Medical eligibility criteria for contraceptive use

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Fourth edition, 2009

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Male surgical sterilization Ring ECPs

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Guidance for postpartum use of combined hormonal contraceptives, and for use of the lactational amenorrhoea method among HIV-infected women has been updated since this publication first appeared on the web in 2009.

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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 third edition of Medical eligibility criteria for contraceptive use, published in 2004, and summarizes the main recommendations of an expert Working Group meeting held at the World Health Organization, Geneva, 1-4 April 2008. (Please see Annex 2 for the list of participants.) The Working Group brought together 43 participants from 23 countries, including nine agency representatives. 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 patch (P), combined vaginal ring (R), combined injectable contraceptives (CICs), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel (LNG) and etonogestrel (ETG) implants, emergency contraceptive pills (ECPs), copper-bearing 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/reproductivehealth). 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 evidencebased 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, The Decision-making tool for family planning clients and providers and Family planning: a global handbook for providers, are 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.

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 35 years, there have been significant advances in the development of new contraceptive technologies, including transitions from high-dose

to low-dose combined oral contraceptives, and from inert to copper-bearing and levonorgestrel-releasing vaginal IUDs. In addition, combined injectable contraceptives, a combined hormonal patch and vaginal 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

Figure 1. The four cornerstones of family planning guidance



Medical eligibility criteria for contraceptive use

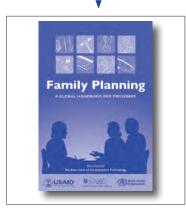


Selected practice recommendations for contraceptive use

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



Decision-making tool for family planning clients and providers



Family planning: a global handbook for providers

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

Process for assuring that the guidelines remain current:

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

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

Reproductive and sexual health care, including family planning services and information, is recognized not only as a key intervention for improving the health of 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. This includes people with disabilities, as specifically mandated under the Convention on the Rights of Persons with Disabilities (articles 23.1 and 25.a).1 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. Information should be presented using language and formats that can be easily understood and accessed by the client.

¹ Convention on the Rights of Persons with Disabilities. United Nations Enable, Rights and Dignity of Persons with Disabilities, 2007 (http://www.un.org/disabilities/, accessed on 13 January 2009).

- 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 and accessible facilities must be available in order for those methods to be offered, and appropriate infection-prevention procedures must be followed.
- 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 the 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).

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

	% of women experie pregnancy within t	% of women continuing use at one year ³		
Method (1)	Typical use¹ (2)	Perfect use ² (3)	(4)	
No method ⁴	85	85		
Spermicides ⁵	29	18	42	
Withdrawal	27	4	43	
Fertility awareness-based methods	25		51	
Standard days method ⁶		5		
Two day method ⁶		4		
Ovulation method ⁶		3		
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 progestogen-only pill	8	0.3	68	
Evra patch	8	0.3	68	
NuvaRing	8	0.3	68	
Depo-Provera	3	0.3	56	
Combined injectable (Lunelle) ⁹	3	0.05	56	
IUD				
ParaGard (copper T)	0.8	0.6	78	
Mirena (LNG-IUS)	0.2	0.2	80	
Implanon	0.05	0.05	84	
Female sterilization	0.5	0.5	100	
Male sterilization	0.15	0.10	100	

Emergency contraceptive pills: treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%. 10

Lactational amenorrhea method: LAM is a highly effective, temporary method of contraception.¹¹

Source: Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive technology: nineteenth revised edition.* New York NY: Ardent Media, 2007.

Notes:

- 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, fertility awareness-based methods, 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 the text for the derivation of estimates for the other methods.
- 2. Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate 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 such populations, 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. The Ovulation and Two Day methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19.
- 7. With spermicidal cream or jelly.
- 8. Without spermicides.
- 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.
- 10. The treatment schedule is one dose within 120 hours after unprotected intercourse, and a second dose 12 hours after the first dose. Both doses of Plan B can be taken at the same time. Plan B (1 dose is 1 white pill) is the only dedicated product specifically marketed for emergency contraception. The Food and Drug Administration has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (1 dose is 2 white pills), Levlen or Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills), Tri-Levlen or Triphasil (1 dose is 4 yellow pills), Jolessa, Portia, Seasonale, or Trivora (1 dose is 4 pink pills), Seasonique (1 dose is 4 light-blue-green pills), Empresse (one dose is 4 orange pills), Alesse, Lessina, or Levlite, (1 dose is 5 pink pills), Aviane (one dose is 5 orange pills), and Lutera (one dose is 5 white pills).
- 11. 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.

EFFECTIVENESS OF METHOD

Contraceptive choice is in part dependent on the effectiveness of the contraceptive method in preventing unplanned pregnancy, which, in turn, is dependent for some methods not only on the protection afforded by the method itself, but also on how consistently and correctly it is used. Table 1 compares the percentage of women experiencing an unintended pregnancy during the first year of contraceptive method use when the method is used perfectly (consistently and correctly) and when it is used typically. Both consistent and correct use can vary greatly with such characteristics as age, income, users' 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.

CONDITIONS THAT EXPOSE A WOMAN TO INCREASED RISK AS A RESULT OF UNINTENDED PREGNANCY

Women with conditions that may make unintended pregnancy an unacceptable health risk should be advised that, because of their relatively higher typicaluse 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.

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.

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

Epilepsy

High blood pressure (systolic >160 mm Hg or diastolic >100 mm Hg)¹

HIV/AIDS²

Ischaemic heart disease

Malignant gestational trophoblastic disease

Malignant liver tumours (hepatoma) and hepatocellular carcinoma of the liver (HCA)

Schistosomiasis with fibrosis of the liver

Severe (decompensated) cirrhosis

Sickle cell disease

STI²

Stroke

Systemic lupus erythematosus (SLE)

Thrombogenic mutations

Tuberculosis

Notes:

- 1. 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.
- 2. 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.

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 healthcare 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.

The second revision of the document was 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 comprised 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.

This fourth edition of the document is based on the recommendations of an expert Working Group meeting held at WHO on 1–4 April 2008, that brought together 43 participants from 23 countries, including nine agency representatives. The expert Working Group comprised: international family planning experts, including clinicians, epidemiologists, policymakers, programme managers; experts in evidence identification and synthesis; experts in pharmacology; and users of the guideline. All members of the expert Working Group were asked to declare any conflict of interest; three of the experts declared a conflict of interest relevant to the subject matter of the meeting. They were not asked to withdraw from recommendation formulation.

At the conclusion of the meeting, the expert Working Group was unable to achieve consensus on the safety of using progestogen-only contraception

1 Dr Glasier: Works at a clinic that receives research support from four companies that manufacture various contraceptive products. Dr Shelton: Has shareholdings in a pharmaceutical company that manufactures antiretroviral therapies. Dr Weisberg: Receives funding for contraceptive research from four contraceptive manufacturers; serves on the advisory board of a manufacturer of the vaccine against human papilloma virus and serves on an advisory board for contraceptive education funded by a contraceptive manufacturer.

among breastfeeding women less than six weeks postpartum, and the Group determined that additional expertise was necessary prior to revising any recommendations for this condition. Therefore, at the request of the expert Working Group, WHO convened a technical consultation on 22 October 2008 to thoroughly evaluate the evidence surrounding hormonal contraceptive use during lactation and its effects on the neonate. The expert Working Group delegated the responsibility for evaluating the scientific evidence, and developing new recommendations if warranted, to the Guidelines Steering Group. The consultation brought together members of the Guidelines Steering Group and four researchers with expertise on the effects of steroidal compounds on neonatal organ systems and the pharmacology and metabolism of hormones present in breast milk. All participants in the consultation were asked to declare any conflict of interest; one participant declared a conflict of interest relevant to the subject matter.2 She was not asked to withdraw from recommendation formulation.

Rarely, new evidence will come to light between meetings of the expert Working Group which merits evaluation and potentially, revision of the recommendations contained within the *Medical eligibility* criteria for contraceptive use. In these cases, the Guideline Steering Group is tasked with evaluating such evidence, and confirming existing guidance or, if necessary, issuing interim guidance. Following the expert Working Group meeting, WHO became aware of new evidence regarding the risk of venous thromboembolism (VTE) in postpartum women. At the request of the Guideline Steering Group, WHO convened a technical consultation on 26 January 2010 via teleconference to review thoroughly the published evidence in this area. The teleconference brought together members of the Guideline Steering Group and three experts on VTE during the postpartum period. All participants in the consultation were asked to declare any conflict of interest; two participants declared a conflict of interest relevant to the subject matter.3 They were not asked to withdraw from recommendation formulation.

² Dr Glasier: Works at a clinic that receives research support from four companies that manufacture various contraceptive products.

³ Dr Glasier: Works at a clinic that receives research support from four companies that manufacture various contraceptive products. Dr Hannaford: Works at an academic centre that has received financial support from two companies that manufacture various contraceptive products.

EVIDENCE IDENTIFICATION AND SYNTHESIS

Using a system that identifies new evidence on an ongoing basis (the Continuous Identification of Research Evidence, or CIRE system), 1 WHO identified recommendations from the third edition of the Medical eligibility criteria for contraceptive use for which new evidence was available. Systematic reviews were then conducted to appraise the complete body of evidence for those recommendations, as well as for one new medical condition that was added to the recommendations: systemic lupus erythematosus. 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. To conduct the systematic reviews. studies were identified using the CIRE system as well as through searches of PubMed and The Cochrane Library from database inception to January 2008. The search also included reviews of reference lists in articles identified by the literature search and contact with experts in the field. The strength and quality of the evidence was graded using the United States Preventive Task Force system.2

The systematic reviews were provided to the expert Working Group prior to the meeting and served as the basis for the Group's deliberations during the meeting. 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. The Group arrived at its recommendations through consensus.

For most recommendations (method/condition combinations), there are a limited number of studies

Mohllajee AP, Curtis KM, Flanagan RG, Rinehart W, Gaffield ML, Peterson HB. Keeping up with evidence: a new system for WHO's evidence-based family planning guidance. *American Journal of Preventive Medicine* 2005;28:483-490. 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 third edition included 1705 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 31 March 2008, proposed that the expert Working Group consider only those recommendations from the third edition for which there was new evidence or for which a compelling case had been made. The Working Group concurred with this proposal on 1 April 2008.

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 "Clar-

² Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM et al. Current methods of the US Preventive Service Task Force: a review of the process. *American Journal of Preventive Medicine* 2001;20:21-35.

ifications/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 expert Working Group developed 86 new recommendations and revised 165 existing recommendations for the 4th edition of the Medical eligibility criteria for contraceptive use. As a result of the deliberations by the group, the 4th edition of the Medical eligibility criteria for contraceptive use will include the medical condition, systemic lupus erythematosus (SLE) and 12 new subconditions will be added to medical conditions already existing in the 3rd edition. The 12 subconditions are: obesity and <18 years of age; deep venous thrombosis/pulmonary embolism (DVT/PE) and established on anticoagulant therapy; acute or flare for viral hepatitis; focal nodular hyperplasia of the liver; three classes of antiretroviral therapies (nucleoside reverse transcriptase inhibitors [NRTIs], non-nucleoside reverse transcriptase inhibitors [NNRTIs], ritonavir-boosted protease inhibitors [PIs]); lamotrigine (an anticonvulsant); and four classes of antimicrobials (broad-spectrum antibiotics, antifungals, antiparasitics, and rifabutin with rifampicin).

All members of the Guideline Steering Group and the Working Group approved the 1870 recommendations at the completion of the meeting on 4 April 2008.

At the conclusion of the meeting, however, the expert Working Group was unable to achieve consensus on the safety of using progestogen-only contraception among breastfeeding women less than six weeks postpartum, and underscored the need to seek addition expertise prior to revising any recommendations for this condition. Therefore, WHO convened a technical consultation on 22 October 2008 to evaluate thoroughly all scientific evidence on this topic. The consultation brought together members of the Guidelines Steering Group and four researchers with expertise in the following disciplines: neonatology, neurology, neuroscience, and paediatrics. Acting on behalf of the expert Working Group, the Guideline Steering Group determined that the current recommendations for progestogen-use among lactating women during the first six weeks postpartum should remain unchanged at the completion of the consultation on 22 October 2008. These recommendations will be reviewed by the full expert Working Group during the next Working Group meeting.

Through efforts to monitor the publication of new research evidence in order to ensure that the guid-

ance in the Medical eligibility criteria for contraceptive use is up-to-date, WHO identified new evidence regarding the risk of venous thromboembolism (VTE) in postpartum women, which indicated the need to re-evaluate recommendations for non-breastfeeding women during the first six weeks postpartum. A systematic review of the topic was prepared and sent to the Guideline Steering Group for their appraisal. Further, a systematic review was prepared on the timing of returning fertility in postpartum, non-lactating women. In light of this evidence, the Guideline Steering Group determined that WHO should re-consider its recommendations regarding use of combined hormonal contraceptives during the postpartum period, and requested that the WHO Secretariat convene a technical consultation to address this topic. Therefore, WHO convened a technical consultation on 26 January 2010 via teleconference to thoroughly review the available scientific evidence in the area. Acting on behalf of the expert Working Group, the Guideline Steering Group issued interim guidance. expanding from eight to 20 the recommendations for postpartum, non-breastfeeding women to reflect this evidence.

These recommendations, and the evidence which supported their development, will be reviewed by the full expert Working Group during the next Working Group meeting.

The Guideline Steering Group approved the 20 updated recommendations at the completion of the teleconference on 26 January 2010.

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. As shown below, 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.

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. A family planning provider may want to consult an expert in the underlying condition.

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

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.

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,

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 category was not given by the Working Group but for which clarifications have been provided.

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

CATEGORY	WITH CLINICAL JUDGEMENT	WITH LIMITED CLINICAL JUDGEMENT
1	Use method in any circumstances	Yes
2	Generally use the method	(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	

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.

INTRODUCING GUIDELINES INTO NATIONAL PROGRAMMES

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

Guidance for countries on the introduction of sexual and reproductive health guidelines, including those for medical eligibility criteria for contraceptive use, is available in the document, *Introducing WHO's sexual* and reproductive health guidelines and tools into national programmes. This document is designed to be used by policy-makers, programme managers, and other health professionals who are embarking on a process to introduce evidence-based practices in sexual and reproductive health into their national or local programmes. Within the document, six overarching principles are recommended for the effective adaptation and implementation of WHO guidance on sexual and reproductive health into a national programme. These principles include: building consensus; building on what exists; identifying possible barriers and facilitating factors; ensuring that adaptations are evidence based; planning scale-up from the beginning; and implementing a range of interventions to change provider practices.

To introduce the *Medical eligibility criteria for* contraceptive use, WHO suggests countries or local authorities follow a six-step process. These steps comprise: planning for advocacy; conducting a situation analysis; adapting the guidance to fit a country's needs, circumstances, and context; designing an implementation strategy; pilot testing an evaluation; and, lastly, advocacy and scale-up. This process may vary depending upon whether the guidance is being introduced for the first time, or is being used to update existing service delivery guidelines. Throughout these steps, WHO stresses the importance that the process for introducing guidance is collaborative and participatory to foster ownership and buy-in among policy-makers, professional bodies and other national experts.

CLIENTS WITH SPECIAL NEEDS

People with disabilities

Medical eligibility criteria address contraceptive use by people with specific medical conditions. In addition, contraceptive provision to people with disabilities may require further considerations. Decisions on appropriate contraception must take into account the nature of the disability and the nature of the method, as well as the expressed desires of the individual. For example, some barrier methods may be difficult to use for those with limited manual dexterity; COCs may not be a preferred method for women with impaired circulation or immobile extremities even in the absence of known thrombogenic mutations because of concerns about an increased risk of DVT; and other methods will be preferable for individuals with intellectual or mental health disabilities who have difficulty remembering to take daily medications. For women who have difficulty with menstrual hygiene, the impact of the contraceptive method on menstrual cycles should also be considered.

Decisions must be based upon informed choice, after adequate sexual health education. Where the nature of the impairment does not allow for independent informed choice, contraceptives should be provided only after a process of supported decision-making including the client as well as relevant parties such as a personal ombudsman, support persons or guardians. The reproductive rights of the individual must be upheld in any such decisions. It is especially important to ensure that decisions about sterilization of people with disabilities are made in an ethical manner.

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 progestogenonly 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 the 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 THIRD EDITION

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

It is expected that the recommendations in the 4th edition of the *Medical eligibility criteria for contraceptive use* will remain valid until 2012. The Department of Reproductive Health and Research at WHO Headquarters in Geneva will be responsible for initiating a review of the guideline at that time.

Table 3. Summary of changes from the third edition of the *Medical eligibility criteria for contraceptive use* (Conditions for which there was a classification change for one or more methods or a major modification to the condition description. Changed classifications are noted in bold).

CONDITION	COC/P/R	CIC	POP	DMPA NET-EN	LNG/ETG Implants	Cu- IUD	LNG-IUD
I = initi	ation , $\mathbf{C} = \mathbf{c}$	ntinuation	, BF = br	eastfeeding	·		
POSTPARTUM (non-breastfeeding women)							
a) < 21 days							
(i) without other risk factors for VTE	3 †	3 †					
(ii) with other risk factors for VTE	3/4 [†]	3/4†					
b) \geq 21 days to 42 days							
(i) without other risk factors for VTE	2 †	2 †					
(ii) with other risk factors for VTE	2/3 [†]	2/3 [†]					
c) > 42 days	1	1					
POSTPARTUM (breastfeeding or non-breastfeeding women, including post-caesarean section)							
a) < 48 hours including insertion immediately after delivery of the placenta						1	1=not BF 3=BF
b) \geq 48 hours to < 4 weeks						3	3
c) ≥ 4 weeks						1	1
d) Puerperal sepsis						4	4
OBESITY	2	2	1	1	1	1	1
a) $\geq 30 \text{ kg/m}^2 \text{ body mass index (BMI)}$							
b) Menarche to < 18 years and ≥ 30 kg/m² body mass index (BMI)	2	2	1	DMPA=2 NET-EN=1 [†]	1	1	1
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)							
a) History of DVT/PE	4	4	2	2	2	1	2
b) Acute DVT/PE	4	4	3	3	3	1	3
c) DVT/PE and established on anti- coagulant therapy	4	4	2	2	2	1	2
d) Family history (first-degree relatives)	2	2	1	1	1	1	1
e) Major surgery							
(i) with prolonged immobilization	4	4	2	2	2	1	2
(ii) without prolonged immobilization	2	2	1	1	1	1	1
f) Minor surgery without immobilization	1	1	1	1	1	1	1

[†] Please consult the relevant method chapter for clarification for this classification.

CONDITION	COC/P/R	CIC	POP		MPA T-EN	LNG/ETG Implants	Cı IU		LNG-IUD		
I = initiation, $C = continuation$, $BF = breastfeeding$											
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)	ı	С		I	С						
People with SLE are at increased risk of ischaemic heart disease, stroke and venous thromboembolism. Categories assigned to such conditions											

People with SLE are at increased risk of ischaemic heart disease, stroke and venous thromboembolism. Categories assigned to such conditions in this guidance should be the same for women with SLE who present with these conditions. For all categories of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors.

a) Positive (or unknown) antiphospholipid antibodies	4	1		4	3	3	3	3	1	1	3	i
b) Severe thrombocytopenia	2	2		2	2	3	2	2	3 †	2 †	2	t
c) Immunosuppressive treatment	2	2		2	2	2	2	2	2	1	2	!
d) None of the above	2	2		2	2	2	2	2	1	1	2	!
GESTATIONAL TROPHOBLASTIC DISEASE				-			•			•		
 a) Decreasing or undetectable β-hCG (human chorionic gonadotropin) levels 	-	1		1	1		1	1	3	3	3	i
b) Persistently elevated β -hCG levels or malignant disease	-	1		1	1		1	1	4	1	4	
VIRAL HEPATITIS	I	С	Ī	С								
a) Acute or flare	3/4 [†]	2	3	3 2	1		1	1	1	l	1	
b) Carrier	1	1	1	1 1	1		1	1	1	l	1	
c) Chronic	1	1	1	1 1	1		1	1	1		1	
CIRRHOSIS												
a) Mild (compensated)	1	I		1	1		1	1	1		1	
b) Severe (decompensated)	4	1		3	3		3	3	1		3	
LIVER TUMOURS												
a) Benign												
i) Focal nodular hyperplasia	2	2		2	2	2		2	1		2	<u>.</u>
ii) Hepatocellular adenoma	4	1		3	3		3	3	1		3	
b) Malignant (hepatoma)	4	1		3/4	3		3	3	1		3	í
ANTIRETROVIRAL THERAPY									I	С	I	С
a) Nucleoside reverse transcriptase inhibitors (NRTIs)	1	t		1	1		1PA=1 -EN=1	1	2/3 [†]	2 †	2/3 [†]	2 †
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2	p†		2 †	2 †		IPA=1 -EN=2†	2 †	2/3 [†]	2 †	2/3 [†]	2 †
c) Ritonavir-boosted protease inhibitors	3	ţ†		3 †	3 †		IPA=1 -EN=2†	2 †	2/3 [†]	2 †	2/3 [†]	2 †
ANTICONVULSANT THERAPY												
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3 [†]		3 [†] 2		3 [†]	ı	1PA=1 NET- N=2†	2 †	1		1	
b) Lamotrigine	3 †			3	1		1	1	1	1 1		
ANTIMICROBIAL THERAPY												
a) Broad-spectrum antibiotics	1	ı		1	1		1	1	1		1	
b) Antifungals	1	ı		1	1		1	1	1		1	
c) Antiparasitics	1	ı		1	1		1	1	1		1	
d) Rifampicin or rifabutin therapy	3	} †		2	3 [†]		ИРА=1 Г-EN=2 [†]	2 †	1		1	

 $^{^\}dagger$ Please consult the relevant method chapter for clarification for this classification.

COMBINED HORMONAL CONTRACEPTIVES (CHCs)

COMBINED ORAL CONTRACEPTIVES (COCS)

Low-dose combined oral contraceptives (COCs) \leq 35 μ g of ethinylestradiol.

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 25 mg plus estradiol cypionate 5 mg
- 2) Mesigyna = norethisterone enantate 50 mg plus estradiol valerate 5 mg

CICs contain the naturally occurring estrogen, estradiol. Estradiol is less potent, has a shorter duration of effect and is more rapidly metabolized than the synthetic estrogens used in other contraceptive formulations such as combined oral contraceptives (COCs), combined contraceptive patch (P) and combined contraceptive ring (R). These differences imply that the type and magnitude of estrogen-related side-effects associated with CICs may be different from those experienced by COC/P/R 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) As CICs are administered by injection, the first-pass metabolism by the liver is avoided, thereby minimizing estradiol's effect 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) AND COMBINED CONTRACEPTIVE VAGINAL RING (R)

The combined contraceptive patch and vaginal ring are relatively new contraceptive methods. Limited information is available on the safety of these methods among women with specific medical conditions. Moreover, epidemiological data on the long-term effects of the combined contraceptive patch or the vaginal ring were not available for the Working Group to review. Most of the available studies received support from the manufacturers of these methods.

According to available evidence, the combined contraceptive patch provides a comparable safety and pharmacokinetic profile to COCs with similar hormone formulations.(9-26) Reports of transient, short-term breast discomfort and skin-site reactions were greater among combined contraceptive patch users; however less than 25% of users experienced these events.(11;15;16;22-24;27) Limited evidence suggests the effectiveness of the patch may decline for women weighing 90 kg or more.(24;26)

According to available evidence, the combined contraceptive vaginal ring provides a comparable safety and pharmacokinetic profile and has similar effects on ovarian function to COCs with similar hormone formulations in healthy women.(27-41) Evidence on obese women (BMI \geq 30 kg/m²) found that weight gain for women in this category was not different between users of the vaginal ring compared with users of COCs.(42) Limited evidence on women post medical and surgical abortion found no serious adverse events and no infection related to use during three cycles of follow-up postabortion,(43) and limited evidence on women with low-grade squamous intraepithelial lesions found that use of the vaginal ring did not worsen the condition.(30)

Pending further evidence, the Working Group concluded that the evidence available for COCs applies to the combined contraceptive patch and vaginal ring. Therefore, the patch and 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 HORMONAL CONTRACEPTIVES (CHCs)

CONDITION * additional comments at end of table	l = i		GORY = continua	ation	CLARIFICATIONS/EVIDENCE						
	COC	Р	R	CIC							
$oldsymbol{ ext{COC}}= ext{combined oral contraceptives} \ oldsymbol{ ext{P}}= ext{combined contraceptive patch} \ oldsymbol{ ext{R}}= ext{combined contraceptive vaginal ring} \ oldsymbol{ ext{CIC}}= ext{combined injectable contraceptives}$											
PERSONAL CHARACTERISTICS AND	REPRODUC	TIVE HISTO	RY								
PREGNANCY	NA	NA	NA	NA	NA = not applicable Clarification: Use of COCs, P, R or CICs is not required. There is no known harm to the woman, the course of her pregnancy, or the fetus if COCs, P, R or CICs are accidentally used during pregnancy.						
AGE*					Evidence: Adolescents using 20 µg						
a) Menarche to < 40 years	1	1	1	1	ethinylestradiol-containing COCs have lower bone mineral density (BMD) when						
b) ≥ 40 years	2	2	2	2	compared to non-users, while higher-dose ethinylestradiol-containing COCs have little to no effect.(44-51) In premenopausal adult women, combined hormonal contraceptive use has little to no effect on bone health, while appearing to preserve bone mass in the perimenopause.(35;52-100) Postmenopausal women who have ever used COCs have similar BMD to women who have never used COCs. (64;68;78;91;101-120) BMD in adolescent or premenopausal women may not accurately predict postmenopausal fracture risk. (119;121-132)						
PARITY											
a) Nulliparous	1	1	1	1							
b) Parous	1	1	1	1							
BREASTFEEDING					Evidence : Clinical studies demonstrate conflicting results regarding effects on milk						
a) < 6 weeks postpartum	4	4	4	4	volume in women exposed to COCs during						
b) ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding)	3	3	3	3	lactation; however, no consistent effects on infant weight have been reported.(133-142) Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to						
c) ≥ 6 months postpartum	2	2	2	2	combined contraceptives through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk of either serious or subtle long-term effects exists.						

CLARIFICATIONS/EVIDENCE CONDITION **CATEGORY** * additional comments at end of table I = initiation, C = continuationР R CIC COC = combined oral contraceptives P = combined contraceptive patch ${f R}=$ combined contraceptive vaginal ring ${f CIC}=$ combined injectable contraceptives

POSTPARTUM (in non-breastfeeding women)

Although the risk of VTE	is the same in I	breastfeeding	as non-bre	astfeeding v	vomen. use	of CHCs is generally not recommended prior	
to 6 months postpartum				T. T	1	or or or or generally not recommended prior	
a) < 21 days*						Clarification: For women up to 6 weeks	
i) without other risk VTE	c factors for	3	3	3	3	postpartum with other risk factors for VTE, such as previous VTE, thrombophilia, immobility, transfusion at delivery, BMI	
ii) with other risk fa	ctors for VTE	3/4	3/4	3/4	3/4	> 30 kg/m ² , postpartum haemorrhage,	
b) \geq 21 days to 42 day	S					immediately post-caesarean delivery, pre-	
i) without other risk VTE	c factors for	2	2	2	2	eclampsia or smoking, use of combined hormonal contraceptives may pose an	
ii) with other risk fa	ctors for VTE	2/3	2/3	2/3	2/3	-	
c) >42 days POST-ABORTION		1	1	1	1	Clarification: COCs, P, R or CICs may be	
a) First trimester		1	1	1	1	started immediately post-abortion.	
b) Second trimester		1	1	1	1	Evidence : Women who started taking COCs	
c) Immediate post-sept	ic abortion	1	1	1	1	immediately after first-trimester medical or surgical abortion did not experience more	
e,sarato poot oupt			'	'	,	side-effects or adverse vaginal bleeding outcomes or clinically significant changes in coagulation parameters compared with women who used a placebo, an IUD, a non-hormonal contraceptive method, or delayed COC initiation.(166-173) Limited evidence on women using the ring immediately after first-trimester medical or surgical abortion found no serious adverse events and no infection related to use of the combined vaginal contraceptive ring during three cycles of follow-up post-abortion.(43)	

CONDITION * additional comments at end of table	l = i	CATE nitiation, C	GORY = continua	ation	CLARIFICATIONS/EVIDENCE
	COC	Р	R	CIC	
					aceptive patch
	ed contracept	ive vaginal ri	ng CIC = co	mbined inject	table contraceptives
PAST ECTOPIC PREGNANCY*	1	1	1	1	
HISTORY OF PELVIC SURGERY	1	1	1	1	
SMOKING					Evidence : COC users who smoked were at increased risk of cardiovascular diseases,
a) Age < 35 years	2	2	2	2	especially myocardial infarction, compared
b) Age \geq 35 years					with those who did not smoke. Studies also showed an increased risk of myocardial
(i) < 15 cigarettes/day	3	3	3	2	infarction with increasing number of cigarettes
ii) ≥ 15 cigarettes/day	4	4	4	3	smoked per day.(174-185)
OBESITY					Evidence : Obese women who use COCs
a) \geq 30 kg/m ² BMI	2	2	2	2	are more likely to experience venous thromboembolism than obese women
b) Menarche to < 18 years and ≥ 30 kg/m² BMI	2	2	2	2	who do not use COCs. The absolute risk of venous thromboembolism in healthy women of reproductive age is small. Limited evidence suggests that obese women who use COCs do not have a higher risk of acute myocardial infarction or stroke than obese non-users.(179;185-191) Limited evidence is inconsistent regarding whether COC effectiveness varies by body weight or BMI. (169-174) Limited evidence suggests obese women are no more likely to gain weight after three cycles of the vaginal ring or COCs than overweight or normal weight women. A similar weight gain during the three months was noted between the COC group and the vaginal ring group across all BMI categories.(198) The effectiveness of the patch decreased among women who weighed > 90 kg; however, no association was found between pregnancy risk and BMI.(26)
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	NA	NA	Clarification: It is desirable to have blood pressure measurements taken before initiation of COC, P, R or CIC use. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy morbidity and mortality risks are high, and COCs, P, R or CICs may be one of the few methods widely available. In such settings, women should not be denied use of COCs, P, R or CICs 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	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, P, R or CICs 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.

CONDITION * additional comments at end of table	_l = iı	CATE nitiation, C		ation	CLARIFICATIONS/EVIDENCE
surantional commonts at one or table	COC	P	R CONTINUE	CIC	
COC					aceptive patch
					table contraceptives
					ctors for cardiovascular disease exist. When reading of blood pressure level is not sufficient to
a) History of hypertension, where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	3	3	3	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.(199-203)
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	3	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, COC, P, R or CIC users with adequately controlled and monitored hypertension should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive COC, P, R or CIC users.
c) Elevated blood pressure levels (properly taken measurements) (i) systolic 140-159 or diastolic 90-99 mm Hg	3	3	3	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.(174;176;183-185;187;199-214)
(ii) systolic ≥160 or diastolic ≥100 mm Hg	4	4	4	4	Discontinuation of COCs in women with hypertension may improve blood pressure control.(215)
d) Vascular disease	4	4	4	4	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	2	2	2	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.(185;201-203;205;216-221)
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*					
a) History of DVT/PE	4	4	4	4	
b) Acute DVT/PE	4	4	4	4	
c) DVT/PE and established on anticoagulant therapy	4	4	4	4	
d) Family history (first-degree relatives)	2	2	2	2	
e) Major surgery	4	4	A		
(i) with prolonged immobilization	4	4	4	4	
(ii) without prolonged immobilizationf) Minor surgery without immobilization	2	2	2 1	2	

CONDITION * additional comments at end of table	l=i		GORY = continua	CLARIFICATIONS/EVIDENCE			
	COC	P	R	CIC			
COC	= combined or	ral contracep			aceptive patch		
$\mathbf{R}=combi$	ned contracept	tive vaginal ri	ng CIC = co	mbined injec	table contraceptives		
KNOWN THROMBOGENIC MUTATIONS (e.g. factor V Leiden; prothrombin mutation; protein S, protein C, and antithrombin deficiencies)	4	4	4	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 twentyfold higher risk of thrombosis than non-users. (191;222-244)		
SUPERFICIAL VENOUS THROMBOSIS*							
a) Varicose veins	1	1	1	1			
b) Superficial thrombophlebitis	2	2	2	2			
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE	4	4	4	4			
STROKE (history of cerebrovascular accident)	4	4	4	4			
KNOWN HYPERLIPIDAEMIAS	2/3	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	2			
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	4	4	4	4			
RHEUMATIC DISEASES							
the <i>Medical eligibility criteria for contracep</i> of SLE, classifications are based on the ass	chaemic heart o tive use should sumption that n rs. Available evi	be the same o other risk fa dence indicat	for women wi actors for card	th SLE who po liovascular dis	olism. Categories assigned to such conditions in resent with these conditions. For all categories lease are present; these classifications must be SLE can be considered good candidates for most		
a) Positive (or unknown) antiphospholipid antibodies	4	4	4	4	Evidence : Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis.(264-266)		
b) Severe thrombocytopenia	2	2	2	2			
c) Immunosuppressive treatment	2	2	2	2			
d) None of the above	2	2	2	2			

CONDITION * additional comments at end of table		ال = ا		CATE on. C			CLARIFICATIONS/EVIDENCE		
	C	I = initiation, C = continuation COC P R CIC							
COC :	= combined oral contracepti			ives F	e con	nbined	contra	ceptive patch	
R = combir	ed con	tracept	ive va	ginal rii	ng Cl	C = co	mbined	d inject	able contraceptives
NEUROLOGIC CONDITIONS									
HEADACHES*		С		С	I	С	ı	С	Clarification: Classification depends on
a) Non-migrainous (mild or severe)	1	2	1	2	1	2	1	2	accurate diagnosis of those severe headaches that are migrainous and those that are not.
b) Migraine									Any new headaches or marked changes in
(i) without aura									headaches should be evaluated. Classification is for women without any other risk factors
Age < 35 years	2	3	2	3	2	3	2	3	for stroke. Risk of stroke increases with age,
Age ≥ 35 years	3	4	3	4	3	4	3	4	hypertension and smoking.
(ii) with aura, at any age	4	4	4	4	4	4	4	4	Evidence : Among women with migraine, women who also had aura had a higher risk
									of stroke than those without aura.(267-269) Women with a history of migraine who use COCs are about two to four times as likely to have an ischaemic stroke as non-users with a history of migraine.(174;189;210;211;268- 273)
EPILEPSY	-	1 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 P, R or CIC use is similar to COC use in this regard remains unclear.	
DEPRESSIVE DISORDERS									
DEPRESSIVE DISORDERS		1	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: COC use did not increase depressive symptoms in women with depression compared to baseline or to non-users with depression.(274-283)
REPRODUCTIVE TRACT INFECTIONS	S AND	DISO	RDEF	RS					
VAGINAL BLEEDING PATTERNS*									
a) Irregular pattern without heavy bleeding	-	1		1		1	-	1	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	-	1		1		1		1	Clarification: Unusually heavy bleeding should raise the suspicion of a serious underlying condition. Evidence: A Cochrane Collaboration review identified one randomized controlled trial evaluating the effectiveness of COC use compared with naproxen and danazol in treating menorrhagic women. Women with menorrhagia did not report worsening of the condition or any adverse events related to COC use.(284)

CONDITION * additional comments at end of table			GORY	otion	CLARIFICATIONS/EVIDENCE		
additional comments at end or lable	COC	nitiation, C P	= continu	CIC			
COC =		ral contracept			aceptive patch		
R = combin	ed contracept	tive vaginal ri	ng CIC = co	ombined injec	table contraceptives		
UNEXPLAINED VAGINAL BLEEDING* (suspicious for serious condition)							
Before evaluation	2	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	1	Evidence : A Cochrane Collaboration review identified one randomized controlled trial evaluating the effectiveness of COC use compared with a gonadotropin-releasing hormone (GnRH) analogue in treating the symptoms of endometriosis. Women with endometriosis did not report worsening of the condition or any adverse events related to COC use.(285)		
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	1			
SEVERE DYSMENORRHOEA	1	1	1	1	Evidence : There was no increased risk of side-effects with COC use among women with dysmenorrhoea compared with women not using COCs. Some COC users had a reduction in pain and bleeding.(286;287)		
GESTATIONAL TROPHOBLASTIC DISEASE					Evidence : Following molar pregnancy evacuation, the balance of evidence found		
a) Decreasing or undetectable β-hCG levels	1	1	1	1	COC use did not increase the risk of post- molar trophoblastic disease, and some COC users experienced a more rapid regression		
b) Persistently elevated β-hCG levels or malignant disease	1	1	1	1	in hCG levels, compared with non-users. (288-295) Limited evidence suggests that use of COCs during chemotherapeutic treatment does not significantly affect the regression or treatment of post-molar trophoblastic disease compared with women who used a non-hormonal contraceptive method or DMPA during chemotherapeutic treatment.(296)		
CERVICAL ECTROPION*	1	1	1	1			
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	2	2	2	2	Evidence: Among women with persistent Human papilloma virus (HPV) infection, long-term COC use (≥ 5 years) may increase the risk of carcinoma in situ and invasive carcinoma.(30;297) Limited evidence on women with low-grade squamous intraepithelial lesions found use of the vaginal ring did not worsen the condition.(30)		
CERVICAL CANCER* (awaiting treatment)	2	2	2	2			

CONDITION * additional comments at end of table	l = i		GORY = continua	ation	CLARIFICATIONS/EVIDENCE
	COC	Р	R	CIC	
					aceptive patch
	ed contracept	ive vaginal r	ing CIC = co	ombined injec	table contraceptives
BREAST DISEASE*					
a) Undiagnosed mass	2	2	2	2	Clarification : Evaluation should be pursued as early as possible.
b) Benign breast disease	1	1	1	1	
c) Family history of cancer	1	1	1	1	Evidence: Women with breast cancer susceptibility genes (such as <i>BRCA1</i> and <i>BRCA2</i>) have a higher baseline risk of breast cancer than women without these genes. The baseline risk of breast cancer is also higher among women with a family history of breast cancer than among those who do not have such a history. Current evidence, however, does not suggest that the increased risk of breast cancer among women with either a family history of breast cancer or breast cancer susceptibility genes is modified by the use of combined oral contraceptives. (298-321)
d) Breast cancer					
(i) current	4	4	4	4	
(ii) past and no evidence of current disease for 5 years	3	3	3	3	
ENDOMETRIAL CANCER*	1	1	1	1	
OVARIAN CANCER*	1	1	1	1	
UTERINE FIBROIDS*					
a) Without distortion of the uterine cavity	1	1	1	1	
b) With distortion of the uterine cavity	1	1	1	1	
PELVIC INFLAMMATORY DISEASE (PID)*					
a) Past PID (assuming no current risk factors for STIs)					
(i) with subsequent pregnancy	1	1	1	1	
(ii) without subsequent pregnancy	1	1	1	1	
b) PID - current	1	1	1	1	

CONDITION		CATE	GORY		CLARIFICATIONS/EVIDENCE		
* additional comments at end of table		nitiation, C					
	COC	Р	R	CIC			
				combined contra			
STIs	ей сопітасері	ive vaginai n	ng GIG =	: combined inject	table contraceptives		
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	1	1	1	1			
b) Other STIs (excluding HIV and hepatitis)	1	1	1	1			
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	1			
d) Increased risk of STIs	1	1	1	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 too limited evidence to draw any conclusions.(317-397)		
HIV/AIDS							
HIGH RISK OF HIV	1	1	1	1	Evidence : The balance of the evidence suggests no association between oral contraceptive use and HIV acquisition, although studies conducted among higherrisk populations have reported inconsistent findings.(398-436)		
HIV INFECTED	1	1	1	1	Evidence: Most studies suggest no increased risk of HIV disease progression with hormonal contraceptive use, as measured by changes in CD4 cell count, viral load or survival. Studies observing that women with HIV who use hormonal contraception have increased risks of acquiring STIs are generally consistent with reports among uninfected women. One direct study found no association between hormonal contraceptive use and an increased risk of HIV transmission to uninfected partners; several indirect studies reported mixed results regarding whether hormonal contraception is associated with an increased risk of HIV-1 DNA or RNA shedding from the genital tract. (437-454)		
AIDS	1	1	1	1	Clarification: Because there may be drug interactions between hormonal contraceptives and antiretroviral (ARV) therapy, refer to the section on drug interactions.		
OTHER INFECTIONS							
SCHISTOSOMIASIS							
a) Uncomplicated	1	1	1	1	Evidence : Among women with uncomplicated schistosomiasis, COC use had no adverse effects on liver function.(455-461)		
b) Fibrosis of the liver (if severe, see cirrhosis)	1	1	1	1			

CONDITION			GORY		CLARIFICATIONS/EVIDENCE
* additional comments at end of table		nitiation, C			
	COC	Р	R	CIC	
					aceptive patch stable contraceptives
TUBERCULOSIS	eu contracep	iive vagillai II		Jilibilieu Ilijeu	Clarification: If a woman is taking rifampicin,
a) Non-pelvic	1	1	1	1	refer to the section on drug interactions.
a) Pelvic	1	1	1	1	Rifampicin is likely to decrease COC effectiveness. The extent to which P or R use
a) i divid	ı	'	I		is similar to COC use in this regard remains unclear.
MALARIA	1	1	1	1	
ENDOCRINE CONDITIONS					
DIABETES					
a) History of gestational disease	1	1	1	1	Evidence : The development of non-insulindependent diabetes in women with a history of gestational diabetes is not increased by the use of COCs.(462-469) Likewise, lipid levels appear to be unaffected by COC use. (470-472)
b) Non-vascular disease					Evidence: Among women with insulin or
(i) non-insulin dependent	2	2	2	2	non-insulin-dependent diabetes, COC use had limited effect on daily insulin requirements
(ii) insulin dependent	2	2	2	2	and no effect on long-term diabetes control (e.g. haemoglobin A _{1C} levels) or progression to retinopathy. Changes in lipid profile and haemostatic markers were limited and most changes remained within normal values. (473-482)
c) Nephropathy/retinopathy/ neuropathy	3/4	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	3/4	Clarification : The category should be assessed according to the severity of the condition.
THYROID DISORDERS					
a) Simple goitre	1	1	1	1	
b) Hyperthyroid	1	1	1	1	
c) Hypothyroid	1	1	1	1	
GASTROINTESTINAL CONDITIONS					
GALL BLADDER DISEASE*					
a) Symptomatic					
(i) treated by cholecystectomy	2	2	2	2	
(ii) medically treated	3	3	3	2	
(iii) current	3	3	3	2	
b) Asymptomatic	2	2	2	2	
HISTORY OF CHOLESTASIS*					
a) Pregnancy related	2	2	2	2	
b) Past-COC related	3	3	3	2	

CONDITION * additional comments at end of table			(CATE	GORY = cor	1	CLARIFICATIONS/EVIDENCE				
	CC			оп, с Р	= 001 F			IC			
coc				tives $\mathbf{P} = \text{combined con}$				continu notah			
									able contraceptives		
VIRAL HEPATITIS	I	С	1	С		С	1	С			
a) Acute or flare	3/4	2	3/4	2	3/4	2	3	2	Clarification: The category should be assessed according to the severity of the		
b) Carrier c) Chronic	1	1	1 1	1	1 1	1	1 1	1	condition. Evidence: Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk of hepatocellular carcinoma.(483;484) For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction.(485-487) Evidence is limited for COC use during active		
CIDDUOCIC									hepatitis.(488;489)		
a) Mild (compensated) b) Severe (decompensated)	1			1	-			1			
LIVER TUMOURS*											
a) Benign											
(i) Focal nodular hyperplasia	2	2	2	2	2	2		2	Evidence: There is limited, direct evidence that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia.(490-492)		
(ii) Hepatocellular adenoma		1	4	4		4		3	Пурографіа.(430 432)		
b) Malignant (hepatoma)				4		4		/4			
ANAEMIAS											
THALASSAEMIA*	-			1	-	1		1			
SICKLE CELL DISEASE	2			<u>. </u>	2		2				
IRON-DEFICIENCY ANAEMIA*	-					1		 1		 1	
DRUG INTERACTIONS				•							
ANTIRETROVIRAL THERAPY									Clarification: Antiretroviral drugs have the		
a) Nucleoside reverse transcriptase inhibitors (NRTIs)	1	I		1	-	1		1	potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data (summarized in		
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2	2	4	2	2	2		2	Annex 1) suggest potential drug interactions between many antiretroviral drugs (particularly		
c) Ritonavir-boosted protease inhibitors	3	3		3	3	3		3	some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the antiretroviral drug. Thus, if a woman on antiretroviral treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended. This is both for preventing HIV transmission and to compensate for any possible reduction in the effectiveness of the hormonal contraceptive. When a COC is chosen, a preparation containing a minimum of 30 µg ethinylestradiol (EE) should be used.		

CONDITION * additional comments at end of table	l = i		GORY = continua	ation	CLARIFICATIONS/EVIDENCE
	COC	P	R	CIC	-
COC :		al contracept			aceptive patch
R = combin	ed contracept	ive vaginal ri	ng CIC = co	ombined injec	table contraceptives
ANTICONVULSANT THERAPY					
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	3	3	2	Clarification: Although the interaction of certain anticonvulsants with COCs, P or R is not harmful to women, it is likely to reduce the effectiveness of COCs, P or R. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. When a COC is chosen, a preparation containing a minimum of 30 µg of EE should be used. Evidence: Use of certain anticonvulsants may decrease the effectiveness of COCs.(493-496)
b) Lamotrigine	3	3	3	3	Clarification: The recommendation for lamotrigine does not apply when lamotrigine is already being taken with other drugs that strongly inhibit (such as sodium valproate) or induce (such as carbamazepine) its metabolism, since, in these cases, the moderate effect of the combined contraceptive is unlikely to be apparent. Evidence: Pharmacokinetic studies show levels of lamotrigine decrease significantly during COC use and increase significantly during the pill-free interval.(497-501) Some women who used both COCs and lamotrigine experienced increased seizure activity in one trial.(497)
ANTIMICROBIAL THERAPY					
a) Broad-spectrum antibiotics	1	1	1	1	Evidence : Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of COCs(502-538), P(539), or R.(540)
b) Antifungals	1	1	1	1	Evidence : Studies of antifungal agents have shown no clinically significant pharmacokinetic interactions with COCs(541-550) or R.(551)
c) Antiparasitics	1	1	1	1	Evidence : Studies of antiparasitic agents have shown no clinically significant pharmacokinetic interactions with COCs. (455;552-556)
d) Rifampicin or rifabutin therapy	3	3	3	2	Clarification: Although the interaction of rifampicin or rifabutin therapy with COCs, P, R or CICs is not harmful to women, it is likely to reduce the effectiveness of COCs, P, R or CICs. Use of other contraceptives should be encouraged for women who are long-term users of either of these drugs. When a COC is chosen, a preparation containing a minimum of 30 µg EE should be used. Evidence: The balance of the evidence suggests that rifampicin reduces the effectiveness of COCs.(557-572) Data on rifabutin are limited, but effects on metabolism of COCs are less than with rifampicin, and small studies have not shown evidence of ovulation.(559;566)

ADDITONAL COMMENTS

AGE

 \geq 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.

POSTPARTUM

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

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

SUPERFICIAL VENOUS THROMBOSIS

Varicose veins: varicose veins are not risk factors for DVT/PE.

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://ihs-classification.org/en/02_klassifikation (accessed 21 Aug 2009).

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.

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

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, CICs, P or R. 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, 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 and R are not expected to 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 lover genital tract STIs.

GALL BLADDER DISEASE

COCs, CICs, P or R may cause a small increased risk of gall bladder disease. There is also concern that COCs, CICs, P or R may worsen existing gall bladder disease. However, unlike COCs, CICs have been shown to have 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 COC-related cholestasis.

HISTORY OF CHOLESTASIS

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

LIVER TUMOURS

There is no evidence regarding hormonal contraceptive use among women with hepatocellular adenoma. COC use in healthy women is associated with development and growth of hepatocellular adenoma.

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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PROGESTOGEN-ONLY CONTRACEPTIVES (POCs)

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE			
* additional comments at end of table	I = initia	tion, $C = con$	tinuation				
	POP	D/NE	LNG/ETG				
POP = progestogen-only pills LNG/ETG = levonorgestrel and etonogestrel implants D/NE = depot medroxyprogesterone acetate (DMPA) / norethisterone enantate (NET-EN)							
			(DMPA) / norethi	sterone enantate (NET-EN)			
PERSONAL CHARACTERISTICS AND		I		NA P. II.			
PREGNANCY	NA	NA	NA	NA = not applicable 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				Evidence: Most studies have found that women			
a) Menarche to < 18 years	1	2	1	lose bone mineral density while using DMPA, but regain bone mineral density after discontinuing			
b) 18 to 45 years	1	1	1	DMPA. It is not known whether DMPA use among			
c) > 45 years	1	2	1	adolescents affects peak bone mass levels or whether adult women with long duration of DMPA use can regain bone mineral density to baseline levels before entering menopause. The relationship between DMPA-associated changes in bone mineral density during the reproductive years and future fracture risk is unknown.(1-41) Studies find no effect or have inconsistent results regarding the effects of POCs other than DMPA on bone mineral density.(42-54)			
PARITY							
a) Nulliparous	1	1	1				
b) Parous	1	1	1				
BREASTFEEDING				Clarification: There is concern that the neonate			
a) < 6 weeks postpartum	3	3	3	may be at risk of exposure to steroid hormones during the first six weeks postpartum. However, in			
b) ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding)	1	1	1	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			
c) ≥ 6 months postpartum	1	1	1	of methods widely available and accessible to breastfeeding women immediately postpartum. Evidence: Direct evidence from clinical studies demonstrates no effect of POCs on breastfeeding performance (55-90) and generally demonstrates no harmful effects from exposure through breast milk in infants less than 6 weeks of age; however, these studies have been inadequately designed to determine whether a risk of either serious or subtle long-term effects exists.(55-59;67;69;71;73;80;83;84) Animal data suggest there is an effect of progesterone on the developing brain; whether similar effects occur following progestogen exposure in humans is unclear.(91-95)			

CONDITION * additional comments at end of table	l – initia	CATEGORY tion, C = con		CLARIFICATIONS/EVIDENCE
additional commonts at one of table	POP	D/NE	LNG/ETG	
POP = proge				and etonogestrel implants
D/NE = depo	ot medroxyproge:	sterone acetate	(DMPA) / norethi	sterone enantate (NET-EN)
(in non-breastfeeding women)				
a) < 21 days	1	1	1	
b) \geq 21 days	1	1	1	
POST-ABORTION				Clarification: POCs may be started immediately
a) First trimester	1	1	1	post-abortion. Evidence : Limited evidence suggests that there
b) Second trimester	1	1	1	are no adverse side effects when Norplant or NET-
c) Immediate post-septic abortion	1	1	1	EN are initiated after first-trimester abortion.(96-99)
PAST ECTOPIC PREGNANCY*	2	1	1	
HISTORY OF PELVIC SURGERY	1	1	1	
SMOKING				
a) Age < 35 years	1	1	1	
b) Age \geq 35 years				
(i) < 15 cigarettes/day	1	1	1	
ii) ≥ 15 cigarettes/day	1	1	1	
OBESITY				Clarification: There is no evidence of a differential
a) \geq 30 kg/m ² BMI	1	1	1	weight gain among normal weight and obese adolescents who use NET-EN; this condition is
b) Menarche to < 18 years and ≥ 30 kg/m² BMI	1	DMPA=2 NET-EN=1	1	classified as Category 1. However, the condition age < 18 years is classified as Category 2 due to evidence regarding potential effects of NET-EN on bone mineral density. Evidence: Obese adolescents who used DMPA were more likely to gain weight than obese nonusers, obese COC users, and non-obese DMPA users. This relationship was not observed among adult women. One small study did not observe increases in weight gain among adolescent Norplant users by any category of baseline weight.(100-108)
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA NA	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 methods widely available. In such settings, women should not be denied use of POCs simply because their blood pressure cannot be measured.

CONDITION * additional comments at end of table		CATEGORY tion, $C = con$		CLARIFICATIONS/EVIDENCE
	POP	D/NE	LNG/ETG	
				and etonogestrel implants sterone enantate (NET-EN)
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, the 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.
				sk factors for cardiovascular disease exist. When ingle reading of blood pressure level is not sufficient t
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 morality risks are high, and POCs are one of the few types of method widely available. In such settings, women should not be denied the use of POCs simply because theil 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 myocardia 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)				should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive POC users. Evidence: Limited evidence suggests that among women with hypertension, those who used POPs or
	1	2	1	should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive POC users. Evidence : Limited evidence suggests that among women with hypertension, those who used POPs of progestogen-only injectables had a small increased risk of cardiovascular events compared with women
(properly taken measurements) (i) systolic 140-159 or	1 2	2	1 2	should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive POC users. Evidence : Limited evidence suggests that among women with hypertension, those who used POPs of progestogen-only injectables had a small increased.

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE
* additional comments at end of table	I = initia	I = initiation, C = continuation		
	POP	D/NE	LNG/ETG	
				and etonogestrel implants
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	n medroxyproges	terone acetate	(DIMPA) / Norethi	isterone enantate (NET-EN)
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*				
a) History of DVT/PE	2	2	2	
b) Acute DVT/PE	3	3	3	Evidence: There is no direct evidence on the use of POCs among women with DVT/PE on anticoagulant therapy. Although evidence on the risk of venous thrombosis with the use of POCs is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COCs.(109-111)
c) DVT/PE and established on anticoagulant therapy	2	2	2	Evidence: There is no direct evidence on the use of POCs among women with DVT/PE on anticoagulant therapy. Although evidence on the risk of venous thrombosis with the use of POCs is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COCs.(109-111) Limited evidence indicates that intramuscular injections of DMPA in women on chronic anticoagulation therapy does not pose a significant risk of hematoma at the injection site or increase the risk of heavy or irregular vaginal bleeding.(112;113)
d) Family history (first-degree relatives)	1	1	1	
e) Major surgery				
(i) with prolonged immobilization	2	2	2	
(ii) without prolonged immobilization	1	1	1	
f) 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*	1 C 2 3	3	1 C 2 3	-
STROKE* (history of cerebrovascular accident)	1 C 2 3	3	1 C 2 3	

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 * additional comments at end of table		CATEGORY tion, C = cor		CLARIFICATIONS/EVIDENCE	
	POP	D/NE	LNG/ETG		
				and etonogestrel implants sterone enantate (NET-EN)	
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		
RHEUMATIC DISEASES					
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)* People with SLE are at increased risk of ischaemic heart disease, stroke and venous thromboembolism. Categories assigned to such conditions in the <i>Medical eligibility criteria for contraceptive use</i> should be the same for women with SLE who present with these conditions. For all categories of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Available evidence indicates that many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives.(114-132)					
		I C			
a) Positive (or unknown) antiphospholipid antibodies	3	3 3	3	Evidence: Antiphospholipid antibodies are associated with a higher risk for both arterial and	

							*
			I	С			
a) Positive (or unknown) antiphospholipid antibodies		3	3	3		3	Evidence : Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis.(133-135)
b) Severe thrombocytopenia		2	3	2		2	
c) Immunosuppressive treatment		2	2	2		2	
d) None of the above		2	2	2		2	
NEUROLOGIC CONDITIONS							
HEADACHES*	- 1	С	-	С	1	С	
a) Non-migrainous (mild or severe) b) Migraine	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
(i) without aura							headaches or marked changes in headaches should
Age < 35 years	1	2	2	2	2	2	be evaluated. Classification is for women without any other risk factors for stroke. Risk of stroke
Age ≥ 35 years	1	2	2	2	2	2	increases with age, hypertension and smoking.
(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.
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: POC use did not increase depressive symptoms in women with depression compared with baseline.(136-139)

CONDITION * additional comments at end of table	CATEGO nents at end of table I = initiation, C =			CLARIFICATIONS/EVIDENCE			
	POP	D/NE	LNG/ETG				
POP = proge				and etonogestrel implants			
D/NE = depo	t medroxyproge	sterone acetate		sterone enantate (NET-EN)			
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*				Clarification: If pregnancy or an underlying			
(suspicious for serious condition) Before evaluation	2	3	3	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				
GESTATIONAL TROPHOBLASTIC DISEASE							
a) Decreasing or undetectable β-hCG levels	1	1	1				
b) Persistently elevated β-hCG levels or malignant 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.(140)			
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				
a) Without distortion of the uterine cavity	1	1	1				
b) With distortion of the uterine cavity	1	1	1				

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE
* additional comments at end of table		tion, $C = con$		
202	POP	D/NE	LNG/ETG	
				and etonogestrel implants sterone enantate (NET-EN)
PELVIC INFLAMMATORY DISEASE (PID)*	- modroxyprogod		(5111171) / 11010411	osorono sinamato (NET EN)
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	
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	Evidence : 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.(141-148)
HIV/AIDS				
HIGH RISK OF HIV	1	1	1	Evidence: The balance of the evidence suggests no association between POC use and HIV acquisition, although studies of DMPA use conducted among higher-risk populations have reported inconsistent findings.(149-173)
HIV-INFECTED	1	1	1	Evidence: Most studies suggest no increased risk of HIV disease progression with hormonal contraceptive use, as measured by changes in CD4 cell count, viral load or survival. Studies observing that women with HIV who use hormonal contraception have increased risks of acquiring STIs are generally consistent with reports among uninfected women. One direct study found no association between hormonal contraceptive use and an increased risk of HIV transmission to uninfected partners; several indirect studies reported mixed results regarding whether hormonal contraception is associated with an increased risk of HIV-1 DNA or RNA shedding from the genital tract.(174-191)
AIDS	1	1	1	Clarification: Because there may be drug interactions between hormonal contraceptives and ARV therapy, refer to the section on drug interactions.

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE
* additional comments at end of table	l = initia	tion, $C = con$		
	POP	D/NE	LNG/ETG	
				and etonogestrel implants
	t medroxyproge:	sterone acetate	(DMPA) / norethi	sterone enantate (NET-EN)
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. (192)
b) Fibrosis of the liver (if severe, see cirrhosis)	1	1	1	
TUBERCULOSIS				Clarification: If a woman is taking rifampicin, refer
a) Non-pelvic	1	1	1	to the section on drug interactions. Rifampicin is likely to decrease the effectiveness of some POCs.
a) Pelvic	1	1	1	
MALARIA	1	1	1	
ENDOCRINE CONDITIONS				
DIABETES*				
a) History of gestational disease	1	1	1	Evidence : POCs had no adverse effects on serum lipid levels in women with a history of gestational diabetes in two small studies.(193;194) Limited evidence is inconsistent regarding the development of non-insulin-dependent diabetes among users of POCs with a history of gestational diabetes. (195-198)
b) Non-vascular disease				Evidence: Among women with insulin or non-
(i) non-insulin dependent	2	2	2	insulin dependent diabetes, limited evidence on the use of progestogen-only methods (POPs, DMPA,
(ii) insulin dependent	2	2	2	LNG implant) suggests that these methods have little effect on short-term or long-term diabetes control (e.g., HbA _{1c} levels), haemostatic markers or lipid profile.(199-202)
c) Nephropathy/retinopathy/ neuropathy	2	3	2	
d) Other vascular disease or diabetes of > 20 years' duration THYROID DISORDERS	2	3	2	
a) Simple goitre	1	1	1	
b) Hyperthyroid	1	1	1	
c) Hypothyroid	1	1	1	
GASTROINTESTINAL CONDITIONS		<u> </u>	<u> </u>	
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	
5/ / Symptomatic				

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE
* additional comments at end of table		tion, $C = con$		
	POP	D/NE	LNG/ETG	
				and etonogestrel implants
•	t medroxyproges	sterone acetate	(DMPA) / norethi	sterone enantate (NET-EN)
HISTORY OF CHOLESTASIS*	1	1	1	
a) Pregnancy-related	2	2	2	
b) Past-COC related VIRAL HEPATITIS				
a) Acute or flare	1	1	1	
,	1	1	1	
b) Carrier	1	1	1	
c) Chronic CIRRHOSIS		- 1	ı	
a) Mild (compensated)	1	1	1	
b) Severe (decompensated)	3	3	3	
LIVER TUMOURS*	<u> </u>	<u> </u>	<u> </u>	
a) Benign (i) Focal nodular hyperplasia	2	2	2	Fuidance. There is limited direct suidance that
(i) Focal nodular hyperplasia	2	2	2	Evidence: There is limited, direct evidence that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia. (203-205)
(ii) Hepatocellular 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. (206-213)
IRON-DEFICIENCY ANAEMIA*	1	1	1	
DRUG INTERACTIONS				
a) Nucleoside reverse transcriptase	1	DMPA=1	1	Clarification: Antiretroviral drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal
inhibitors (NRTIs) b) Non-nucleoside reverse	2	NET-EN=1 DMPA=1	2	contraceptives. Limited data (summarized in Annex 1) suggest potential drug interactions between many antiretroviral drugs (particularly
transcriptase inhibitors (NNRTIs)	0	NET-EN=2	0	some NNRTIs and ritonavir-boosted protease
c) Ritonavir-boosted protease inhibitors	3	DMPA=1 NET-EN=2	2	inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the antiretroviral drug. Thus, if a woman on antiretroviral treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended. This is both for preventing HIV transmission and to compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

CONDITION * additional comments at end of table	I = initia	CATEGORY tion, C = con		CLARIFICATIONS/EVIDENCE				
	P0P	D/NE	LNG/ETG					
POP = progestogen-only pills LNG/ETG = levonorgestrel and etonogestrel implants D/NE = depot medroxyprogesterone acetate (DMPA) / norethisterone enantate (NET-EN)								
ANTICONVULSANT THERAPY								
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	DMPA=1 NET-EN=2	2	Clarification: Although the interaction of certain anticonvulsants with POPs, NET-EN and LNG/ETG implants is not harmful to women, it is likely to reduce the effectiveness of POPs, NET-EN and LNG/ETG implants. Whether increasing the hormone dose of POPs alleviates this concern remains unclear. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is Category 1 because its effectiveness is not decreased by the use of certain anticonvulsants. Evidence: Use of certain anticonvulsants may decrease the effectiveness of POCs.(214-216)				
b) Lamotrigine	1	1	1	Evidence : No drug interactions have been reported among women with epilepsy taking lamotrigine and using POCs.(217)				
ANTIMICROBIAL THERAPY								
a) Broad-spectrum antibiotics	1	1	1					
b) Antifungals	1	1	1					
c) Antiparasitics	1	1	1					
d) Rifampicin or rifabutin therapy	3	DMPA=1 NET-EN=2	2	Clarification: Although the interaction of rifampicin or rifabutin with POPs, NET-EN and LNG/ETG implants is not harmful to women, it is likely to reduce the effectiveness of POPs, NET-EN and LNG/ETG implants. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is Category 1 because its effectiveness is not decreased by the use of rifampicin or rifabutin. Whether increasing the hormone dose of POPs alleviates this concern remains unclear.				

ADDITIONAL COMMENTS

PAST ECTOPIC PREGNANCY

POPs have a higher absolute rate of ectopic pregnancy compared with other POCs, but still less than using no method. The 75 μ g desogestrel-containing pill inhibits ovulation in most cycles, which suggests a low risk of ectopic pregnancy.

HYPERTENSION

Vascular disease: there is concern regarding hypo-estrogenic effects and reduced high-density lipoprotein (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 VEIN THROMBOSIS/PULMONARY EMBOLISM

Women on anticoagulation therapy who have a history of hemorrhagic ovarian cysts may benefit from DMPA use.

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.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

Severe thrombocytopenia increases the risk of bleeding. POCs may be useful in the treatment of menorrhagia in women with severe thrombocytopenia. However, given the increased or erratic bleeding that may be seen on initiation of DMPA and its irreversibility for 11-13 weeks after administration, initiation of this method in women with severe thrombocytopenia should be done with caution.

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://ihs-classification.org/en/02_klassifikation (accessed 21 Aug 2009).

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, treatment of this condition renders a woman sterile.

OVARIAN CANCER

While awaiting treatment, women may use POCs. In general, 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 STIs.

DIABETES

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.

LIVER TUMOURS

There is no evidence regarding hormonal contraceptive use among women with hepatocellular adenoma. Given that COC use in healthy women is associated with development and growth of hepatocellular adenoma, it is not known whether other hormonal contraceptives have similar effects.

IRON-DEFICIENCY ANAEMIA

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

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EMERGENCY CONTRACEPTIVE 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 * additional comments at end of table	CATEGORY	CLARIFICATIONS/EVIDENCE
PREGNANCY	NA	NA = not applicable 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	
PAST 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 CHC 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 the use of ECPs in cases of rape.

INTRAUTERINE DEVICES (IUDs)

CONDITION	CATEGORY		CLARIFICATIONS/EVIDENCE			
* additional comments at end of table						
	Cu-IUD	LNG-IUD				
Cu-IUD =	copper-bearing IUD	vonorgestrel-releasing IUD (20 μg/24 hours)				
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) \geq 20 years	1	1				
PARITY			Evidence: There are conflicting data regarding whether IUD			
a) Nulliparous	2	2	use is associated with infertility among nulliparous women, although well-conducted studies suggest no increased risk.			
b) Parous	1	1	(1-9)			
POSTPARTUM* (breastfeeding or non-breastfeeding women, including caesarean section)						
a) < 48 hours including insertion immediately after delivery of the placenta			Evidence : Immediate postpartum copper IUD insertion, particularly when insertion occurs immediately after delivery of the placenta, is associated with lower expulsion rates than delayed postpartum insertion. Additionally, post			
(i) breastfeeding	1	3	than delayed postpartum insertion. Additionally, post- placental placement at the time of caesarean section has			
(ii) non-breastfeeding	1	1	lower expulsion rates than post-placental vaginal insertions.			
b) \geq 48 hours to $<$ 4 weeks	3	3	Insertion complications of perforation and infection are not increased by IUD placement at any time during the			
$c) \ge 4$ weeks	1	1	postpartum period.(10-24)			
d) Puerperal sepsis	4	4				
POST-ABORTION*						
a) First trimester	1	1	Clarification: IUDs can be inserted immediately after first-			
b) Second trimester	2	2	trimester, spontaneous or induced abortion. Evidence : There was no difference in risk of complications			
c) Immediate post-septic abortion	4	4	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 a Cu-IUD.(25-37)			
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				

CONDITION * additional comments at end of table	CATEGORY I = initiation, C = continuation		CLARIFICATIONS/EVIDENCE
	Cu-IUD	LNG-IUD	
Cu-IUD = 0	copper-bearing IUD	LNG-IUD = le	vonorgestrel-releasing IUD (20 μg/24 hours)
OBESITY			
a) \geq 30 kg/m ² BMI	1	1	
b) Menarche to < 18 years and $\ge 30 \text{ kg/m}^2\text{BMI}$	1	1	
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	Clarification: While a blood pressure measurement may be appropriate for good preventive 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.
CARDIOVASCULAR DISEASE			
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	1	2	
multiple risk factors do exist, the risk of card classify a woman as hypertensive.		nay increase substar	o other risk factors for cardiovascular disease exist. When titally. A single reading of blood pressure level is not sufficient to
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 mm Hg	1	1	
(ii) systolic ≥160 or diastolic ≥100 mm Hg	1	2	
d) Vascular disease	1	2	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	1	1	

CONDITION * additional comments at end of table	CATEGORY I = initiation, C = continuation			CLARIFICATIONS/EVIDENCE
	Cu-IUD	LNG-IUD		
Cu-IUD = 0	copper-bearing IUD	LNG-	IUD = le	vonorgestrel-releasing IUD (20 μg/24 hours)
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)*				
a) History of DVT/PE	1	9)	
b) Acute DVT/PE	1	2 3		Evidence : Although evidence on the risk of venous thrombosis with the use of POCs is inconsistent, any small increased risk is substantially less than that with COCs. (38-40)
c) DVT/PE and established on anticoagulant therapy	1	2		Evidence : Although evidence on the risk of venous thrombosis with the use of POCs is inconsistent, any small increased risk is substantially less than that with COCs.(38-40) Limited evidence indicates that insertion of the LNG-IUD does not pose major bleeding risks in women on chronic anticoagulant therapy.(41-43)
d) Family history (first-degree relatives)	1	1		
e) Major surgery				
(i) with prolonged immobilization	1	2	<u> </u>	
(ii) without prolonged immobilization	1	1		
f) 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	1	I	С	
ISCHAEMIC HEART DISEASE*		2	3	
STROKE* (history of cerebrovascular accident)	1	2)	
KNOWN HYPERLIPIDAEMIAS	1	2	<u> </u>	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.

CONDITION * additional comments at end of table	CATEGORY I = initiation, C = continuation				CLARIFICATIONS/EVIDENCE		
additional commonts at one of table	Cu-		= continuation LNG-IUD				
Cu-IUD =					vonorgestrel-releasing IUD (20 µg/24 hours)		
RHEUMATIC DISEASES							
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)							
People with SLE are at increased risk of ischaemic heart disease, stroke and venous thromboembolism. Categories assigned to such conditions in the <i>Medical eligibility criteria for contraceptive use</i> should be the same for women with SLE who present with these conditions. For all categories of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Available evidence indicates that many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives.(44-62)							
	ı	С					
a) Positive (or unknown) antiphospholipid antibodies	1	1	3		Evidence : Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis.(63;64)		
b) Severe thrombocytopenia	3	2	2		Clarification: Severe thrombocytopenia increases the risk of bleeding. The category should be assessed according to the severity of the thrombocytopenia and its clinical manifestations. In women with very severe thrombocytopenia who are at risk for spontaneous bleeding, consultation with a specialist and certain pretreatments may be warranted. Evidence: The LNG-IUD may be a useful treatment for menorrhagia in women with severe thrombocytopenia.(43)		
c) Immunosuppressive treatment	2	1	2				
d) None of the above	1	1		2			
NEUROLOGIC CONDITIONS							
HEADACHES*				С	Clarification: Any new headaches or marked changes in		
a) Non-migrainous (mild or severe)	1		1	1	headaches should be evaluated.		
b) Migraine							
(i) without aura							
Age < 35 years	1		2	2			
Age ≥ 35 years	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.		
REPRODUCTIVE TRACT INFECTION	S AND D	SORDEF	RS				
VAGINAL BLEEDING PATTERNS				С			
a) Irregular pattern without heavy bleeding	1	1		1			
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. Evidence: Evidence from studies examining the treatment effects of the LNG-IUD among women with heavy or prolonged bleeding reported no increase in adverse effects and found the LNG-IUD to be beneficial in the treatment of menorrhagia.(65-72)		

CONDITION * additional comments at end of table					CLARIFICATIONS/EVIDENCE
		·IUD		i-IUD	
Cu-IUD = 0	copper-be	aring IUD	LNG	-IUD = lev	vonorgestrel-releasing IUD (20 μg/24 hours)
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition)	l	С	I	С	
Before evaluation	4	2	4	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. There is no need to remove the IUD before evaluation.
ENDOMETRIOSIS		2		1	Evidence : LNG-IUD use among women with endometriosis decreased dysmenorrhoea, pelvic pain and dyspareunia. (73-77)
BENIGN OVARIAN TUMOURS (including cysts)		1		1	
SEVERE DYSMENORRHOEA*		2		1	
GESTATIONAL TROPHOBLASTIC DISEASE					Evidence : Limited evidence suggests that women using an IUD following uterine evacuation for a molar pregnancy are
a) Decreasing or undetectable $\beta\text{-hCG}$ levels	;	3		3	not at increased risk of developing post-molar trophoblastic disease when compared to women using other methods of contraception.(78-81)
b) Persistently elevated β-hCG levels or malignant disease		4		4	
CERVICAL ECTROPION		1		1	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)*		1	·	2	
CERVICAL CANCER* (awaiting treatment)	4	C 2	4	C 2	
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	С	I	С	
	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. (82-88)
b) With distortion of the uterine cavity	,	4		4	

CONDITION				CLARIFICATIONS/EVIDENCE	
* additional comments at end of table	I = init	iation, C	= contir	nuation	
	Cu-	·IUD	LNG	-IUD	
Cu-IUD = 0	copper-be	aring IUD	LNG-	IUD = lev	vonorgestrel-releasing IUD (20 µg/24 hours)
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	۷	1	
b) Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion	:	2	2	2	
PELVIC INFLAMMATORY DISEASE (PID)*	ı	С	I	С	Clarification for continuation: Treat the PID using appropriate antibiotics. There is usually no need for removal
a) Past PID (assuming no current risk factors for STIs)					of the IUD if the client wishes to continue its use (See Selected practice recommendations for contraceptive use. WHO: Geneva, 2005). Continued use of an IUD depends on
(i) with subsequent pregnancy	1	1	1	1	the woman's informed choice and her current risk factors for
(ii) without subsequent pregnancy	2	2	2	2	STIs and PID. Evidence : Among IUD users treated for PID, there was no
b) PID - current	4	2	4	2	difference in clinical course if the IUD was removed or left in place.(89-91)
STIs	I	С	I	С	
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. (92-98)
b) Other STIs (excluding HIV and hepatitis)	2	2	2	2	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	
d) Increased risk of STIs	2/3	2	2/3	2	Clarification: If a woman has a very high individual likelihood of exposure to gonorrhoea or chlamydial infection, the condition is 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.(99)
HIV/AIDS					
HIGH RISK OF HIV		С	I	С	Evidence: Among women at risk for HIV, copper IUD use
	2	2	2	2	did not increase risk of HIV acquisition.(100-110)

CONDITION	CATEGORY			CLARIFICATIONS/EVIDENCE	
* additional comments at end of table	I = init	iation, C	C = continuation		
	Cu-	IUD	LNG	-IUD	
Cu-IUD =	copper-be	aring IUD	LNG-	-IUD = lev	vonorgestrel-releasing IUD (20 μg/24 hours)
HIV-INFECTED	- 1	С	I	С	Evidence: Among IUD users, limited evidence shows
	2	2	2	2	no increased risk of overall complications or infectious complications when comparing HIV- infected with non-infected women. IUD use did not adversely affect progression of HIV when compared to hormonal contraceptive use among HIV-infected women. Furthermore, IUD use among HIV-infected women was not associated with increased risk of transmission to sexual partners.(111-119)
AIDS	3	2	3	2	Clarification for continuation: IUD users with AIDS
Clinically well on ARV therapy	2	2	2	2	should be closely monitored for pelvic infection.
OTHER INFECTIONS				,	
SCHISTOSOMIASIS					
a) Uncomplicated		1		1	
b) Fibrosis of the liver (if severe, see cirrhosis)		1	-	1	
TUBERCULOSIS*	1	С	I	С	
a) Non-pelvic	1	1	1	1	
a) Pelvic	4	3	4	3	
MALARIA		1	-	1	
ENDOCRINE CONDITIONS					
DIABETES					
a) History of gestational disease		1	-	1	
b) Non-vascular disease					
(i) non-insulin dependent		1		2	Evidence: Limited evidence on the use of the LNG-IUD
(ii) insulin dependent		1		2	among women with insulin- or non-insulin-dependent diabetes suggests that these methods have little effect on short-term or long-term diabetes control (e.g. HbA _{1c} levels), haemostatic markers or lipid profile.(120;121)
c) Nephropathy/retinopathy/ neuropathy	-	1	2	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	I		I		
GALL BLADDER DISEASE					
a) Symptomatic					
(i) treated by cholecystectomy		1	2	2	
(ii) medically treated	-	1	4	2	
(iii) current		1	4	2	
b) Asymptomatic	-	1		2	

CONDITION * additional comments at end of table	of table I = initiation, C = continuation Cu-IUD LNG-IUD		uation	CLARIFICATIONS/EVIDENCE	
			IUD		
Cu-IUD = 0	copper-bea	aring IUD	LNG-IUD = lev		vonorgestrel-releasing IUD (20 μg/24 hours)
HISTORY OF CHOLESTASIS*					
a) Pregnancy-related	1		1		
b) Past-COC related	1		2		
VIRAL HEPATITIS					
a) Acute or flare	1		1		
b) Carrier	1		1		
c) Chronic	1		1		
CIRRHOSIS					
a) Mild (compensated)	1		1		
b) Severe (decompensated)	1		3		
LIVER TUMOURS*					
a) Benign					
(i) Focal nodular hyperplasia	1		2		
(ii) Hepatocellular adenoma	1		3		
b) Malignant (hepatoma)	1		3		
ANAEMIAS					
THALASSAEMIA*	2)	1		
SICKLE CELL DISEASE*	2		1		
IRON-DEFICIENCY ANAEMIA*	2)	1		
DRUG INTERACTIONS					
ANTIRETROVIRAL THERAPY	I	С	ı	С	Clarification: There is no known interaction between
a) Nucleoside reverse transcriptase inhibitors (NRTIs)	2/3	2	2/3	2	antiretroviral 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
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2/3	2	2/3	2	well on antiretroviral therapy, in which case both insertion and continuation are classified as Category 2 (see HIV/AIDS
c) Ritonavir-boosted protease inhibitors	2/3	2	2/3	2	condition).
ANTICONVULSANT THERAPY					
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		Evidence : Limited evidence suggests that use of certain anticonvulsants does not interfere with the contraceptive effectiveness of the LNG-IUD.(122)
b) Lamotrigine	1		1		Evidence : No drug interactions have been reported among women with epilepsy taking lamotrigine and using the LNG-IUD.(123)
ANTIMICROBIAL THERAPY					
a) Broad-spectrum antibiotics	1		1		
b) Antifungals	1		1		
c) Antiparasitics	1		1		
d) Rifampicin or rifabutin therapy	1		1		Evidence : Rifampicin or rifabutin therapy: One cross- sectional survey found that rifabutin had no impact on the effectiveness of LNG-IUD.(122)

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.

POSTPARTUM

< 48 hours, \geq 48 hours to < 4 weeks: there is concern that the neonate may be at risk due to exposure to steroid hormones with LNG-IUD use during the first 4 weeks.

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 VEIN THROMBOSIS/PULMONARY EMBOLISM

The LNG-IUD may be a useful treatment for menorrhagia in women on chronic anticoagulation therapy.

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://ihs-classification.org/en/02_klassifikation (accessed 21 Aug 2009).

SEVERE DYSMENORRHOEA

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

CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

There is some theoretical concern that LNG-IUDs may enhance the 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.

TUBERCULOSIS:

Pelvic: insertion of an IUD may substantially worsen the condition.

HISTORY OF CHOLESTASIS

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

LIVER TUMOURS

There is no evidence regarding hormonal contraceptive use among women with hepatocellular adenoma. Given that COC use in healthy women is associated with development and growth of hepatocellular adenoma, it is not known whether other hormonal contraceptives have similar effects.

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 $\ensuremath{\mathsf{IUDs}}.$

IRON-DEFICIENCY ANAEMIA

There is concern about an increased risk of blood loss with copper $\ensuremath{\mathsf{IUDs}}.$

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COPPER IUD FOR EMERGENCY CONTRACEPTION (E-IUD)

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.

IUDs for emergency contraception 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 * additional comments at end of table	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

BARRIER METHODS (BARR)

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 * additional comments at end of table				CLARIFICATIONS/EVIDENCE
	С	S	D	
C = male latex condoms, male polyurethane condoms, female condoms			S = spermicio	de D = diaphragm (with spermicide), cervical cap

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.

higher typical-use failure rates.				
PERSONAL CHARACTERISTICS ANI	REPRODUCT	IVE HISTORY		
PREGNANCY	NA	NA	NA	NA = not applicable 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) \geq 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 : The diaphragm and cap are unsuitable until uterine involution is complete.
b) \geq 6 weeks postpartum	1	1	1	
POST-ABORTION				
a) First trimester	1	1	1	
b) Second trimester	1	1	1	Clarification : The 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	
SMOKING				
a) Age < 35 years	1	1	1	
b) Age \geq 35 years				
(i) <15 cigarettes/day	1	1	1	
ii) ≥15 cigarettes/day	1	1	1	
OBESITY*				
a) \geq 30 kg/m ² BMI	1	1	1	
b) Menarche to $<$ 18 years and \ge 30 kg/m ² BMI	1	1	1	
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA	NA	NA	Clarification: While a blood pressure measurement may be appropriate for good preventive health care, it is not required for safe and effective barrier method use. Women should not be denied the use of barrier methods simply because their blood pressure cannot be measured.

CONDITION		CATEGORY		CLARIFICATIONS/EVIDENCE			
* additional comments at end of table	I = initia	tion, $C = conf$	tinuation				
	С	S	D				
C = male latex condoms, male polyureth	nane condoms, f	emale condoms	S = spermici	de D = diaphragm (with spermicide), cervical cap			
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.							
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)							
(i) systolic 140-159 or diastolic 90-99 mm Hg	1	1	1				
(ii) systolic ≥160 or diastolic ≥100 mm Hg	1	1	1				
d) Vascular disease	1	1	1				
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) Acute DVT/PE	1	1	1				
c) DVT/PE and established on anticoagulant therapy	1	1	1				
d) Family history (first-degree relatives)	1	1	1				
e) Major surgery							
(i) with prolonged immobilization	1	1	1				
(ii) without prolonged immobilization	1	1	1				
f) Minor surgery without immobilization	1	1	1				

CONDITION * additional comments at end of table	CATEGORY I = initiation, C = continuation			CLARIFICATIONS/EVIDENCE				
additional comments at end of table	C	S S	D					
C = male latex condoms, male polyureth			S = spermici	de D = diaphragm (with spermicide), cervical cap				
Women with conditions which make	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							
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					
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, risk of atrial fibrillation, history of subacute bacterial endocarditis)	1	1	2					
RHEUMATIC DISEASES								
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)								
a) Positive (or unknown) antiphospholipid antibodies	1	1	1					
b) Severe thrombocytopenia	1	1	1					
c) Immunosuppressive treatment	1	1	1					
d) None of the above	1	1	1					
NEUROLOGIC CONDITIONS								
HEADACHES								
a) Non-migrainous (mild or severe)	1	1	1					
b) Migraine								
(i) without aura								
Age < 35 years	1	1	1					
Age ≥ 35 years	1	1	1					
(ii) with aura, at any age	1	1	1					
EPILEPSY	1	1	1					
DEPRESSIVE DISORDERS								
DEPRESSIVE DISORDERS	1	1	1					

CONDITION * additional comments at end of table	I = initia	CATEGORY ation, $C = cont$		CLARIFICATIONS/EVIDENCE
	С	S	D	
C = male latex condoms, male polyurethane condoms, female condoms			S = spermicid	le D = diaphragm (with spermicide), cervical cap

				be advised that barrier methods for pregnancy ly and correctly because of their relatively
REPRODUCTIVE TRACT INFECTIONS	S AND DISOR	DERS		
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	
BENIGN OVARIAN TUMOURS (including cysts)	1	1	1	
SEVERE DYSMENORRHOEA	1	1	1	
GESTATIONAL TROPHOBLASTIC DISEASE				
a) Decreasing or undetectable β-hCG levels	1	1	1	
b) Persistently elevated β-hCG levels or malignant 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	
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.

CONDITION * additional comments at end of table	l = ini <u>t</u> ia	CATEGORY ation, C = con	tinuation	CLARIFICATIONS/EVIDENCE
	С	S	D	
C = male latex condoms, male polyureth	nane condoms, f	emale condoms	S = spermici	de D = diaphragm (with spermicide), cervical cap
Women with conditions which make prevention may not be appropriate to higher typical-use failure rates.	pregnancy an or those who c	unacceptable cannot use the	risk should b m consistently	e advised that barrier methods for pregnancy y and correctly because of their relatively
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	
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	4	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	3	3	
AIDS*	1	3	3	
OTHER INFECTIONS				
SCHISTOSOMIASIS				
a) Uncomplicated	1	1	1	
b) Fibrosis of the liver	1	1	1	
TUBERCULOSIS				
a) Non-pelvic	1	1	1	
a) Pelvic	1	1	1	
MALARIA	1	1	1	
HISTORY OF TOXIC SHOCK SYNDROME*	1	1	3	
URINARY TRACT INFECTION*	1	1	2	

CONDITION * additional comments at end of table	CATEGORY I = initiation, C = continuation		tinuation	CLARIFICATIONS/EVIDENCE
at ond or table	C	S	D	
C = male latex condoms, male polyuretr			S = spermici	de D = diaphragm (with spermicide), cervical cap
Women with conditions which make prevention may not be appropriate for higher typical-use failure rates.	pregnancy an or those who d	unacceptable cannot use the	risk should be m consistently	e advised that barrier methods for pregnancy and correctly because of their relatively
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				
a) Pregnancy-related	1	1	1	
b) Past-COC related	1	1	1	
VIRAL HEPATITIS				
a) Acute or flare	1	1	1	
b) Carrier	1	1	1	
c) Chronic	1	1	1	
CIRRHOSIS				
a) Mild (compensated)	1	1	1	
b) Severe (decompensated)	1	1	1	
LIVER TUMOURS				
a) Benign				
(i) Focal nodular hyperplasia	1	1	1	
(ii) Hepatocellular adenoma	1	1	1	
b) Malignant (hepatoma)	1	1	1	

CONDITION * additional comments at end of table	CATEGORY $I = initiation, C = continuation$		tinuation	CLARIFICATIONS/EVIDENCE
	С	S	D	
C = male latex condoms, male polyureth	ane condoms, fo	emale condoms	S = spermio	cide D = diaphragm (with spermicide), cervical cap
Women with conditions which make prevention may not be appropriate fo higher typical-use failure rates.	pregnancy an r those who c	unacceptable annot use the	risk should t m consistent	pe advised that barrier methods for pregnancy ly and correctly because of their relatively
ANAEMIAS				
THALASSAEMIA	1	1	1	
SICKLE CELL DISEASE	1	1	1	
IRON-DEFICIENCY ANAEMIA	1	1	1	
DRUG INTERACTIONS				
ANTIRETROVIRAL THERAPY				
a) Nucleoside reverse transcriptase inhibitors (NRTIs)	1	3	3	Clarification: There is no known drug interaction between ARV therapy and barrier method use. However, HIV infection and AIDS as conditions are classified as Category 3 for spermicides and diaphragms (see HIV/AIDS condition above.)
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	1	3	3	
c) Ritonavir-boosted protease inhibitors	1	3	3	
ANTICONVULSANT THERAPY				
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1	1	1	
b) Lamotrigine	1	1	1	
ANTIMICROBIAL THERAPY				
a) Broad-spectrum antibiotics	1	1	1	
b) Antifungals	1	1	1	
c) Antiparasitics	1	1	1	
d) Rifampicin or rifabutin therapy	1	1	1	
ALLERGY TO LATEX	3	1	3	Clarification: This does not apply to plastic condoms/diaphragm

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 in a client with subacute 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 4 for diaphragm use is assigned due to concerns about the spermicide, not the diaphragm.

HIV-INFECTED

Use of spermicides and/or diaphragms (with spermicide) can disrupt the cervical mucosa, which may lead to increased viral shedding and HIV transmission to uninfected sexual partners.

AIDS

Use of spermicides and/or diaphragms (with spermicide) can disrupt the cervical mucosa, which may lead to increased viral shedding and HIV transmission to uninfected sexual partners.

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.

REFERENCE LIST

(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 (FAB)

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 that 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

CONDITION	CATE	GORY	CLARIFICATIONS/EVIDENCE		
* additional comments at end of table	SYM	CAL			
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY					
Women with conditions which make for pregnancy prevention may not be	Women with conditions which make pregnancy an unacceptable risk should be advised that fertility awareness-based methods for pregnancy prevention may not be appropriate for them because of their relatively-higher typical-use failure rates.				
PREGNANCY	NA	NA	Clarification : Fertility awareness-based methods are not relevant during pregnancy.		
LIFE STAGE			Clarification: Menstrual irregularities are common in post-		
a) Post-menarche	С	С	menarche and peri-menopause and may complicate the use of fertility awareness-based methods		
b) Peri-menopause	С	С			
BREASTFEEDING*					
a) < 6 weeks postpartum	D	D			
b) \geq 6 weeks	С	D			
c) After menses begin	С	С			
POSTPARTUM* (in non-breastfeeding women)					
a) < 4 weeks	D	D			
b) \geq 4 weeks	А	D			
POST-ABORTION*	С	D			
REPRODUCTIVE TRACT INFECTIONS	S AND DISORDER	RS			
IRREGULAR VAGINAL BLEEDING*	D	D			
VAGINAL DISCHARGE*	D	А			
OTHER					
USE OF DRUGS THAT AFFECT CYCLE REGULARITY, HORMONES AND/OR FERTILITY SIGNS*	C/D	C/D			
DISEASES THAT ELEVATE BODY TEMPERATURE*					
a) Chronic diseases	С	А			
b) Acute diseases	D	А			

ADDITIONAL COMMENTS

BREASTFEEDING

Fertility awareness-based methods during breastfeeding may be less effective than when not breastfeeding.

BREASTFEEDING

< 6 weeks postpartum: women who are primarily breast-feeding and are amenorrhoeic are unlikely to have sufficient ovarian function to produce detectable fertility signs and hormonal changes during the first 6 weeks 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. First postpartum menstrual cycles in breastfeeding women vary significantly in length. It takes several cycles for the return to regularity. When she has had at least three postpartum menses and her cycles are regular again, she can use a calendar-based method. When she has had at least four postpartum menses and her most recent cycle was 26-32 days long, she can use the Standard Days Method. Prior to that time, a barrier method should be offered if the woman plans to use a fertility awareness-based method later.

POSTPARTUM

< 4 weeks: non-breastfeeding woman are not likely to have sufficient ovarian function to either require a fertility awareness-based method or have detectable fertility signs or hormonal changes prior to 4 weeks postpartum. Although the risk of pregnancy is low, a method that is 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; the likelihood increases rapidly with time postpartum. Women can use calendar-based methods as soon as they have completed at least three postpartum menses and cycles are regular again. A woman can use the Standard Days Method when she has had at least four postpartum menses and her most recent cycle was 26-32 days long. 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: the 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

The presence of this condition makes fertility awarenessbased 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 THAT AFFECT CYCLE REGULARITY, HOR-MONES 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. Calendar-based methods are only appropriate if menstrual cycles are regular and predictable.

DISEASES THAT 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 (LAM)

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 that 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. A woman infected with HIV, however, can transmit the virus to her child through breastfeeding. Yet breastfeeding, and especially early and exclusive breastfeeding, is one of the most critical factors for improving child survival. Breastfeeding also confers many other benefits in addition to reducing the risk of death.

There is now strong evidence that giving antiretroviral drugs (ARVs) to either the HIV-infected mother or HIV-exposed infant or both can significantly reduce the risk of transmitting HIV through breastfeeding (http://www.who.int/hiv/topics/mtct). This transforms the landscape in which decision should be made by national health authorities and individual mothers. In the presence of ARVs, either lifelong antiretroviral therapy to the mother or other ARV interventions to the mother or infant, the infant

can receive all the benefits of breastfeeding with little risk of becoming HIV infected. In some well-resourced countries with low infant and child mortality rates, avoidance of all breastfeeding will still be appropriate.

HIV-infected mothers should receive the appropriate ARV interventions and should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided. When mothers decide to stop breastfeeding, they should stop gradually within one month and infants should be provided with safe and adequate replacement feeds to enable normal growth and development.

Mothers known to be HIV infected should only give commercial infant formula milk as a replacement feed to their HIV-uninfected infants or infants who are of unknown HIV status, when specific conditions are met:

- a. safe water and sanitation are assured at the household level and in the community, **and**,
- the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant, and,
- the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition, and,
- d. the mother or caregiver can, in the first six months, exclusively give infant formula milk, **and**,
- e. the family is supportive of this practice, and,
- f. the mother or caregiver can access health care that offers comprehensive child health services.

If infants and young children are known to be HIV infected, mothers are strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding as per the recommendations

for the general population, that is up to two years or beyond.

Women who are HIV infected should receive skilled counselling to help them. They should also have access to follow-up care and support, including family planning and nutritional support.

MEDICATION USED DURING BREASTFEEDING

In order to protect infant health, breastfeeding is not recommended for women using such drugs as: antimetabolites, bromocriptine, certain anticoagulants, corticosteroids (high doses), ciclosporin, 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 can all make breastfeeding difficult.

COITUS INTERRUPTUS (CI)

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.

SIE

SURGICAL STERILIZATION PROCEDURES (STER)

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.

FEMALE SURGICAL STERILIZATION

CONDITION	CATEGORY	CLARIFICATIONS/EVIDENCE
* additional comments at end of table	A = accept C = caution	
PERSONAL CHARACTERISTICS AND	D = delay S = special	
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 referral information and obtaining reversal) that can be identified before sterilization.(1-19)
PARITY*		
a) Nulliparous	А	
b) Parous	А	
BREASTFEEDING	А	
POSTPARTUM*		
a) < 7 days	А	
7 to < 42 days	D	
\geq 42 days	А	
b) Pre-eclampsia/eclampsia		
(i) mild pre-eclampsia	А	
(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	
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	А	
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	

CONDITION	CATEGORY	CLARIFICATIONS/EVIDENCE
* additional comments at end of table	A = accept C = caution D = delay S = special	
PAST ECTOPIC PREGNANCY	А	
SMOKING		
a) Age < 35 years	А	
b) Age ≥ 35 years		
(i) < 15 cigarettes/day	А	
ii) \geq 15 cigarettes/day	А	
OBESITY		Clarification: The procedure may be more difficult. There is an
a) \geq 30 kg/m ² BMI	С	increased risk of wound infection and disruption. Obese women may have limited respiratory function and may be more likely to require
b) Menarche to < 18 years and	С	general anaesthesia.
\geq 30 kg/m ² BMI		Evidence : Women who were obese were more likely to have complications when undergoing sterilization.(20-23)
CARDIOVASCULAR DISEASE		
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE* (such as older age, smoking, diabetes and hypertension)	S	
multiple risk factors do exist, the risk of card classify a woman as hypertensive.	liovascular disease may increase	on that no other risk factors for cardiovascular disease exist. When e substantially. A single reading of blood pressure level is not sufficient to
a) Hypertension: adequately controlled	С	
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.
(i) systolic 140-159 or diastolic 90-99 mm Hg	С	Careful monitoring of blood pressure intra-operatively is particularly necessary in this situation.
(ii) systolic ≥160 or diastolic ≥100 mm Hg	S	
c) Vascular disease	S	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current blood pressure is measurable and normal)	А	
DEEP VENOUS THROMBOSIS (DVT)/ PULMONARY EMBOLISM (PE)		Clarification : To reduce the risk of DVT/PE, early ambulation is recommended.
a) History of DVT/PE	А	
b) Acute DVT/PE	D	
c) DVT/PE and established on anticoagulant therapy	S	
d) Family history (first-degree relatives)	А	
e) Major surgery		
(i) with prolonged immobilization	D	
(ii) without prolonged immobilization	А	
f) Minor surgery without immobilization	А	

CONDITION	CATEGORY	CLARIFICATIONS/EVIDENCE
* additional comments at end of table	$\mathbf{A} = \mathbf{accept} \mathbf{C} = \mathbf{caution}$	
KNOWN THROMBOGENIC MUTATIONS (e.g., factor V Leiden; prothrombin mutation; protein S, protein C, and antithrombin deficiencies)	D = delay S = special 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	А	
b) Superficial thrombophlebitis	А	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE*		
a) Current ischaemic heart disease	D	
b) History of ischaemic heart disease	С	
STROKE (history of cerebrovascular accident)	С	
KNOWN HYPERLIPIDAEMIAS	А	Clarification : Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
VALVULAR HEART DISEASE		
a) Uncomplicated	С	Clarification: The woman requires prophylactic antibiotics.
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	S	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.
RHEUMATIC DISEASES		
in the MEC should be the same for women wassumption that no other risk factors for car	naemic heart disease, stroke and with SLE who present with these diovascular disease are present;	venous thromboembolism. Categories assigned to such conditions conditions. For all categories of SLE, classifications are based on the these classifications must be modified in the presence of such risk sidered good candidates for most contraceptive methods, including
a) Positive (or unknown) antiphospholipid antibodies	S	
b) Severe thrombocytopenia	S	
c) Immunosuppressive treatment	S	
d) None of the above	С	
NEUROLOGIC CONDITIONS		
HEADACHES		
a) Non-migrainous (mild or severe)	А	
b) Migraine		
(i) without aura		
Age < 35 years	А	
Age ≥ 35 years	А	
(ii) with aura, at any age	А	
EPILEPSY	С	

CONDITION * additional comments at end of table	CATEGORY A = accept C = caution D = delay S = special	CLARIFICATIONS/EVIDENCE
DEPRESSIVE DISORDERS		
DEPRESSIVE DISORDERS	С	
REPRODUCTIVE TRACT INFECTIONS	S AND DISORDERS	
VAGINAL BLEEDING PATTERNS		
a) Irregular pattern without heavy bleeding	А	
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	А	
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition)		Clarification : The condition must be evaluated before the procedure is performed
Before evaluation	D	
ENDOMETRIOSIS	S	
BENIGN OVARIAN TUMOURS (including cysts)	А	
SEVERE DYSMENORRHOEA	А	
GESTATIONAL TROPHOBLASTIC DISEASE		
a) Decreasing or undetectable β-hCG levels	А	
b) Persistently elevated β-hCG levels or malignant disease	D	
CERVICAL ECTROPION	А	
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	А	
CERVICAL CANCER* (awaiting treatment)	D	
BREAST DISEASE		
a) Undiagnosed mass	А	
b) Benign breast disease	А	
c) Family history of cancer	А	
d) Breast cancer		
(i) current	С	
(ii) past and no evidence of current disease for 5 years	А	
ENDOMETRIAL CANCER*	D	
OVARIAN CANCER*	D	
UTERINE FIBROIDS*		
a) Without distortion of the uterine cavity	С	
b) With distortion of the uterine cavity	С	

CONDITION * additional comments at end of table		CLARIFICATIONS/EVIDENCE
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
(i) with subsequent pregnancy	А	mobility of the uterus.
(ii) without subsequent pregnancy	С	
b) PID - current	D	
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)	А	
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	А	
d) Increased risk of STIs	А	
HIV/AIDS		
HIGH RISK OF HIV	А	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	А	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 that the procedure be delayed.
OTHER INFECTIONS		
SCHISTOSOMIASIS		
a) Uncomplicated	Α	
b) Fibrosis of the liver (if severe, see cirrhosis)	С	Clarification: Liver function may need to be evaluated.
TUBERCULOSIS		
a) Non-pelvic	А	
b) Pelvic	S	
MALARIA	А	

CONDITION * additional comments at end of table		CLARIFICATIONS/EVIDENCE
ENDOCRINE CONDITIONS		
DIABETES*		Clarification: If blood glucose is not well controlled, referral to a
a) History of gostational diagona	Λ	higher-level facility is recommended.
a) History of gestational disease b) Non-vascular disease	А	Clarification. There is a possible degrees in healing and an
,	C	Clarification: There is a possible decrease in healing and an increased risk of wound infection. Use of prophylactic antibiotics is
(i) non-insulin dependent	C	recommended.
(ii) insulin dependent	С	Evidence : Diabetic women were more likely to have complications when undergoing sterilization.(22)
c) Nephropathy/retinopathy/ neuropathy	S	mon anod going ocomeaton(LE)
d) Other vascular disease or diabetes of > 20 years' duration	S	
THYROID DISORDERS*		
a) Simple goitre	А	
b) Hyperthyroid	S	
c) Hypothyroid	С	
GASTROINTESTINAL CONDITIONS		
GALL BLADDER DISEASE		
a) Symptomatic		
(i) treated by cholecystectomy	А	
(ii) medically treated	А	
(iii) current	D	
b) Asymptomatic	А	
HISTORY OF CHOLESTASIS		
a) Pregnancy related	А	
b) Past-COC related	А	
VIRAL HEPATITIS*		Clarification: Appropriate infection-prevention procedures,
a) Acute or flare	D	including universal precautions, must be carefully observed with all surgical procedures.
b) Carrier	А	Salgion procedures.
c) Chronic	А	
CIRRHOSIS		Clarification: Liver function and clotting might be altered. Liver
a) Mild (compensated)	А	function should be evaluated.
b) Severe (decompensated)	S	
LIVER TUMOURS		Clarification: Liver function and clotting might be altered. Liver
a) Benign		function should be evaluated.
(i) Focal nodular hyperplasia	А	
(ii) Hepatocellular adenoma	С	
b) Malignant (hepatoma)	С	

CONDITION * additional comments at end of table	CATEGORY A = accept C = caution D = delay S = special	CLARIFICATIONS/EVIDENCE
ANAEMIAS		
THALASSAEMIA	С	
SICKLE CELL DISEASE*	С	
IRON-DEFICIENCY ANAEMIA		Clarification: The underlying disease should be identified. Both
a) Hb < 7g/dl	D	preoperative haemoglobin (Hb) level and operative blood loss are important factors in women with anaemia. If peripheral perfusion is
a) Hb ≥ 7 to < 10g/dl	С	inadequate, this may decrease wound healing.
OTHER CONDITIONS RELEVANT ONL	Y FOR FEMALE SURGICAL	STERILIZATION
LOCAL INFECTION	D	Clarification: There is an increased risk of postoperative infection.
COAGULATION DISORDERS*	S	
RESPIRATORY DISEASES		
a) Acute (bronchitis, pneumonia)	D	Clarification : The procedure should be delayed until the condition is corrected. There are increases in anaesthesia-related and other perioperative risks.
b) Chronic		
(i) asthma	S	
(ii) bronchitis	S	
(iii) emphysema	S	
(iv) lung infection	S	
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*	С	
KIDNEY DISEASE*	С	
SEVERE NUTRITIONAL DEFICIENCIES*	С	
PREVIOUS ABDOMINAL OR PELVIC SURGERY	С	Evidence : Women with previous abdominal or pelvic surgery were more likely to have complications when undergoing sterilization. (21;22;24-26)
STERILIZATION CONCURRENT WITH ABDOMINAL SURGERY		
a) Elective	С	
b) Emergency (without previous counselling)	D	
c) Infectious condition	D	
STERILIZATION CONCURRENT WITH CAESAREAN SECTION*	А	

MALE SURGICAL STERILIZATION

Sterilization does 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 * additional comments at end of table		CLARIFICATIONS/EVIDENCE
PERSONAL CHARACTERISTICS AND I	REPRODUCTIVE HISTORY	
YOUNG AGE	С	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	С	
HIV/AIDS		
HIGH RISK OF HIV	А	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	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		Clarification: The presence of an AIDS-related illness may require
On ARV therapy	S	that the procedure be delayed.
ENDOCRINE CONDITIONS		
DIABETES*	С	Clarification: If blood glucose is not well controlled, referral to a higher-level facility is recommended.
ANAEMIAS		
SICKLE CELL DISEASE	А	
OTHER CONDITIONS RELEVANT ONL	Y FOR MALE SURGICAL S	TERILIZATION
LOCAL INFECTION*		
a) Scrotal skin infection	D	
b) Active STI	D	
c) Balanitis	D	
d) Epididymitis or orchitis	D	
COAGULATION DISORDERS*	S	
PREVIOUS SCROTAL INJURY	С	
SYSTEMIC INFECTION OR GASTROENTERITIS*	D	
LARGE VARICOCELE*	С	
LARGE HYDROCELE*	С	
FILIARIASIS; ELEPHANTIASIS*	D	
INTRASCROTAL MASS*	D	
CRYPTORCHIDISM	С	
INGUINAL HERNIA*	S	

ADDITIONAL COMMENTS FOR FEMALE 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 the time of delivery): there may have been significant blood loss and anaemia.

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 the 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 when the procedure is performed, particularly if blood sugar is not well controlled before the procedure.

THYROID DISORDERS

The woman is at higher 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.

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 dose not increase the risk of complications in a surgically stable client.

ADDITIONAL COMMENTS FOR MALE STERILIZATION

DIABETES

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

LOCAL INFECTION

There is an increased risk of postoperative infection.

COAGULATION DISORDERS

Bleeding disorders lead to an increased risk of postoperative haematoma formation which, in turn, leads to an increased risk of 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 underlying disease.

INGUINAL HERNIA

Vasectomy can be performed concurrent with hernia repair.

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SUMMARY TABLES (SUMM)

CONDITION	COC	CIC	P/R	POP	DMPA NET-EN	LNG/ ETG	Cu-IUD	LNG-IUD
					WEI EN	Implants		
	itiation, C =	continuation	on, BF = br	eastfeeding	NA = not a			
PERSONAL CHARACTERISTIC					, 			
PREGNANCY	NA [†]	NA [†]	NA [†]	NA [†]	NA [†]	NA [†]	4 [†]	4 [†]
AGE	Menarche	Mena	arche	Menarche	Menarche	Menarche	Menarche	Menarche
	to < 40=1	to <		to < 18=1	to < 18=2	to < 18=1	to < 20=2	to < 20=2
	≥40=2	<u>≥</u> 4	0=2	18-45=1	18-45=1	18-45=1	≥20=1	≥20=1
				>45=1	>45=2	>45=1		
PARITY								
a) Nulliparous	1	1	1	1	1	1	2	2
b) Parous	1	1	1	1	1	1	1	1
BREASTFEEDING	,			0.4	0+	0+		
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) \geq 6 months postpartum	2	2	2	1	1	1		
POSTPARTUM (non-breastfeeding women)								
a) < 21 days				1	1	1		
(i) without other risk factors for VTE	3 [†]	3 [†]	3 [†]					
(ii) with other risk factors for VTE	3/4†	$3/4^{\dagger}$	3/4†					
b) \geq 21 days				1	1	1		
(i) without other risk factors for VTE	2 [†]	2†	2 [†]					
(ii) with other risk factors for VTE	2/3 [†]	2/3†	2/3 [†]					
c) > 42 days	1	1	1	1	1	1		
POSTPARTUM (breastfeeding or non-breastfeeding women, including after caesarean section)								
a) < 48 hours including insertion immediately after delivery of the placenta							1	1=not BF 3=BF
b) \geq 48 hours to <4 weeks							3	3
c) \geq 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

 $^{^{\}dagger}$ Please consult the tables in the text for a clarification to this classification

CONDITION	COC	CIC	P/R	POP	DMPA NET-EN	LNG/ ETG Implants	Cu-IUD	LNG-IUD
I = in	itiation, C =	continuation	on, BF = br	eastfeeding	, NA = not	applicable		
HISTORY OF PELVIC SURGERY (see postpartum, including caesarean section)	1	1	1	1	1	1	1	1
SMOKING								
a) Age < 35 years	2	2	2	1	1	1	1	1
b) Age \geq 35 years								
(i) <15 cigarettes/day	3	2	3	1	1	1	1	1
(ii) ≥15 cigarettes/day	4	3	4	1	1	1 1	1	1
OBESITY a) \geq 30 kg/m ² BMI	2	2	2	1	1	1	1	1
b) Menarche to < 18 years and ≥ 30 kg/m² BMI	2	2	2	1	DMPA=2 NET-EN=1 [†]	1	1	1
BLOOD PRESSURE MEASUREMENT UNAVAILABLE	NA [†]	NA [†]	NA [†]	NA [†]				
CARDIOVASCULAR DISEASE		<u></u>		<u> </u>	<u> </u>			
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 c) Elevated blood pressure levels (properly taken measurements)	3†	3 [†]	3 [†]	1 [†]	2 [†]	1 [†]	1	1
(i) systolic 140-159 or diastolic 90-99 mm Hg	3	3	3	1	2	1	1	1
(ii) systolic ≥160 or diastolic ≥100 mm Hg	4	4	4	2	3	2	1	2
d) Vascular disease	4	4	4	2	3	2	1	2
PRESURE DURING PREGNANCY (where current blood pressure is measurable and normal)	2	2	2	1	1	1	1	1

 $^{^{\}scriptscriptstyle\dagger}$ Please consult the tables in the text for a clarification to this classification

CONDITION	COC	CIC	P/R	POP	DMPA NET-EN	LNG/ ETG Implants	Cu-IUD	LNG-IUD
	itiation. C =	 - continuatio	on. BF = bre	l eastfeeding	. NA = not	<u> </u>		
DEEP VENOUS THROMBOSIS (DVT)/PULMONARY EMBOLISM (PE)	,		,		,			
a) History of DVT/PE	4	4	4	2	2	2	1	2
b) Acute DVT/PE	4	4	4	3	3	3	1	3
c) DVT/PE and established on anticoagulant therapy	4	4	4	2	2	2	1	2
d) Family history (first-degree relatives)	2	2	2	1	1	1	1	1
e) Major surgery								
(i) with prolonged immobilization	4	4	4	2	2	2	1	2
(ii) without prolonged im- mobilization	2	2	2	1	1	1	1	1
f) 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	1 C 2 3	3	1 C 2 3	1	1 C 2 3
(history of cerebrovascular accident)	4	4	4	1 C 2 3	3	1 C 2 3	1	2
KNOWN HYPERLIPIDAEMIAS	2/3 [†]	2/3 [†]	2/3†	2 [†]	2 [†]	2†	1 †	2†
VALVULAR HEART DISEASE								
a) Uncomplicated	2	2	2	1	1	1	1	1 1
b) Complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)	4	4	4	1	1	1	2 [†]	2 [†]
RHEUMATIC DISEASES								
SYSTEMIC LUPUS ERYTHEMATOSUS					I C		I C	
a) Positive (or unknown) antiphospholipid antibodies	4	4	4	3	3 3	3	1 1	3
b) Severe thrombocytopenia	2	2	2	2	3 2	2	3 [†] 2 [†]	2†
c) Immunosuppressive treatment	2	2	2	2	2 2	2	2 1	2
d) None of the above	2	2	2	2	2 2	2	1 1	2

 $^{^{\}dagger}$ Please consult the tables in the text for a clarification to this classification

CONDITION		OC		IC		/R		OP	NE	/IPA Γ-EN	E ⁻ Impl	IG/ FG lants	Cu-I	UD	LNG	i-IUD
	itiatio	1, C =	conti	inuatio	on, BF	= br	eastfe	eding	, NA =	= not	applic	able				
NEUROLOGIC CONDITIONS	ı		ı		,		,									
HEADACHES	1	С	I	С	1	С	1	С	1	С	1	С				С
a) Non-migrainous	1 [†]	2^{\dagger}	1 [†]	2^{\dagger}	1 [†]	2^{\dagger}	1 [†]	1 [†]	11	t	1 [†]	1 [†]				
(mild or severe)																
b) Migraine																
(i) without aura																
Age < 35 years	2†	3†	2†	3⁺	2†	3⁺	1 [†]	2^{\dagger}	2†	2^{\dagger}	2†	2^{\dagger}	11	t	2†	2^{\dagger}
Age ≥ 35 years	3 [†]	4^{\dagger}	3 [†]	4^{\dagger}	3 [†]	4^{\dagger}	1 [†]	2^{\dagger}	2†	2^{\dagger}	2†	2^{\dagger}	11	t	2†	2^{\dagger}
(ii) with aura (at any age)	4 [†]	4 [†]	4 [†]	4^{\dagger}	4 [†]	4^{\dagger}	2†	3 [†]	2†	3^{\dagger}	2†	3^{\dagger}	11	†	2†	3 [†]
EPILEPSY	1	†	1	†	1	†	-	 †	-	1 †	-	1 †	1			1
		lf or	n treati	ment,	see DF	RUG IN	ITERA	CTIONS	S secti	on						
DEPRESSIVE DISORDERS																
DEPRESSIVE DISORDERS	1	†	1	1 †	1	†	-	1 †	-	1 [†]	-	1 [†]	11	t	-	1 [†]
REPRODUCTIVE TRACT INFEC	TIONS	S AND	DISO	RDER	S											
VAGINAL BLEEDING PATTERNS																С
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	†	4	<u>2</u> †	4	2†	4	2†	2†	t	1 [†]	2 [†]
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition)		n+		D+) +		D+		D+		D+	 	C 2†		C
Before evaluation		<u>†</u>		2†		2†		2†		3†		3†	1 1		-	2 [†]
ENDOMETRIOSIS BENIGN OVARIAN TUMOURS		<u>1</u> 1		1 1		1 1		1 1		1 1		1 1	1			1 1
(including cysts) SEVERE DYSMENORRHOEA		 1		1		1		1		1		1	2			1
GESTATIONAL TROPHOBLASTIC DISEASE		I		I		I		1		1		1				I
a) Decreasing or undetectable β-hCG levels		1		1		1		1		1		1	3			3
b) Persistently elevated β-hCG levels or malignant 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)		2		2		2		1		2		2	4	C 2	4	C 2

[†] Please consult the tables in the text for a clarification to this classification

CONDITION	COC	CIC	P/R	POP	DMPA	LNG/	Cu-IUD	LNG	-IUD
					NET-EN	ETG Implants			
	itiation. C =	continuation	n. BF = br	ı eastfeeding	. NA = not :				
BREAST DISEASE			, 5.		,				
a) Undiagnosed mass	2 [†]	2 [†]	2^{\dagger}	2 [†]	2 [†]	2 [†]	1	2	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) Breast cancer									
(i) current	4	4	4	4	4	4	1	4	1
(ii) past and no evidence of current disease for 5 years	3	3	3	3	3	3	1	3	3
ENDOMETRIAL CANCER							I C	l	С
0	1	1	1	1	1	1	4 2	4	2
OVARIAN CANCER	1	1 1	1	 1	1	1	1 C 3 2	3	C 2
UTERINE FIBROIDS	'	'	'	'	'	'	0 2	"	
a) Without distortion of the	1	1	1	1	1	1	1	1	.
uterine cavity	'		ı	1	'	'	'	'	
b) With distortion of the uterine cavity	1	1	1	1	1	1	4	4	1
ANATOMICAL ABNORMALITIES									
a) That distort the uterine cavity							4	4	1
b) That do not distort the uterine cavity							2	2	2
PELVIC INFLAMMATORY DISEASE (PID)									
a) Past PID (assuming no current risk factors of STIs)							I C	1 1	С
(i) with subsequent	1	1	1	1	1	1	1 1	1	1
pregnancy ii) without subsequent	1	1	1	1	1	1	2 2	2	2
pregnancy		4	4				4 0+	1	O+
b) PID – current STIs	1	1	1	1	1	1	4 2 [†]	4	2†
a) Current purulent cervicitis	1	1	1	1	1	1	4 2	4	C 2 [†]
or chlamydial infection or gonorrhoea	'	l	ı	'	'	'	4 2'	4	۷'
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

 $^{^{\}scriptscriptstyle\dagger}$ Please consult the tables in the text for a clarification to this classification

CONDITION	COC	CIC	P/R	POP	DMPA NET-EN	LNG/ ETG Implants	Cu-IUD	LNG-IUD
l = in	itiation, C =	continuatio	on, BF = bro	eastfeeding	, NA = not	applicable		
HIV/AIDS								
							I C	I C
HIGH RISK OF HIV	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		If on treatme	ent, see DRU	IG INTERACT	ONS section	']	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
2) Tale 1111 period		I		ı ent see DRH		IONS section	1	1
MALARIA	1	1	1	1	1	1	1	1
ENDOCRINE CONDITIONS	1	1		<u> </u>			<u> </u>	1
DIABETES								
	1	4		1	1	1	1	1
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	1 1	1
c) Hypothyroid	1	1 1	1 1	1 1	1	1 1	1 1	1
GASTROINTESTINAL CONDITI	<u> </u>	'	'	'	'	'	'	'
GALL BLADDER DISEASE								
a) Symptomatic								
(i) treated by	2	2	2	2	2	2	1	2
cholecystectomy	2		2	0	0		-	0
(ii) medically treated	3	2	3	2	2	2	1	2
(iii) current	3	2	3	2	2	2 2	1	2
b) Asymptomatic	2	2	2	2	2		1	2
HISTORY OF CHOLESTASIS						4		
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	1 C	I C	I C					
a) Acute or flare	3/4† 2	3 2	3/4† 2	1	1	1	1	1
b) Carrier	1 1	1 1	1 1	1	1	1	1	1
c) Chronic	1 1	1 1	1 1	1	1	1	1	1

[†] Please consult the tables in the text for a clarification to this classification

CONDITION	COC	CIC	P/R	POP	DMPA NET-EN	LNG/ ETG Implants	Cu-	IUD	LNG	-IUD
I = ini	itiation, C =	continuation	on, BF = bro	eastfeeding	, NA = not a	applicable				
CIRRHOSIS										
a) Mild (compensated)	1	1	1	1	1	1	-	1	1	i
b) Severe (decompensated)	4	3	4	3	3	3	-	1	3	3
LIVER TUMOURS										
a) Benign										
(i) Focal nodular hyperplasia	2	2	2	2	2	2	-	1	2	
(ii) Hepatocellular adenoma	4	3	4	3	3	3	-	1	3	3
b) Malignant (hepatoma)	4	3/4	4	3	3	3		1	3	3
ANAEMIAS										
THALASSAEMIA	1	1	1	1	1	1	4	2	1	
SICKLE CELL DISEASE	2	2	2	1	1	1	2	2	1	
IRON-DEFICIENCY ANAEMIA	1	1	1	1	1	1	2	2	1	
DRUG INTERACTIONS										
ANTIRETROVIRAL THERAPY (SEE ANNEX	1)					I	С	I	С
a) Nucleoside reverse transcriptase inhibitors (NRTIs)	1 [†]	1	1	1	DMPA=1 NET-EN=1	1	2/3†	2†	2/3†	2†
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2 [†]	2 [†]	2 [†]	2 [†]	DMPA=1 NET-EN=2 [†]	2 [†]	2/3†	2^{\dagger}	2/3†	2†
c) Ritonavir-boosted protease inhibitors	3 [†]	3 [†]	3 [†]	3 [†]	DMPA=1 NET-EN=2 [†]	2 [†]	2/3 [†]	2^{\dagger}	2/3†	2†
ANTICONVULSANT THERAPY										
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3 [†]	2	3 [†]	3 [†]	DMPA=1 NET-EN=2 [†]	2 [†]	-	1	1	ı
b) Lamotrigine	3 [†]	3	3	1	1	1	1		1	
ANTIMICROBIAL THERAPY										
a) Broad-spectrum antibiotics	1	1	1	1	1	1	-	1	1	
b) Antifungals	1	1	1	1	1	1	-	1 1		
c) Antiparasitics	1	1	1	1	1	1	-	1	1	
d) Rifampicin or rifabutin therapy	3 [†]	2 [†]	3 [†]	3 [†]	DMPA=1 NET-EN=2 [†]	2 [†]	_	1	1	

 $^{^{\}dagger}$ Please consult the tables in the text for a clarification to this classification

ANNEX 1. HORMONAL CONTRACEPTIVES AND ANTIRETROVIRAL THERAPIES

Limited data from small, mostly unpublished studies suggest that the pharmacokinetics of COCs may be altered by some antiretroviral (ARV) therapies. Few studies have measured clinical outcomes. However, large decreases in contraceptive steroid level in the blood are seen with ritonavir-boosted protease inhibitors. Decreases of this size have the potential to compromise contraceptive effectiveness. Some of the interactions between contraceptives and ARVs have also led to increased ARV toxicity. With regard to the smaller effects seen with non-nucleoside reverse transcriptase inhibitors (NNRTIs), the clinical significance is unknown, especially since studies have not examined

steady-state levels of contraceptive hormones. To date, no clinically significant interactions have been reported between contraceptive hormones and nucleoside reverse transcriptase inhibitors (NRTIs).

The following tables summarize the evidence available to date regarding drug interactions between ARV therapies and hormonal contraceptives. For up-to-date, detailed information on HIV drug interactions, we recommend consulting an external resource such as the HIV Drug Interactions website: www.hiv-druginteractions.org.

Table 1. COC-ARV drug interactions

ARV	CONTRACEPTIVE EFFECTS	ARV EFFECTS
All	CONTINUE TIVE ETTEOTO	And Elifedia
NUCLEOSIDE REVERSE TRANSCRIF	PTASE INHIBITORS (NRTIS)	
Tenofovir disaproxil fumarate (TDF)	EE↔NGM↔(1)	Tenofovir↔(1)
Zidovudine (ZDV or AZT)		Zidovudine↔(2) No change in viral load or CD4+(2)
NON-NUCLEOSIDE REVERSE TRANS	SCRIPTASE INHIBITORS (NNRTIS)	
Efavirenz (EFV or EFZ)	EE↑(3), EE→(4), NGM↓(4), LNG↓(4) Pregnancy rate 2.6/100 woman-years in one study where up to 80% used hormonal contraceptives (35% used COC)(5)	Efavirenz↔(3;4)
Etravirine	EE↔NET↔(6)	Etravirine ↑(6) Concurrent administration, generally safe and well tolerated(6)
Nevirapine (NVP)	EE↔NET↔(7)	Nevirapine ← (7)
PROTEASE INHIBITORS AND RITON	AVIR-BOOSTED PROTEASE INHIBITORS	
Atazanavir/ritonavir (ATV/r)	EE↑NET↑(8)	
Darunavir/ritonavir (DRV/r)	EE↓NET↔(9)	Darunavir↔(9)
Fos-amprenavir/ ritonavir (FPV/r)	EE↓(10;11) NET↓(11)	Amprenavir ↔ ritonavir↑ Elevated liver transaminases(10)
Indinavir (IDV)†	EE↔NET↔(12)	
Lopinavir/ritonavir (LPV/r)	EE↓NET↔(13)	
Nelfinavir (NFV)	EE↓NET↔(14)	
Saquinavir (SQV)†		Saquinavir ↔(15;16)
Tipranavir/ritonavir (TPV/r)	EE↓(17)	↑ skin and musculoskeletal adverse events; possible drug hypersensitivity reaction(17)

Legend:

 \leftrightarrow no change or change \leq 30%;

 \uparrow increase > 30%;

↓ decrease > 30%

Abbreviations:

COC = combined oral contraceptive

 $\mathsf{EE} = \mathsf{ethinylestradiol}$

LNG = levonorgestrel

NET = norethindrone

NGM = norgestimate

[†] Saquinavir and indinavir are commonly given boosted by ritonavir, but there are no data on contraceptive interactions with the boosted regimens.

Table 2. DMPA-ARV Drug interactions

ARV	CONTRACEPTIVE EFFECTS	ARV EFFECTS			
NUCLEOSIDE REVERSE TRANSCR	IPTASE INHIBITORS (NRTIS)				
Zidovudine (ZDV or AZT)		Zidovudine↔(2) No change in viral load			
NON-NUCLEOSIDE REVERSE TRA	NSCRIPTASE INHIBITORS (NNRTIS)				
Efavirenz (EFV or EFZ)	MPA↔(18;19) No ovulations during three cycles(18;19) Pregnancy rate 2.6/100 woman-years in one study where up to 80% used hormonal contraceptives (65% used POIs)(5)	Efavirenz ↔ (18) No change in viral load or CD4+, no grade 3- or 4-related adverse events † (20)			
Nevirapine (NVP)	MPΔ↔(18)				
PROTEASE INHIBITORS AND RITO	NAVIR-BOOSTED PROTEASE INHIBITORS				
Nelfinavir (NFV)	MPA↔(18)	Nelfinavir ↔(18) No change in viral load or CD4+, no grade 3- or 4-related adverse events [†] (20)			

Legend:

 \leftrightarrow no change or change \leq 30%;

 \uparrow increase > 30%;

Abbreviations:

 $\label{eq:MPA} \text{MPA} = \text{medroxyprogesterone acetate}$

POIs = progestogen-only injectables

[†] The trial applied the standardized National Institutes of Health Division of AIDS Table for Grading Severity of Adult and Pediatric Adverse Events, December 2004 (Clarification dated August 2009), http://rsc.tech-res.com/safetyandpharmacovigilance. Grade 3 events are classified as severe. Severe events are defined as symptoms that limit activity or may require some assistance; require medical intervention or therapy; and may require hospitalization. Grade 4 events are classified as life threatening. Life-threatening events include symptoms that result in extreme limitation of activity and require significant assistance; significant medical intervention and therapy are required; and hospitalization or hospice are probable.

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