. She should also use condoms or abstain from sex until she has worn a patch for 7 days in a row.
- If delayed removal occurs during week 4 of patch use (i.e. the scheduled hormone-free week), while a woman is using the third patch of her cycle, she should remove the patch as soon as possible. She should keep the same patch start day. No additional contraceptive protection is needed.

Management of dosing errors during CVR use[1]

Extension of CVR-free interval (i.e. forgetting to insert a new CVR after the 7-day CVR-free interval)

- If the CVR-free interval is extended for ≤ 48 hours (i.e. if the total CVR-free interval is > 7 days and ≤ 9 days), a new CVR should be inserted as soon as possible. The woman should keep the same CVR removal day, meaning that she should insert/remove the CVR on the scheduled CVR insertion/removal day as she would without a dosing error. No additional contraceptive protection is needed.
- If the CVR-free interval is extended for > 48 hours (i.e. if the total CVR-free interval is > 9 days), a new CVR should be inserted as soon as possible. The woman should keep the same CVR removal day. She should also use condoms or abstain from sex until she has worn a CVR for 7 days in a row. If unprotected sexual intercourse occurred during the previous 5 days, she may wish to consider emergency contraception.

[1] New recommendation for the third edition.

Unscheduled removal of CVR (i.e. CVR is removed before the end of the cycle)

- If the CVR is removed for ≤ 48 hours at an unscheduled time, it should be reinserted as soon as possible. The woman should then keep the CVR in place until the removal day as originally scheduled. No additional contraceptive protection is needed.
- If the CVR is removed for > 48 hours at an unscheduled time, it should be reinserted as soon as possible. The woman should then keep the CVR in place until the removal day as originally scheduled.
  - The woman should also use condoms or abstain from sex until she has worn a CVR for 7 days in a row.
  - If the unscheduled removal of CVR occurred during the third week of CVR use, the woman should omit the CVR-free week by finishing the third week of CVR use and starting a new CVR immediately. If she is unable to start a new CVR immediately after the third week of CVR use, she should use condoms or abstain from sex until she has worn a CVR for 7 days in a row.
  - If the unscheduled removal of CVR occurred during the first week of CVR use and unprotected sexual intercourse occurred during the previous 5 days, the woman may wish to consider emergency contraception.

Extended use of CVR

- If the same CVR is used for up to 28 days (< 4 weeks), then additional contraception is not needed. A hormone-free interval can be taken, if desired, but should not exceed 7 days.
- If the same CVR is used for 28–35 days (≥ 4 weeks but < 5 weeks), insert a new CVR and skip the hormone-free interval. No additional contraceptive protection is needed.

Remarks *(See references 3, 4, 6, 7, 40)*

The GDG 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 or experience usage errors with the patch or CVR should consider an alternative contraceptive method that is less dependent on the user to be effective (e.g. IUD, implant or injectable contraceptive).

Most studies considered by the GDG on late or missed doses of CHCs examined COCs. However, two studies examined the patch, and seven studies examined the CVR. The GDG noted that the evidence for "missed pill" recommendations is primarily derived from studies of women using 30–35 µg ethinyl estradiol 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 GDG's recommendations:

- It is important to resume COC, patch or CVR use (take an active pill, reapply or apply a new patch, or reinsert or insert a new CVR) as soon as possible when doses have been missed.
- If doses are missed, the chance that pregnancy will occur depends not only on the duration of missed doses (i.e. how many days of pill, patch or CVR use were missed), but also on when those doses were missed. Based on data regarding ovulation, the GDG determined that missing 3 or more active (hormonal) pills (2 or more for pills containing ≤ 20 µg ethinyl estradiol) 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 series of active pills, i.e. when the hormone-free interval is extended. Although there

is limited evidence on dosage errors with patch and CVR use, these methods are considered to be similar to COC use, and thus these principles have been extrapolated to patch and CVR use.
- Limited evidence on pills containing ≤ 20 µg ethinyl estradiol suggests that there may be a higher risk of pregnancy when these pills are missed than when pills containing 30–35 µg ethinyl estradiol are missed. Accordingly, the GDG recommended a more cautious approach when pills containing ≤ 20 µg of ethinyl estradiol are missed.
- Field experience from the first edition of the *Selected practice recommendations for contraceptive use* highlighted the need for simple "missed pill" recommendations.

Appropriate follow-up after initiation of COCs, the patch[1] and the CVR[1]

These recommendations address the minimum frequency of follow-up recommended for safe and effective use of these methods. 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.

- An annual follow-up visit is recommended.
- There are added benefits from a three-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.

NEW recommendation 3.5

An annual follow-up visit is recommended after initiating the patch or CVR.

Remarks *(See references 8–11, 40)*

The GDG 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.

[1] New recommendation for the third edition.

7.4.2 Combined injectable contraceptives (CICs)

Two CIC formulations are considered here:

1. Cyclofem = medroxyprogesterone acetate 25 mg plus estradiol cypionate 5 mg
2. Mesigyna = norethisterone enanthate 50 mg plus estradiol valerate 5 mg.

Initiation of CICs

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

Having menstrual cycles

- Within 7 days after the start of menstrual bleeding: The first CIC injection can be given. No additional contraceptive protection is needed.
- More than 7 days since the start of menstrual bleeding: The first CIC injection can be given if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

- The first CIC injection can be given at any time if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Postpartum (breastfeeding)

- Less than 6 weeks postpartum and primarily breastfeeding: CICs should not be used (MEC category 4).
- 6 weeks to 6 months postpartum and primarily breastfeeding: Use of CICs is generally not recommended (MEC category 3) unless other more appropriate methods are not available or not acceptable.
- More than 6 months postpartum and amenorrhoeic: The first CIC injection can be given as advised for other amenorrhoeic women.
- More than 6 months postpartum and menstrual cycles have returned: The first CIC injection can be given as advised for other women having menstrual cycles.

Postpartum (non-breastfeeding)

- Less than 21 days postpartum: Use of CICs is generally not recommended unless other more appropriate methods are not available or not acceptable. 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 (i.e. depending on national, regional and/or local programme protocols), some contraceptive methods may be provided during this period.
- 21 or more days postpartum and menstrual cycles have not returned: The first CIC injection can be given immediately if it is reasonably certain that the woman is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- 21 or more days postpartum and menstrual cycles have returned: The first CIC injection can be given as advised for other women having menstrual cycles.

Post-abortion

- The first CIC injection can be given immediately post-abortion. No additional contraceptive protection is needed.

Switching from another hormonal method

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

Switching from a nonhormonal method (other than the IUD)

- The first CIC injection can be given immediately if it is reasonably certain that the woman is not pregnant; there is no need to wait for her next menstrual period.
  - Within 7 days of the start of menstrual bleeding: No additional contraceptive protection is needed.
  - More than 7 days since the start of menstrual bleeding: 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)

- Within 7 days after the start of menstrual bleeding: The first CIC injection can be given. No additional contraceptive protection is needed. The IUD can be removed at that time.
- More than 7 days since the start of menstrual bleeding: The first CIC injection can be given if it is reasonably certain that the woman is not pregnant.
  - Sexually active in this menstrual cycle: It is recommended that the IUD be removed at the time of her next menstrual period.
  - Not sexually active in this menstrual cycle: 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 the woman is amenorrhoeic or has irregular bleeding, the injection can be given as advised for other amenorrhoeic women.

Remarks *(See references 3, 4, 12, 13)*

The GDG 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 has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Examinations and tests needed before initiation of CICs

In healthy women, no examinations or tests are essential or mandatory before initiating CICs. However, there is special consideration for blood pressure screening; it is desirable to have blood pressure measurements taken before initiation of CICs. It is important to note that in settings where blood pressure measurements are unavailable, women should not be denied use of CICs simply because their blood pressure cannot be measured.

Examination or test	CICs*
Breast examination by provider	C
Pelvic/genital examination	C
Cervical cancer screening	C
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ It is desirable to have blood pressure measurements taken before initiation of CICs. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy-related morbidity and mortality risks are high, and hormonal methods are among the few methods that are widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

Timing for repeat CIC injections (reinjection) for continuation of method

Reinjection interval

- Repeat CIC injections should be provided every four 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 this 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 the woman 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.

Remarks *(See references 14–18)*

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

References for combined hormonal contraceptives (CHCs)

1. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
2. Brahmi D, Curtis KM. When can a woman start combined hormonal contraceptives (CHCs)? A systematic review. Contraception. 2013;87(5):524–38. doi:10.1016/j.contraception.2012.09.010.
3. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ. 2000;321(7271):1259–62.
4. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception. 2001;63(4):211–5.
5. Elomaa K, Ranta S, Tuominen J, Lähteenmäki P. Charcoal treatment and risk of escape ovulation in oral contraceptive users. Hum Reprod. 2001;16(1):76–81.
6. Zapata LB, Steenland MW, Brahmi D, Marchbanks PA, Curtis KM. Effect of missed combined hormonal contraceptives on contraceptive effectiveness: a systematic review. Contraception. 2013;87(5):685–700. doi:10.1016/j.contraception.2012.08.035.
7. Dragoman M, Petrie K, Torgal A, Thomas T, Cremers S, Westhoff CL. Contraceptive vaginal ring effectiveness is maintained during 6 weeks of use: a prospective study of normal BMI and obese women. Contraception. 2013;87(4):432–6. doi:10.1016/j.contraception.2012.12.001.

8. Steenland MW, Zapata LB, Brahmi D, Marchbanks P, Curtis KM. Appropriate follow up to detect potential adverse events after initiation of select contraceptive methods: a systematic review. Contraception. 2013;87(5):611–24. doi:10.1016/j.contraception.2012.09.017.
9. Steenland MW, Zapata LB, Brahmi D, Marchbanks PA, Curtis KM. The effect of follow-up visits or contacts after contraceptive initiation on method continuation and correct use. Contraception. 2013;87(5):625–30. doi:10.1016/j.contraception.2012.09.018.
10. Nisenbaum MG, Melo NR, Giribela CR, Morais TL, Guerra GM, de Angelis K et al. Effects of a contraceptive containing drospirenone and ethinyl estradiol on blood pressure and autonomic tone: a prospective controlled clinical trial. Eur J Obstet Gynecol Reprod Biol. 2014;175:62–6. doi:10.1016/j.ejogrb.2014.01.006.
11. Berenson AB, Rahman M. A randomized controlled study of two educational interventions on adherence with oral contraceptives and condoms. Contraception. 2012;86(6):716–24. doi:10.1016/j.contraception.2012.06.007.
12. Petta CA, Hays M, Brache V, Massai R, Hua Y, Alvarez-Sánchez F et al. Delayed first injection of the once-a-month injectable contraceptive containing 25 mg of medroxyprogesterone acetate and 5 mg E2 cypionate: effects on ovarian function. Fertil Steril. 2001;75(4):744–8.
13. Petta CA, Hays M, Brache V, Massai R, Hua Y, Alvarez-Sánchez F 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(6):363–8.
14. Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Pharmacokinetic and pharmacodynamic investigations with monthly injectable contraceptive preparations. Contraception. 1985;31:453–69.
15. Bahamondes L, Lavin P, Ojeda G, Petta CA, Diaz J, Maradiegue E et al. Return to fertility after discontinuation of the once a month injectable contraceptive Cyclofem. Contraception. 1997;55:307–10.
16. Bassol S, Hernandez C, Nava MP, Trujillo AM, Luz de la Cruz D. A comparative study on the return to ovulation following chronic use of once-a-month injectable contraceptives. Contraception. 1995;51:307–11.
17. Garza-Flores J, Rodriguez V, Perez-Palacios G, Virutamasen P, TangKeow P, Konsayreepong R et al; World Health Organization Task Force on Long-acting Systemic Agents for Fertility Regulation. A multi-centered pharmacokinetic, pharmacodynamic study of once-a-month injectable contraceptives. I. Different doses of HRP112 and of DepoProvera. Contraception. 1987;36:441–57.
18. 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.

7.5 Emergency contraception

Emergency contraception (EC), or post-coital contraception, refers to methods of contraception that can be used to prevent pregnancy in the first few days after intercourse. It is also intended for emergency use following unprotected intercourse, contraceptive failure or misuse (such as forgotten pills or torn condoms), rape or coerced sex.

This section provides recommendations on four methods of EC: the copper-bearing intrauterine device (Cu-IUD) for EC and three different types of emergency contraceptive pills (ECPs): ulipristal acetate ECPs (UPA-ECPs), levonorgestrel-only ECPs (LNG-ECPs) and combined estrogen–progestogen ECPs (combined ECPs).

EC is safe to use for most women. To help determine if women with a particular medical condition or characteristic can safely use EC, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition* (MEC) *(1)*.

There are several options for emergency contraception. The Cu-IUD is an effective EC method that reduces the risk of pregnancy by more than 99% if inserted within 120 hours after intercourse *(2–5)*. ECPs also substantially reduce the risk of pregnancy. However, it is important to note that the effectiveness of each method varies according to individual circumstances including the type of ECP chosen, the day of the menstrual cycle, and the length of time between unprotected intercourse and initiation of ECPs. In addition, effectiveness of ECPs may be reduced with additional acts of unprotected intercourse in the same cycle, use of other medications (e.g. cytochrome P450 3A4 [CYP 3A4] enzyme inducers), and higher body weight or body mass index (BMI) *(6–7)*.

EC does not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended.

When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

7.5.1 Copper-bearing IUDs (Cu-IUD) for EC, and emergency contraceptive pills (ECPs)

Regimens – one of the following options should be selected

- Cu-IUD for EC
- UPA-ECPs: Single dose – one 30 mg tablet[1]
- LNG-ECPs:
  - Single dose (preferred LNG regimen) – 1.50 mg (two 0.75 mg tablets)
  - Split dose – one dose of 0.75 mg, followed by a second dose of 0.75 mg 12 hours later
- Combined ECPs:
  - Split dose – one dose of 100 µg of ethinyl estradiol plus 0.50 mg of LNG, followed by a second dose of 100 µg of ethinyl estradiol plus 0.50 mg of LNG 12 hours later.

Timing

- The Cu-IUD can be inserted up to 120 hours after unprotected intercourse.
- Ideally, UPA-ECPs, LNG-ECPs or combined ECPs should be taken as early as possible after unprotected intercourse, within 120 hours. However, the woman should be advised that the effectiveness of the ECP(s) is reduced the longer the interval between having unprotected intercourse and taking ECP(s). UPA-ECPs may be more effective between 72 hours and 120 hours after unprotected intercourse than other ECPs.

NEW recommendation 4.1

A woman should take a dose of UPA-ECP as early as possible after intercourse, within 120 hours.

Remarks *(See references 8–17, 32)*

The Guideline Development Group (GDG) 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. One study suggests that UPA-ECPs are more effective than LNG-ECPs between 72 hours and 120 hours after unprotected intercourse; no studies were identified that compared UPA-ECPs directly to combined ECPs. Effectiveness after 120 hours is unknown.

The GDG considered evidence that UPA-ECPs and LNG-ECPs are preferable to combined ECPs because they cause less nausea and vomiting.

The GDG also considered evidence that the single-dose regimen of LNG-ECPs is at least as effective as the split-dose regimen of LNG-ECPs (see details above). Programmes can provide either the single- or split-dose option, depending on available preparations. The GDG, however, considered the single-dose option to be preferable to the split-dose option because of compliance considerations.

Provision of an advance supply of ECPs

- An advance supply of ECPs may be given to a woman to ensure that she will have them available when needed and can take them as soon as possible after unprotected intercourse.

Remarks *(See references 18–24)*

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

The GDG 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.

[1] New recommendation for the third edition.

Users of other methods of contraception may wish to consider the use of emergency contraception in the following circumstances, as needed:

- Progestogen-only injectable (POI) contraceptive users: If the woman is more than two 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 EC, if appropriate.
- Progestogen-only pill (POP) users: If a woman having menstrual cycles (including a woman who is breastfeeding) has missed 1 or more pills by more than 3 hours, she may wish to consider the use of EC, if appropriate.
- Combined oral contraceptive (COC) users (pills containing 30–35 µg of ethinyl estradiol): If she missed 3 or more active (hormonal) pills in the first week (including starting a pack 3 or more days late) and had unprotected sex, she may wish to consider the use of EC.
- Combined injectable contraceptive (CIC) users: If the woman 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 EC, if appropriate.
- Standard Days Method (SDM) users: If the woman has unprotected intercourse on cycle days 8–19, she may wish to consider the use of EC, if appropriate.

Prevention of nausea and vomiting when taking ECPs

- LNG-ECPs or UPA-ECPs[1] are preferable to combined 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.

[1] New recommendation for the third edition.

NEW recommendation 4.2

LNG-ECPs or UPA-ECPs are preferable to combined 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.

Remarks *(See references 17, 25–30)*

The GDG 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 GDG 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 ECPs than in women taking LNG-ECPs or UPA-ECPs.
- Evidence indicates that anti-emetics reduce the occurrence of nausea and vomiting in women taking combined 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 GDG considered, it could not be established whether taking ECPs with food alters the risk of nausea or vomiting.

Management of vomiting in women after taking ECPs

Vomiting within 2 hours after taking a dose of pills (LNG-ECPs or combined ECPs)

- Another ECP dose should be taken as soon as possible. If the woman is taking combined 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.

Vomiting within 3 hours after taking a dose of UPA-ECP[1]

- Another UPA dose should be taken as soon as possible.

NEW recommendation 4.3

If the woman vomits within 3 hours after taking a dose of UPA-ECP, she should take another dose as soon as possible.

Remarks

The GDG noted that LNG-ECPs and UPA-ECPs are less likely to cause nausea and vomiting than are combined ECPs.

The GDG considered that 2 hours was sufficient for hormone absorption of LNG-ECPs or combined ECPs and that no action is required if a woman vomits after this time. Three hours was considered sufficient for absorption of UPA.

7.5.2 Resumption or initiation of regular contraception after using EC[2]

After using a copper-bearing IUD (Cu-IUD) for EC

- No additional contraceptive protection is needed if she has a Cu-IUD inserted.

After using LNG-ECPs and combined ECPs

NEW recommendation 4.4

Following administration of LNG-ECPs or combined ECPs, a woman may resume her contraceptive method, or start any contraceptive method immediately, including a Cu-IUD.

Timing:

- Following administration of LNG-ECPs or combined ECPs, a woman may resume her contraceptive method, or start any contraceptive method immediately, including a Cu-IUD. If she wishes to start the LNG-IUD, it can be inserted at any time if it can be determined that she is not pregnant.
  - If she does not start immediately but returns for a method, she may start combined hormonal contraceptives (COCs, patch, CVR or injectable contraceptives) or progestogen-only contraceptives (POPs, DMPA or NET-EN injectable contraceptives or implants) at any time if it is reasonably certain that she is not pregnant.
  - If she does not start immediately but returns for an IUD, she can have it inserted at any time if it is reasonably certain that she is not pregnant. If she is amenorrhoeic, she can have an IUD inserted at any time if it can be determined that she is not pregnant.

Need for additional contraception:
The woman should be advised to abstain from sexual intercourse or use barrier contraception for 2 days after starting POPs or 7 days after starting combined hormonal contraceptives (COCs, patch, CVR or injectable contraceptives) or other progestogen-only contraceptives (DMPA or NET-EN injectable contraceptives, implants or LNG-IUD) and to have early pregnancy testing at the appropriate time, if warranted (e.g. if no withdrawal bleed occurs within three weeks).

Remarks

As stated in the MEC, 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 GDG recognized that the checklist of six criteria will be helpful to the provider in determining whether a woman who is postpartum and breastfeeding may be pregnant (see section 7.1: How can a health-care provider be reasonably certain that a woman is not pregnant?). However, for a woman who is postpartum and non-breastfeeding, or one who is amenorrhoeic (non-postpartum), these six criteria do not apply and other means should be used to determine whether she is pregnant.

[1] New recommendation for the third edition.
[2] New recommendation for the third edition.

After using UPA-ECPs[1]

NEW recommendation 4.5

Following administration of UPA-ECPs, the woman may resume or start any progestogen-containing method (either combined hormonal contraceptives or progestogen-only contraceptives) on the 6th day after taking UPA. She can have an LNG-IUD inserted immediately if it can be determined that she is not pregnant. She can have the Cu-IUD inserted immediately.

Timing:

- Following administration of UPA-ECPs, the woman may resume or start any progestogen-containing method (either combined hormonal contraceptives [CHCs] or progestogen-only contraceptives [POCs]) on the 6th day after taking UPA. She can have an LNG-IUD inserted immediately if it can be determined that she is not pregnant.
  - If she does not start on the 6th day but returns for a method, she may start CHCs (COCs, patch, CVR or injectable contraceptives) or POCs (POPs, DMPA or NET-EN injectable contraceptives, implants or the LNG-IUD) at any time if it is reasonably certain that she is not pregnant. If she is amenorrhoeic, she can have the LNG-IUD inserted at any time if it can be determined that she is not pregnant.
- Following administration of UPA-ECPs, she can have the Cu-IUD inserted immediately.
  - If she does not start immediately but returns for the Cu-IUD, she can have it inserted at any time if it is reasonably certain that she is not pregnant. If she is amenorrhoeic, she can have the Cu-IUD inserted at any time if it can be determined that she is not pregnant.

Need for additional contraception:

The woman should be advised to abstain from sexual intercourse or use barrier contraception from the time she takes UPA until she is protected by her new method of contraception. If regular hormonal contraception is initiated 6 days after taking UPA, she will need to continue to abstain from sexual intercourse or use barrier contraception according to the recommendations for contraceptive initiation (e.g. an additional 2 days for POPs or an additional 7 days for all other hormonal methods). She should also be advised to have pregnancy testing at the appropriate time, if warranted (e.g. if no withdrawal bleed occurs). She does not need to abstain from sexual intercourse or use additional contraceptive protection if she has a Cu-IUD inserted.

Remarks *(See reference 31)*

UPA (an anti-progestogen) and progestogen-containing contraceptive methods may interact, potentially decreasing the effectiveness of either drug. The GDG determined that starting a regular progestogen-containing method (including a combined hormonal method) on the 6th day after taking UPA was sufficient time to avoid potential drug interaction while sperm is viable in female genital tract after unprotected intercourse.

The GDG considered that if delaying initiation of progestogen-containing methods for 6 days after use of UPA is unacceptable to a woman, she may start any method immediately and will need early pregnancy testing at the appropriate time (e.g. if no withdrawal bleed occurs within three weeks).

The GDG determined that if regular hormonal contraception is initiated on the 6th day after taking UPA, continuing to abstain from sexual intercourse or using barrier contraception for the length of time recommended for routine contraceptive initiation (e.g. an additional 2 days for POPs or an additional 7 days for all other hormonal methods) would be sufficient to prevent pregnancy.

As stated in the MEC, 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 GDG recognized that the checklist of six criteria will be helpful to the provider in determining whether a woman who is postpartum and breastfeeding may be pregnant (see

[1] New recommendation for the third edition.

section 7.1: How can a health-care provider be reasonably certain that a woman is not pregnant?). However, for a woman who is postpartum and non-breastfeeding, or one who is amenorrhoeic (non-postpartum), these six criteria do not apply and other means should be used to determine whether she is pregnant.

References for emergency contraception (EC)

1. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
2. Cleland K, Zhu H, Goldstuck N, Cheng L, Trussell J. The efficacy of intrauterine devices for emergency contraception: a systematic review of 35 years of experience. Hum Reprod. 2012;27(7):1994–2000. doi:10.1093/humrep/des140.
3. Wu S, Godfrey EM, Wojdyla D, Dong J, Cong J, Wang C et al. Copper T380A intrauterine device for emergency contraception: a prospective, multicentre, cohort clinical trial. BJOG. 2010;117(10):1205–10. doi:10.1111/j.1471-0528.2010.02652.x.
4. Turok DK, Godfrey EM, Wojdyla D, Dermish A, Torres L, Wu SC. Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle. Hum Reprod. 2013;28(10):2672–6. doi:10.1093/humrep/det330.
5. Zhou L, Xiao B. Emergency contraception with Multiload Cu-375 SL IUD: a multicenter clinical trial. Contraception. 2001;64(2):107–12.
6. Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D et al. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. Contraception. 2011:84(4):363–7. doi:10.1016/j.contraception.2011.02.009.
7. Trussell J, Rodríguez G, Ellertson C. Updated estimates of the effectiveness of the Yuzpe regimen of emergency contraception. Contraception. 1999;59(3):147–51.
8. Cleland K, Zhu H, Goldstuck N, Cheng L, Trussell J. The efficacy of intrauterine devices for emergency contraception: a systematic review of 35 years of experience. Hum Repro. 2012;27(7):1994–2000. doi:10.1093/humrep/des140.
9. Glasier, AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet. 2010;375(9714):555–62. doi:10.1016/S0140-6736(10)60101-8.
10. Raymond E, Taylor D, Trussell J, Steiner MJ. Minimum effectiveness of the levonorgestrel regimen of EC. Contraception. 2004;69(1):79–81.
11. Fine P, Mathe H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48–120 hours after intercourse for emergency contraception. Obstet Gynecol. 2010;115(2 Pt 1):257–63. doi:10.1097/AOG.0b013e3181c8e2aa.
12. Dada OA Godfrey EM, Piaggio G, von Hertzen H. A randomized, double blind, noninferiority study to compare two regimens of levonorgestrel for emergency contraception in Nigeria. Contraception. 2010;82(4):373–8. doi:10.1016/j.contraception.2010.06.004.
13. Ngai SW, Fan S, Li S, Cheng L, Ding J, Jing X et al. A randomized trial to compare 24h versus 12h double dose regimen of levonorgestrel for emergency contraception. Hum Reprod. 2005;20(1):307–11.
14. Ellertson C, Evans M, Ferden S, Leadbetter C, Spears A, Johnstone K et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. Obstet Gynecol. 2003;101(6):1168–71.
15. Piaggio G, von Hertzen H. Effect of delay in the administration of levonorgestrel for emergency contraception. Presented at the XVII FIGO World Congress of Gynecology and Obstetrics, 2–7 November 2003, Santiago, Chile.
16. Rodrigues I, Grou F, Joly J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. Am J Obstet Gynecol. 2001;184(4):531–7. doi:10.1067/mob.2001.111102.
17. von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bartfai G et al.; WHO Research Group on Post-ovulatory Methods of Fertility Regulation. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet. 2002;360(9348):1803–10. doi:10.1016/S0140-6736(02)11767-3.
18. Belzer M, Yoshida E, Tejirian T, Tucker D, Chung K, Sanchez K. Advanced supply of emergency contraception for adolescent mothers increased utilization without reducing condom or primary contraception use. J Adolesc Health. 2003;32:122–3.
19. Ellertson C, Ambardekar S, Hedley A, Coyaji K, Trussell J, Blanchard K. Emergency contraception: randomized comparison of advance provision and information only. Obstet Gynecol. 2001;98(4):570–5.
20. Glasier A, Baird D. The effects of self-administering emergency contraception. New Engl J Med. 1998;339(1):1–4. doi:10.1056/NEJM199807023390101.
21. Jackson RA, Bimla Schwartz E, Freedman L, Darney P. Advance supply of emergency contraception: effect on use and usual contraception – a randomized trial. Obstet Gynecol. 2003;102(1):8–16.
22. Lovvorn A, Nerquaye-Tetteh J, Glover EK, Amankwah-Poku A, Hays M, Raymond E. Provision of emergency contraceptive pills to spermicide users in Ghana. Contraception. 2000;61(4):287–93.
23. Raine T, Harper C, Leon K, Darney P. Emergency contraception: advance provision in a young, high-risk clinic population. Obstet Gynecol. 2000;96(1):1–7.

24. Roye CF. Routine provisions of emergency contraception to teens and subsequent condom use: a preliminary study [letter]. J Adolesc Health. 2001;28(3):165–6.
25. Rodriguez MI, Godfrey EM, Warden M, Curtis KM. Prevention and management of nausea and vomiting with emergency contraception: a systematic review. Contraception. 2013;87(5):583–9. doi:10.1016/j.contraception.2012.09.031.
26. Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception. 2002;66(4):269–73.
27. Ellertson C, Webb A, Blanchard K, Bigrigg A, Haskell S, Shochet T, Trussell J. Modifying the Yuzpe regimen of emergency contraception: a multicenter randomized controlled trial. Obstet Gynecol. 2003;101(6):1160–7.
28. Ho PC, Kwan MS. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. Hum Reprod. 1993;8(3):389–92.
29. Ragan RE, Rock RW, Buck HW. Metoclopramide pretreatment attenuates emergency contraceptive-associated nausea. Am J Obstet Gynecol. 2003;188(2):330–3.
30. Raymond EG, Creinin MD, Barnhart KT, Lovvorn AE, Rountree RW, Trussell J. Meclizine for prevention of nausea associated with use of emergency contraceptive pills: a randomized trial. Obstet Gynecol. 2000;95(2):271–7.
31. Salcedo J, Rodriguez MI, Curtis KM, Kapp N. When can a woman resume or initiate contraception after taking emergency contraceptive pills? A systematic review. Contraception. 2013;87(5):602–4. doi:10.1016/j.contraception.2012.08.013.
32. Rodriguez MI, Gaffield ME. How can a woman take emergency contraceptive pills? (unpublished, available upon request).

7.6 Standard Days Method®

Standard Days Method (SDM) is a type of fertility awareness-based (FAB) method. FAB methods – which also include the Ovulation Method, the TwoDay Method and the sympto-thermal method – can be used in combination with abstinence or barrier methods during the fertile time. Specifically, with SDM, a woman with a regular cycle of 26–32 days in length should avoid unprotected intercourse on cycle days 8–19. For details of all FAB methods, please refer to *Family planning: a global handbook for providers (1)*.

SDM can be safely used by most women. Women with conditions that make pregnancy an unacceptable risk should be advised that SDM for pregnancy prevention may not be appropriate for them because of the relatively higher typical-use failure rates. To help determine if women with certain medical conditions or characteristics can safely use SDM, please refer to the *Medical eligibility criteria for contraceptive use, fifth edition (2)*.

SDM does not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

Initiation of SDM

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

- Another method of contraception should be provided for protection on days 8–19 if the woman desires. Give supplies in advance.

SDM users who have unprotected intercourse between days 8–19

- Use of emergency contraception should be considered, if appropriate.

Use of SDM in women who have two or more cycles outside the 26–32 day range, within any one year of use

- The woman should be advised that the method may not be appropriate for her because of a higher risk of pregnancy. Help her consider another method.

Remarks *(See references 3–5)*

The Guideline Development Group (GDG) 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.

References for Standard Days Method (SDM)

1. Family planning: a global handbook for providers: 2011 update. World Health Organization, Johns Hopkins Bloomberg School of Public Health, United States Agency for International Development; 2011 (http://apps.who.int/iris/bitstream/10665/44028/1/9780978856373_eng.pdf, accessed 8 July 2016).
2. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
3. Arévalo M, Sinau I, Jennings V. A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning. Contraception. 2000;60(6):357–60.
4. Wilcox AJ, Dunson D, Baird DD. The timing of the "fertile window" in the menstrual cycle: day specific estimates from a prospective study. BMJ. 2000;321:1259–62. doi:10.1136/bmj.321.7271.1259.
5. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception. 2001;63(4):211–5.

7.7 Male sterilization

Male sterilization, or vasectomy, is a low-risk procedure that involves occlusion of the vas deferens and can be performed in an outpatient setting. Both the no-scalpel and conventional incision procedures are quick, safe and effective. Sterilization should be regarded as a permanent method and all individuals and couples considering this option should be counselled accordingly, to ensure that every client makes a voluntary, informed decision. Particular attention must be given in the case of young people, men who have not yet been fathers, and clients with mental health problems, including depressive conditions. In addition to receiving counselling about the permanence of this method, all clients should be carefully counselled about the availability of alternative, long-acting, highly effective methods for women. The national laws and existing norms for the delivery of sterilization procedures must be considered in the decision-making process.

There is no medical condition that would be an absolute contraindication for male sterilization, although some conditions and circumstances will require that certain precautions are taken. To help determine if men with certain medical conditions or characteristics can safely have a vasectomy, please refer to the *Medical eligibility criteria for contraceptive use*, fifth edition *(1)*. For further details on vasectomy please refer to *Family planning: a global handbook for providers (2)*.

Sterilization does not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended. When used correctly and consistently, condoms offer one of the most effective methods of protection against STIs, including HIV. Female condoms are effective and safe, but are not used as widely by national programmes as male condoms.

7.7.1 Vasectomy

Reliance on a vasectomy for contraception

- The man should be advised to wait three 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 three-month waiting period.

Remarks *(See references 3–92)*

The Guideline Development Group (GDG) considered that vasectomy is highly effective when the procedure is properly performed and when the man waits for three months after the vasectomy before having unprotected intercourse. The GDG reviewed evidence that a three-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 GDG also reviewed evidence that having had 20 ejaculations after vasectomy (in the absence of a three-month waiting period) is not a reliable determinant of vasectomy effectiveness. The man, however, should resume sexual activity (while using contraceptive protection) during the three-month waiting period after his vasectomy in order to clear any remaining sperm from his semen.

Examinations and tests before providing vasectomy

In healthy men, only a genital examination is essential and mandatory before undergoing vasectomy. However, blood pressure screening is desirable for procedures performed under local anaesthesia.

Examination or test	Vasectomy*
Genital examination	A
Routine laboratory tests	C
Haemoglobin test	C
STI risk assessment: medical history and physical examination	C
STI/HIV screening: laboratory tests	C
Blood pressure screening	C‡

* Class A: The examination or test is essential and mandatory in all circumstances for safe and effective use of the contraceptive method; Class B: The examination or test 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 the examination or test should be balanced against the benefits of making the contraceptive method available; Class C: The examination or test does not contribute substantially to safe and effective use of the contraceptive method.

‡ For procedures performed using local anaesthesia.

References for male sterilization

1. Medical eligibility criteria for contraceptive use, fifth edition. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/, accessed 8 July 2016).
2. Family planning: a global handbook for providers: 2011 update. World Health Organization, Johns Hopkins Bloomberg School of Public Health, United States Agency for International Development; 2011 (http://apps.who.int/iris/bitstream/10665/44028/1/9780978856373_eng.pdf, accessed 8 July 2016).
3. Albert PS, Mininberg DT, Davis JE. The nitrofurans as sperm immobilising agents: their tissue toxicity and their clinical application. Br J Urol. 1975;47:459–62.
4. Albert PS, Seebode J. Nitrofurazone: vas irrigation as adjunct in vasectomy. Urology. 1977;10:450–1.
5. Albert PS, Seebode J. Nitrofurazone: vas irrigation as an adjunct in vasectomy. Fertil Steril. 1978;29:442–3.
6. Albert PS, Salerno RG, Kapoor SN, Davis JE. The nitrofurans as sperm immobilizing agents. J Urol. 1975;113:69–70.
7. Albert PS, Salerno RG, Kapoor SN, Davis JE. The nitrofurans as sperm-immobilizing agents, their tissue toxicity, and their clinical application in vasectomy. Fertil Steril. 1975;26:485–91.
8. Alderman PM. The lurking sperm. A review of failures in 8879 vasectomies performed by one physician. JAMA. 1988;259:3142–4.
9. Alderman PM. General and anomalous sperm disappearance characteristics found in a large vasectomy series. Fertil Steril. 1989;51:859–62.
10. Anonymous. One thousand vasectomies. BMJ. 1973;4(5886):216–21.
11. Arellano Lara S, Gonzalez Barrera JL, Hernandez Ono A, Moreno Alcazar O, Espinosa Perez J. No-scalpel vasectomy: review of the first 1000 cases in a family medicine unit. Arch Med Res. 1997;28:517–22.
12. Badrakumar C, Gogoi NK, Sundaram SK. Semen analysis after vasectomy: when and how many? Br J Urol Int. 2000;86(4):479–81.
13. Barone MA, Nazerali H, Cortes M, Chen-Mok M, Pollack AE, Sokal D. A prospective study of time and number of ejaculations to azoospermia after vasectomy by ligation and excision. J Urol. 2003;170:892–6. doi:10.1097/01.ju.0000075505.08215.28.
14. Barros D'Sa IJ, Guy PJ. No-scalpel vasectomy: a cautionary tale of failure. Br J Urol Int. 2003;92:331–2.
15. Bedford JM, Zelikovsky G. Viability of spermatozoa in the human ejaculate after vasectomy. Fertil Steril. 1979;32:460–3.
16. Belker AM, Sexter MS, Sweitzer SJ, Raff MJ. The high rate of noncompliance for post-vasectomy semen examination: medical and legal considerations. J Urol. 1990;144(2 Pt 1):284–6.
17. Berthelsen JG. [Irrigation of the vas deferens during vasectomy]. Ugeskrift for Laeger. 1975;137:1527–9 (in Danish).
18. Berthelsen JG. Perioperative irrigation of the vas deferens during vasectomy. Scand J Urol Nephrol. 1976;10:100–2.
19. Berthelsen JG, Gandrup P. [Investigation of fertility after vasectomy by means of eosin differential staining (vital staining) of the spermatozoa]. Ugeskrift for Laeger. 1979;141:2116–8 (in Danish).
20. Bradshaw HD, Rosario DJ, James MJ, Boucher NR. Review of current practice to establish success after vasectomy. Br J Surg. 2001;88(2):290–3.
21. Chan J, Anderson R, Glasier A. Post-vasectomy semen analysis: unnecessary delay or belt and braces? Br J Fam Plann. 1997;23(3):77–9.
22. Cortes M, Flick A, Barone MA, Amatya R, Pollack AE, Otero-Flores J et al. Results of a pilot study of the time to

azoospermia after vasectomy in Mexico City. Contraception. 1997;56:215–22.

23. Craft I. Irrigation at vasectomy and the onset of "sterility". Br J Urol. 1973;45:441–2.
24. Craft I, McQueen J. Effect of irrigation of the vas on post-vasectomy semen-counts. Lancet. 1972;1(7749):515–6.
25. Davies AH, Sharp RJ, Cranston D, Mitchell RG. The long-term outcome following "special clearance" after vasectomy. Br J Urol. 1990;66:211–2.
26. De Knijff DW, Vrijhof HJ, Arends J, Janknegt RA. Persistence or reappearance of nonmotile sperm after vasectomy: does it have clinical consequences? Fertil Steril. 1997;67:332–5.
27. Edwards IS. Vasectomy: elimination of motile sperm [letter]. Med J Aust 1976;1(25):978.
28. Edwards IS. Vasectomy: a simple postoperative regimen. Med J Aust. 1977;1:814–7.
29. Edwards IS. Vasectomy: irrigation with euflavine. Med J Aust. 1977;1:847–9.
30. Edwards IS. Postvasectomy testing: reducing the delay [letter]. Med J Aust. 1981;1:649.
31. Edwards IS. Earlier testing after vasectomy, based on the absence of motile sperm. Fertil Steril. 1993;59:431–6.
32. Edwards IS, Farlow JL. Non-motile sperms persisting after vasectomy: do they matter? BMJ. 1979;1(6156):87–8.
33. Esho JO, Cass AS. Recanalization rate following methods of vasectomy using interposition of fascial sheath of vas deferens. J Urol. 1978;120:178–9.
34. Esho JO, Cass AS, Ireland GW. Morbidity associated with vasectomy. J Urol. 1973;110:413–5.
35. Esho JO, Ireland GW, Cass AS. Recanalization following vasectomy. Urology. 1974;3:211–4.
36. Esho JO, Ireland GW, Cass AS. Vasectomy: comparison of ligation and fulguration methods. Urology. 1974;3:337–8.
37. Freund M, Davis JE. Disappearance rate of spermatozoa from the ejaculate following vasectomy. Fertil Steril. 1969;20:163–70.
38. Gandrup P, Berthelsen JG, Nielsen OS. Irrigation during vasectomy: a comparison between sterile water and the spermicide euflavine. J Urol. 1982;127:60–1.
39. Goldstein M. Vasectomy failure using an open-ended technique. Fertil Steril. 1983;40:699–700.
40. Gupta AS, Kothari LK, Devpura TP. Vas occlusion by tantalum clips and its comparison with conventional vasectomy in man: reliability, reversibility, and complications. Fertil Steril. 1977;28:1086–9.
41. Haldar N, Cranston D, Turner E, MacKenzie I, Guillebaud J. How reliable is a vasectomy? Long-term follow-up of vasectomised men. Lancet. 2000;356(9223):43–4.
42. Hamilton DW. Immediate sterility after vasectomy. Med J Aust. 1977;1:402–3.
43. Jackson P, Phillips B, Prosser E et al. A male sterilization clinic. BMJ. 1970;4:295–7.
44. Jensen UH, Siemsen SJ. [Vasectomy with immediate sterility]. Ugeskrift for Laeger. 1978;140:916–7 (in Danish).
45. Jones JS. Percutaneous vasectomy: a simple modification eliminates the steep learning curve of no-scalpel vasectomy. J Urol. 2003;169(4):1434–6. doi:10.1097/01.ju.0000047366.58553.1c.
46. Jouannet P, David G. Evolution of the properties of semen immediately following vasectomy. Fertil Steril. 1978;29:435–41.
47. Klapproth HJ, Young IS. Vasectomy, vas ligation and vas occlusion. Urology. 1973;1:292–300.
48. Koneitzko D, Reinecke F. [Prolonged demonstration of spermatozoa after vasectomy]. Deutsche Medizinische Wochenschrift. 1973;98:1221–3 (in German).
49. Kumar V, Kaza RM. A combination of check tug and fascial interposition with no-scalpel vasectomy. J Fam Plann Reprod Health Care. 2001;27(2):100.
50. Labrecque M, Nazerali H, Mondor M, Fortin V, Nasution M. Effectiveness and complications associated with 2 vasectomy occlusion techniques. J Urol. 2002;168(6):2495–8. doi:10.1097/01.ju.0000032801.68305.3f.
51. Lauritsen NP, Klove-Mogensen M, Glavind K. Vasectomy with rivanol injection and fertility control by vital staining with eosin. Int Urol Nephrol. 1987;19:419–22.
52. Lee C, Paterson IS. Review of current practice to establish success after vasectomy. Br J Surg 2001;88:1267–8.
53. Lehtonen T. Effect of irrigation of vas deferens on sperm analyses after vasectomy. Annales Chirurgiae et Gynaecologiae Fenniae. 1975;64:224–6.
54. Lehtonen T. Vasectomy for voluntary male sterilisation. Scand J Urol Nephrol. 1975;9:174–6.
55. Lemack GE, Goldstein M. Presence of sperm in the pre-vasectomy reversal semen analysis: incidence and implications. J Urol. 1996;155(1):167–9.
56. Leungwattanakij S, Lertsuwannaroj A, Ratana-Olarn K. Irrigation of the distal vas deferens during vasectomy: does it accelerate the post-vasectomy sperm-free rate? Int J Androl. 2001;24(4):241–5.
57. Lewis EL, Brazil CK, Overstreet JW. Human sperm function in the ejaculate following vasectomy. Fertil Steril. 1984;42:895–8.
58. Linnet L. [Control of vasectomy. A prospective study of the semen of 45 vasectomized patients and experience from control study of 197 patients in whom vasectomy was undertaken employing fascial interposition]. Ugeskrift for Laeger. 1977;139:1708–14 (in Danish).
59. Linnet L, Linnet-Jepsen P. [Acceptability of offers of vasectomy control]. Ugeskrift for Laeger. 1980;142:637–40 (in Danish).
60. Maatman TJ, Aldrin L, Carothers GG. Patient noncompliance after vasectomy. Fertil Steril. 1997;68:552–5.
61. McEwan J, Newton J, Yates-Bell A. Hospital family planning: a vasectomy service. Contraception. 1974;9:177–92.

62. Madrigal V, Edelman DA, Goldsmith A. Male sterilization in El Salvador: a preliminary report. J Reprod Med. 1975;14:167–70.
63. Marshall S, Lyon RP. Transient reappearance of sperm after vasectomy. JAMA. 1972;219:1753–4.
64. Marshall S, Lyon RP. Variability of sperm disappearance from the ejaculate after vasectomy. J Urol. 1972;107:815–7.
65. Marwood RP, Beral V. Disappearance of spermatozoa from ejaculate after vasectomy. BMJ. 1979;1(6156):87.
66. Mason RG, Dodds L, Swami SK. Sterile water irrigation of the distal vas deferens at vasectomy: does it accelerate clearance of sperm? A prospective randomized trial. Urology. 2002;59(3):424–7.
67. Nazerali H, Thapa S, Hays M, Pathak LR, Pandey KR, Sokal DC. Vasectomy effectiveness in Nepal: a retrospective study. Contraception. 2003;67(5):397–401.
68. O'Brien TS, Cranston D, Ashwin P, Turner E, MacKenzie IZ, Guillebaud J. Temporary reappearance of sperm 12 months after vasectomy clearance. Br J Urol. 1995;76:371–2.
69. Orr D, Moore B. Vasectomy as a contraceptive method. Irish Med J. 1989,82:19–20.
70. Pearce I, Adeyoju A, Bhatt RI, Mokete M, Brown SCW. The effect of perioperative distal vasal lavage on subsequent semen analysis after vasectomy: a prospective randomized controlled trial. Br J Urol Int. 2002;90:282–5.
71. Penna RM, Potash J, Penna SM. Elective vasectomy: a study of 843 patients. J Fam Pract. 1979;8:857–8.
72. Philp T, Guillebaud J, Budd D. Late failure of vasectomy after two documented analyses showing azoospermic semen. BMJ (Clinical Research Edition). 1984;289(6437):77–9.
73. Poddar AK, Roy S. Disappearance of spermatozoa from semen after vasectomy. J Pop Res. 1976;3:61–70.
74. Rees RW. Vasectomy: problems of follow up. Proc R Soc Med. 1973;66:2–4.
75. Rhodes DB, Mumford SD, Free MJ. Vasectomy: efficacy of placing the cut vas in different fascial planes. Fertil Steril. 1980;33:433–8.
76. Richardson DW, Aitken RJ, Loudon NB. The functional competence of human spermatozoa recovered after vasectomy. J Reprod Fertil. 1984;70:575–9.
77. Robson AJ, Hunt PK. Flushing of the vas deferens during vasectomy. Can Med Assoc J. 1978;118:770–1.
78. Santiso R, Pineda MA, Marroquín M, Bertrand JT. Vasectomy in Guatemala: a follow-up study of five hundred acceptors. Soc Biol. 1981;28:253–64.
79. Schmidt SS. Vasectomy by section, luminal fulguration and fascial interposition: results from 6248 cases. Br J Urol. 1995;76:373–4.
80. Schraibman IG. One thousand vasectomies. BMJ. 1973;4:418.
81. Sekhon GS. Percutaneous vasectomy: a comparative study using a new instrument and technique. Indian J Med Res. 1970;58:1433–42.
82. Sivanesaratnam V. Onset of azoospermia after vasectomy. NZ Med J. 1985;98(778):331–3.
83. Smith AG, Crooks J, Singh NP, Scoot R, Lloyd SN. Is the timing of post-vasectomy seminal analysis important? Br J Urol. 1998;81:458–60.
84. Sokal DC, Irsula B, Hays M, Chen-Mok M, Barone MA; the Investigator Study Group. Vasectomy by ligation and excision, with versus without fascial interposition: a randomized controlled trial. BMC Med. 2004;2:6. doi:10.1186/1741-7015-2-6.
85. Sorensen TT, Knudsen PR, Hangaard J. [Outpatient vasectomy]. Ugeskrift for Laeger. 1980;143:26–7 (in Danish).
86. Stamm H, Acheampong A. [Vasectomy within the scope of contraception]. Gynakologische Rundschau. 1984;24:85–97 (in Danish).
87. Tailly G, Vereecken RL, Verduyn H. A review of 357 bilateral vasectomies for male sterilization. Fertil Steril. 1984;41:424–7.
88. Temmerman M, Cammu H, Devroey P, Ad Amy JJ. Evaluation of one-hundred open-ended vasectomies. Contraception. 1986;33:529–32.
89. Thompson B, MacGregor JE, MacGillivray I, Garvie WH. Experience with sperm counts following vasectomy. Br J Urol. 1991;68:230–3.
90. Urquhart-Hay D. Immediate sterility after vasectomy. BMJ. 1973;3(5876):378–9.
91. Varela Rico J et al. Vasectomy with immediate sterilization using intraductal phenylmercuric acetate. Curr Ther Res Clin Exp. 1979;26:881–4.
92. Yu HY, Halim A, Evans PR. Chlorhexidine for irrigation of vas: a clinical trial and the study of viability of non-motile sperms in post-vasectomy patients with trypan blue uptake. Br J Urol. 1976;48:371–5.

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