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New recommendations on the safety of contraceptive methods for women with medical conditions: World Health Organization's *Medical eligibility criteria for contraceptive use, fourth edition*

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Background

The World Health Organization (WHO) publication, *Medical eligibility criteria for contraceptive use* (MEC), provides evidence-based recommendations on whether a contraceptive method can be safely used according to more than 80 medical conditions and characteristics. The guideline is intended to be a reference during the preparation of national family planning/sexual and reproductive health programmes for delivery of contraceptives. *Medical eligibility criteria for contraceptive use* was first published in 1996; subsequently in 2000 and 2004. A WHO expert Working Group reviewed in April 2008 the new evidence in the third edition and developed 251 new recommendations for the fourth edition, including recommendations for an additional medical condition, systemic lupus erythematosus (SLE), and 12 new sub-conditions to existing medical conditions. This article highlights the updated recommendations, and describes the development of the new guidance.

Guideline development process

Systematic reviews of the evidence were conducted and provided before the meeting. The Working Group included users of the guideline, plus 43 experts, from 23 countries, specializing in international family planning, scientific evidence analysis, and pharmacology. The systematic reviews provided the basis for deliberations during the meeting, and the recommendations were adopted through consensus.

Definitions of recommendation categories

A numerical category, ranging from 1 to 4, is assigned to each medical condition to show whether a certain contraceptive method is safe to use. The categories are:

1 = no restriction on use
2 = the advantages of using the method generally outweigh the theoretical or proven risks
3 = the theoretical or proven risks usually outweigh the advantages of using the method;
4 = an unacceptable health risk.

Where resources for clinical judgement are limited, the four can be simplified into two categories. Medical conditions in category 1 or 2 indicate that the contraceptive method can be used, conditions in category 3 or 4 indicate that it should not.

Different categories of recommendations may apply to the initiation of methods ('I') and the continuation ('C'). If 'I' and 'C' are not denoted, the same category applies to both.

For male and female surgical sterilization, the safety of the procedure for each medical condition is defined according to the following four categories:

- 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
- S (special) = The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment for general anaesthesia, and other medical support.

New recommendations for contraceptives for women with SLE

Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives. However, it is important to note that there is increased risk of ischaemic heart disease, stroke and venous thromboembolism.[1-3] Therefore, a woman with SLE, plus one of these co-existing conditions, should receive the same recommendations as other women with these conditions.

These recommendations are divided into four sub-categories based on evidence of differing risks for different complications of the disease. The sub-categories are: positive (or unknown) antiphospholipid antibodies, severe thrombocytopaenia, immunosuppressive treatment, and women with none of these risk factors.

Positive antiphospholipid antibodies significantly increase a woman's risk of arterial and venous thrombosis,[4,5] and she should avoid the use of combined hormonal methods: combined oral contraceptives (COC), patch (P), ring (R) and combined injectable contraceptive (CIC). Progestogen-only methods should also be used with caution because of the thrombotic risks. There are no restrictions on the use of the copper intrauterine device (cu-IUD).

Severe thrombocytopaenia increases the risk of bleeding. The risk factor should be assessed according to the severity of the thrombocytopaenia and its clinical manifestations, for example, menorrhagia, which is common. All hormonal contraceptives, including the levonorgestrel-releasing IUD (LNG-IUD),[6] may be useful to treat menorrhagia in women with severe thrombocytopaenia; the benefits of the methods generally outweigh the risks. However, the depot medroxyprogesterone acetate (DMPA) method should be initiated only with caution, since it may lead to increased or erratic bleeding and the method is irreversible for 11-13 weeks after administration.

Women with very severe thrombocytopaenia are at risk of spontaneous bleeding, and are advised to consult a specialist and undergo certain pre-treatments before insertion of an IUD.

For women on immunosuppressive therapy, the benefits of all contraceptive methods generally outweigh the risks if there are no other complications. This is also true for SLE without complications.

For all sub-conditions of SLE, there are no restrictions on the use of barrier methods. However, SLE is one of the conditions that may make unintended pregnancy an unacceptable health risk. Women with SLE should be advised that the sole use of behaviour-based and barrier methods for contraception may not be the most appropriate choice for them because of the relatively higher typical use failure rates of these methods.

For women with SLE who desire permanent sterilization, the procedure can be performed with caution in the absence of any risk factors. However, specialist care or extra precautions are needed when performing a surgical sterilization for women with complications of SLE.

Table. New and updated WHO Medical eligibility categories for contraceptive methods[‡] for women with medical conditions, 2009

Condition	1. No restriction	2. Advantages generally outweigh risks	3. Risks generally outweigh advantages	4. Unacceptable health risk	Sterilization
Systemic lupus erythematosus (SLE)					
Positive (or unknown) antiphospholipid antibodies	Cu-IUD		POP, DMPA, NET-EN, LNG & ETG implants, LNG-IUD	COC, P, R, CIC	Special
Severe thrombocytopaenia		COC, P, R, CIC, POP, DMPA (C), NET-EN (C), LNG & ETG implants, Cu-IUD (C), LNG-IUD	DMPA (I), NET-EN (I), Cu-IUD (I)		Special
Immunosuppressive treatment	Cu-IUD (C)	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD (I), LNG-IUD			Special
None of the above	Cu-IUD	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, LNG-IUD			Caution
Antiretroviral therapy					
Nucleoside reverse transcriptase inhibitors (NRTIs)	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants	Cu-IUD[†], LNG-IUD[†]	Cu-IUD (I)[Σ] or LNG-IUD (I)[Σ], spermicides, diaphragm with spermicides		
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	DMPA	COC, P, R, CIC, POP, NET-EN, LNG & ETG implants, Cu-IUD & LNG-IUD[†]	Cu-IUD (I)[Σ] or LNG-IUD (I)[Σ], spermicides, diaphragm with spermicides		
Ritonavir-boosted protease inhibitors	DMPA	NET-EN, LNG & ETG implants, Cu-IUD[†], LNG-IUD[†]	COC, P, R, CIC, POP, Cu-IUD (I)[Σ], LNG-IUD (I) [Σ], spermicides, diaphragm with spermicides		
HIV and AIDS					
High risk of HIV				Diaphragm with spermicide	
HIV-infected			Spermicides		
AIDS			Spermicides		
Antconvulsant therapy					
Certain anticonvulsants (phenytoin, barbiturates carbamazepine, primidone, topiramate, oxcarbazepine)	DMPA	NET-EN, LNG & ETG implants			
Lamotrigine	POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD		COC, P, R, CIC		
Antimicrobial therapy					
Broad-spectrum antibiotics, antifungals, antiparasitics	COC, P, R, CIC, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD				
Rifampicin or rifabutin therapy	DMPA	NET-EN, LNG & ETG implants			
Postpartum (breastfeeding or non-breastfeeding women, including post-caesarean section)					
<48 hours including insertion immediately after delivery of the placenta	Cu-IUD, LNG-IUD if not breastfeeding		LNG-IUD if breastfeeding		

Condition	1. No restriction	2. Advantages generally outweigh risks	3. Risks generally outweigh advantages	4. Unacceptable health risk	Sterilization
Obesity					
Menarche to <18 years and ≥ 30 kg/m² body mass index	NET-EN	DMPA			
Cirrhosis					
Mild (compensated) cirrhosis	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD				Accept
Viral hepatitis					
Acute or flare	POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD	for continuation: COC P, R, CIC	For initiation COC, P, R, CIC	For initiation if condition is severe: COC, P, R	
Carrier	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD				
Chronic	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, Cu-IUD, LNG-IUD				Accept
Liver tumours					
Liver tumour – Benign focal nodular hyperplasia	Cu-IUD	COC, P, R, CIC, POP, DMPA, NET-EN, LNG & ETG implants, LNG-IUD			Accept
Deep vein thrombosis (DVT)/pulmonary embolism (PE)					
DVT/PE and established on anticoagulant therapy	Cu-IUD	POP, DMPA, NET-EN, LNG & ETG implants, LNG-IUD		COC, P, R, CIC	Special

Abbreviations: C = continuation; CIC = combined injectable contraceptive; COC = combined oral contraceptive; cu-IUD = copper-bearing intrauterine device; DMPA = depot medroxyprogesterone acetate injectable; ETG = etonogestrel; I = initiation; LNG = levonorgestrel; LNG-IUD = levonorgestrel intrauterine device; NET-EN = norethisterone enantate injectable; P = combined hormonal patch; POP = progestogen-only pill; R = combined hormonal vaginal ring;

‡ No new restrictions for the use of barrier methods (condoms, spermicides, and diaphragm with spermicides) were added, unless otherwise indicated.
† If clinically well
Σ If not clinically well

Updated recommendations

Antiretroviral (ARV) therapy

For women taking nucleoside reverse transcriptase inhibitors (NRTI), or non-nucleoside reverse transcriptase inhibitors (NNRTI), there are no restrictions on the use of oral, injectable or implantable contraceptives. Those who take Ritonavir-boosted protease inhibitors are advised against using oral contraceptives because limited data suggest potential drug interactions which may alter the safety and effectiveness of both the hormonal contraceptive and the ARV.[7-14] Injectable and implantable contraceptives can be used. Both copper-bearing and LNG-releasing IUDs can be used in conjunction with ARV therapies. The insertion of either type of IUD is not advised in a new user who is clinically unwell, but post-insertion illness does not require removal of the IUD

While there are no known drug interactions between ARV therapy and the use of barrier contraceptive methods, the use of spermicides alone, or diaphragms (with spermicides) should be avoided for reasons discussed below in recommendations for women with HIV or AIDS.[15] Condoms are safe for use with any ARV therapy.

HIV and AIDS

The use of a diaphragm (with spermicide) should be avoided in women at high risk of HIV infection, because the repeated high dosage of the spermicide nonoxynol-9 is associated with the increased risk of genital lesions, causing greater vulnerability to HIV infection.[16] Because spermicides can disrupt the cervical mucosa, which may lead to increased viral shedding and HIV transmission to uninfected sexual partners, women diagnosed with HIV-infection or AIDS are advised against using them.

Anticonvulsant therapy

Women taking lamotrigine monotherapy are advised against simultaneously using combined hormonal contraceptive methods, because such use can alter both the safety and effectiveness of the two drugs.[17-21] Women taking lamotrigine can safely use progestogen-only methods, IUDs and barrier methods. Women taking other enzyme-inducing anticonvulsants can now use DMPA, norethisterone enantate (NET-EN), and implants, because there is no evidence of harmful drug interactions.[19]

Antimicrobial therapy

There are no restrictions on the use of any contraceptive method for women taking broad-spectrum antibiotics, antifungals or antiparasitics. Those taking rifampicin or rifabutin therapy should avoid the use of combined hormonal methods and progesterone-only pills (POPs) because studies suggest these therapies reduce the efficacy of the methods.[22-37] Rifampicin or rifabutin users can, however, use DMPA, NET-EN and implants; there is no evidence that these methods cause harmful drug interactions.

IUD insertion postpartum

A copper-bearing or LNG-releasing IUD can be inserted within 48 hours after delivery of the placenta (this includes post-caesarean section and breastfeeding or non-breastfeeding women). Immediate IUD insertion is associated with lower expulsion rates than delayed postpartum insertion.[38] Breastfeeding women are generally advised against using the LNG-IUD.

DMPA and obesity

Girls between the age of onset of menarche and <18 years with a body mass index (BMI) ≥30 can use DMPA, but studies show that they are more likely to gain weight than obese adolescents who do not use DMPA, or adolescents who are not obese and use DMPA.[39]

Liver conditions

Women diagnosed with mild cirrhosis, chronic viral hepatitis, or who are carriers of viral hepatitis, can safely use all types of hormonal contraception and barrier methods. Recent studies suggest that COCs do not increase the rate or severity of cirrhotic fibrosis, nor increase the risk of hepatocellular carcinoma in women with chronic hepatitis. Furthermore, using COCs does not appear to trigger liver failure or severe liver dysfunction in women who are carriers of viral hepatitis.[40] Voluntary surgical sterilization is a safe, acceptable method.

Women diagnosed with focal nodular hyperplasia can generally use all types of contraception (hormonal, IUDs and barrier methods), as studies show no influence on either the progression or regression of the liver lesions.[41] Surgical sterilization is also considered acceptable.

Because liver cells do not have progestogen receptors, progestogen-only methods do not directly affect liver function. Therefore, women with an acute episode or flare of viral hepatitis can safely use these methods or IUDs. However, because oestrogen-containing methods are metabolised in the liver, initiating the use of COCs, P, R, or CICs should be avoided (category 3 or 4). If one of these methods was initiated before diagnosis, the benefits of continuing contraception usually outweigh the risks.[40]

Deep venous thrombosis/pulmonary embolism (DVT/PE)

New recommendations are now available for women diagnosed with DVT/PE who are established on anticoagulant therapy. Combined hormonal methods (COCs, P, R, CICs) should be avoided, but progestogen-only methods and the copper-bearing IUD can generally be used. DMPA use does not pose a significant risk of haematoma at the injection site, or increase the risk of heavy or irregular vaginal bleeding in women on long-term anticoagulant therapy.[42] Barrier methods are also safe. For surgical sterilization, the procedure should follow the 'special' category stipulations.

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For additional information

Complete information on the 4th edition of the Medical eligibility criteria for contraceptive use can be accessed at: (http://www.who.int/reproductivehealth/publications/family_planning)

Shifting the paradigm: Broadening Horizons – *Sexual rights: an IPPF declaration*

> **'Too often denied and too long neglected, sexual rights deserve our attention and priority. It is time to respect them. It is time to demand them.'**

Jacqueline Sharpe, President of IPPF

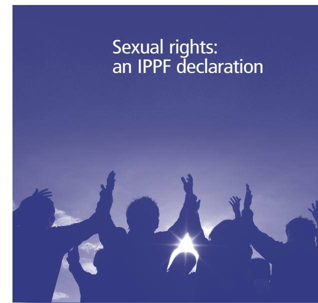
Approved by the Governing Council – IPPF's highest decision-making body – in May 2008, *Sexual rights: an IPPF declaration* was developed by a panel of internationally renowned experts in sexual and reproductive health and rights, staff and senior volunteers.

The Declaration offers an ambitious and encompassing framework for the highest attainable standard of health. It is grounded in core international treaties and agreements and is informed by the findings and recommendations of several treaty bodies and UN Special Rapporteurs.

It aims explicitly to identify sexual rights and support an inclusive vision of sexuality. This vision seeks to respect, protect and advance the rights of all persons to sexual autonomy, and to promote sexual health and rights within a framework of non-discrimination.

The Declaration expands IPPF's vision and its belief that sexual health and reproductive health are integral elements of the rights of all people, regardless of age, sex, race, gender identity, sexual orientation, disability, HIV status and social and marital status, to enjoy the highest attainable standard of health.

This document is an invaluable tool for rights-based interventions and sexual rights advocacy because sexuality is an integral part of the personhood of every human being.



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