

Medical eligibility criteria for contraceptive use

Fifth edition 2015

Executive summary

*Medical eligibility criteria
for contraceptive use (MEC).
Improving the quality of care in
family planning.*



Photo: WHO

Executive summary

During 9–12 March 2014 and 24–25 September 2014, the World Health Organization (WHO) convened two meetings of a Guideline Development Group (GDG), consisting of 68 individuals representing a wide range of stakeholders for the purpose of reviewing and, where appropriate, revising its Medical eligibility criteria for contraceptive use, fourth edition (MEC) guidance. Fourteen topics (encompassing over 575 recommendations) were reviewed by the GDG as part of the revision. All other existing recommendations within the fourth edition were confirmed by the GDG and did not undergo formal review for the updated fifth edition of the MEC.

Recommendations are provided for:

- Combined hormonal contraceptive use (CHC) by age group
- CHC use among breastfeeding women
- CHC use among postpartum women
- CHC use among women with superficial venous disorders
- CHC use among women with known dyslipidaemias without other known cardiovascular risk factors
- Progestogen-only contraceptive (POC) and levonorgestrel-releasing intrauterine device (LNG-IUD) use among breastfeeding women
- Use of subcutaneously-administered depot medroxyprogesterone acetate (DMPA-SC) as a new method added to the guideline
- Sino-Implant (II) as a new method added to the guideline
- Emergency contraceptive pills (ECPs) – Ulipristal acetate (UPA) as a new method added to the guideline; use of CYP3A4 inducers and obesity as new conditions for ECP use
- Intrauterine device (IUD) use for women with increased risk of sexually transmitted infections (STIs)
- Use of progesterone-releasing vaginal ring as a new method added to the guideline
- Hormonal contraception for women at high risk of HIV infection, women living with HIV, and women living with HIV using antiretroviral therapy (ART)

In addition to the recommendations themselves, the executive summary provides an introduction to the guideline, a description of the methods used to develop the recommendations for this fifth edition, and a summary of changes (from the fourth edition to the fifth edition of the MEC). It is anticipated that the Medical eligibility criteria for contraceptive use, fifth edition will be available online by 1 July 2015. In the interim, the fourth edition of the guideline, along with this summary of new recommendations, is available online at www.who.int/reproductivehealth/publications/family_planning

Acronyms and abbreviations

ART	antiretroviral therapy	IUD	intrauterine device
ARV	antiretroviral (medication)	LAM	lactational amenorrhoea method
β-hCG	beta-human chorionic gonadotropin	LDL	low-density lipoprotein
BF	breastfeeding	LNG	levonorgestrel
BMD	bone mineral density	LNG-IUD	levonorgestrel-releasing intrauterine device
BMI	body mass index	MEC	Medical eligibility criteria for contraceptive use (WHO publication)
C	continuation	MI	myocardial infarction
CD4	cluster of differentiation 4	NA	not applicable
CDC	United States Centers for Disease Control and Prevention	NET-EN	norethisterone enanthate
CHC	combined hormonal contraception	NIH	National Institutes of Health (United States of America)
CI	coitus interruptus	NNRTI	non-nucleoside reverse transcriptase inhibitor
CIC	combined injectable contraceptive	NRTI	nucleoside/nucleotide reverse transcriptase inhibitor
CIRE	Continuous Identification of Research Evidence	OC	oral contraceptive (pill)
COC	combined oral contraceptive (pill)	P	combined contraceptive patch
CRPD	United Nations Convention on the Rights of Persons with Disabilities	PE	pulmonary embolism
Cu-IUD	copper-bearing intrauterine device	PI	protease inhibitor
CVR	combined contraceptive vaginal ring	PID	pelvic inflammatory disease
CYP3A4	cytochrome P450 3A4 enzyme	PICO	population, intervention, comparator, outcome
DMPA	depot medroxyprogesterone acetate	POC	progestogen-only contraceptive
DMPA-IM	depot medroxyprogesterone acetate – intramuscular	POI	progestogen-only injectable
DMPA-SC	depot medroxyprogesterone acetate – subcutaneous	POP	progestogen-only pill
DVT	deep vein thrombosis	PRISMA	Preferred reporting items for systematic reviews and meta-analyses
ECP	emergency contraceptive pill	PVR	progesterone-releasing vaginal ring
EE	ethinyl estradiol	RCT	randomized controlled trial
E-IUD	emergency intrauterine device	SC	subcutaneous
EMA	European Medicines Agency	SI (I)/SI (II)	Sino-implant (I) / Sino-implant (II)
ETG	etonogestrel	SLE	systemic lupus erythematosus
FAB	fertility awareness-based methods	SPR	Selected practice recommendations for contraceptive use (WHO publication)
FDA	United States Food and Drug Administration	STER	sterilization (male and female)
GDG	Guideline Development Group	STI	sexually transmitted infection
GRADE	Grading Recommendations, Assessment, Development and Evaluation	SVT	superficial venous thrombosis
GRC	Guidelines Review Committee	UN	United Nations
GSG	Guideline Steering Group	UNDP	United Nations Development Programme
HbA1c	glycated haemoglobin	UNFPA	United Nations Population Fund
HDL	high-density lipoprotein	UNICEF	United Nations Children's Fund
I	initiation	UPA	ulipristal acetate
ICPD	International Conference on Population and Development	USAID	United States Agency for International Development
IM	intramuscular	VTE	venous thromboembolism
		WHO	World Health Organization

Introduction

This document is part of the process for improving the quality of care in family planning. *Medical eligibility criteria for contraceptive use* (MEC), the first edition of which was published in 1996, presents current World Health Organization (WHO) guidance on the safety of various contraceptive methods for use in the context of specific health conditions and characteristics. This is the fifth edition of the MEC – the latest in the series of periodic updates.

In the MEC, the safety of each contraceptive method is determined by several considerations in the context of the medical condition or medically relevant characteristics; primarily, whether the contraceptive method worsens the medical condition or creates additional health risks, and secondarily, whether the medical circumstance makes the contraceptive method less effective. The safety of the method should be weighed along with the benefits of preventing unintended pregnancy.

This document covers the following family planning methods: low-dose (≤ 35 mcg ethinyl estradiol) combined¹ oral contraceptives (COCs), combined patch (P), combined vaginal ring (CVR), combined injectable contraceptives (CICs), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enanthate (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), progesterone-releasing vaginal ring (PVR), barrier methods (BARR), fertility awareness-based methods (FAB), lactational amenorrhoea method (LAM), coitus interruptus (CI), and female and male sterilization (STER).

For each medical condition or medically relevant characteristic, contraceptive methods are placed into one of four numbered categories. Depending upon the individual, more than one condition may need to be considered together to determine contraceptive eligibility. These conditions and characteristics include, among others: age, weeks/months postpartum, breastfeeding status, venous

thromboembolism, superficial venous disorders, dyslipidaemias, puerperal sepsis, past ectopic pregnancy, history of severe cardiovascular disease, migraines, severe liver disease, use of CYP3A4 inducer, repeat use of ECPs, rape, obesity, increased risk of sexually transmitted infections, high risk of HIV infection, living with HIV, use of antiretroviral therapy.

MEC categories for contraceptive eligibility

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.

Target audience

The intended audience for this publication includes policy-makers, family planning programme managers and the scientific community. The MEC aims to provide guidance to national family planning and reproductive health programmes in the preparation of guidelines for delivery of contraceptive services. It is not meant to serve 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.

¹ “Combined” refers to a combination of ethinyl estradiol and a progestogen.

Guideline development methods

The Guideline Development Group (GDG), convened by WHO on 14–15 May 2013, 9–12 March 2014 and 24–25 September 2014, consisted of 68 individuals representing a wide range of stakeholders. Their mandate was to review and, where appropriate, revise the guidance in the fourth edition of the MEC to develop the fifth edition.

For this revision process, the GDG prioritized the review of: (a) six topics identified as important to the field and/or those topics with new evidence that may warrant a change in the existing recommendation; (b) two topics for which interim guidance was issued following the publication of the fourth edition; (c) contraceptive eligibility recommendations for the inclusion of four new contraceptive methods in the fifth edition; and (d) two topics to provide greater clarity for the recommendations in the fourth edition relating to these topics, at the request of the Guidelines Review Committee. Therefore, recommendations for a total of 14 topics were reviewed for the fifth edition of the MEC.

The GDG considered the overall quality of the available scientific evidence, paying particular attention to the strength and consistency of the data, according to the Grading Recommendations, Assessment, Development and Evaluation (GRADE) approach to evidence review.² To formulate recommendations using the four MEC categories for contraceptive eligibility, the GDG considered potential harms related to contraceptive use, the GRADE evidence profiles, the benefits of preventing unintended pregnancy, and applied an approach towards values and preferences that prioritized the availability of a wide range of contraceptive options. The GDG reached its decisions through consensus, which entailed discussion, debate and consultation with experts to reconcile any disagreements. For certain recommendations, the GDG added clarification statements to provide further explanation or guidance on interpretation of the numerical classification. For each contraceptive method, the GDG considered the potential benefits and risks of its use with respect to each of the medical conditions or medically relevant physiologic

or personal characteristics assessed (such as age, breastfeeding, smoking status).

Updated evidence. In many instances, either no new evidence has been identified since the publication of the fourth edition of the MEC (2009), or evidence emerging since that publication confirms previous research findings. Therefore, in many cases the recommendations that were published in the fourth edition have been reviewed and confirmed by the GDG with no changes made. For such recommendations that remained unchanged, the WHO Secretariat updated the evidence statements, references and citations that appear in the contraceptive method tables in the full guideline document.

WHO will initiate a review of the recommendations in this document in four years. In the interim, WHO will continue to monitor the body of evidence informing these recommendations and will convene additional consultations, as needed, should new evidence necessitate reconsideration of existing recommendations. Such updates may be particularly warranted for issues where the evidence base may change rapidly. These interim recommendations will be made available on the WHO's web pages for sexual and reproductive health. WHO encourages research to address key unresolved issues related to establishing medical eligibility criteria for contraceptive use. WHO also invites comments and suggestions for improving this guidance.

Summary of reviewed recommendations

Fourteen topics (encompassing over 575 recommendations) were reviewed by the GDG during the 2014 revision of the MEC. The GRADE approach was applied to assess the quality of the available evidence, and this provided the basis for the formulation of recommendations (see central column). For some topics, multiple outcomes of interest and/or contraceptive methods were examined. For these topics, GRADE assessments of the quality of evidence are presented, either a single assessment or a range. An explanation of the process followed to select and prioritize these topics is included in the full document. All other recommendations were confirmed by the GDG and did not undergo formal review for the updated fifth edition of the MEC. A summary of the changes between the fourth and fifth editions of this document follows.

² Further information is available at the website of the GRADE working group: <http://www.gradeworkinggroup.org/index.htm>

Topics reviewed for the Medical eligibility criteria for contraceptive use (MEC), fifth edition

Topic	MEC recommendation	GRADE assessment of quality of evidence ^a
1. Recommendations for combined hormonal contraceptive (CHC) use by age group (CHCs include combined oral contraceptives, combined injectable contraceptives, combined patch and combined vaginal ring)		
< 40 years	Women from menarche through 40 years of age can use CHCs without restriction (MEC Category 1).	Range: Low to very low
≥ 40 years	Women 40 years and older can generally use CHCs (MEC Category 2).	
2. Recommendations for CHC use among breastfeeding women		
< 6 weeks postpartum	Breastfeeding women < 6 weeks postpartum should not use CHCs (MEC Category 4).	Range: Low to very low
≥ 6 weeks to <6 months postpartum	Breastfeeding women ≥ 6 weeks to < 6 months postpartum (primarily breastfeeding) generally should not use CHCs (MEC Category 3).	
≥ 6 months postpartum	Breastfeeding women ≥ 6 months postpartum can generally use CHCs (MEC Category 2).	
3. Recommendations for CHC use among postpartum women		
< 21 days postpartum without other risk factors for venous thromboembolism (VTE)	Women who are < 21 days postpartum and do not have other risk factors for VTE generally should not use CHCs (MEC Category 3).	Range: Low to very low
< 21 days postpartum with other risk factors for VTE	Women who are < 21 days postpartum with other risk factors for VTE should not use CHCs (MEC Category 4).	
≥ 21 days to 42 days postpartum without other risk factors for VTE	Women who are ≥ 21 days to 42 days postpartum without other risk factors for VTE can generally use CHCs (MEC Category 2).	
≥ 21 days to 42 days postpartum with other risk factors for VTE	Women who are ≥ 21 days to 42 days postpartum with other risk factors for VTE generally should not use CHCs (MEC Category 3).	
> 42 days postpartum	Women who are > 42 days postpartum can use CHCs without restriction (MEC Category 1).	
4. Recommendations for CHC use among women with superficial venous disorders		
Varicose veins	Women with varicose veins can use CHCs without restriction (MEC Category 1).	Very low
Superficial venous thrombosis (SVT)	Women with SVT can generally use CHCs (MEC Category 2).	

Topic	MEC recommendation	GRADE assessment of quality of evidence ^a
5. Recommendations for CHC use among women with known dyslipidaemias		
Known dyslipidaemias without other known cardiovascular risk factors	Women with known dyslipidaemias without other known cardiovascular risk factors can generally use CHCs (MEC Category 2).	Very low; reviewed for clarity as requested by the GRC
6. Recommendations for progestogen-only contraceptive (POC) and levonorgestrel-releasing intrauterine device (LNG-IUD) use among breastfeeding women		
6a. POC use among breastfeeding women (POCs include progestogen-only pills, implants and injectables)		
< 6 weeks postpartum	Breastfeeding women who are < 6 weeks postpartum can generally use progestogen-only pills (POPs) and levonorgestrel (LNG) and etonogestrel (ETG) implants (MEC Category 2). Breastfeeding women who are < 6 weeks postpartum generally should not use progestogen-only injectables (POIs) (DMPA or NET-EN) (MEC Category 3).	Range: Low to very low
≥ 6 weeks to < 6 months postpartum	Breastfeeding women who are ≥ 6 weeks to < 6 months postpartum can use POPs, POIs, and LNG and ETG implants without restriction (MEC Category 1).	
≥ 6 months postpartum	Breastfeeding women who are ≥ 6 months postpartum can use POPs, POIs, and LNG and ETG implants without restriction (MEC Category 1).	
6b. LNG-IUD use among breastfeeding women		
< 48 hours postpartum	Breastfeeding women who are < 48 hours postpartum can generally use LNG-IUDs (MEC Category 2).	Very low
≥ 48 hours to < 4 weeks postpartum	Breastfeeding women who are ≥ 48 hours to < 4 weeks postpartum generally should not have an LNG-IUD inserted (MEC Category 3).	
≥ 4 weeks postpartum	Breastfeeding women who are ≥ 4 weeks postpartum can use an LNG-IUD without restriction (MEC Category 1).	
Puerperal sepsis	Breastfeeding (and non-breastfeeding) women with puerperal sepsis should not have an LNG-IUD inserted (MEC Category 4).	
7. Recommendations for use of subcutaneously-administered depot medroxyprogesterone acetate (DMPA-SC) – new method added to the guideline		
All recommendations	Recommendations for DMPA-SC will follow the current recommendations for DMPA-IM (intramuscular).	Very low

Topic	MEC recommendation	GRADE assessment of quality of evidence ^a
8. Recommendations for Sino-implant (II) – new method added to the guideline		
All recommendations	Recommendations for Sino-implant (II) will follow the current recommendations for LNG implants.	Range: Moderate to very low
9. Recommendations for emergency contraceptive pills (ECPs) – ulipristal acetate (UPA) as a new method added to the guideline; use of CYP3A4 inducers and obesity as new conditions for ECP use		
Pregnancy	For pregnant women, ECP use is not applicable.	Very low
Breastfeeding	Breastfeeding women can use combined oral contraceptive pills (COCs) or LNG for ECPs without restriction (MEC Category 1). Women who are breastfeeding can generally use UPA for ECPs (MEC Category 2).	
Past ectopic pregnancies	Women who have experienced past ectopic pregnancies can use COCs, LNG or UPA for ECPs without restriction (MEC Category 1).	
History of severe cardiovascular disease	Women with history of severe cardiovascular disease, including ischaemic heart disease, cerebrovascular attack or other thromboembolic conditions, can generally use COCs, LNG or UPA for ECPs (MEC Category 2).	
Migraines	Women with migraines can generally use COCs, LNG or UPA for ECPs (MEC Category 2).	
Severe liver disease	Women with severe liver disease, including jaundice (a personal characteristic and sign of liver disease prior to diagnosis), can generally use COCs, LNG or UPA for ECPs (MEC Category 2).	
Use of CYP3A4 inducer	Women using CYP3A4 inducers can use COCs, LNG or UPA for ECPs without restriction (MEC Category 1).	
Repeat use of ECP	There are no restrictions on repeated use for COCs, LNG or UPA for ECPs (MEC Category 1).	
Rape	There are no restrictions for use of COCs, LNG or UPA for ECPs in cases of rape (MEC Category 1).	Moderate
Obesity	Women who are obese can use COCs, LNG or UPA for ECPs without restriction (MEC Category 1).	
10. Intrauterine device (IUD) use for women with increased risk of sexually transmitted infections (STIs)		
IUD initiation	Many women with increased risk of STIs can generally undergo either copper-bearing IUD (Cu-IUD) or LNG-IUD initiation (MEC Category 2). Some women at increased risk (very high individual likelihood) of STIs generally should not have an IUD inserted until appropriate testing and treatment occur (MEC Category 3).	No new evidence identified, so quality of evidence not evaluated using GRADE process; reviewed for clarity as requested by the GRC
IUD continuation	Women at increased risk of STIs can generally continue use of either Cu-IUD or LNG-IUD (MEC Category 2).	

Topic	MEC recommendation	GRADE assessment of quality of evidence ^a
11. Recommendations for use of progesterone-releasing vaginal ring – new method added to the guideline		
Breastfeeding and ≥ 4 weeks postpartum	Women who are actively breastfeeding and are ≥ 4 weeks postpartum can use the progesterone-releasing vaginal ring without restrictions (MEC Category 1).	Low
12. Recommendations for use of hormonal contraception for women at high risk of HIV infection, women living with HIV, and women living with HIV using antiretroviral therapy (ART)		
12a. Women at high risk of HIV infection		
<p>Women at high risk of acquiring HIV can use the following hormonal contraceptive methods without restriction: COCs, combined injectable contraceptives (CICs), combined contraceptive patches and rings, POPs, POIs (DMPA and NET-EN), and LNG and ETG implants (MEC Category 1).</p> <p>Women at high risk of acquiring HIV can generally use LNG-IUDs (MEC Category 2).</p>		Range: Moderate to very low
12b. Women living with asymptomatic or mild HIV clinical disease (WHO stage 1 or 2)		
<p>Women living with asymptomatic or mild HIV clinical disease (WHO stage 1 or 2) can use the following hormonal contraceptive methods without restriction: COCs, CICs, combined contraceptive patches and rings, POPs, POIs (DMPA and NET-EN), and LNG and ETG implants (MEC Category 1).</p> <p>Women living with asymptomatic or mild HIV clinical disease (WHO stage 1 or 2) can generally use the LNG-IUD (MEC Category 2).</p>		
12c. Women living with severe or advanced HIV clinical disease (WHO stage 3 or 4)		
<p>Women living with severe or advanced HIV clinical disease (WHO stage 3 or 4) can use the following hormonal contraceptive methods without restriction: COCs, CICs, combined contraceptive patches and rings, POPs, POIs (DMPA and NET-EN), and LNG and ETG implants (MEC Category 1).</p> <p>Women living with severe or advanced HIV clinical disease (WHO stage 3 or 4) generally should not initiate use of the LNG-IUD (MEC Category 3) until their illness has improved to asymptomatic or mild HIV clinical disease (WHO stage 1 or 2).</p>		Range: Moderate to very low

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