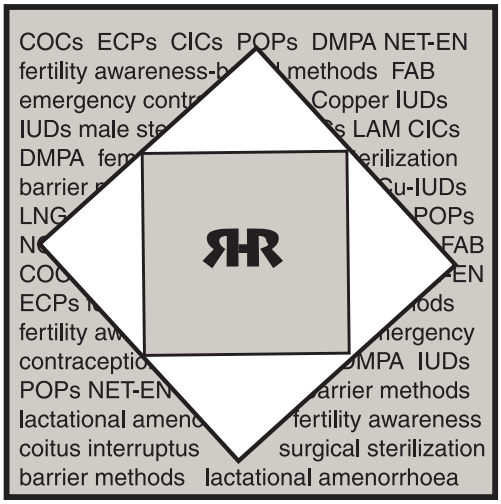
MEDICAL ELIGIBILITY CRITERIA FOR CONTRACEPTIVE USE



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Executive summary

This document is one important step in a process for improving access to quality of care in family planning by reviewing the medical eligibility criteria for selecting methods of contraception. It updates the second edition of ***Improving access to quality care in family planning: medical eligibility criteria for contraceptive use***, published in 2000, and summarizes the main recommendations of an expert Working Group meeting held at the World Health Organization, Geneva, 21–24 October 2003. (Please see Annex 2 for the list of participants.) The Working Group brought together 36 participants from 18 countries, including representatives of many agencies and organizations. The document provides recommendations for appropriate medical eligibility criteria based on the latest clinical and epidemiological data and is intended to be used by policy-makers, family planning programme managers and the scientific community. It aims to provide guidance to national family planning/reproductive health programmes in the preparation of guidelines for service delivery of contraceptives. It should not be seen or used as the actual guidelines but rather as a reference.

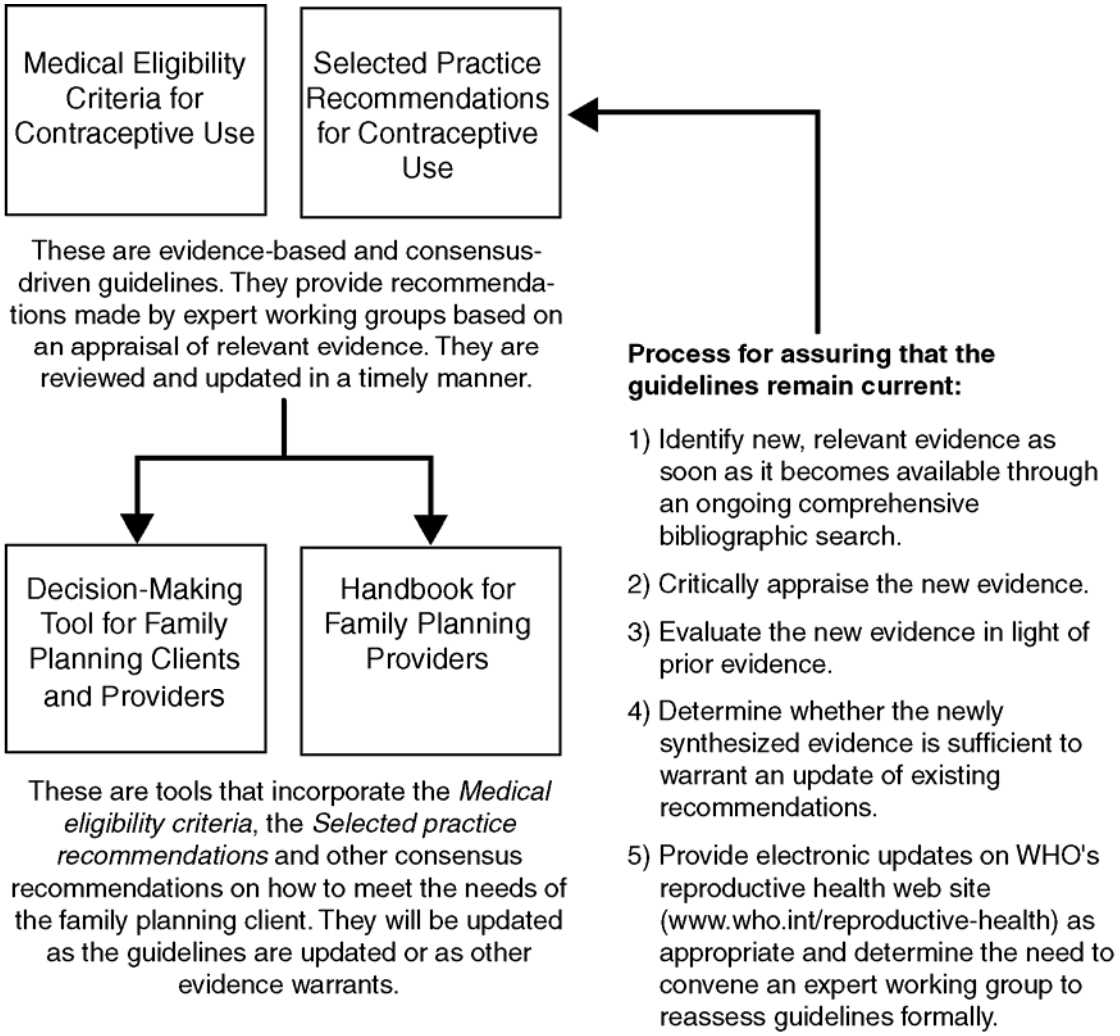
The document covers the following family planning methods: low-dose combined oral contraceptives (COCs), combined injectable contraceptives (CICs), combined patch (P), combined vaginal ring (R), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel (LNG) and etonogestrel (ETG) implants, emergency contraceptive pills (ECPs), copper intrauterine devices (Cu-IUDs), levonorgestrel-releasing IUDs (LNG-IUDs), copper-IUD for emergency contraception (E-IUD), barrier methods (BARR), fertility awareness-based methods (FAB), lactational amenorrhoea method (LAM), coitus interruptus (CI), and female and male sterilization (STER).

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

Overview

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

Figure 1. The four cornerstones of family planning guidance



Goal

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

The document does not provide rigid guidelines but rather gives recommendations that provide a basis for rationalizing the provision of various contraceptives in view of the most up-to-date information available on the safety of the methods for people with certain health conditions.

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

Background

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

Reproductive and sexual health care

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

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

While this document primarily addresses medical eligibility criteria for contraceptive use, considerations of social, behavioural, and other non-medical criteria, particularly client preference, must 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 imposed or limited by direct or indirect social, economic and cultural factors. From the women's point of view, choices are made in a particular time, societal and cultural context; choices are complex, multifactorial and subject to change. Decision-making for contraceptive methods usually requires the need to make trade-offs among the different methods, with advantages and disadvantages of specific contraceptive methods varying according to individual circumstances, perceptions, and interpretations.

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

Issues of service quality and access that affect method use

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

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

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

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

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

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

Effectiveness of method

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

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

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

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

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

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

Note: This table has been adapted from the source document by changing the title, changing the trade names of methods to generic names and by modifying footnotes.

Notes:

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

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

[3] Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

[4] The percentages becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among populations where contraception is not used, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

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

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

[7] With spermicidal cream or jelly.

[8] Without spermicides.

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

Conditions that expose a woman to increased risk as a result of unintended pregnancy

Women with conditions that may make pregnancy an unacceptable health risk should be advised that, because of their relatively higher typical-use failure rates, sole use of barrier methods for contraception and behaviour-based methods of contraception may not be the most appropriate choice for them. These conditions are noted in Table 2.

Table 2. Conditions that expose a woman to increased risk as a result of unintended pregnancy

Breast cancer
Complicated valvular heart disease
Diabetes: insulin-dependent; with nephropathy/retinopathy/neuropathy or other vascular disease; or of > 20 years' duration
Endometrial or ovarian cancer
High blood pressure (systolic >160 mm Hg or diastolic >100 mm Hg)[†]
HIV/AIDS*
Ischaemic heart disease
Malignant gestational trophoblastic disease
Malignant liver tumours (hepatoma)
Schistosomiasis with fibrosis of the liver
Severe (decompensated) cirrhosis
Sickle cell disease
STI*
Stroke
Thrombogenic mutations
Tuberculosis

[†] Throughout this document, blood pressure measurements are given in mm Hg. To convert to kPa, multiply by 0.1333. For example, 120/80 mm Hg = 16.0/10.7 kPa.

* Dual protection is strongly recommended for protection against HIV/AIDS and other STIs when a risk of STI/HIV transmission exists. This can be achieved through the simultaneous use of condoms with other methods or the consistent and correct use of condoms alone.

Return to fertility

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

STIs and contraception: Dual protection

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

Method of work

This document builds on a process initiated in 1994 that culminated in the 1996 publication of the document, ***Improving access to quality care in family planning: medical eligibility criteria for contraceptive use.*** In the initial process, which was created to reach agreement on appropriate eligibility criteria for widely used contraceptive methods, a number of agencies and organizations collaborated in an in-depth review of the epidemiological and clinical evidence relevant to medical eligibility criteria of well established contraceptive methods. The process involved comparing the eligibility criteria used by different agencies for various contraceptives, preparing summaries of published medical and epidemiological literature relevant to medical eligibility criteria, and preparing a draft classification for review by a larger group of experts and agencies. Two expert Working Group meetings were organized by WHO, in March 1994 and May 1995, to review the background classifications and to formulate recommendations; publication of the document followed in 1996.

The first revision of the 1996 document was based on the recommendations of an expert Working Group meeting held at WHO on 8-10 March 2000, that brought together 32 participants from 17 countries, including representatives of many agencies and organizations. The Working Group reviewed new evidence since the last Working Group meetings in 1994 and 1995. This new evidence was primarily obtained from a systematic review of the most recent literature, which was conducted to identify and summarize new evidence for medical eligibility criteria of contraceptive methods.

This third edition of the document is based on the recommendations of an expert Working Group meeting held at WHO on 21–24 October 2003, that brought together 36 participants from 18 countries, including representatives of many agencies and organizations. The Working Group was comprised of international family planning experts, including clinicians, epidemiologists, policy-makers and programme experts. The Working Group also included experts in evidence identification and synthesis and users of the guideline. A Guideline Steering Group was established for this edition. All members of the Working Group were asked to declare conflicts of interests and none were declared.

Using a system to identify new evidence on an ongoing basis (the Continuous Identification of Research Evidence or CIRE, www.infoforhealth.org/cire/cire_pub.pl), WHO identified 151

current recommendations for which new evidence was available since the second edition. WHO also decided to develop recommendations for 3 new conditions and 3 new contraceptive methods in this third edition. Systematic reviews were conducted to appraise the complete body of evidence for these 151 recommendations and for the new conditions and new methods. A systematic, comprehensive search of bibliographic databases, such as MEDLINE, yielded all primary studies, through August 2003, that described use of contraceptive methods among women with certain conditions (e.g., the risk of stroke for women with migraines who use COCs). The purpose of these systematic reviews was to identify direct evidence for the appropriateness of contraceptive method use by women with selected conditions. Information on indirect evidence or theoretical considerations was obtained for these recommendations when direct evidence was sought but not available. The strength and quality of the evidence was graded using the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) system (www.gradeworkinggroup.org). The grading of the evidence was provided to the Working Group as each relevant recommendation was considered. Issues of cost were considered primarily in terms of availability and access to contraceptive services, as well as potential resource constraints. Programmatic implications of the recommendations were also considered by the Working Group. The recommendations primarily concern safety issues and these issues were considered in light of their applicability in a variety of settings.

For most recommendations (method/condition combinations), there are a limited number of studies that address the use of a specific method by women with a specific condition. Thus, most of the decisions regarding eligibility criteria using evidence were often necessarily based on extrapolations from studies that primarily included healthy women, as well as on theoretical considerations and expert opinion. Evidence was particularly limited for newer products and for those with limited usage. The total body of evidence considered by the Working Group included:

- evidence based on direct studies or observations of the contraceptive method used by women (or men) with the condition;
- evidence derived from effects of the contraceptive method used by women (or men) without the condition;
- indirect evidence or theoretical concerns based on studies of suitable animal models, human laboratory studies, or analogous clinical situations.

Where the Working Group had a systematic review of the evidence to consider as they made a recommendation, the evidence is cited in this document alongside the recommendation. The recommendations for which no evidence is cited were based on expert opinion and/or evidence obtained from sources other than systematic reviews. As noted below, over 1000 of the recommendations in this edition are unchanged from those made in the first edition. The evidence for the first edition was provided to the 1994 and 1995 Working Groups in a series of background papers prepared for the project.

The second edition included 1287 recommendations. These recommendations are widely used globally and, therefore, WHO determined that any changes should be based on new evidence unless there was a compelling reason to do otherwise. The Guideline Steering Group, which convened on 21 October 2003, proposed that the expert Working Group consider only those recommendations from the second edition for which there was new evidence or for which a compelling case had been made. The Working Group concurred

with this proposal on 22 October and, thus, the remainder of the Working Group meeting was focused on 151 current recommendations, three new conditions and three new contraceptive methods.

The Working Group was charged with determining the eligibility criteria for each condition and method of contraception by selecting a category (1 through 4, as described below). Where the Working Group determined that guidance in addition to the category was required, that guidance was provided by the Working Group as a "Clarification". Where new evidence was considered by the Working Group, this evidence has been summarized and presented under the heading “Evidence,” in the column labelled "Clarifications/Evidence”. In addition to the clarifications of guidance and the summaries of the evidence, comments have been provided at the end of each contraceptive method section by the WHO Secretariat for selected methods/conditions.

The final list of 1705 recommendations was approved by all members of the Guideline Steering Group and the Working Group at the completion of the meeting on 24 October 2003.

How to use this document

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

The guidance in this document is intended for interpretation at country and programme levels in a manner that reflects the diversity of situations and settings in which contraceptives are provided. While it is unlikely that the classification of categories in this document would change during this process, it is very likely that the application of these categories 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.

Using the tables

The Working Group addressed medical criteria for the initiation and continuation of use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while she is using the method. When the Working Group determined that categories for initiation and continuation were different, these differences are noted in the columns 'I=Initiation' and 'C=Continuation'. Where I and C are not denoted, the category is the same for initiation and continuation of use.

On the basis of this classification system, the eligibility criteria for initiating and continuing use of a specific contraceptive method are presented in this document in a set of tables. The first column indicates the condition. Several conditions were subdivided to differentiate between varying degrees of the condition. The second column classifies the condition for

initiation and/or continuation into one of the four categories described below. If necessary, the third column gives clarification or evidence regarding the classification, as described in the section above.

A summary table is included at the end of the document covering medical eligibility criteria by condition for hormonal methods and IUDs. A summary of the conditions or categories that were revised for this edition is included at the end of this section.

TYPE OF CONTRACEPTIVE		
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/ EVIDENCE**
Condition	Condition classified from 1 to 4 The categories for fertility awareness-based methods and surgical sterilization are described at the beginning of the relevant section.	Clarifications and evidence regarding the classification

NA denotes a condition for which a ranking was not given by the Working Group but for which clarifications have been provided.

Classification of categories

The medical eligibility criteria in this document were based on the method of work described above and aim to ensure an adequate margin of safety.

Each condition was defined as representing either an individual's characteristics (e.g., age, history of pregnancy) or a known pre-existing medical/pathological condition (e.g., diabetes, hypertension). It is expected that national and institutional health and service delivery environments will decide the most suitable means for screening for conditions according to their public health importance. Client history will often be the most appropriate approach.

The conditions affecting eligibility for the use of each contraceptive method were classified under one of the following four categories:

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

Using the categories in practice

Categories 1 and 4 are self-explanatory. Classification of a method/condition as category 2 indicates the method can generally be used, but careful follow-up may be required. However, provision of a method to a woman with a condition classified as category 3 requires careful clinical judgement and access to clinical services; for such a woman, the severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account. For a method/condition classified as category 3, use of that method is not usually recommended unless other more appropriate methods are not available or acceptable. Careful follow-up will be required.

Where resources for clinical judgement are limited, such as in community-based services, the four-category classification framework can be simplified into two categories. With this simplification, a classification of Category 3 indicates that a woman is not medically eligible to use the method.

CATEGORY	WITH CLINICAL JUDGEMENT	WITH LIMITED CLINICAL JUDGEMENT
1	Use method in any circumstances	Yes (Use the method)
2	Generally use the method	
3	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	No (Do not use the method)
4	Method not to be used	

Programmatic implications

Programmatic issues that need to be addressed include:

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

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

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

Clients with special needs

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

Adolescents

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

problems and make informed and voluntary decisions. Every effort should be made to prevent service and method costs from limiting the options available.

Summary of changes from the second edition

A summary of the classification changes or major condition modifications from the second edition is given in Table 3.

It is recognized that some of the eligibility criteria in this report will need to be reviewed in the light of new research findings from studies being completed and/or currently in progress. It is intended that this document will be updated on a continual basis in order to reflect the latest scientific evidence and findings.

Table 3. Summary of changes from the second edition

(Conditions for which there was a classification change for one or more methods or a major modification to the condition description. Changed classifications are highlighted in blue.)

CONDITION	COC	CIC	POP	DMPA NET-EN	LNG/ ETG	Cu-IUD		LNG-IUD	
I = Initiation, **C** = Continuation									
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY									
OBESITY ≥30 kg/m² body mass index (BMI)	2	2	1	1	1	1		1	
CARDIOVASCULAR DISEASE									
KNOWN THROMBOGENIC MUTATIONS (e.g. Factor V Leiden; Prothrombin mutation; Protein S, Protein C and Antithrombin deficiencies)	4	4	2	2	2	1		2	
DEPRESSIVE DISORDERS									
DEPRESSIVE DISORDERS	1	1	1	1	1	1		1	
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS									
UTERINE FIBROIDS									
a) Without distortion of the uterine cavity	1	1	1	1	1	1		1	
b) With distortion of the uterine cavity	1	1	1	1	1	4		4	
PELVIC INFLAMMATORY DISEASE (PID)									
a) Past PID (assuming no current risk factors of STIs)						I	C	I	C
(i) with subsequent pregnancy	1	1	1	1	1	1	1	1	1
ii) without subsequent pregnancy	1	1	1	1	1	2	2	2	2
b) PID - current	1	1	1	1	1	4	2	4	2

CONDITION	COC	CIC	POP	DMPA NET-EN	LNG/ ETG	Cu-IUD		LNG-IUD	
I = Initiation, **C** = Continuation									
STIs						I	C	I	C
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	1	1	4	2	4	2
b) Other STIs (excluding HIV and hepatitis)	1	1	1	1	1	2	2	2	2
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	1	1	2	2	2	2
d) Increased risk of STIs	1	1	1	1	1	2/3	2	2/3	2
HIV/AIDS									
HIGH RISK OF HIV						I	C	I	C
	1	1	1	1	1	2	2	2	2
HIV-INFECTED	1	1	1	1	1	2	2	2	2
AIDS	1	1	1	1	1	3	2	3	2
Clinically well on ARV therapy	See ANTIRETROVIRAL THERAPY below					2	2	2	2
DRUG INTERACTIONS									
DRUGS WHICH AFFECT LIVER ENZYMES									
a) Rifampicin	3	2	3	2	3	1		1	
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	2	3	2	3	1		1	
ANTIBIOTICS (excluding rifampicin)									
a) Griseofulvin	2	1	2	1	2	1		1	
b) Other antibiotics	1	1	1	1	1	1		1	
ANTIRETROVIRAL THERAPY						I	C	I	C
	2	2	2	2	2	2/3	2	2/3	2

In addition, the following changes were made which are not included in the summary of changes:

1. Patch, ring and etonogestrel implants

Three new methods (patch, ring and etonogestrel implants) were added. The patch and ring are grouped with CICs but are given the same category ratings as COCs. The etonogestrel implants are grouped with, and are given the same category ratings as, the levonorgestrel implants.

2. Barrier methods

For the conditions of high risk of HIV, HIV-infected, and AIDS, spermicide use is a Category 4.

For the conditions of high risk of HIV, HIV-infected, and AIDS, diaphragm (with spermicide) and cervical cap are Category 3.

3. Female surgical sterilization

The condition of known thrombogenic mutations (e.g. Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies) has been added for female surgical sterilization and is Category A.

The condition of depressive disorders has been added for female surgical sterilization and is a Category C.

For the condition of other STIs (excluding HIV and hepatitis), female surgical sterilization is Category A.

For the condition of previous abdominal or pelvic surgery, female surgical sterilization is Category C.

4. Male surgical sterilization

The condition of young age has been added for male surgical sterilization and is Category C.

The condition of depressive disorders has been added for male surgical sterilization and is Category C.

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LOW-DOSE COMBINED ORAL CONTRACEPTIVES

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY		
PREGNANCY	NA	**Clarification:** Use of COCs is not required. There is no known harm to the woman, the course of her pregnancy, or the fetus if COCs are accidentally used during pregnancy.
AGE*		
a) Menarche to < 40 years	1	
b) ≥ 40 years	2	
PARITY		
a) Nulliparous	1	
b) Parous	1	
BREASTFEEDING*		
a) < 6 weeks postpartum	4	
b) ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding)	3	
c) ≥ 6 months postpartum	2	
POSTPARTUM* (in non-breastfeeding women)		
a) < 21 days	3	
b) ≥ 21 days	1	
POST-ABORTION		
a) First trimester	1	**Clarification:** COCs may be started immediately post-abortion.
b) Second trimester	1	
c) Immediate post-septic abortion	1	
PAST ECTOPIC PREGNANCY*	1	
HISTORY OF PELVIC SURGERY	1	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
SMOKING a) Age < 35 years b) Age ≥ 35 years (i) <15 cigarettes/day (ii) ≥15 cigarettes/day	 2 3 4	**Evidence:** COC users who smoked were at increased risk of cardiovascular diseases, especially myocardial infarction, compared with those who did not smoke. Studies also showed an increased risk of myocardial infarction with increasing number of cigarettes smoked per day.[1-12]
OBESITY ≥ 30 kg/m^2 body mass index (BMI)	2	**Evidence:** Obese women who used COCs were at increased risk of VTE compared with non-users. The absolute risk of VTE remained small. Data are limited regarding the impact of obesity on COC effectiveness.[6, 13, 14]
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	**Clarification:** It is desirable to have blood pressure measurements taken before initiation of COC use. However, in some settings blood pressure measurements are unavailable. In many of these settings pregnancy morbidity and mortality risks are high, and COCs are one of the few methods widely available. In such settings, women should not be denied use of COCs simply because their blood pressure cannot be measured.
CARDIOVASCULAR DISEASE		
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	3/4	**Clarification:** When a woman has multiple major risk factors, any of which alone would substantially increase the risk of cardiovascular disease, use of COCs may increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two risk factors assigned a category 2 may not necessarily warrant a higher category.
HYPERTENSION*		
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.		
a) History of hypertension, where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	3	**Clarification:** Evaluation of cause and level of hypertension is recommended, as soon as feasible. **Evidence:** Women who did not have a blood pressure check before COC use had an increased risk of acute myocardial infarction and stroke.[15-19]

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
HYPERTENSION (Cont'd)		
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	3	**Clarification:** Women adequately treated for hypertension are at reduced risk of acute myocardial infarction and stroke as compared with untreated women. Although there are no data, COC users with adequately controlled and monitored hypertension should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive COC users.
c) Elevated blood pressure levels (properly taken measurements)		
(i) systolic 140-159 or diastolic 90-99	3	**Evidence:** Among women with hypertension, COC users were at increased risk of stroke, acute myocardial infarction, and peripheral arterial disease compared with non-users.[1, 3, 9-11, 15-31]
(ii) systolic ≥160 or diastolic ≥100	4	
d) Vascular disease	4	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	2	**Evidence:** Women who had a history of high blood pressure in pregnancy, who also used COCs, had an increased risk of myocardial infarction and venous thromboembolism, compared with COC users who did not have a history of high blood pressure during pregnancy. The absolute risks of acute myocardial infarction and venous thromboembolism in this population remained small.[11, 17-19, 21, 32-37]
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*		
a) History of DVT/PE	4	
b) Current DVT/PE	4	
c) Family history of DVT/PE (first-degree relatives)	2	
d) Major surgery		
(i) with prolonged immobilization	4	
(ii) without prolonged immobilization	2	
e) Minor surgery without immobilization	1	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	4	**Clarification**: Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening. **Evidence:** Among women with thrombogenic mutations, COC users had a two to twenty-fold higher risk of thrombosis than non-users.[38-51]
SUPERFICIAL VENOUS THROMBOSIS* a) Varicose veins b) Superficial thrombophlebitis	 1 2	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE*	4	
STROKE* (history of cerebrovascular accident)	4	
KNOWN HYPERLIPIDAEMIAS	2/3	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening. While some types of hyperlipidaemias are risk factors for vascular disease, the category should be assessed according to the type, its severity, and the presence of other cardiovascular risk factors.
VALVULAR HEART DISEASE* a) Uncomplicated b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	 2 4	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
NEUROLOGIC CONDITIONS		
HEADACHES*	I / C	
a) Non-migrainous (mild or severe)	1 / 2	**Clarification:** Classification depends on accurate diagnosis of those severe headaches that are migrainous and those that are not. Any new headaches or marked changes in headaches should be evaluated. Classification is for women without any other risk factors for stroke. Risk of stroke increases with age, hypertension and smoking.
b) Migraine		**Evidence:** Among women with migraine, women who also had aura had a higher risk of stroke than those without aura.[52-54] Among women with migraine, those who used COCs had a 2 to 4-fold increased risk of stroke compared with women who did not use COCs.[20, 26-28, 53-58]
(i) without aura		
Age < 35	2 / 3	
Age ≥ 35	3 / 4	
(ii) with aura, at any age	4 / 4	
EPILEPSY	1	**Clarification:** If a woman is taking anticonvulsants, refer to the section on drug interactions. Certain anticonvulsants lower COC effectiveness.
DEPRESSIVE DISORDERS		
DEPRESSIVE DISORDERS	1	**Clarification**: The classification is based on data for women with selected depressive disorders. No data on bipolar disorder or postpartum depression were available. There is a potential for drug interactions between certain antidepressant medications and hormonal contraceptives. **Evidence**: COC use did not increase depressive symptoms in women with depression compared to baseline or to non-users with depression.[59-61]
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS		
VAGINAL BLEEDING PATTERNS*		
a) Irregular pattern ***without*** heavy bleeding	1	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	1	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition.

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
UNEXPLAINED VAGINAL BLEEDING* (suspicious for serious condition) Before evaluation	2	**Clarification:** If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
ENDOMETRIOSIS*	1	
BENIGN OVARIAN TUMOURS (including cysts)	1	
SEVERE DYSMENORRHOEA	1	**Evidence:** There was no increased risk of side-effects with COC use among women with dysmenorrhoea compared to women not using COCs. Some COC users had a reduction in pain and bleeding.[62, 63]
TROPHOBLAST DISEASE a) Benign gestational trophoblastic disease b) Malignant gestational trophoblastic disease	 1 1	 **Evidence:** Among women with benign or malignant gestational trophoblastic disease, there was no difference in mean times to hCG normalization or incidence of postmolar trophoblastic disease for COC users compared to non-hormonal users.[64-71]
CERVICAL ECTROPION*	1	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	2	**Evidence:** Among women with persistent HPV infection, long-term COC use (≥ 5 years) may increase the risk of carcinoma in situ and invasive carcinoma.[72]
CERVICAL CANCER* (awaiting treatment)	2	
BREAST DISEASE* a) Undiagnosed mass b) Benign breast disease c) Family history of cancer	 2 1 1	 **Clarification:** Evaluation should be pursued as early as possible. **Evidence:** Among COC users with a family history of breast cancer, there was no increased risk of breast cancer compared with non-COC users with a family history of breast cancer.[73-80] Among women with BRCA1 mutations, COC users may have a small increased risk of breast cancer compared with non-users.[81-83]

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
BREAST DISEASE (Cont'd)		
d) Breast cancer		
(i) current	4	
(ii) past and no evidence of current disease for 5 years	3	
ENDOMETRIAL CANCER*	1	
OVARIAN CANCER*	1	
UTERINE FIBROIDS*		
a) Without distortion of the uterine cavity	1	
b) With distortion of the uterine cavity	1	
PELVIC INFLAMMATORY DISEASE (PID)*		
a) Past PID (assuming no current risk factors for STIs)		
(i) with subsequent pregnancy	1	
(ii) without subsequent pregnancy	1	
b) PID - current	1	
STIs*		
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	
b) Other STIs (excluding HIV and hepatitis)	1	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
STIs (Cont'd)		
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	
d) Increased risk of STIs	1	**Evidence:** Evidence suggests that there may be an increased risk of chlamydial cervicitis among COC users at high risk of STIs. For other STIs, there is either evidence of no association between COC use and STI acquisition or limited evidence to draw any conclusions.[84-160]
HIV/AIDS		
HIGH RISK OF HIV*	1	**Evidence:** Overall, evidence is inconsistent regarding whether there is any increased risk of HIV acquisition among COC users compared with non-users.[161-198]
HIV-INFECTED	1	**Evidence:** Limited evidence suggests no association between COC use and changes in RNA levels or CD4 counts among HIV-infected women. There is also limited evidence showing no association between COC use and female to male HIV transmission, and mixed results regarding increased risk of HIV and herpes simplex virus (HSV) shedding among HIV-infected women using hormonal contraception.[161, 199-204]
AIDS	1	
On ARV therapy	2	**Clarification**: If a woman is taking antiretroviral (ARV) therapy, refer to the section on drug interactions. Because there may be drug interactions between hormonal contraceptives and ARVs, AIDS with ARV therapy is classified as Category 2.
OTHER INFECTIONS		
SCHISTOSOMIASIS		
a) Uncomplicated	1	**Evidence:** Among women with uncomplicated schistosomiasis, COC use had no adverse effects on liver function.[205-211]
b) Fibrosis of liver (if severe, see cirrhosis)	1	
TUBERCULOSIS		
a) Non-pelvic	1	**Clarification:** If a woman is taking rifampicin, refer to the section on drug interactions. Rifampicin is likely to decrease COC effectiveness.
b) Known pelvic	1	
MALARIA	1	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
ENDOCRINE CONDITIONS		
DIABETES*		
a) History of gestational disease	1	
b) Non-vascular disease		
(i) non-insulin dependent	2	
(ii) insulin dependent	2	
c) Nephropathy/ retinopathy/ neuropathy	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
d) Other vascular disease or diabetes of > 20 years' duration	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
THYROID DISORDERS		
a) Simple goitre	1	
b) Hyperthyroid	1	
c) Hypothyroid	1	
GASTROINTESTINAL CONDITIONS		
GALL-BLADDER DISEASE*		
a) Symptomatic		
(i) treated by cholecystectomy	2	
(ii) medically treated	3	
(iii) current	3	
b) Asymptomatic	2	
HISTORY OF CHOLESTASIS*		
a) Pregnancy-related	2	
b) Past COC-related	3	
VIRAL HEPATITIS*		
a) Active	4	
b) Carrier	1	

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
CIRRHOSIS*		
a) Mild (compensated)	3	
b) Severe (decompensated)	4	
LIVER TUMOURS*		
a) Benign (adenoma)	4	
b) Malignant (hepatoma)	4	
ANAEMIAS		
THALASSAEMIA*	1	
SICKLE CELL DISEASE	2	
IRON-DEFICIENCY ANAEMIA*	1	
DRUG INTERACTIONS		
DRUGS WHICH AFFECT LIVER ENZYMES		
a) Rifampicin	3	**Clarification:** Although the interaction of rifampicin or certain anticonvulsants with COCs is not harmful to women, it is likely to reduce the effectiveness of COCs. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Whether increasing the hormone dose of COCs is of benefit remains unclear. **Evidence:** Use of rifampicin and certain anticonvulsants decreased the contraceptive effectiveness of COCs.[212-237]
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	
ANTIBIOTICS (excluding rifampicin)		
a) Griseofulvin	2	
b) Other antibiotics	1	**Evidence:** The contraceptive effectiveness of COCs was not affected by coadministration of most broad-spectrum antibiotics.[238-290]

* See also additional comments at end of table

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) ≤ 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS/EVIDENCE**
ANTIRETROVIRAL THERAPY	2	**Clarification**: It is important to note that antiretroviral drugs (ARV) have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. The limited data available (outlined in Annex 1) suggest that potential drug interactions between many ARVs (particularly some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs)) and hormonal contraceptives may alter safety and effectiveness of both the hormonal contraceptives and the ARVs. It is not known whether the contraceptive effectiveness of progestogen-only injectable contraceptives (such as depot medroxyprogesterone acetate and norethisterone enantate) would be compromised, as these methods provide higher blood hormone levels than other progestogen-only hormonal contraceptives, as well as than combined oral contraceptives. Studies are underway to evaluate potential interactions between depot medroxyprogesterone acetate and selected PI and NNRTI drugs. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended for preventing HIV transmission and may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive. **Evidence:** See Annex 1.

* See also additional comments at end of table

Additional comments

AGE

Menarche to < 40 years: Theoretical concerns about the use of combined hormonal contraceptives among young adolescents have not been substantiated.

≥ 40 years: The risk of cardiovascular disease increases with age and may also increase with combined hormonal contraceptive use. In the absence of other adverse clinical conditions, combined hormonal contraceptives can be used until menopause.

BREASTFEEDING
< 6 weeks postpartum: There is some theoretical concern that the neonate may be at risk due to exposure to steroid hormones during the first 6 weeks postpartum.

≥ 6 weeks to < 6 months (primarily breastfeeding): Use of COCs during breastfeeding diminishes the quantity of breast milk, decreases the duration of lactation, and may thereby adversely affect the growth of the infant.

POSTPARTUM
< 21 days: There is some theoretical concern regarding the association between combined hormonal contraceptive use up to 3 weeks postpartum and risk of thrombosis in the mother. Blood coagulation and fibrinolysis are essentially normalized by 3 weeks postpartum.

PAST ECTOPIC PREGNANCY
The risk of future ectopic pregnancy is increased among women who have had an ectopic pregnancy in the past. Combined hormonal contraceptives provide protection against pregnancy in general, including ectopic gestation.

HYPERTENSION
Vascular disease: Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)
Family history of DVT/PE (first-degree relatives): Some conditions which increase the risk of DVT/PE are heritable.

Major surgery: The degree of risk of DVT/PE associated with major surgery varies depending on the length of time that a woman is immobilized. There is no need to stop combined hormonal contraceptives prior to female surgical sterilization.

SUPERFICIAL VENOUS THROMBOSIS
Varicose veins: Varicose veins are not risk factors for DVT/PE.

CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE

Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

STROKE

Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

VALVULAR HEART DISEASE
Among women with valvular heart disease, combined hormonal contraceptive use may further increase the risk of arterial thrombosis; women with complicated valvular heart disease are at greatest risk.

HEADACHES
Aura is a specific focal neurologic symptom. For more information on this and other diagnostic criteria, see: Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders, 2nd Edition. Cephalalgia. 2004; 24 (Suppl 1): 1- 150.
http://216.25.100.131/ihscommon/guidelines/pdfs/ihc_II_main_no_print.pdf

VAGINAL BLEEDING PATTERNS
Irregular menstrual bleeding patterns are common among healthy women.

UNEXPLAINED VAGINAL BLEEDING
There are no conditions that cause vaginal bleeding that will be worsened in the short term by use of combined hormonal contraceptives.

ENDOMETRIOSIS

Combined hormonal contraceptives do not worsen, and may alleviate, the symptoms of endometriosis.

CERVICAL ECTROPION
Cervical ectropion is not a risk factor for cervical cancer, and there is no need for restriction of combined hormonal contraceptive use.

CERVICAL CANCER (awaiting treatment)
There is some theoretical concern that combined hormonal contraceptive use may affect prognosis of the existing disease. While awaiting treatment, women may use combined hormonal contraceptives. In general, treatment of this condition renders a woman sterile.

BREAST DISEASE
Family history of cancer: Women with BRCA1 or BRCA2 mutations have a much higher baseline risk of breast cancer than women who do not have these mutations. Most women with a family history of breast cancer do not have these mutations.

Breast cancer: Breast cancer is a hormonally sensitive tumour, and the prognosis of women with current or recent breast cancer may worsen with combined hormonal contraceptive use.

ENDOMETRIAL CANCER
COC use reduces the risk of developing endometrial cancer. While awaiting treatment, women may use COCs. In general, treatment of this condition renders a woman sterile.

OVARIAN CANCER
COC use reduces the risk of developing ovarian cancer. While awaiting treatment, women may use COCs. In general, treatment of this condition renders a woman sterile.

UTERINE FIBROIDS
COCs do not appear to cause growth of uterine fibroids.

PELVIC INFLAMMATORY DISEASE (PID)
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs.

STIs
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs.

HIGH RISK OF HIV
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs.

DIABETES
Although carbohydrate tolerance may change with combined hormonal contraceptive use, the major concerns are vascular disease due to diabetes and additional risk of arterial thrombosis due to combined hormonal contraceptive use.

GALL-BLADDER DISEASE
COCs may cause a small increased risk of gall-bladder disease. There is also concern that COCs may worsen existing gall-bladder disease.

HISTORY OF CHOLESTASIS
Pregnancy-related: History of pregnancy-related cholestasis may predict an increased risk of developing COC-associated cholestasis.

Past COC-related: History of COC-related cholestasis predicts an increased risk with subsequent COC use.

VIRAL HEPATITIS
Active: COCs are metabolized by the liver, and their use may adversely affect women whose liver function is compromised.

CIRRHOSIS
COCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised.

LIVER TUMOURS
COCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. In addition, COC use may enhance the growth of tumours.

THALASSAEMIA
There is anecdotal evidence from countries where thalassaemia is prevalent that COC use does not worsen the condition.

IRON-DEFICIENCY ANAEMIA
Combined hormonal contraceptive use may decrease menstrual blood loss.

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COMBINED INJECTABLE CONTRACEPTIVES (CICs)

Combined injectable contraceptives (CICs) provide for the release of a natural estrogen plus a progestogen and act through the inhibition of ovulation.[1-5] Two CIC formulations, both given at four-week intervals, are considered here:

1) **Cyclofem** = Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg
2) **Mesigyna** = Norethisterone enantate 50mg plus estradiol valerate 5mg

Because the estrogens in CICs may be more physiologic and may be less potent compared with the synthetic estrogens of combined oral contraceptives (COCs), the type and magnitude of estrogen-related side-effects associated with CICs may be different from those experienced by COC users. In fact, short-term studies of CICs have shown little effect on blood pressure, haemostasis and coagulation, lipid metabolism, and liver function in comparison with COCs.[6-8] In addition, the parenteral administration of CICs eliminates the first-pass effect of the hormones on the liver.

However, CICs are a relatively new contraceptive method, and there are few epidemiological data on their long-term effects. There is also the concern that, while the effect of the hormonal exposure associated with use of COCs and progestogen-only pills (POPs) can be reduced immediately by discontinuing their use, this is not the case with injectables, for which the effect continues for some time after the last injection.

Pending further evidence, the Working Group concluded that the evidence available for COCs applies to CICs in many but not all instances. Therefore, the Working Group assigned categories for CICs somewhere between the categories for COCs and POPs. However, for severe pathologies (e.g., ischaemic heart disease), the classification of conditions was the same as for COCs. The assigned categories should, therefore, be considered a preliminary, best judgement, which will be re-evaluated as new data become available.

COMBINED CONTRACEPTIVE PATCH (P)

The combined contraceptive patch uses a square 20 cm^2, three-layer system applied to the buttocks, torso, abdomen, or upper arm, to release ethinylestradiol and a progestogen (norelgestromin) transdermally. The contraceptive effect of the combined patch is achieved through inhibition of ovulation.[9] The combined contraceptive patch currently available for consideration was:
Evra = 17-deacetyl norgestimate (norelgestromin) 150μg plus ethinylestradiol 20μg (both dosages are approximate daily release rates).

The combined contraceptive patch is a new contraceptive method. Relatively limited information is available on the safety of the combined contraceptive patch among healthy women and even less information is available for women with specific medical conditions. Moreover, epidemiological data on the long-term effects of the combined contraceptive patch were not available for the Working Group to review and all available studies received support from the patch manufacturer.

According to available evidence, the combined contraceptive patch provides a comparable safety and pharmacokinetic profile to COCs with similar hormone formulations.[9-18] Reports of transient, short-term breast discomfort and skin site reactions occurred among less than 25% of combined contraceptive patch users.[10-13] Limited evidence suggests the effectiveness of the patch may decline for women weighing 90kg or more.[10-11] To date, no studies have examined whether the avoidance of the first-pass effect of hormones on the liver with patch use lessens concerns about drug interactions or use of the patch among women with liver conditions.

Pending further evidence, the Working Group concluded that the evidence available for COCs applies to the patch. Therefore, the patch should have the same categories as COCs. The assigned categories should, therefore, be considered a preliminary, best judgement, which will be re-evaluated as new data become available.

COMBINED VAGINAL RING (R)

The combined contraceptive vaginal ring releases ethinylestradiol and a progestogen (etonogestrel) from a 54mm ethylene vinyl acetate copolymer ring. The contraceptive effect of the combined vaginal ring is achieved through inhibition of ovulation.[19-20] The vaginal ring formulation currently available for consideration was: **NuvaRing** = etonogestrel 120 μg plus ethinylestradiol 15 μg (both dosages are approximate daily release rates).

The combined contraceptive vaginal ring is a new contraceptive method. Relatively limited information is available on the safety of the combined contraceptive ring among healthy women and even less information is available for women with specific medical conditions. Moreover, epidemiological data on the long-term effects of the combined contraceptive ring were not available for the Working Group to review and all available studies received support from the ring manufacturer.

According to available evidence, the combined contraceptive vaginal ring provides a comparable safety and pharmacokinetic profile to COCs with similar hormone formulations.[20-25] Evidence among healthy women suggests the vaginal ring does not alter vaginal flora,[23-24] and limited evidence on women with low-grade squamous intraepithelial lesions found use of the vaginal ring did not worsen the condition.[23] To date, no studies have examined whether the avoidance of the first-pass effect of hormones on the liver with vaginal ring use lessens concerns about drug interactions or use of the ring among women with liver conditions.

Pending further evidence, the Working Group concluded that the evidence available for COCs applies to the ring. Therefore, the ring should have the same categories as COCs. The assigned categories should, therefore, be considered a preliminary, best judgement, which will be re-evaluated as new data become available.

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY				
PREGNANCY	NA	NA	NA	**Clarification:** Use of CICs, P, or R is not required. There is no known harm to the woman, the course of her pregnancy, or the fetus if CICs, P, or R are accidentally used during pregnancy.
AGE*				
a) Menarche to < 40 years	1	1	1	
b) ≥ 40 years	2	2	2	
PARITY				
a) Nulliparous	1	1	1	
b) Parous	1	1	1	
BREASTFEEDING*				
a) < 6 weeks postpartum	4	4	4	
b) ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding)	3	3	3	
c) ≥ 6 months postpartum	2	2	2	
POSTPARTUM* (in non-breastfeeding women)				
a) < 21 days	3	3	3	
b) ≥ 21 days	1	1	1	
POST-ABORTION				
a) First trimester	1	1	1	**Clarification:** CICs, P, or R may be started immediately post-abortion.
b) Second trimester	1	1	1	
c) Immediate post-septic abortion	1	1	1	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
PAST ECTOPIC PREGNANCY*	1	1	1	
HISTORY OF PELVIC SURGERY	1	1	1	
SMOKING				
a) Age < 35 years	2	2	2	
b) Age ≥ 35 years				
(i) <15 cigarettes/day	2	3	3	
(ii) ≥15 cigarettes/day	3	4	4	
OBESITY ≥ 30 kg/m^2 body mass index (BMI)	2	2	2	**Evidence:** Limited evidence suggests the effectiveness of the patch may decline for women weighing 90kg or more.[10-11]
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	NA	**Clarification:** It is desirable to have blood pressure measurements taken before initiation of CIC, P, or R use. However, in some settings blood pressure measurements are unavailable. In many of these settings, pregnancy morbidity and mortality risks are high, and CICs, P, or R may be one of the few methods available. In such settings, women should not be denied use of CICs, P, or R simply because their blood pressure cannot be measured.
CARDIOVASCULAR DISEASE				
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	3/4	3/4	3/4	**Clarification:** When a woman has multiple major risk factors, any of which alone would substantially increase the risk of cardiovascular disease, use of CICs, P, or R may increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two risk factors assigned a category 2 may not necessarily warrant a higher category.

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
HYPERTENSION*				
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.				
a) History of hypertension, where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	3	3	3	**Clarification:** Evaluation of cause and level of hypertension is recommended as soon as feasible.
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	3	3	3	**Clarification:** Women adequately treated for hypertension are at reduced risk of acute myocardial infarction and stroke as compared with untreated women. Although there are no data, CIC, P, or R users with adequately controlled and monitored hypertension should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive CIC, P, or R users.
c) Elevated blood pressure levels (properly taken measurements)				
(i) systolic 140-159 or diastolic 90-99	3	3	3	
(ii) systolic ≥160 or diastolic ≥100	4	4	4	
d) Vascular disease	4	4	4	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	2	2	2	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*				
a) History of DVT/PE	4	4	4	
b) Current DVT/PE	4	4	4	
c) Family history of DVT/PE (first-degree relatives)	2	2	2	
d) Major surgery				
(i) with prolonged immobilization	4	4	4	
(ii) without prolonged immobilization	2	2	2	
e) Minor surgery without immobilization	1	1	1	
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	4	4	4	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
SUPERFICIAL VENOUS THROMBOSIS*				
a) Varicose veins	1	1	1	
b) Superficial thrombophlebitis	2	2	2	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE*	4	4	4	
STROKE* (history of cerebrovascular accident)	4	4	4	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
KNOWN HYPERLIPIDAEMIAS	2/3	2/3	2/3	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening. While some types of hyperlipidaemias are risk factors for vascular disease, the category should be assessed according to the type, its severity, and the presence of other cardiovascular risk factors.
VALVULAR HEART DISEASE*				
a) Uncomplicated	2	2	2	
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	4	4	4	
NEUROLOGIC CONDITIONS				
HEADACHES*	I C	I C	I C	
a) Non-migrainous (mild or severe)	1 2	1 2	1 2	**Clarification:** Classification depends on accurate diagnosis of those severe headaches that are migrainous and those that are not. Any new headaches or marked changes in headaches should be evaluated. Classification is for women without any other risk factors for stroke. Risk of stroke increases with age, hypertension and smoking.
b) Migraine				
(i) without aura				
Age < 35	2 3	2 3	2 3	
Age ≥ 35	3 4	3 4	3 4	
(ii) with aura, at any age	4 4	4 4	4 4	
EPILEPSY	1	1	1	**Clarification:** If a woman is taking anticonvulsants, refer to the section on drug interactions. Certain anticonvulsants lower COC effectiveness. The extent to which CIC, P or R use are similar to COC use in this regard remains unclear.

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
DEPRESSIVE DISORDERS				
DEPRESSIVE DISORDERS	1	1	1	**Clarification:** The classification is based on data for women with selected depressive disorders. No data on bipolar disorder or postpartum depression were available. There is a potential for drug interactions between certain antidepressant medications and hormonal contraceptives.
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS				
VAGINAL BLEEDING PATTERNS*				
a) Irregular pattern ***without*** heavy bleeding	1	1	1	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	1	1	1	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition.
UNEXPLAINED VAGINAL BLEEDING* (suspicious for serious condition)				
Before evaluation	2	2	2	**Clarification:** If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
ENDOMETRIOSIS*	1	1	1	
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	
SEVERE DYSMENORRHOEA	1	1	1	
TROPHOBLAST DISEASE				
a) Benign gestational trophoblastic disease	1	1	1	
b) Malignant gestational trophoblastic disease	1	1	1	
CERVICAL ECTROPION*	1	1	1	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	2	2	2	**Evidence:** Limited evidence on women with low-grade squamous intraepithelial lesions found use of the vaginal ring did not worsen the condition.[23]
CERVICAL CANCER* (awaiting treatment)	2	2	2	
BREAST DISEASE*				
a) Undiagnosed mass	2	2	2	**Clarification:** Evaluation should be pursued as early as possible.
b) Benign breast disease	1	1	1	
c) Family history of cancer	1	1	1	
d) Breast cancer				
(i) current	4	4	4	
(ii) past and no evidence of current disease for 5 years	3	3	3	
ENDOMETRIAL CANCER*	1	1	1	
OVARIAN CANCER*	1	1	1	
UTERINE FIBROIDS*				
a) Without distortion of the uterine cavity	1	1	1	
b) With distortion of the uterine cavity	1	1	1	
PELVIC INFLAMMATORY DISEASE (PID)*				
a) Past PID (assuming no current risk factors for STIs)				
i) with subsequent pregnancy	1	1	1	
ii) without subsequent pregnancy	1	1	1	
b) PID - current	1	1	1	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
STIs*				
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	
b) Other STIs (excluding HIV and hepatitis)	1	1	1	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	
d) Increased risk of STIs	1	1	1	
HIV/AIDS				
HIGH RISK OF HIV*	1	1	1	
HIV-INFECTED	1	1	1	
AIDS	1	1	1	
On ARV therapy	2	2	2	**Clarification**: If a woman is taking antiretroviral (ARV) therapy, refer to the section on drug interactions. Because there may be drug interactions between hormonal contraceptives and ARVs, AIDS with ARV therapy is classified as Category 2.
OTHER INFECTIONS				
SCHISTOSOMIASIS				
a) Uncomplicated	1	1	1	
b) Fibrosis of liver (if severe, see cirrhosis)	1	1	1	
TUBERCULOSIS				
a) Non-pelvic	1	1	1	**Clarification:** If a woman is taking rifampicin, refer to the section on drug interactions. Rifampicin is likely to decrease COC effectiveness. The extent to which CIC, P, or R use is similar to COC use in this regard remains unclear.
b) Known pelvic	1	1	1	
MALARIA	1	1	1	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
ENDOCRINE CONDITIONS				
DIABETES*				
a) History of gestational disease	1	1	1	
b) Non-vascular disease				
(i) non-insulin dependent	2	2	2	
(ii) insulin dependent	2	2	2	
c) Nephropathy/ retinopathy/ neuropathy	3/4	3/4	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
d) Other vascular disease or diabetes of >20 years' duration	3/4	3/4	3/4	**Clarification:** The category should be assessed according to the severity of the condition.
THYROID DISORDERS				
a) Simple goitre	1	1	1	
b) Hyperthyroid	1	1	1	
c) Hypothyroid	1	1	1	
GASTROINTESTINAL CONDITIONS				
GALL-BLADDER DISEASE*				
a) Symptomatic				
(i) treated by cholecystectomy	2	2	2	
(ii) medically treated	2	3	3	
(iii) current	2	3	3	
b) Asymptomatic	2	2	2	
HISTORY OF CHOLESTASIS*				
a) Pregnancy-related	2	2	2	
b) Past COC or CIC related	2	3	3	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	**CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
VIRAL HEPATITIS*				
a) Active	3/4	4	4	**Clarification:** The category should be assessed according to the severity of the condition.
b) Carrier	1	1	1	**Clarification**: In women with symptomatic viral hepatitis, CICs, P and R should be withheld until liver function returns to normal or 3 months after the woman becomes asymptomatic, whichever occurs earlier.
CIRRHOSIS*				
a) Mild (compensated)	2	3	3	
b) Severe (decompensated)	3	4	4	
LIVER TUMOURS*				
a) Benign (adenoma)	3	4	4	
b) Malignant (hepatoma)	3/4	4	4	
ANAEMIAS				
THALASSAEMIA	1	1	1	
SICKLE CELL DISEASE	2	2	2	
IRON-DEFICIENCY ANAEMIA*	1	1	1	
DRUG INTERACTIONS				
DRUGS WHICH AFFECT LIVER ENZYMES				
a) Rifampicin	2	3	3	**Clarification:** Although the interaction of rifampicin or certain anticonvulsants with P or R use is not harmful to women, it is likely to reduce P or R effectiveness. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs.
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	2	3	3	
ANTIBIOTICS (excluding rifampicin)				
a) Griseofulvin	1	2	2	
b) Other antibiotics	1	1	1	

* See also additional comments at end of table

COMBINED INJECTABLE CONTRACEPTIVES (CICs), PATCH (P), RING (R)	CICs, patch, and ring do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation C=Continuation			**CLARIFICATIONS/EVIDENCE**
	CICs	**P**	**R**	
ANTIRETROVIRAL THERAPY	2	2	2	**Clarification:** It is important to note that antiretroviral drugs (ARV) have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. The limited data available (outlined in Annex 1) suggest that potential drug interactions between many ARVs (particularly some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs)) and hormonal contraceptives may alter safety and effectiveness of both the hormonal contraceptives and the ARVs. It is not known whether the contraceptive effectiveness of progestogen-only injectable contraceptives (such as depot medroxyprogesterone acetate and norethisterone enantate) would be compromised, as these methods provide higher blood hormone levels than other progestogen-only hormonal contraceptives, as well as than combined oral contraceptives. Studies are underway to evaluate potential interactions between depot medroxyprogesterone acetate and selected PI and NNRTI drugs. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended for preventing HIV transmission and may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

* See also additional comments at end of table

Additional comments

AGE
Menarche to < 40 years: Theoretical concerns about the use of combined hormonal contraceptives among young adolescents have not been substantiated.

≥ 40 years: The risk of cardiovascular disease increases with age and may also increase with combined hormonal contraceptive use. In the absence of other adverse clinical conditions, combined hormonal contraceptives can be used until menopause.

BREASTFEEDING
< 6 weeks postpartum: There is some theoretical concern that the neonate may be at risk due to exposure to steroid hormones during the first 6 weeks postpartum.

≥ 6 weeks to < 6 months (primarily breastfeeding): Use of combined hormonal contraceptives during breastfeeding diminishes the quantity of breast milk, decreases the duration of lactation, and may thereby adversely affect the growth of the infant.

POSTPARTUM
< 21 days: There is some theoretical concern regarding the association between combined hormonal contraceptive use up to 3 weeks postpartum and risk of thrombosis in the mother. Blood coagulation and fibrinolysis are essentially normalized by 3 weeks postpartum.

PAST ECTOPIC PREGNANCY
The risk of future ectopic pregnancy is increased among women who have had an ectopic pregnancy in the past. Combined hormonal contraceptives provide protection against pregnancy in general, including ectopic gestation.

HYPERTENSION
Vascular disease: Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)
Family history of DVT/PE (first-degree relatives): Some conditions which increase the risk of DVT/PE are heritable.

Major surgery: The degree of risk of DVT/PE associated with major surgery varies depending on the length of time that a woman is immobilized. There is no need to stop combined hormonal contraceptives prior to female surgical sterilization.

SUPERFICIAL VENOUS THROMBOSIS
Varicose veins: Varicose veins are not risk factors for DVT/PE.

CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE
Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

STROKE
Among women with underlying vascular disease, the increased risk of arterial thrombosis associated with combined hormonal contraceptive use should be avoided.

VALVULAR HEART DISEASE
Among women with valvular heart disease, combined hormonal contraceptive use may further increase the risk of arterial thrombosis; women with complicated valvular heart disease are at greatest risk.

HEADACHES
Aura is a specific focal neurologic symptom. For more information on this and other diagnostic criteria, see: Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders, 2nd Edition. Cephalalgia. 2004; 24 (Suppl 1): 1- 150.
http://216.25.100.131/ihscommon/guidelines/pdfs/ihc_II_main_no_print.pdf

VAGINAL BLEEDING PATTERNS
Irregular menstrual bleeding patterns are common among healthy women.

UNEXPLAINED VAGINAL BLEEDING
There are no conditions that cause vaginal bleeding that will be worsened in the short term by use of combined hormonal contraceptives.

ENDOMETRIOSIS

Combined hormonal contraceptives do not worsen, and may alleviate, the symptoms of endometriosis.

CERVICAL ECTROPION
Cervical ectropion is not a risk factor for cervical cancer, and there is no need for restriction of combined hormonal contraceptive use.

CERVICAL CANCER (awaiting treatment)
There is some theoretical concern that combined hormonal contraceptive use may affect prognosis of the existing disease. While awaiting treatment, women may use combined hormonal contraceptives. In general, treatment of this condition renders a woman sterile.

BREAST DISEASE
Family history of cancer: Women with BRCA1 or BRCA2 mutations have a much higher baseline risk of breast cancer than women who do not have these mutations. Most women with a family history of breast cancer do not have these mutations.

Breast cancer: Breast cancer is a hormonally sensitive tumour, and the prognosis of women with current or recent breast cancer may worsen with combined hormonal contraceptive use.

ENDOMETRIAL CANCER
It is not known whether CIC, P, or R use reduces the risk of developing endometrial cancer, as is the case with COCs. While awaiting treatment, women may use CICs, P or R. In general, treatment of this condition renders a woman sterile.

OVARIAN CANCER
It is not known whether CIC, P, or R use reduces the risk of developing ovarian cancer, as is the case with COCs. While awaiting treatment, women may use CICs, P, or R. In general, treatment of this condition renders a woman sterile.

UTERINE FIBROIDS
COCs do not appear to cause growth of uterine fibroids and CICs, P, or R are not expected to do either.

PELVIC INFLAMMATORY DISEASE (PID)
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs. Whether CICs, P or R reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STIs.

STIs
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs. Whether CICs, P or R reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STIs.

HIGH RISK OF HIV
COCs may reduce the risk of PID among women with STIs, but do not protect against HIV or lower genital tract STIs. Whether CICs, P or R reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STIs.

DIABETES
Although carbohydrate tolerance may change with combined hormonal contraceptive use, the major concerns are vascular disease due to diabetes and additional risk of arterial thrombosis due to combined hormonal contraceptive use.

GALL-BLADDER DISEASE
P or R, like COCs, may cause a small increased risk of gall-bladder disease. There is also concern that they may worsen existing gall-bladder disease. However, unlike COCs, CICs have been shown to have a minimal effect on liver function in healthy women, and have no first-pass effect on the liver.

HISTORY OF CHOLESTASIS
Pregnancy-related: History of pregnancy-related cholestasis may predict an increased risk of developing cholestasis associated with combined hormone therapy.

Past COC or CIC related: History of COC- or CIC-related cholestasis predicts an increased risk associated with P or R use. Unlike COCs, CICs have been shown to have a minimal effect on liver function in healthy women and have no first-pass effect on the liver.

VIRAL HEPATITIS
Active: Unlike COCs, CICs have been shown to have a minimal effect on liver function in healthy women and have no first-pass effect on the liver. However, because CICs are metabolized by the liver, they could, in theory, lead to adverse effects in women whose liver function is already compromised.

CIRRHOSIS
Unlike COCs, CICs have been shown to have a minimal effect on liver function in healthy women and have no first-pass effect on the liver. However, because CICs are metabolized by the liver, they could, in theory, lead to adverse effects in women whose liver function is already compromised

LIVER TUMOURS

Unlike COCs, CICs have been shown to have a minimal effect on liver function in healthy women and have no first-pass effect on the liver. However, because CICs are metabolized by the liver, they could, in theory, lead to adverse effects in women whose liver function is already compromised.

IRON-DEFICIENCY ANAEMIA

Combined hormonal contraceptive use may decrease menstrual blood loss.

References for combined injectable contraceptives, patch, and ring

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PROGESTOGEN-ONLY CONTRACEPTIVES

POP = Progestogen-only pill (POP)
D/NE = Depot medroxyprogesterone acetate (DMPA)/norethisterone enantate (NET-EN)
LNG/ETG = Levonorgestrel implants (Norplant and Jadelle) and etonogestrel implants (Implanon)

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY				
PREGNANCY	NA			**Clarification:** Use of POCs is not required. There is no known harm to the woman, the course of her pregnancy, or the fetus if POCs are accidentally used during pregnancy. However, the relationship between DMPA use during pregnancy and its effects on the fetus remains unclear.
AGE*				
a) Menarche to < 18 years	1	2	1	**Evidence:** Limited evidence shows decreased bone mineral density over time among adolescent DMPA users, but not among levonorgestrel implant users. No studies have examined whether DMPA use among adolescents affects peak bone mass levels.[1-5]
b) 18 to 45 years	1	1	1	**Evidence:** In general, current DMPA users had decreased bone mineral density compared with non-users; this decrease was usually within one standard deviation of normal values.[6] Results for current Norplant users were mixed.[6] One study of Implanon users showed no change in bone mineral density over two years.[7]
c) > 45 years	1	2	1	**Evidence:** Older DMPA users had decreased bone mineral density compared with non-users. However, limited evidence found that women gained bone mass following discontinuation of DMPA prior to menopause. Further, among postmenopausal women, there was no difference in bone mineral density between former DMPA users and never users.[8-13]

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
PARITY				
a) Nulliparous	1	1	1	
b) Parous	1	1	1	
BREASTFEEDING				
a) < 6 weeks postpartum	3	3	3	**Clarification:** There is concern that the neonate may be at risk of exposure to steroid hormones during the first 6 weeks postpartum. However, in many settings pregnancy morbidity and mortality risks are high, and access to services is limited. In such settings, POCs may be one of the few types of methods widely available and accessible to breastfeeding women immediately postpartum. **Evidence:** Studies have shown that among breast-feeding women less than 6 weeks postpartum, progestogen-only contraceptives did not affect breast-feeding performance and infant health and growth. However, there are no data evaluating the effects of progestogen exposure via breast milk on brain and liver development.[14-38]
b) ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding)	1	1	1	
c) ≥ 6 months postpartum	1	1	1	
POSTPARTUM* (in non-breastfeeding women)				
a) < 21 days	1	1	1	
b) ≥ 21 days	1	1	1	
POST-ABORTION				
a) First trimester	1	1	1	**Clarification:** POCs may be started immediately post-abortion. **Evidence:** Limited evidence suggests that there are no adverse side effects when Norplant or NET-EN are initiated after a first trimester abortion.[39-42]
b) Second trimester	1	1	1	
c) Immediate post-septic abortion	1	1	1	

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	**D/NE**	**LNG/ETG**	
PAST ECTOPIC PREGNANCY*	2	1	1	
HISTORY OF PELVIC SURGERY	1	1	1	
SMOKING				
a) Age < 35 years	1	1	1	
b) Age ≥ 35 years				
i) <15 cigarettes/day	1	1	1	
ii) ≥15 cigarettes/day	1	1	1	
OBESITY ≥ 30 kg/m^2 body mass index (BMI)	1	1	1	**Evidence:** Studies provide conflicting evidence regarding whether obese women are at increased risk of weight gain and bleeding problems with DMPA use relative to non-obese women with DMPA use.[43-45] Studies show that obese women do not experience decreased effectiveness when using Norplant soft capsules or Jadelle.[46-48]
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	NA	**Clarification:** It is desirable to have blood pressure measurements taken before initiation of POC use. However, in some settings blood pressure measurements are unavailable. In many of these settings, pregnancy morbidity and mortality risks are high, and POCs are one of the few types of methods widely available. In such settings, women should not be denied use of POCs simply because their blood pressure cannot be measured.
CARDIOVASCULAR DISEASE				
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	2	3	2	**Clarification:** When multiple major risk factors exist, risk of cardiovascular disease may increase substantially. Some POCs may increase the risk of thrombosis, although this increase is substantially less than with COCs. The effects of DMPA and NET-EN may persist for some time after discontinuation.

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	**D/NE**	**LNG/ETG**	
HYPERTENSION*				
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.				
a) History of hypertension where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	2	2	2	**Clarification:** It is desirable to have blood pressure measurements taken before initiation of POC use. However, in some settings blood pressure measurements are unavailable. In many of these settings pregnancy morbidity and mortality risks are high, and POCs are one of the few types of methods widely available. In such settings, women should not be denied use of POCs simply because their blood pressure cannot be measured.
b) Adequately controlled hypertension where blood pressure CAN be evaluated	1	2	1	**Clarification:** Women adequately treated for hypertension are at reduced risk of acute myocardial infarction and stroke as compared with untreated women. Although there are no data, POC users with adequately controlled and monitored hypertension should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive POC users.
c) Elevated blood pressure levels (properly taken measurements)				**Evidence:** Limited evidence suggests that among women with hypertension, those who used POPs or progestogen-only injectables had a small increased risk of cardiovascular events compared with women who did not use these methods.[49]
i) systolic140-159 or diastolic 90-99	1	2	1	
ii) systolic $\geq$ 160 or diastolic $\geq$ 100	2	3	2	
d) Vascular disease	2	3	2	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	1	1	1	

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*				
a) History of DVT/PE	2	2	2	
b) Current DVT/PE	3	3	3	
c) Family history of DVT/PE (first-degree relatives)	1	1	1	
d) Major surgery				
i) with prolonged immobilization	2	2	2	
ii) without prolonged immobilization	1	1	1	
e) Minor surgery without immobilization	1	1	1	
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	2	2	2	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
SUPERFICIAL VENOUS THROMBOSIS				
a) Varicose veins	1	1	1	
b) Superficial thrombophlebitis	1	1	1	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE*	I: 2 / C: 3	3	I: 2 / C: 3	
STROKE* (history of cerebrovascular accident)	I: 2 / C: 3	3	I: 2 / C: 3	

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**						
CONDITION	**CATEGORY** I=Initiation, C=Continuation						**CLARIFICATIONS/EVIDENCE**
	POP		**D/NE**		**LNG/ETG**		
KNOWN HYPERLIPIDAEMIAS	2		2		2		**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening. Some types of hyperlipidaemias are risk factors for vascular disease.
VALVULAR HEART DISEASE							
a) Uncomplicated	1		1		1		
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	1		1		1		
NEUROLOGIC CONDITIONS							
HEADACHES*	I	C	I	C	I	C	
a) Non-migrainous (mild or severe)	1	1	1	1	1	1	**Clarification:** Classification depends on accurate diagnosis of those severe headaches that are migrainous and those that are not. Any new headaches or marked changes in headaches should be evaluated. Classification is for women without any other risk factors for stroke. Risk of stroke increases with age, hypertension, and smoking.
b) Migraine							
i) without aura							
Age < 35	1	2	2	2	2	2	
Age ≥ 35	1	2	2	2	2	2	
ii) with aura, at any age	2	3	2	3	2	3	
EPILEPSY	1		1		1		**Clarification:** If a woman is taking anticonvulsants, refer to the section on drug interactions. Certain anticonvulsants lower POC effectiveness.

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
DEPRESSIVE DISORDERS				
DEPRESSIVE DISORDERS	1	1	1	**Clarification:** The classification is based on data for women with selected depressive disorders. No data on bipolar disorder or postpartum depression were available. There is a potential for drug interactions between certain antidepressant medications and hormonal contraceptives. **Evidence:** POCs did not increase depressive symptoms in women with depression compared to baseline.[50-53]
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS				
VAGINAL BLEEDING PATTERNS*				
a) Irregular pattern ***without*** heavy bleeding	2	2	2	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2	2	2	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition.
UNEXPLAINED VAGINAL BLEEDING* (suspicious for serious underlying condition) Before evaluation	2	3	3	**Clarification:** If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
ENDOMETRIOSIS	1	1	1	
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	
SEVERE DYSMENORRHOEA	1	1	1	

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
TROPHOBLAST DISEASE				
a) Benign gestational trophoblastic disease	1	1	1	
b) Malignant gestational trophoblastic disease	1	1	1	
CERVICAL ECTROPION	1	1	1	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	1	2	2	**Evidence:** Among women with persistent HPV infection, long-term DMPA use (≥ 5 years) may increase the risk of carcinoma in situ and invasive carcinoma.[54]
CERVICAL CANCER (awaiting treatment)*	1	2	2	
BREAST DISEASE*				
a) Undiagnosed mass	2	2	2	**Clarification:** Evaluation should be pursued as early as possible.
b) Benign breast disease	1	1	1	
c) Family history of cancer	1	1	1	
d) Breast cancer				
(i) current	4	4	4	
(ii) past and no evidence of current disease for 5 years	3	3	3	
ENDOMETRIAL CANCER*	1	1	1	
OVARIAN CANCER*	1	1	1	
UTERINE FIBROIDS*				
a) Without distortion of the uterine cavity	1	1	1	
b) With distortion of the uterine cavity	1	1	1	

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
PELVIC INFLAMMATORY DISEASE (PID)*				
a) Past PID (assuming no current risk factors for STIs)				
(i) with subsequent pregnancy	1	1	1	
(ii) without subsequent pregnancy	1	1	1	
b) PID - current	1	1	1	
STIs*				
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	**Evidence:** Limited evidence suggests that there may be an increased risk of chlamydial cervicitis among DMPA users at high risk of STIs. For other STIs, there is either evidence of no association between DMPA use and STI acquisition or too limited evidence to draw any conclusions. There is no evidence for other POCs.[55-61]
b) Other STIs (excluding HIV and hepatitis)	1	1	1	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	
d) Increased risk of STIs	1	1	1	
HIV/AIDS				
HIGH RISK OF HIV*	1	1	1	**Evidence:** Overall, evidence is inconsistent regarding whether there is any increased risk of HIV acquisition among POC users compared with non-users.[62-78]
HIV-INFECTED	1	1	1	**Evidence:** Studies are conflicting regarding whether there is an increased risk of HIV and herpes simplex virus (HSV) shedding among HIV-infected women using DMPA.[79-81]

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
AIDS	1	1	1	
On ARV therapy	2	2	2	**Clarification:** If a woman is taking antiretroviral (ARV) therapy, refer to the section on drug interactions. Because there may be drug interactions between hormonal contraceptives and ARVs, AIDS with ARV therapy is classified as Category 2.
OTHER INFECTIONS				
SCHISTOSOMIASIS				
a) Uncomplicated	1	1	1	**Evidence:** Among women with uncomplicated schistosomiasis, limited evidence showed that DMPA use had no adverse effects on liver function.[82]
b) Fibrosis of liver (if severe, see cirrhosis)	1	1	1	
TUBERCULOSIS				
a) Non-pelvic	1	1	1	**Clarification:** If a woman is taking rifampicin, refer to the section on drug interactions. Rifampicin is likely to decrease POC effectiveness.
b) Known pelvic	1	1	1	
MALARIA	1	1	1	
ENDOCRINE CONDITIONS				
DIABETES*				
a) History of gestational disease	1	1	1	
b) Non-vascular disease				
(i) non-insulin dependent	2	2	2	
(ii) insulin dependent	2	2	2	

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
DIABETES (Cont'd)				
c) Nephropathy/ retinopathy/ neuropathy	2	3	2	
d) Other vascular disease or diabetes of >20 years' duration	2	3	2	
THYROID DISORDERS				
a) Simple goitre	1	1	1	
b) Hyperthyroid	1	1	1	
c) Hypothyroid	1	1	1	
GASTROINTESTINAL CONDITIONS				
GALL-BLADDER DISEASE				
a) Symptomatic				
(i) treated by cholecystectomy	2	2	2	
(ii) medically treated	2	2	2	
(iii) current	2	2	2	
b) Asymptomatic	2	2	2	
HISTORY OF CHOLESTASIS*				
a) Pregnancy-related	1	1	1	
b) Past COC-related	2	2	2	
VIRAL HEPATITIS*				.
a) Active	3	3	3	
b) Carrier	1	1	1	
CIRRHOSIS*				
a) Mild (compensated)	2	2	2	
b) Severe (decompensated)	3	3	3	

* See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
LIVER TUMOURS*				
a) Benign (adenoma)	3	3	3	
b) Malignant (hepatoma)	3	3	3	
ANAEMIAS				
THALASSAEMIA	1	1	1	
SICKLE CELL DISEASE	1	1	1	**Evidence:** Among women with sickle cell disease, POC use did not have adverse effects on haematological parameters and, in some studies, was beneficial with respect to clinical symptoms.[83-90]
IRON-DEFICIENCY ANAEMIA*	1	1	1	
DRUG INTERACTIONS				
DRUGS WHICH AFFECT LIVER ENZYMES				
a) Rifampicin	3	2	3	**Clarification:** Although the interaction of rifampicin or certain anticonvulsants with POPs and LNG/ETG implants is not harmful to women, it is likely to reduce the effectiveness of POPs and LNG/ETG implants. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Whether increasing the hormone dose of POPs alleviates this concern remains unclear. **Evidence:** Use of certain anticonvulsants decreased the contraceptive effectiveness of POCs.[91-93]
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	2	3	
ANTIBIOTICS (excluding rifampicin)				
a) Griseofulvin	2	1	2	
b) Other antibiotics	1	1	1	

See also additional comments at end of table

PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)	**POCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
CONDITION	**CATEGORY** I=Initiation, C=Continuation			**CLARIFICATIONS/EVIDENCE**
	POP	D/NE	LNG/ETG	
ANTIRETROVIRAL THERAPY	2	2	2	**Clarification**: It is important to note that antiretroviral drugs (ARV) have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. The limited data available (outlined in Annex 1) suggest that potential drug interactions between many ARVs (particularly some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs)) and hormonal contraceptives may alter safety and effectiveness of both the hormonal contraceptives and the ARVs. It is not known whether the contraceptive effectiveness of progestogen-only injectable contraceptives (such as depot medroxyprogesterone acetate and norethisterone enantate) would be compromised, as these methods provide higher blood hormone levels than other progestogen-only hormonal contraceptives, as well as than combined oral contraceptives. Studies are underway to evaluate potential interactions between depot medroxyprogesterone acetate and selected PI and NNRTI drugs. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended for preventing HIV transmission and may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

* See also additional comments at end of table

Additional comments

AGE

Menarche to < 18 years: For women under 18 years of age, there are theoretical concerns regarding the hypo-estrogenic effects of DMPA use, including whether these women will achieve their appropriate peak bone mass.

> 45 years: For women greater than age 45, there are theoretical concerns regarding hypo-estrogenic effects of DMPA use, including whether these women will regain all lost bone mass after discontinuation of DMPA.

POSTPARTUM

< 21 days: POCs may be safely used by non-breastfeeding women immediately postpartum.

PAST ECTOPIC PREGNANCY

POPs have a higher absolute rate of ectopic pregnancy compared with other POCs, but still less than using no method.

HYPERTENSION

Vascular disease: There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA and NET-EN. However, there is little concern about these effects with regard to POPs or LNG/ETG implants. The effects of DMPA and NET-EN may persist for some time after discontinuation.

DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)

Some POCs may increase the risk of venous thrombosis, although this increase is substantially less than with COCs.

CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE

There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA and NET-EN. However, there is little concern about these effects with regard to POPs or LNG/ETG implants. The effects of DMPA and NET-EN may persist for some time after discontinuation.

STROKE

There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA and NET-EN. However, there is little concern about these effects with regard to POPs or LNG/ETG implants. The effects of DMPA and NET-EN may persist for some time after discontinuation.

HEADACHES

Aura is a specific focal neurologic symptom. For more information on this and other diagnostic criteria, see: Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders, 2nd Edition. Cephalalgia. 2004; 24 (Suppl 1): 1- 150.
http://216.25.100.131/ihscommon/guidelines/pdfs/ihc_II_main_no_print.pdf

There is concern that severe headaches may increase with use of NET-EN, DMPA and implants. The effects of NET-EN and DMPA may persist for some time after discontinuation.

VAGINAL BLEEDING PATTERNS

Irregular menstrual bleeding patterns are common among healthy women. POC use frequently induces an irregular bleeding pattern. Implant use may induce irregular bleeding patterns, especially during the first 3-6 months, but these patterns may persist longer. ETG users are more likely than LNG users to develop amenorrhoea.

UNEXPLAINED VAGINAL BLEEDING

POCs may cause irregular bleeding patterns which may mask symptoms of underlying pathology. The effects of DMPA and NET-EN may persist for some time after discontinuation.

CERVICAL CANCER (awaiting treatment)

There is some theoretical concern that POC use may affect prognosis of the existing disease. While awaiting treatment, women may use POCs. In general, treatment of this condition renders a woman sterile.

BREAST DISEASE

Breast cancer: Breast cancer is a hormonally sensitive tumour, and the prognosis of women with current or recent breast cancer may worsen with POC use.

ENDOMETRIAL CANCER

While awaiting treatment, women may use POCs. In general, the treatment of this condition renders a woman sterile.

OVARIAN CANCER

While awaiting treatment, women may use POCs. In general, the treatment of this condition renders a woman sterile.

UTERINE FIBROIDS

POCs do not appear to cause growth of uterine fibroids.

PELVIC INFLAMMATORY DISEASE (PID)
Whether POCs, like COCs, reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STI.

STIs
Whether POCs, like COCs, reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STI.

HIGH RISK OF HIV
Whether POCs, like COCs, reduce the risk of PID among women with STIs is unknown, but they do not protect against HIV or lower genital tract STI.

DIABETES
Non-vascular disease: POCs may alter carbohydrate metabolism.

Nephropathy, retinopathy, neuropathy: There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA and NET-EN. The effects of DMPA and NET-EN may persist for some time after discontinuation. Some POCs may increase the risk of thrombosis, although this increase is substantially less than with COCs.

Other vascular disease or diabetes of > 20 years' duration: There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA and NET-EN. The effects of DMPA and NET-EN may persist for some time after discontinuation. Some POCs may increase the risk of thrombosis, although this increase is substantially less than with COCs.

HISTORY OF CHOLESTASIS
Theoretically, a history of COC-related cholestasis may predict subsequent cholestasis with POC use. However, this has not been documented.

VIRAL HEPATITIS
Active: POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. This concern is similar to, but less than, that with COCs.

CIRRHOSIS
POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. This concern is similar to, but less than, that with COCs.

LIVER TUMOURS
POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. In addition, POC use may enhance the growth of tumours. This concern is similar to, but less than, that with COCs.

IRON-DEFICIENCY ANAEMIA
Changes in the menstrual pattern associated with POC use have little effect on haemoglobin levels.

References for progestogen-only contraception

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EMERGENCY CONTRACEPTIVE PILLS

EMERGENCY CONTRACEPTION PILLS (ECPs) (including levonorgestrel contraceptive pills and combined oral contraceptive pills)	**ECPs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
PREGNANCY	NA	**Clarification:** Although this method is not indicated for a woman with a known or suspected pregnancy, there is no known harm to the woman, the course of her pregnancy, or the fetus if ECPs are accidentally used.
BREASTFEEDING	1	
HISTORY OF ECTOPIC PREGNANCY	1	
HISTORY OF SEVERE CARDIOVASCULAR COMPLICATIONS* (ischaemic heart disease, cerebrovascular attack, or other thromboembolic conditions)	2	
ANGINA PECTORIS*	2	
MIGRAINE*	2	
SEVERE LIVER DISEASE (including jaundice)*	2	
REPEATED ECP USE	1	**Clarification:** Recurrent ECP use is an indication that the woman requires further counselling on other contraceptive options. Frequently repeated ECP use may be harmful for women with conditions classified as 2, 3 or 4 for COC, CIC or POC use.
RAPE*	1	

* Additional comments

HISTORY OF SEVERE CARDIOVASCULAR COMPLICATIONS
The duration of use of ECPs is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.

ANGINA PECTORIS
The duration of use of ECPs is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.

MIGRAINE
The duration of use of ECPs is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.

SEVERE LIVER DISEASE (including jaundice)
The duration of use of ECPs is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.

RAPE
There are no restrictions for use of ECPs in cases of rape.

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INTRAUTERINE DEVICES

Cu-IUD = Copper-bearing IUD
LNG-IUD = Levonorgestrel-releasing IUD (20 g/24hours)

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY			
PREGNANCY	4	4	**Clarification:** The IUD is not indicated during pregnancy and should not be used because of the risk of serious pelvic infection and septic spontaneous abortion.
AGE*			
a) Menarche to < 20 years	2	2	
b) ≥ 20 years	1	1	
PARITY*			
a) Nulliparous	2	2	**Evidence:** There are conflicting data regarding whether IUD use is associated with infertility among nulliparous women, although recent, well-conducted studies suggest no increased risk.[1-9]
b) Parous	1	1	
POSTPARTUM* (breastfeeding or non-breastfeeding, including post-caesarean section)			
a) < 48 hours	2	3	**Evidence:** There was some increase in expulsion rates with delayed postpartum insertion compared to immediate insertion and with immediate postpartum insertion compared to interval insertion.[10-16]
b) 48 hours to < 4 weeks	3	3	
c) ≥ 4 weeks	1	1	
d) Puerperal sepsis	4	4	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
POST-ABORTION*			
a) First trimester	1	1	**Clarification:** IUDs can be inserted immediately after first-trimester, spontaneous or induced abortion. **Evidence:** There was no difference in risk of complications for immediate versus delayed insertion of an IUD after abortion. Expulsion was greater when an IUD was inserted following a second-trimester abortion versus following a first-trimester abortion. There were no differences in safety or expulsions for post-abortion insertion of an LNG-IUD compared with Cu-IUD.[17-30]
b) Second trimester	2	2	
c) Immediate post-septic abortion	4	4	
PAST ECTOPIC PREGNANCY*	1	1	
HISTORY OF PELVIC SURGERY (see postpartum, including caesarean section)	1	1	
SMOKING			
a) Age < 35 years	1	1	
b) Age ≥ 35 years			
(i) < 15 cigarettes/day	1	1	
(ii) ≥ 15 cigarettes/day	1	1	
OBESITY ≥ 30 kg/m^2 body mass index (BMI)	1	1	
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	**Clarification:** While a blood pressure measurement may be appropriate for good preventative health care, it is not materially related to safe and effective IUD use. Women should not be denied use of IUDs simply because their blood pressure cannot be measured.

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
CARDIOVASCULAR DISEASE			
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	1	2	
HYPERTENSION*			
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.			
a) History of hypertension where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	1	2	
b) Adequately controlled hypertension where blood pressure CAN be evaluated	1	1	
c) Elevated blood pressure levels (properly taken measurements)			
(i) systolic 140-159 or diastolic 90-99	1	1	
(ii) systolic $\geq$ 160 or diastolic $\geq$ 100	1	2	
d) Vascular disease	1	2	.
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	1	1	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
DEEP VENOUS THROMBOEMBOLISM (DVT)/PULMONARY EMBOLISM (PE)*			
a) History of DVT/PE	1	2	
b) Current DVT/PE	1	3	
c) Family history of DVT/PE (first-degree relatives)	1	1	
d) Major surgery			
(i) with prolonged immobilization	1	2	
(ii) without prolonged immobilization	1	1	
e) Minor surgery without immobilization	1	1	
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	1	2	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
SUPERFICIAL VENOUS THROMBOSIS			
a) Varicose veins	1	1	
b) Superficial thrombophlebitis	1	1	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE*	1	I: 2 / C: 3	
STROKE* (history of cerebrovascular accident)	1	2	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
KNOWN HYPERLIPIDAEMIAS	1	2	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
VALVULAR HEART DISEASE			
a) Uncomplicated	1	1	
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	2	2	**Clarification:** Prophylactic antibiotics to prevent endocarditis are advised for insertion.
NEUROLOGIC CONDITIONS			
HEADACHES*		I / C	
a) Non-migrainous (mild or severe)	1	1 / 1	**Clarification:** Any new headaches or marked changes in headaches should be evaluated.
b) Migraine			
(i) without aura			
Age < 35	1	2 / 2	
Age ≥ 35	1	2 / 2	
(ii) with aura, at any age	1	2 / 3	
EPILEPSY	1	1	
DEPRESSIVE DISORDERS			
DEPRESSIVE DISORDERS	1	1	**Clarification**: The classification is based on data for women with selected depressive disorders. No data on bipolar disorder or postpartum depression were available. There is a potential for drug interactions between certain antidepressant medications and hormonal contraceptives.

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS			
VAGINAL BLEEDING PATTERNS*		I C	
a) Irregular pattern ***without*** heavy bleeding	1	1 1	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2	1 2	**Clarification:** Unusually heavy bleeding should raise the suspicion of a serious underlying condition. **Evidence:** Among women with heavy or prolonged bleeding, LNG-IUDs were beneficial in treating menorrhagia.[31-35]
UNEXPLAINED VAGINAL BLEEDING (suspicion for serious condition)	I C	I C	**Clarification:** If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation. There is no need to remove the IUD before evaluation.
Before evaluation	4 2	4 2	
ENDOMETRIOSIS*	2	1	**Evidence:** LNG-IUD use among women with endometriosis decreased dysmenorrhoea and pelvic pain.[36, 37]
BENIGN OVARIAN TUMOURS (including cysts)	1	1	
SEVERE DYSMENORRHOEA*	2	1	
TROPHOBLAST DISEASE*			
a) Benign gestational trophoblastic disease	3	3	
b) Malignant gestational trophoblastic disease	4	4	.
CERVICAL ECTROPION	1	1	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)*	1	2	
CERVICAL CANCER* (awaiting treatment)	I C	I C	
	4 2	4 2	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**				
CONDITION	**CATEGORY** I=Initiation, C=Continuation				**CLARIFICATIONS/EVIDENCE**
	Cu-IUD		**LNG-IUD**		
BREAST DISEASE*					
a) Undiagnosed mass	1		2		
b) Benign breast disease	1		1		
c) Family history of cancer	1		1		
d) Breast cancer:					
(i) current	1		4		
(ii) past and no evidence of current disease for 5 years	1		3		
ENDOMETRIAL CANCER*	I	C	I	C	
	4	2	4	2	
OVARIAN CANCER*	3	2	3	2	
UTERINE FIBROIDS*					
a) Without distortion of the uterine cavity	1		1		**Evidence:** Among women with fibroids, there were no adverse health events with LNG-IUD use and there was a decrease in symptoms and size of fibroids for some women.[38-44]
b) With distortion of the uterine cavity	4		4		
ANATOMICAL ABNORMALITIES*					
a) Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion)	4		4		
b) Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion	2		2		

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.				
CONDITION	**CATEGORY** I=Initiation, C=Continuation				**CLARIFICATIONS/EVIDENCE**
	Cu-IUD		**LNG-IUD**		
PELVIC INFLAMMATORY DISEASE (PID)*	I	C	I	C	
a) Past PID (assuming no known current risk factors for STIs)					
(i) with subsequent pregnancy	1	1	1	1	
(ii) without subsequent pregnancy	2	2	2	2	
b) PID - current	4	2	4	2	**Clarification for continuation:** Treat the PID using appropriate antibiotics. There is usually no need for removal of the IUD if the client wishes to continue its use. (See ***Selected Practice Recommendations for Contraceptive Use***. WHO: Geneva, 2002). Continued use of an IUD depends on the woman's informed choice and her current risk factors for STIs and PID. **Evidence:** Among IUD users treated for PID, there was no difference in clinical course if the IUD was removed or left in place.[45-47]
STIs*	I	C	I	C	
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	4	2	4	2	**Clarification for continuation:** Treat the STI using appropriate antibiotics. There is usually no need for removal of the IUD if the client wishes to continue its use. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STIs and PID. **Evidence:** There is no evidence regarding whether IUD insertion among women with STIs increases the risk of PID compared with no IUD insertion. Among women who have an IUD inserted, the absolute risk of subsequent PID was low among women with STI at the time of insertion but greater than among women with no STI at the time of IUD insertion.[48-54]
b) Other STIs (excluding HIV and hepatitis)	2	2	2	2	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.				
CONDITION	**CATEGORY** I=Initiation, C=Continuation				**CLARIFICATIONS/EVIDENCE**
	Cu-IUD		**LNG-IUD**		
STIs (Cont'd)					
d) Increased risk of STIs	2/3	2	2/3	2	**Clarification for initiation**: If a woman has a very high individual likelihood of exposure to gonorrhoea or chlamydial infection, the condition is a Category 3. **Evidence:** Using an algorithm to classify STI risk status among IUD users, one study reported that 11% of high STI-risk women experienced IUD-related complications compared with 5% of those not classified as high risk.[50]
HIV/AIDS					
HIGH RISK OF HIV*	I	C	I	C	
	2	2	2	2	**Evidence:** Among women at risk of HIV, copper IUD use did not increase risk of HIV acquisition.[55-65]
HIV-INFECTED	2	2	2	2	**Evidence:** Among IUD users, there is limited evidence showing no increased risk of overall complications or infection-related complications when comparing HIV-infected women with non-infected women. Furthermore, IUD use among HIV-infected women was not associated with increased risk of transmission to sexual partners.[55, 66-69]
AIDS	3	2	3	2	**Clarification for continuation:** IUD users with AIDS should be closely monitored for pelvic infection.
Clinically well on ARV therapy	2	2	2	2	
OTHER INFECTIONS					
SCHISTOSOMIASIS					
a) Uncomplicated	1		1		
b) Fibrosis of the liver (if severe, see cirrhosis)	1		1		
TUBERCULOSIS*	I	C	I	C	
a) Non-pelvic	1	1	1	1	
b) Known pelvic	4	3	4	3	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
MALARIA	1	1	
ENDOCRINE CONDITIONS			
DIABETES*			
a) History of gestational disease	1	1	
b) Non-vascular disease			
(i) non-insulin dependent	1	2	
(ii) insulin dependent	1	2	
c) Nephropathy/ retinopathy/ neuropathy	1	2	
d) Other vascular disease or diabetes of >20 years' duration	1	2	
THYROID DISORDERS			
a) Simple goitre	1	1	
b) Hyperthyroid	1	1	
c) Hypothyroid	1	1	
GASTROINTESTINAL CONDITIONS			
GALL-BLADDER DISEASE			
a) Symptomatic			
(i) treated by cholecystectomy	1	2	
(ii) medically treated	1	2	
(iii) current	1	2	
b) Asymptomatic	1	2	
HISTORY OF CHOLESTASIS*			
a) Pregnancy-related	1	1	
b) Past COC-related	1	2	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**		
CONDITION	**CATEGORY** I=Initiation, C=Continuation		**CLARIFICATIONS/EVIDENCE**
	Cu-IUD	**LNG-IUD**	
VIRAL HEPATITIS*			
a) Active	1	3	
b) Carrier	1	1	
CIRRHOSIS*			
a) Mild (compensated)	1	2	
b) Severe (decompensated)	1	3	
LIVER TUMOURS*			
a) Benign (adenoma)	1	3	
b) Malignant (hepatoma)	1	3	
ANAEMIAS			
THALASSAEMIA*	2	1	
SICKLE CELL DISEASE*	2	1	
IRON-DEFICIENCY ANAEMIA*	2	1	
DRUG INTERACTIONS			
DRUGS WHICH AFFECT LIVER ENZYMES			
a) Rifampicin	1	1	**Evidence:** One study found that rifabutin, which is in the same class of drugs as rifampicin, has no impact on the effectiveness of LNG-IUD.[70]
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1	1	
ANTIBIOTICS (excluding rifampicin)	1	1	
a) Griseofulvin	1	1	
b) Other antibiotics	1	1	

* See also additional comments at end of table

INTRAUTERINE DEVICES (IUDs)	**IUDs do not protect against STI/HIV. If there is risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**				
CONDITION	**CATEGORY** I=Initiation, C=Continuation				**CLARIFICATIONS/EVIDENCE**
	Cu-IUD		**LNG-IUD**		
ANTIRETROVIRAL THERAPY	I	C	I	C	
	2/3	2	2/3	2	**Clarification**: There is no known drug interaction between ARV therapy and IUD use. However, AIDS as a condition is classified as Category 3 for insertion and Category 2 for continuation unless the woman is clinically well on ARV therapy in which case, both insertion and continuation are classified as Category 2. (See AIDS condition above.)

* See also additional comments at end of table

Additional comments

AGE
Menarche to < 20 years: There is concern both about the risk of expulsion due to nulliparity and risk of STIs due to sexual behaviour in younger age groups.

PARITY
Nulliparous: Nulliparity is related to an increased risk of expulsion.

POSTPARTUM
< 48 hours, 48 hours to < 4 weeks, ≥ 4 weeks: Concern that the neonate may be at risk due to exposure to steroid hormones with LNG-IUD use during the first 6 weeks postpartum is the same as for other POCs.

Puerperal sepsis: Insertion of an IUD may substantially worsen the condition.

POST-ABORTION
Immediate post-septic abortion: Insertion of an IUD may substantially worsen the condition.

PAST ECTOPIC PREGNANCY
The absolute risk of ectopic pregnancy is extremely low due to the high effectiveness of IUDs. However, when a woman becomes pregnant during IUD use, the relative likelihood of ectopic pregnancy is greatly increased.

HYPERTENSION
There is theoretical concern about the effect of LNG on lipids. There is no restriction for copper IUDs.

DEEP VENOUS THROMBOEMBOLISM (DVT)/ PULMONARY EMBOLISM (PE)
Some progestogens may increase the risk of venous thrombosis, although this increase is substantially less than for COCs.

CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE
There is theoretical concern about the effect of LNG on lipids. There is no restriction for copper IUDs.

STROKE
There is theoretical concern about the effect of LNG on lipids. There is no restriction for copper IUDs.

HEADACHES
Aura is a specific focal neurologic symptom. For more information on this and other diagnostic criteria, see: Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders, 2nd Edition. Cephalalgia. 2004; 24 (Suppl 1): 1- 150.
http://216.25.100.131/ihscommon/guidelines/pdfs/ihc_II_main_no_print.pdf

VAGINAL BLEEDING PATTERNS
LNG-IUD use frequently causes changes in menstrual bleeding patterns. Over time, LNG-IUD users are more likely than non-users to become amenorrhoeic, thus LNG-IUDs are sometimes used as a treatment to correct heavy bleeding.

ENDOMETRIOSIS
Copper IUD use may worsen dysmenorrhoea associated with the condition.

SEVERE DYSMENORRHOEA
Dysmenorrhoea may intensify with copper IUD use. LNG-IUD use has been associated with reduction of dysmenorrhoea.

TROPHOBLAST DISEASE
There is an increased risk of perforation since the treatment for the condition may require multiple uterine curettages.

CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

There is some theoretical concern that LNG-IUDs may enhance progression of CIN.

CERVICAL CANCER (awaiting treatment)
There is concern about the increased risk of infection and bleeding at insertion. The IUD will likely need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

BREAST DISEASE
Breast cancer: Breast cancer is a hormonally sensitive tumour. Concerns about progression of the disease may be less with LNG-IUDs than with COCs or higher-dose POCs.

ENDOMETRIAL CANCER
There is concern about the increased risk of infection, perforation and bleeding at insertion. The IUD will likely need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

OVARIAN CANCER
The IUD will likely need to be removed at the time of treatment but, until then, the woman is at risk of pregnancy.

UTERINE FIBROIDS
Without distortion of the uterine cavity: Women with heavy or prolonged bleeding should be assigned the category for that condition.

With distortion of the uterine cavity: Pre-existing uterine fibroids that distort the uterine cavity may be incompatible with insertion and proper placement of the IUD.

ANATOMICAL ABNORMALITIES
Distorted uterine cavity: In the presence of an anatomic abnormality that distorts the uterine cavity, proper IUD placement may not be possible.

PELVIC INFLAMMATORY DISEASE (PID)
IUDs do not protect against STI/HIV/PID. In women at low risk of STIs, IUD insertion poses little risk of PID. Current risk of STIs and desire for future pregnancy are relevant considerations.

STIs
IUDs do not protect against STI/HIV/PID. Among women with chlamydial infection or gonorrhoea, the potential increased risk of PID with IUD insertions should be avoided. The concern is less for other STIs.

HIGH RISK OF HIV

IUDs do not protect against STI/HIV/PID.

TUBERCULOSIS
Known pelvic: Insertion of an IUD may substantially worsen known the condition.

DIABETES
Whether the amount of LNG released by the IUD may slightly influence carbohydrate and lipid metabolism is unclear. Some progestogens may increase the risk of thrombosis, although this increase is substantially less than for COCs.

HISTORY OF CHOLESTASIS
There is concern that a history of COC-related cholestasis may predict subsequent cholestasis with LNG use. Whether there is any risk with use of an LNG-IUD is unclear.

VIRAL HEPATITIS
Active: POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. This concern is similar to, but less than, that with COCs.

CIRRHOSIS
POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. This concern is similar to, but less than, that with COCs.

LIVER TUMOURS
POCs are metabolized by the liver and their use may adversely affect women whose liver function is compromised. In addition, POC use may enhance the growth of tumours. This concern is similar to, but less than, that with COCs.

THALASSAEMIA
There is concern about an increased risk of blood loss with copper IUDs.

SICKLE CELL DISEASE
There is concern about an increased risk of blood loss with copper IUDs.

IRON-DEFICIENCY ANAEMIA
There is concern about an increased risk of blood loss with copper IUDs.

References for intrauterine devices

1. Cramer DW et al. Tubal infertility and the intrauterine device. ***New England Journal of Medicine,*** 1985, 312:941-7.
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COPPER IUD FOR EMERGENCY CONTRACEPTION

This method is highly effective for preventing pregnancy. A copper-releasing IUD (Cu-IUD) can be used within 5 days of unprotected intercourse as an emergency contraceptive. However, when the time of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after intercourse, if necessary, as long as the insertion does not occur more than 5 days after ovulation.

The eligibility criteria for interval Cu-IUD insertion also apply for the insertion of Cu-IUDs as emergency contraception.

COPPER IUD FOR EMERGENCY CONTRACEPTION	**IUDs for emergency contraception do not protect against STI/HIV. If there is risk of STI/HIV, the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
PREGNANCY	4	**Clarification**: The IUD is not indicated during pregnancy and should not be used because of the risk of serious pelvic infection and septic spontaneous abortion.
RAPE*		
a) High risk of STI	3	
b) Low risk of STI	1	

*** Additional comments**

RAPE

IUDs do not protect against STI/HIV/PID. Among women with chlamydial infection or gonorrhoea, the potential increased risk of PID with IUD insertion should be avoided. The concern is less for other STIs.

PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY 1
Pregnancy 1
Age 1
Parity 1
Postpartum 1
Post-abortion 1
Past ectopic pregnancy 1
History of pelvic surgery 1
Smoking 2
Obesity 2
Blood pressure measurement unavailable 2
CARDIOVASCULAR DISEASE 2
Multiple risk factors for arterial cardiovascular disease 2
Hypertension 2
History of high blood pressure during pregnancy 3
Deep venous thrombosis (DVT)/pulmonary embolism (PE) 3
Known thrombogenic mutations 3
Superficial venous thrombosis 3
Current and history of ischaemic heart disease 3
Stroke 3
Known hyperlipidaemias 4
Valvular heart disease 4
NEUROLOGIC CONDITIONS 4
Headaches 4
Epilepsy 4
DEPRESSIVE DISORDERS 4
Depressive disorders 4
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS 4
Unexplained vaginal bleeding 4
Endometriosis 4
Benign ovarian tumours 5
Severe dysmenorrhoea 5
Trophoblast disease 5
Cervical ectropion 5
Cervical intraepithelial neoplasia (CIN) 5
Cervical cancer 5
Breast disease 5
Endometrial cancer 5
Ovarian cancer 5
Uterine fibroids 5
Anatomical abnormalities 6
Pelvic inflammatory disease (PID) 6
STIs 6
HIV/AIDS 6
High risk of HIV 6
HIV-infected 6
AIDS 6

OTHER INFECTIONS 6
Schistosomiasis 6
Tuberculosis 6
Malaria 7
History of toxic shock syndrome 7
Urinary tract infection 7
ENDOCRINE CONDITIONS 7
Diabetes 7
Thyroid disorders 7
GASTROINTESTINAL CONDITIONS 7
Gall-bladder disease 7
History of cholestasis 7
Viral hepatitis 8
Cirrhosis 8
Liver tumours 8
ANAEMIAS 8
Thalassaemia 8
Sickle cell disease 8
Iron-deficiency anaemia 8
DRUG INTERACTIONS 8
Drugs which affect liver enzymes 8
Antibiotics 8
Antiretroviral therapy 8
Allergy to latex 9
Additional comments 10
References for barrier methods 11

BARRIER METHODS

C = Male latex condoms, male polyurethane condoms, female condoms
S = Spermicide (film, tablets, foam, gel)
D = Diaphragm (with spermicide), cervical cap

BARRIER METHODS	**If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY				
PREGNANCY	NA	NA	NA	**Clarification:** None of these methods are relevant for contraception during known pregnancy. However, for women who continue to be at risk of STI/HIV during pregnancy, the correct and consistent use of condoms is recommended.
AGE				
a) Menarche to < 40 years	1	1	1	
b) ≥ 40 years	1	1	1	
PARITY				
a) Nulliparous	1	1	1	
b) Parous	1	1	2	**Clarification:** There is a higher risk of cervical cap failure in parous women than in nulliparous women.
POSTPARTUM				
a) < 6 weeks postpartum	1	1	NA	**Clarification:** Diaphragm and cap are unsuitable until uterine involution is complete.
b) ≥ 6 weeks postpartum	1	1	1	
POST-ABORTION				
a) First trimester	1	1	1	
b) Second trimester	1	1	1	**Clarification:** Diaphragm and cap are unsuitable until 6 weeks after second-trimester abortion.
c) Immediate post-septic abortion	1	1	1	
PAST ECTOPIC PREGNANCY	1	1	1	
HISTORY OF PELVIC SURGERY	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
SMOKING				
a) Age < 35	1	1	1	
b) Age > 35				
(i) <15 cigarettes/day	1	1	1	
(ii) ≥15 cigarettes/day	1	1	1	
OBESITY* ≥ 30 kg/m^2 body mass index (BMI)	1	1	1	
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	NA	**Clarification:** While a blood pressure measurement may be appropriate for good preventative health care, it is not required for safe and effective barrier method use. Women should not be denied use of barrier methods simply because their blood pressure cannot be measured.
CARDIOVASCULAR DISEASE				
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	1	1	1	
HYPERTENSION				
a) History of hypertension where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	1	1	1	
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	1	1	1	
c) Elevated blood pressure levels (properly taken measurements)	1	1	1	
(i) systolic 140-159 or diastolic 90-99	1	1	1	
(ii) systolic ≥160 or diastolic ≥100	1	1	1	
d) Vascular disease	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	1	1	1	
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)				
a) History of DVT/PE	1	1	1	
b) Current DVT/PE	1	1	1	
c) Family history of DVT/PE (first degree relatives)	1	1	1	
d) Major surgery				
(i) with prolonged immobilization	1	1	1	
(ii) without prolonged immobilization	1	1	1	
e) Minor surgery without immobilization	1	1	1	
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	1	1	1	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
SUPERFICIAL VENOUS THROMBOSIS				
a) Varicose veins	1	1	1	
b) Superficial thrombophlebitis	1	1	1	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE	1	1	1	
STROKE (history of cerebrovascular accident)	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
KNOWN HYPERLIPIDAEMIAS	1	1	1	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
VALVULAR HEART DISEASE*				
a) Uncomplicated	1	1	1	
b) Complicated (pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)	1	1	2	
NEUROLOGIC CONDITIONS				
HEADACHES				
a) Non-migrainous (mild or severe)	1	1	1	
b) Migraine				
(i) without aura				
Age < 35	1	1	1	
Age ≥ 35	1	1	1	
(ii) With aura, at any age	1	1	1	
EPILEPSY	1	1	1	
DEPRESSIVE DISORDERS				
DEPRESSIVE DISORDERS	1	1	1	
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS				
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition)				
Before evaluation	1	1	1	**Clarification:** If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
ENDOMETRIOSIS	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	
SEVERE DYSMENORRHOEA	1	1	1	
TROPHOBLAST DISEASE				
a) Benign gestational trophoblastic disease	1	1	1	
b) Malignant gestational trophoblastic disease	1	1	1	
CERVICAL ECTROPION	1	1	1	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	1	1	1	**Clarification: The cap should not be used.** There is no restriction for diaphragm use.
CERVICAL CANCER* (awaiting treatment)	1	2	1	**Clarification: The cap should not be used.** There is no restriction for diaphragm use.
BREAST DISEASE				
a) Undiagnosed mass	1	1	1	
b) Benign breast disease	1	1	1	
c) Family history of cancer	1	1	1	
d) Breast cancer				
(i) current	1	1	1	
(ii) past and no evidence of current disease for 5 years	1	1	1	
ENDOMETRIAL CANCER	1	1	1	
OVARIAN CANCER	1	1	1	
UTERINE FIBROIDS				
a) Without distortion of the uterine cavity	1	1	1	
b) With distortion of the uterine cavity	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
ANATOMICAL ABNORMALITIES	1	1	NA	**Clarification:** The diaphragm cannot be used in certain cases of prolapse. Cap use is not appropriate for a client with a markedly distorted cervical anatomy.
PELVIC INFLAMMATORY DISEASE (PID)				
a) Past PID (assuming no current risk factors of STIs)				
(i) with subsequent pregnancy	1	1	1	
(ii) without subsequent pregnancy	1	1	1	
b) PID current	1	1	1	
STIS				
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	
b) Other STIs (excluding HIV and hepatitis)	1	1	1	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	
d) Increased risk of STIs	1	1	1	
HIV/AIDS				
HIGH RISK OF HIV*	1	4	3	**Evidence:** Repeated and high-dose use of the spermicide nonoxynol-9 was associated with increased risk of genital lesions, which may increase the risk of acquiring HIV infection.[1]
HIV-INFECTED	1	4	3	
AIDS	1	4	3	
OTHER INFECTIONS				
SCHISTOSOMIASIS				
a) Uncomplicated	1	1	1	
b) Fibrosis of liver	1	1	1	
TUBERCULOSIS				

* See also additional comments at end of table

BARRIER METHODS	If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
a) Non-pelvic	1	1	1	
b) Known pelvic	1	1	1	
MALARIA	1	1	1	
HISTORY OF TOXIC SHOCK SYNDROME*	1	1	3	
URINARY TRACT INFECTION*	1	1	2	.
ENDOCRINE CONDITIONS				
DIABETES				
a) History of gestational disease	1	1	1	
b) Non-vascular disease				
(i) non-insulin dependent	1	1	1	
(ii) insulin dependent	1	1	1	
c) Nephropathy/ retinopathy/neuropathy	1	1	1	
d) Other vascular disease or diabetes of > 20 years' duration	1	1	1	
THYROID DISORDERS				
a) Simple goitre	1	1	1	
b) Hyperthyroid	1	1	1	
c) Hypothyroid	1	1	1	
GASTROINTESTINAL CONDITIONS				
GALL-BLADDER DISEASE				
a) Symptomatic				
(i) treated by cholecystectomy	1	1	1	
(ii) medically treated	1	1	1	
(iii) current	1	1	1	
b) Asymptomatic	1	1	1	
HISTORY OF CHOLESTASIS				

* See also additional comments at end of table

BARRIER METHODS	**If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
a) Pregnancy-related	1	1	1	
b) Past COC-related	1	1	1	
VIRAL HEPATITIS				
a) Active	1	1	1	
b) Carrier	1	1	1	
CIRRHOSIS				
a) Mild (compensated)	1	1	1	
b) Severe (decompensated)	1	1	1	
LIVER TUMOURS				
a) Benign (adenoma)	1	1	1	
b) Malignant (hepatoma)	1	1	1	
ANAEMIAS				
THALASSAEMIA	1	1	1	
SICKLE CELL DISEASE	1	1	1	
IRON-DEFICIENCY ANAEMIA	1	1	1	
DRUG INTERACTIONS				
DRUGS WHICH AFFECT LIVER ENZYMES				
a) Rifampicin	1	1	1	
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1	1	1	
ANTIBIOTICS (excluding rifampicin)				
a) Griseofulvin	1	1	1	
b) Other antibiotics	1	1	1	
ANTIRETROVIRAL THERAPY	1	1	1	

* See also additional comments at end of table

BARRIER METHODS	**If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**			
Women with conditions which make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively-higher typical-use failure rates.				
CONDITION	**CATEGORY**			**CLARIFICATIONS/EVIDENCE**
	C	S	D	
ALLERGY TO LATEX	3	1	3	**Clarification:** This does not apply to plastic condoms/diaphragms.

* See also additional comments at end of table

Additional comments

OBESITY
Severe obesity may make diaphragm and cap placement difficult.

VALVULAR HEART DISEASE
Risk of urinary tract infection with the diaphragm may increase risk in a client with sub-acute bacterial endocarditis.

CERVICAL CANCER (awaiting treatment)
Repeated and high-dose use of nonoxynol-9 can cause vaginal and cervical irritation or abrasions.

HIGH RISK OF HIV
Category 3 for diaphragm use is assigned due to concerns about the spermicide, not the diaphragm.

HISTORY OF TOXIC SHOCK SYNDROME
Toxic shock syndrome has been reported in association with contraceptive sponge and diaphragm use.

URINARY TRACT INFECTION
There is a potential increase of urinary tract infection with diaphragms and spermicides.

References for barrier methods

1. Wilkinson D et al. Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men. Cochrane Database of Systematic Reviews, 2002, 4:CD003936.

FERTILITY AWARENESS-BASED METHODS

Fertility awareness-based (FAB) methods of family planning involve identification of the fertile days of the menstrual cycle, whether by observing fertility signs such as cervical secretions and basal body temperature, or by monitoring cycle days. FAB methods can be used in combination with abstinence or barrier methods during the fertile time. If barrier methods are used, refer to the section on barrier methods (BARR).

There are no medical conditions which become worse because of use of FAB methods. In general, these methods can be provided without concern for health effects to people who choose them. However, there are a number of conditions that make their use more complex. The existence of these conditions suggests that (1) use of these methods should be delayed until the condition is corrected or resolved or (2) they will require special counselling, and a more highly trained provider is generally necessary to ensure correct use.

Definitions

SYM	Symptoms-based methods	FAB methods based on observation of fertility signs (e.g., cervical secretions, basal body temperature) such as the Cervical Mucus Method, the Symptothermal Method, and the Two Day Method.
CAL	Calendar-based methods	FAB methods based on calendar calculations such as the Calendar Rhythm Method and the Standard Days Method.
A	Accept	There is no medical reason to deny the particular FAB method to a woman in this circumstance.
C	Caution	The method is normally provided in a routine setting, but with extra preparation and precautions. For FAB methods, this usually means that special counselling may be needed to ensure correct use of the method by a woman in this circumstance.
D	Delay	Use of this method should be delayed until the condition is evaluated or corrected. Alternative temporary methods of contraception should be offered.
NA	Not applicable	

FERTILITY AWARENESS-BASED METHODS	Fertility awareness-based methods do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.		
Women with conditions which make pregnancy an unacceptable risk should be advised that fertility awareness-based methods may not be appropriate for them because of their relatively-higher typical-use failure rates.			
CONDITION	**CATEGORY**		**CLARIFICATIONS/EVIDENCE**
	SYM	**CAL**	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY			
PREGNANCY	NA		**Comments:** FAB methods are not relevant during pregnancy.
LIFE STAGE			
a) Post-menarche	C	C	**Clarification:** Menstrual irregularities are common in post-menarche and peri-menopause and may complicate the use of FAB methods.
b) Peri-menopause	C	C	
BREASTFEEDING*			
a) < 6 weeks postpartum	D	D	
b) ≥ 6 weeks	C	D	
c) After menses begin	C	C	
POSTPARTUM* (in non-breastfeeding women)			
a) < 4 weeks	D	D	
b) ≥ 4 weeks	A	D	
POST-ABORTION*	C	D	
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS			
IRREGULAR VAGINAL BLEEDING*	D	D	
VAGINAL DISCHARGE*	D	A	
OTHER			
USE OF DRUGS WHICH AFFECT CYCLE REGULARITY, HORMONES AND/OR FERTILITY SIGNS*	C/D	C/D	
DISEASES WHICH ELEVATE BODY TEMPERATURE*			
a) Chronic diseases	C	A	
b) Acute diseases	D	A	

* See also additional comments at end of table

Additional comments

BREASTFEEDING
FAB methods during breastfeeding may be less effective than when not breastfeeding.

< 6 weeks postpartum: Women who are primarily breastfeeding and are amenorrhoeic are unlikely to have sufficient ovarian function to produce detectable fertility signs and hormonal changes during the first 6 months postpartum. However, the likelihood of resumption of fertility increases with time postpartum and with substitution of breast milk by other foods.

After menses begin: When the woman notices fertility signs (particularly cervical secretions), she can use a symptoms-based method. When she has had 3 postpartum menses, she can use a calendar-based method. Prior to that time, a barrier method should be offered if the woman plans to use a FAB method later.

POSTPARTUM
< 4 weeks: Non-breastfeeding women are not likely to have sufficient ovarian function to either require a FAB method or to have detectable fertility signs or hormonal changes prior to 4 weeks postpartum. Although the risk of pregnancy is low, a method appropriate for the postpartum period should be offered.

≥ 4 weeks: Non-breastfeeding women are likely to have sufficient ovarian function to produce detectable fertility signs and/or hormonal changes at this time; likelihood increases rapidly with time postpartum. Women can use calendar-based methods as soon as they have completed 3 postpartum menses. Methods appropriate for the postpartum period should be offered prior to that time.

POST-ABORTION
Post-abortion women are likely to have sufficient ovarian function to produce detectable fertility signs and/or hormonal changes; likelihood increases with time post-abortion. Women can start using calendar based methods after they have had at least one post-abortion menses (e.g. women who before this pregnancy had most cycles between 26 and 32 days can use the Standard Days Method then). Methods appropriate for the post-abortion period should be offered prior to that time.

IRREGULAR VAGINAL BLEEDING
Presence of this condition makes FAB methods unreliable. Therefore, barrier methods should be recommended until the bleeding pattern is compatible with proper method use. The condition should be evaluated and treated as necessary.

VAGINAL DISCHARGE
Because vaginal discharge makes recognition of cervical secretions difficult, the condition should be evaluated and treated if needed prior to providing methods based on cervical secretions.

USE OF DRUGS WHICH AFFECT CYCLE REGULARITY, HORMONES AND/OR FERTILITY SIGNS
Use of certain mood-altering drugs such as lithium, tricyclic antidepressants, and anti-anxiety therapies, as well as certain antibiotics and anti-inflammatory drugs, may alter cycle regularity or affect fertility signs. The condition should be carefully evaluated and a barrier method offered until the degree of effect has been determined or the drug is no longer being used.

DISEASES WHICH ELEVATE BODY TEMPERATURE
Elevated temperature levels may make basal body temperature difficult to interpret, but there is no effect on cervical secretions. Thus the use of a method that relies on temperature should be delayed until the acute disease abates. Temperature-based methods are not appropriate for women with chronically-elevated temperatures. In addition, some chronic diseases interfere with cycle regularity, making calendar-based methods difficult to interpret.

LACTATIONAL AMENORRHOEA METHOD

The lactational amenorrhoea method does not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.
Women with conditions which make pregnancy an unacceptable risk should be advised that the lactational amenorrhoea method may not be appropriate for them because of its relatively-higher typical-use failure rates.

The Bellagio Consensus provided the scientific basis for defining the conditions under which breastfeeding can be used safely and effectively for birth-spacing purposes, and programmatic guidelines were developed for the use of lactational amenorrhoea in family planning. These guidelines include the following three criteria, all of which must be met to ensure adequate protection from an unplanned pregnancy: **1) Amenorrhoea; 2) Fully or nearly fully breastfeeding;** and **3) Less than six months postpartum**.

The main indications for breastfeeding remain the need to provide an ideal food for the infant and to protect it against disease. There are no medical conditions in which the use of lactational amenorrhoea is restricted and there is no documented evidence of its negative impact on maternal health. However, certain conditions or obstacles which affect breastfeeding may also affect the duration of amenorrhoea, making this a less useful choice for family planning purposes. These include**:**

HIV infection

Breastfeeding should be promoted, protected, and supported in all populations, for all women who are HIV-negative or of unknown HIV status. When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life, and should then be discontinued as soon as it is feasible. Women who are HIV-positive should receive counselling that includes information about both the risks and benefits of various infant feeding options based on local assessments, guidance in selecting the most suitable option for their situation, and be supported in their choice. They should also have access to follow-up care and support, including family planning and nutritonal support.

Medication used during breastfeeding

In order to protect infant health, breastfeeding is not recommended for women using such drugs as: anti-metabolites, bromocriptine, certain anticoagulants, corticosteroids (high doses), cyclosporin, ergotamine, lithium, mood-altering drugs, radioactive drugs, and reserpine.

Conditions affecting the newborn

Congenital deformities of the mouth, jaw or palate; newborns who are small-for-date or premature and needing intensive neonatal care; and certain metabolic disorders of the infant all can make breastfeeding difficult.

COITUS INTERRUPTUS

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

Women with conditions that make pregnancy an unacceptable risk should be advised that coitus interruptus may not be appropriate for them because of its relatively-higher typical-use failure rates.

Coitus interruptus (CI), also known as withdrawal, is a traditional family planning method in which the man completely removes his penis from the vagina, and away from the external genitalia of the female partner, before he ejaculates. CI prevents sperm from entering the woman s vagina, thereby preventing contact between spermatozoa and the ovum.

This method may be appropriate for couples:

- who are highly motivated and able to use this method effectively;
- with religious or philosophical reasons for not using other methods of contraception;
- who need contraception immediately and have entered into a sexual act without alternative methods available;
- who need a temporary method while awaiting the start of another method;
- who have intercourse infrequently.

Some benefits of CI are that the method, if used correctly, does not affect breastfeeding and is always available for primary use or use as a back-up method. In addition, CI involves no economic cost or use of chemicals. There are no health risks associated directly with CI. Men and women who are at high risk of STI/HIV infection should use a condom with each act of intercourse.

CI is unforgiving of incorrect use, and its effectiveness depends on the willingness and ability of the couple to use withdrawal with every act of intercourse.

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SURGICAL STERILIZATION PROCEDURES

Given that sterilization is a surgical procedure that is intended to be permanent, special care must be taken to assure that every client makes a voluntary informed choice of the method. Particular attention must be given in the case of young people, nulliparous women, men who have not yet been fathers, and clients with mental health problems, including depressive conditions. All clients should be carefully counselled about the intended permanence of sterilization and the availability of alternative, long-term, highly effective methods. This is of extra concern for young people. The national laws and existing norms for the delivery of sterilization procedures must be considered in the decision process.

Transcervical methods of female sterilization are not addressed in these recommendations.

There is no medical condition that would absolutely restrict a person's eligibility for sterilization, although some conditions and circumstances will require that certain precautions are taken, including those where the recommendation is C (Caution), D (Delay), or S (Special). For some of these conditions and circumstances, the theoretical or proven risks may outweigh the advantages of undergoing sterilization, particularly female sterilization. Where the risks of sterilization outweigh the benefits, long-term, highly effective contraceptive methods are a preferable alternative. Decisions in this regard will have to be made on an individual basis, considering the risks and benefits of sterilization versus the risks of pregnancy, and the availability and acceptability of highly effective, alternative methods.

The following classification of conditions into the four different categories is based on an in-depth review of the epidemiological and clinical evidence relevant to medical eligibility. Sterilization procedures should only be performed by well-trained providers in appropriate clinical settings using proper equipment and supplies. Appropriate service delivery guidelines, including infection prevention protocols, should be followed to maximize client safety.

DEFINITIONS

A	**Accept**	There is no medical reason to deny sterilization to a person with this condition.
C	**Caution**	The procedure is normally conducted in a routine setting, but with extra preparation and precautions.
D	**Delay**	The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be provided.
S	**Special**	The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate procedure and anaesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.

A. Female surgical sterilization

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY		
PREGNANCY	D	
YOUNG AGE*	C	**Clarification:** Young women, like all women, should be counselled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods. **Evidence:** Studies show that up to 20% of women sterilized at a young age later regret this decision, and that young age is one of the strongest predictors of regret (including request for reversal information and obtaining reversal) that can be identified before sterilization.[1-19]
PARITY*		
a) Nulliparous	A	
b) Parous	A	
BREASTFEEDING	A	
POSTPARTUM*		
a) < 7 days	A	
7 to < 42 days	D	
≥ 42 days	A	
b) Pre-eclampsia/ eclampsia		
(i) mild pre-eclampsia	A	
(ii) severe pre-eclampsia/ eclampsia	D	
c) Prolonged rupture of membranes: 24 hours or more	D	
d) Puerperal sepsis, intrapartum or puerperal fever	D	
e) Severe antepartum or postpartum haemorrhage	D	
f) Severe trauma to the genital tract: cervical or vaginal tear at time of delivery	D	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
POSTPARTUM (Cont'd)		
g) Uterine rupture or perforation	S	**Clarification:** If exploratory surgery or laparoscopy is conducted and the patient is stable, repair of the problem and tubal sterilization may be performed concurrently if no additional risk is involved.
POST-ABORTION*		
a) Uncomplicated	A	
b) Post-abortal sepsis or fever	D	
c) Severe post-abortal haemorrhage	D	
d) Severe trauma to the genital tract: cervical or vaginal tear at time of abortion	D	
e) Uterine perforation	S	**Clarification:** If exploratory surgery or laparoscopy is conducted, repair of the problem and tubal sterilization may be performed concurrently if no additional risk is involved.
f) Acute haematometra	D	
PAST ECTOPIC PREGNANCY	A	
SMOKING		
a) Age < 35 years	A	
b) Age ≥ 35 years		
(i) <15 cigarettes/day	A	
(ii) ≥15 cigarettes/day	A	
OBESITY ≥ 30 kg/m^2 body mass index (BMI)	C	**Clarification:** The procedure may be more difficult. There is an increased risk of wound infection and disruption. Obese women may have limited respiratory function and may be more likely to require general anaesthesia. **Evidence:** Women who were obese were more likely to have complications when undergoing sterilization.[20-23]

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	**Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
CARDIOVASCULAR DISEASE		
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE* (such as older age, smoking, diabetes and hypertension)	S	
HYPERTENSION		
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.		
a) Hypertension, adequately controlled	C	
b) Elevated blood pressure levels (properly taken measurements)		**Clarification:** Elevated blood pressure should be controlled before surgery. There are increased anaesthesia-related risks and an increased risk of cardiac arrhythmia with uncontrolled hypertension. Careful monitoring of blood pressure intraoperatively is particularly necessary in this situation.
(i) systolic 140-159 or diastolic 90-99	C	
(ii) systolic ≥160 or diastolic ≥100	S	
c) Vascular disease	S	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	A	
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)		
a) History of DVT/PE	A	**Clarification:** To reduce the risk of DVT/PE, early ambulation is recommended.
b) Current DVT/PE	D	
c) Family history of DVT/PE (first-degree relatives)	A	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
DEEP VENOUS THROMBOSIS (DVT)/PULMONARY EMBOLISH (PE) (Cont'd)		
d) Major surgery (i) with prolonged immobilization (ii) without prolonged immobilization e) Minor surgery without immobilization	 D A A	
KNOWN THROMBOGENIC MUTATIONS (e.g., Factor V Leiden; Prothrombin mutation; Protein S, Protein C, and Antithrombin deficiencies)	A	**Clarification**: Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
SUPERFICIAL VENOUS THROMBOSIS a) Varicose veins b) Superficial thrombophlebitis	 A A	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE* a) Current ischaemic heart disease b) History of ischaemic heart disease	 D C	
STROKE (history of cerebrovascular accident)	C	
KNOWN HYPERLIPIDAEMIAS	A	**Clarification:** Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
VALVULAR HEART DISEASE a) Uncomplicated b) Complicated (pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)	 C S	 **Clarification:** The woman requires prophylactic antibiotics. **Clarification:** The woman is at high risk for complications associated with anaesthesia and surgery. If the woman has atrial fibrillation that has not been successfully managed or current subacute bacterial endocarditis, the procedure should be delayed.

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	**Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
NEUROLOGIC CONDITIONS		
HEADACHES a) Non-migrainous (mild or severe) b) Migraine (i) without aura *Age < 35* *Age ≥ 35* (ii) with aura (at any age)	 A A A A	
EPILEPSY	C	
DEPRESSIVE DISORDERS		
DEPRESSIVE DISORDERS	C	
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS		
VAGINAL BLEEDING PATTERNS a) Irregular pattern ***without*** heavy bleeding b) Heavy or prolonged bleeding (includes regular and irregular patterns)	 A A	
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition) Before evaluation	 D	 **Clarification:** The condition must be evaluated before the procedure is performed.
ENDOMETRIOSIS	S	
BENIGN OVARIAN TUMOURS (including cysts)	A	
SEVERE DYSMENORRHOEA	A	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	**Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
TROPHOBLAST DISEASE		
a) Benign gestational trophoblastic disease	A	
b) Malignant gestational trophoblastic disease	D	
CERVICAL ECTROPION	A	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	A	
CERVICAL CANCER* (awaiting treatment)	D	
BREAST DISEASE		
a) Undiagnosed mass	A	
b) Benign breast disease	A	
c) Family history of cancer	A	
d) Breast cancer		
(i) current	C	
(ii) past and no evidence of current disease for 5 years	A	
ENDOMETRIAL CANCER*	D	
OVARIAN CANCER*	D	
UTERINE FIBROIDS*		
a) Without distortion of the uterine cavity	C	
b) With distortion of the uterine cavity	C	
PELVIC INFLAMMATORY DISEASE (PID)*		
a) Past PID (assuming no current risk factors for STIs)		**Clarification:** A careful pelvic examination must be performed to rule out recurrent or persistent infection and to determine the mobility of the uterus.
(i) with subsequent pregnancy	A	
(ii) without subsequent pregnancy	C	
b) PID - current	D	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
STIs*		
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	D	**Clarification:** If no symptoms persist following treatment, sterilization may be performed.
b) Other STIs (excluding HIV and hepatitis)	A	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	A	
d) Increased risk of STIs	A	
HIV/AIDS		
HIGH RISK OF HIV	A	**Clarification:** No routine screening is needed. Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures. The use of condoms is recommended following sterilization.
HIV-INFECTED	A	
AIDS	S	**Clarification:** The presence of an AIDS-related illness may require that the procedure be delayed.
OTHER INFECTIONS		
SCHISTOSOMIASIS		
a) Uncomplicated	A	
b) Fibrosis of liver	C	**Clarification:** Liver function may need to be evaluated.
TUBERCULOSIS		
a) Non-pelvic	A	
b) Known pelvic	S	
MALARIA	A	
ENDOCRINE CONDITIONS		
DIABETES*		**Clarification:** If blood glucose is not well controlled, referral to a higher-level facility is recommended.
a) History of gestational disease	A	
b) Non-vascular disease:		**Clarification:** There is a possible decrease in healing and an increased risk of wound infection. Use of prophylactic antibiotics is recommended.
(i) non-insulin dependent	C	
(ii) insulin dependent	C	**Evidence:** Diabetic women were more likely to have complications when undergoing sterilization.[22]
c) Nephropathy/ retinopathy/neuropathy	S	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
DIABETES (Cont'd)		
d) Other vascular disease or diabetes of > 20 years' duration	S	
THYROID DISORDERS*		
a) Simple goitre	A	
b) Hyperthyroid	S	
c) Hypothyroid	C	
GASTROINTESTINAL CONDITIONS		
GALL-BLADDER DISEASE		
a) Symptomatic		
(i) treated by cholecystectomy	A	
(ii) medically treated	A	
(iii) current	D	
b) Asymptomatic	A	
HISTORY OF CHOLESTASIS		
a) Pregnancy-related	A	
b) Past COC-related	A	
VIRAL HEPATITIS*		
a) Active	D	**Clarification:** Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures.
b) Carrier	A	
CIRRHOSIS		
a) Mild (compensated)	C	**Clarification:** Liver function and clotting might be altered. Liver function should be evaluated.
b) Severe (decompensated)	S	
LIVER TUMOURS		
a) Benign (adenoma)	C	**Clarification:** Liver function and clotting might be altered. Liver function should be evaluated.
b) Malignant (hepatoma)	C	
ANAEMIAS		
THALASSAEMIA	C	
SICKLE-CELL DISEASE*	C	

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
IRON-DEFICIENCY ANAEMIA a) Hb < 7g/dl b) Hb ≥ 7 to < 10g/dl	 D C	**Clarification:** The underlying disease should be identified. Both preoperative Hb level and operative blood loss are important factors in women with anaemia. If peripheral perfusion is inadequate, this may decrease wound healing.
OTHER CONDITIONS RELEVANT ONLY FOR FEMALE SURGICAL STERILIZATION		
LOCAL INFECTION Abdominal skin infection	 D	**Clarification:** There is an increased risk of postoperative infection.
COAGULATION DISORDERS*	S	
RESPIRATORY DISEASES* a) Acute (bronchitis, pneumonia) b) Chronic (i) asthma (ii) bronchitis (iii) emphysema (iv) lung infection	 D S S S S	**Clarification:** The procedure should be delayed until the condition is corrected. There are increases in anaesthesia-related and other perioperative risks.
SYSTEMIC INFECTION OR GASTROENTERITIS*	D	
FIXED UTERUS DUE TO PREVIOUS SURGERY OR INFECTION*	S	
ABDOMINAL WALL OR UMBILICAL HERNIA	S	**Clarification:** Hernia repair and tubal sterilization should be performed concurrently, if possible.
DIAPHRAGMATIC HERNIA*	C	
KIDNEY DISEASE*	C	
SEVERE NUTRITIONAL DEFICIENCIES*	C	
PREVIOUS ABDOMINAL OR PELVIC SURGERY	C	**Evidence:** Women with previous abdominal or pelvic surgery were more likely to have complications when undergoing sterilization.[21, 22, 24-26]

* See also additional comments at end of table

FEMALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV (including during the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
STERILIZATION CONCURRENT WITH ABDOMINAL SURGERY		
a) Elective	C	
b) Emergency (without previous counselling)	D	
c) Infectious condition	D	
STERILIZATION CONCURRENT WITH CAESAREAN SECTION*	A	

* See also additional comments at end of table

B. Male surgical sterilization

MALE SURGICAL STERILIZATION	**Sterilization does not protect against STI/HIV. If there is risk of STI/HIV, the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY		
YOUNG AGE	C	**Clarification:** Young men, like all men, should be counselled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods. **Evidence:** Men who underwent vasectomy at young ages were more likely to have the procedure reversed than those who underwent vasectomy at older ages.[18]
DEPRESSIVE DISORDERS		
DEPRESSIVE DISORDERS	C	
HIV/AIDS		
HIGH RISK OF HIV **HIV-INFECTED**	A A	**Clarification:** No routine screening is needed. Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures. The use of condoms is recommended following sterilization.
AIDS	S	**Clarification:** The presence of an AIDS-related illness may require a delay in the procedure.
ENDOCRINE CONDITIONS		
DIABETES*	C	
ANAEMIAS		
SICKLE-CELL DISEASE	A	
OTHER CONDITIONS RELEVANT ONLY FOR MALE SURGICAL STERILIZATION		
LOCAL INFECTIONS*		
a) scrotal skin infection	D	
b) active STI	D	
c) balanitis	D	
d) epididymitis or orchitis	D	
COAGULATION DISORDERS*	S	
PREVIOUS SCROTAL INJURY	C	
SYSTEMIC INFECTION OR GASTROENTERITIS*	D	

* See also additional comments at end of table

MALE SURGICAL STERILIZATION	Sterilization does not protect against STI/HIV. If there is risk of STI/HIV, the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.	
CONDITION	**CATEGORY**	**CLARIFICATIONS/EVIDENCE**
LARGE VARICOCELE*	C	
LARGE HYDROCELE*	C	
FILARIASIS; ELEPHANTIASIS*	D	
INTRASCROTAL MASS*	D	
CRYPTORCHIDISM	C	**Clarification:** If cryptorchidism is bilateral, and fertility has been demonstrated, this will require extensive surgery to locate the vas, and this becomes category S. If the cryptorchidism is unilateral, and fertility has been demonstrated, vasectomy may be performed on the normal side and semen analysis performed, as per routine. If the man continues to have a persistent presence of sperm, more extensive surgery may be required to locate the other vas, and this becomes category S.
INGUINAL HERNIA*	S	

* See also additional comments at end of table

Additional comments

A. Female surgical sterilization

PARITY

Nulliparous: Nulliparous women, like all women, should be counselled about the permanency of sterilization and the availability of alternative, long-term, highly effective methods.

POSTPARTUM

< 7 days postpartum: Sterilization can be safely performed immediately postpartum.

7 to < 42 days: There is an increased risk of complications when the uterus has not fully involuted.

Pre-eclampsia/eclampsia: There are increased anaesthesia-related risks.

Prolonged rupture of membranes, 24 hours or more: There is an increased risk of postoperative infection.

Puerperal sepsis, intrapartum or puerperal fever: There is an increased risk of postoperative infection.

Severe antepartum or postpartum haemorrhage: The woman may be anaemic and unable to tolerate further blood loss.

Severe trauma to the genital tract: cervical or vaginal tear at time of delivery: There may have been significant blood loss and anaemia. The procedure may be more painful.

Uterine rupture or perforation: There may have been significant blood loss or damage to abdominal contents.

POST-ABORTION

Post-abortal sepsis or fever: There is an increased risk of postoperative infection.

Severe post-abortal haemorrhage: The woman may be anaemic and unable to tolerate further blood loss.

Severe trauma to the genital tract: cervical or vaginal tear at time of abortion: The woman may be anaemic and unable to tolerate further blood loss. The procedure may be more painful.

Uterine perforation: There may have been significant blood loss or damage to abdominal contents.

Acute haematometra: The woman may be anaemic and unable to tolerate further blood loss.

MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE

When multiple risk factors are present concurrently, the woman may be at high risk for complications associated with anaesthesia and surgery.

CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE

The woman is at high risk for complications associated with anaesthesia and surgery.

CERVICAL CANCER (awaiting treatment)

In general, the treatment renders a woman sterile.

ENDOMETRIAL CANCER

In general, the treatment renders a woman sterile.

OVARIAN CANCER

In general, the treatment renders a woman sterile.

UTERINE FIBROIDS

Depending on the size and location of the fibroids, it might be difficult to localize the tubes and mobilize the uterus.

PELVIC INFLAMMATORY DISEASE (PID)

PID can lead to an increased risk of post-sterilization infection or adhesions.

STIs

There is an increased risk of postoperative infection.

DIABETES

There is a risk of hypoglycaemia or ketoacidosis.

THYROID DISORDERS

The woman is at high risk for complications associated with anaesthesia and surgery.

VIRAL HEPATITIS

The woman is at high risk for complications associated with anaesthesia and surgery.

SICKLE-CELL DISEASE
There is an increased risk of pulmonary, cardiac or neurologic complications and possible increased risk of wound infection.

COAGULATION DISORDERS
Women with coagulation disorders are at increased risk of haematologic complications of surgery.

RESPIRATORY DISEASES
For laparoscopy, the woman may experience acute cardiorespiratory complications induced by pneumoperitoneum or the Trendelenburg position.

SYSTEMIC INFECTION OR GASTROENTERITIS
There are increased risks of postoperative infection, complications from dehydration, and anaesthesia-related complications.

FIXED UTERUS DUE TO PREVIOUS SURGERY OR INFECTION
Decreased mobility of the uterus, fallopian tubes and bowel may make laparoscopy and minilaparotomy difficult and increase the risk of complications.

DIAPHRAGMATIC HERNIA
For laparoscopy, the woman may experience acute cardiorespiratory complications induced by pneumoperitoneum or the Trendelenburg position.

KIDNEY DISEASE
Blood clotting may be impaired. There may be an increased risk of infection and hypovolemic shock. Condition may cause baseline anaemia, electrolyte disturbances and abnormalities in drug metabolism and excretion.

SEVERE NUTRITIONAL DEFICIENCIES
There may be an increased risk of wound infection and impaired healing.

STERILIZATION CONCURRENT WITH CAESAREAN SECTION
Concurrent sterilization does not increase the risk of complications in a surgically stable client.

B. Male surgical sterilization

COAGULATION DISORDERS
Bleeding disorders lead to an increased risk of postoperative haematoma formation which, in turn, leads to an increased risk of infection.

DIABETES
Diabetics are more likely to get postoperative wound infections. If signs of infection appear, treatment with antibiotics needs to be given.

LOCAL INFECTIONS
There is an increased risk of postoperative infection.

SYSTEMIC INFECTION OR GASTROENTERITIS
There is an increased risk of postoperative infection.

LARGE VARICOCELE
The vas may be difficult or impossible to locate; a single procedure to repair varicocele and perform a vasectomy decreases the risk of complications.

LARGE HYDROCELE
The vas may be difficult or impossible to locate; a single procedure to repair hydrocele and perform a vasectomy decreases the risk of complications.

FILARIASIS; ELEPHANTIASIS
If elephantiasis involves the scrotum, it may be impossible to palpate the spermatic cord and testis.

INTRASCROTAL MASS
This may indicate an underlying disease.

INGUINAL HERNIA
Vasectomy can be performed concurrent with hernia repair.

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SUMMARY TABLES								
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I = Initiation, **C** = Continuation								
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY								
PREGNANCY	NA*	NA*	NA*	NA*	NA*	NA*	4*	4*
AGE	Menarche to <40=1 ≥40=2	Menarche to <40=1 ≥40=2		Menarche to <18=1 18-45=1 >45=1	Menarche to <18=2 18-45=1 >45=2	Menarche to <18=1 18-45=1 >45=1	Menarche to <20=2 ≥20=1	Menarche to <20=2 ≥20=1
PARITY								
a) Nulliparous	1	1	1	1	1	1	2	2
b) Parous	1	1	1	1	1	1	1	1
BREASTFEEDING								
a) < 6 weeks postpartum	4	4	4	3*	3*	3*		
b) 6 weeks to < 6 months (primarily breastfeeding)	3	3	3	1	1	1		
c) ≥ 6 months postpartum	2	2	2	1	1	1		
POSTPARTUM (non-breastfeeding women)								
a) < 21 days	3	3	3	1	1	1		
b) ≥ 21 days	1	1	1	1	1	1		
POSTPARTUM (breastfeeding or non-breastfeeding women, including post-caesarean section)								
a) < 48 hours							2	3
b) ≥ 48 hours to <4 weeks							3	3
c) ≥ 4 weeks							1	1
d) Puerperal sepsis							4	4
POST-ABORTION								
a) First trimester	1*	1*	1*	1*	1*	1*	1*	1*
b) Second trimester	1	1	1	1	1	1	2	2
c) Immediate post-septic abortion	1	1	1	1	1	1	4	4
PAST ECTOPIC PREGNANCY	1	1	1	2	1	1	1	1

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES								
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**	**LNG-IUD**
I = Initiation, **C** = Continuation								
HISTORY OF PELVIC SURGERY (including caesarean section) (see also postpartum section)	1	1	1	1	1	1	1	1
SMOKING								
a) Age < 35	2*	2	2	1	1	1	1	1
b) Age ≥ 35								
(i) <15 cigarettes/day	3*	2	3	1	1	1	1	1
(ii) ≥15 cigarettes/day	4*	3	4	1	1	1	1	1
OBESITY ≥30 kg/m^2 body mass index (BMI)	2	2	2	1	1	1	1	1
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*
CARDIOVASCULAR DISEASE								
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	3/4*	3/4*	3/4*	2*	3*	2*	1	2
HYPERTENSION								
a) History of hypertension where blood pressure CANNOT be evaluated (including hypertension during pregnancy)	3*	3*	3*	2*	2*	2*	1	2
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	3*	3*	3*	1*	2*	1*	1	1
c) Elevated blood pressure levels (properly taken measurements)								
(i) systolic 140-159 or diastolic 90-99	3	3	3	1	2	1	1	1
(ii) systolic >160 or diastolic >100	4	4	4	2	3	2	1	2
d) Vascular disease	4	4	4	2	3	2	1	2

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SUMMARY TABLES								
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**	**LNG-IUD**
I = Initiation, **C** = Continuation								
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	2	2	2	1	1	1	1	1
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)								
a) History of DVT/PE	4	4	4	2	2	2	1	2
b) Current DVT/PE	4	4	4	3	3	3	1	3
c) Family history (first-degree relatives)	2	2	2	1	1	1	1	1
d) Major surgery								
(i) with prolonged immobilization	4	4	4	2	2	2	1	2
(ii) without prolonged immobilization	2	2	2	1	1	1	1	1
e) Minor surgery without immobilization	1	1	1	1	1	1	1	1
KNOWN THROMBOGENIC MUTATIONS (e.g. Factor V Leiden; Prothrombin mutation; Protein S, Protein C and Antithrombin deficiencies)	4*	4*	4*	2*	2*	2*	1*	2*
SUPERFICIAL VENOUS THROMBOSIS								
a) Varicose veins	1	1	1	1	1	1	1	1
b) Superficial thrombophlebitis	2	2	2	1	1	1	1	1
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE	4	4	4	I: 2 / C: 3	3	I: 2 / C: 3	1	I: 2 / C: 3
STROKE (history of cerebrovascular accident)	4	4	4	I: 2 / C: 3	3	I: 2 / C: 3	1	2
KNOWN HYPERLIPIDAEMIAS (screening is NOT necessary for safe use of contraceptive methods)	2/3*	2/3*	2/3*	2*	2*	2*	1*	2*

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES								
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**	**LNG-IUD**
I = Initiation, **C** = Continuation								
VALVULAR HEART DISEASE								
a) Uncomplicated	2	2	2	1	1	1	1	1
b) Complicated (pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)	4	4	4	1	1	1	2*	2*
NEUROLOGIC CONDITIONS								
HEADACHES	I C	I C	I C	I C	I C	I C		I C
a) Non-migrainous (mild or severe)	1* 2*	1* 2*	1* 2*	1* 1*	1* 1*	1* 1*	1*	1* 1*
b) Migraine								
(i) without aura								
Age <35	2* 3*	2* 3*	2* 3*	1* 2*	2* 2*	2* 2*	1*	2* 2*
Age ≥35	3* 4*	3* 4*	3* 4*	1* 2*	2* 2*	2* 2*	1*	2* 2*
(ii) with aura (at any age)	4* 4*	4* 4*	4* 4*	2* 3*	2* 3*	2* 3*	1*	2* 3*
EPILEPSY	1*	1*	1*	1*	1*	1*	1	1
DEPRESSIVE DISORDERS								
DEPRESSIVE DISORDERS	1*	1*	1*	1*	1*	1*	1*	1*
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS								
VAGINAL BLEEDING PATTERNS								I C
a) Irregular pattern ***without*** heavy bleeding	1	1	1	2	2	2	1	1 1
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	1*	1*	1*	2*	2*	2*	2*	1* 2*
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition)							I C	I C
Before evaluation	2*	2*	2*	2*	3*	3*	4* 2*	4* 2*
ENDOMETRIOSIS	1	1	1	1	1	1	2	1
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	1	1	1	1	1

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES								
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**	**LNG-IUD**
I = Initiation, **C** = Continuation								
SEVERE DYSMENORRHOEA	1	1	1	1	1	1	2	1
TROPHOBLAST DISEASE								
a) Benign gestational trophoblastic disease	1	1	1	1	1	1	3	3
b) Malignant gestational trophoblastic disease	1	1	1	1	1	1	4	4
CERVICAL ECTROPION	1	1	1	1	1	1	1	1
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	2	2	2	1	2	2	1	2
CERVICAL CANCER (awaiting treatment)							I / C	I / C
	2	2	2	1	2	2	4 / 2	4 / 2
BREAST DISEASE								
a) Undiagnosed mass	2*	2*	2*	2*	2*	2*	1	2
b) Benign breast disease	1	1	1	1	1	1	1	1
c) Family history of cancer	1	1	1	1	1	1	1	1
d) Cancer								
(i) current	4	4	4	4	4	4	1	4
(ii) past and no evidence of current disease for 5 years	3	3	3	3	3	3	1	3
ENDOMETRIAL CANCER							I / C	I / C
	1	1	1	1	1	1	4 / 2	4 / 2
OVARIAN CANCER							I / C	I / C
	1	1	1	1	1	1	3 / 2	3 / 2
UTERINE FIBROIDS								
a) Without distortion of the uterine cavity	1	1	1	1	1	1	1	1
b) With distortion of the uterine cavity	1	1	1	1	1	1	4	4
ANATOMICAL ABNORMALITIES								
a) That distort the uterine cavity							4	4
b) That do not distort the uterine cavity							2	2

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES										
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**		**LNG-IUD**	
I = Initiation, **C** = Continuation										
PELVIC INFLAMMATORY DISEASE (PID)										
a) Past PID (assuming no current risk factors of STIs)							I	C	I	C
(i) with subsequent pregnancy	1	1	1	1	1	1	1	1	1	1
ii) without subsequent pregnancy	1	1	1	1	1	1	2	2	2	2
b) PID - current	1	1	1	1	1	1	4	2*	4	2*
STIs							I	C	I	C
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	1	1	1	4	2*	4	2*
b) Other STIs (excluding HIV and hepatitis)	1	1	1	1	1	1	2	2	2	2
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	1	1	1	2	2	2	2
d) Increased risk of STIs	1	1	1	1	1	1	2/3*	2	2/3*	2
HIV/AIDS										
HIGH RISK OF HIV							I	C	I	C
	1	1	1	1	1	1	2	2	2	2
HIV-INFECTED	1	1	1	1	1	1	2	2	2	2
AIDS	1*	1*	1*	1*	1*	1*	3	2*	3	2*
Clinically well on ARV therapy	See ANTIRETROVIRAL THERAPY below						2	2	2	2
OTHER INFECTIONS										
SCHISTOSOMIASIS										
a) Uncomplicated	1	1	1	1	1	1	1		1	
b) Fibrosis of the liver	1	1	1	1	1	1	1		1	
TUBERCULOSIS							I	C	I	C
a) Non-pelvic	1*	1*	1*	1*	1*	1*	1	1	1	1
b) Known pelvic	1*	1*	1*	1	1	1	4	3	4	3
MALARIA	1	1	1	1	1	1	1		1	

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES								
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**	**LNG-IUD**
I = Initiation, **C** = Continuation								
ENDOCRINE CONDITIONS								
DIABETES								
a) History of gestational disease	1	1	1	1	1	1	1	1
b) Non-vascular disease								
(i) non-insulin dependent	2	2	2	2	2	2	1	2
(ii) insulin dependent	2	2	2	2	2	2	1	2
c) Nephropathy/ retinopathy/ neuropathy	3/4*	3/4*	3/4*	2	3	2	1	2
d) Other vascular disease or diabetes of >20 years' duration	3/4*	3/4*	3/4*	2	3	2	1	2
THYROID DISORDERS								
a) Simple goitre	1	1	1	1	1	1	1	1
b) Hyperthyroid	1	1	1	1	1	1	1	1
c) Hypothyroid	1	1	1	1	1	1	1	1
GASTROINTESTINAL CONDITIONS								
GALL-BLADDER DISEASE								
a) Symptomatic								
(i) treated by cholecystectomy	2	2	2	2	2	2	1	2
(ii) medically treated	3	2	3	2	2	2	1	2
(iii) current	3	2	3	2	2	2	1	2
b) Asymptomatic	2	2	2	2	2	2	1	2
HISTORY OF CHOLESTASIS								
a) Pregnancy-related	2	2	2	1	1	1	1	1
b) Past COC-related	3	2	3	2	2	2	1	2
VIRAL HEPATITIS								
a) Active	4	3/4*	4*	3	3	3	1	3
c) Carrier	1	1	1	1	1	1	1	1
CIRRHOSIS								
a) Mild (compensated)	3	2	3	2	2	2	1	2
b) Severe (decompensated)	4	3	4	3	3	3	1	3

* Please consult the tables in the text for a clarification to this classification

SUMMARY TABLES										
CONDITION	**COC**	**CIC**	**P/R**	**POP**	**DMPA NET-EN**	**LNG/ ETG Implants**	**Cu-IUD**		**LNG-IUD**	
I = Initiation, **C** = Continuation										
LIVER TUMOURS										
a) Benign (adenoma)	4	3	4	3	3	3	1		3	
b) Malignant (hepatoma)	4	3/4	4	3	3	3	1		3	
ANAEMIAS										
THALASSAEMIA	1	1	1	1	1	1	2		1	
SICKLE CELL DISEASE	2	2	2	1	1	1	2		1	
IRON-DEFICIENCY ANAEMIA	1	1	1	1	1	1	2		1	
DRUG INTERACTIONS										
DRUGS WHICH AFFECT LIVER ENZYMES										
a) Rifampicin	3*	2*	3*	3*	2*	3*	1		1	
b) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*	2*	3*	3*	2	3	1		1	
ANTIBIOTICS (excluding rifampicin)										
a) Griseofulvin	2	1	2	2	1	2	1		1	
b) Other antibiotics	1	1	1	1	1	1	1		1	
ANTIRETROVIRAL THERAPY							I	C	I	C
	2*	2*	2*	2*	2*	2*	2/3*	2	2/3*	2

* Please consult the tables in the text for a clarification to this classification

Annex 1. COCs and antiretroviral therapies

Few data from small, mostly unpublished studies suggest that the pharmacokinetics of a single dose of COCs may be altered by various antiretroviral (ARV) therapies. However, no clinical outcome studies have been conducted and the clinical significance of such changes, especially when the COCs have not been allowed to reach steady-state, is unknown. The following table summarizes the evidence to date regarding the effects of ARVs on contraceptive steroid levels and the effects of hormonal contraceptives on ARV levels.

Table 1. Pharmacokinetic COC-ARV drug interactions.

ARV	Contraceptive steroid levels	ARV levels
Protease inhibitors		
Nelfinavir	↓	No data
Ritonavir	↓	No data
Lopinavir/ritonavir	↓	No data
Atazanavir	↑	No data
Amprenavir	↑	↓
Indinavir	↑	No data
Saquinavir	No data	No change
Non-nucleoside reverse transcriptase inhibitors		
Nevirapine	↓	No change
Efavirenz	↑	No change
Delavirdine	?↑	No data

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