

# National Contraception Clinical Guidelines

*A companion to the National Contraception and Fertility Planning Policy and Service Delivery Guidelines*

2012



health

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Department:  
Health  
REPUBLIC OF SOUTH AFRICA

# NATIONAL CONTRACEPTION CLINICAL GUIDELINES

*A companion to the National Contraception and Fertility Planning  
Policy and Service Delivery Guidelines*

Published by the Department of Health  
Private Bag X828  
Pretoria 0001  
South Africa  
December 2012

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These contraception clinical guidelines are a companion to the *National Contraception and Fertility Planning Policy and Service Delivery Guidelines (DOH, 2012)* which include the following sections:

Section A: Background and Context

Chapter 1: The bigger picture

Chapter 2: Contraception in South Africa: An overview

Section B: Policy Framework

Chapter 3: Guiding principles, objectives and priority activities

Section C: Service Delivery Guidelines

Chapter 4: Levels of service delivery

Chapter 5: Quality of care

Chapter 6: Special considerations for service delivery (adolescents, migrants, sex workers, LGBTI, men)

Section D: The Client's Consultation: Contraception or conception?

Chapter 7: Client's consultation: Fertility choices and planning

Chapter 8: Client's consultation: Contraception

Chapter 9: Client's consultation: Towards healthy conception

## Foreword by the Minister of Health

The National Contraception and Fertility Planning Policy and Service Delivery Guidelines and National Contraception Clinical Guidelines are extremely important documents aimed at reprioritising contraception and fertility planning in South Africa, with an emphasis on dual protection.

Contraception is one of the most powerful public health tools for any country. Providing women with access to safe and effective contraception is a critical element of women's health. Enabling women to make choices about their fertility is empowering and offers women better economic and social opportunities. Birth spacing also improves the opportunities for children to thrive physically and emotionally. Engaging men in sexual and reproductive health encourages shared responsibility in their roles as partners and parents.

The adoption of the revised Contraception Policy takes place within the context of renewed international focus - at the 2012 global Family Planning Summit held in London, the importance of contraception to human development, gender empowerment, HIV and sexual and reproductive health was once again emphasised.

Against this background I am delighted to release the revised policy on contraception and fertility planning. It is being launched during an exciting period in the history of health care in South Africa, with the re-engineering of primary health care, emphasis on health systems strengthening, implementation of the National Core Standards, and closely linked to this, the introduction of the National Health Insurance.

In addition, the policy has been developed against the background of the HIV epidemic. About one third of young South African women are HIV positive, and contraceptive provision and fertility advice must take this into account. Similarly, two thirds of South Africa's young women are HIV negative but are at risk of HIV infection, and their counseling and choices need to take issues related to risk and prevention into consideration.

Noting the above, much depends on the successful implementation of this policy. Contraception is one of the World Health Organization's four strategic prongs for the prevention of mother-to-child transmission of HIV. Contraception and planning for conception contributes to the reduction of HIV transmission, thereby supporting the National Strategic Plan on HIV, STIs and TB (2012-2016). It has enormous potential to contribute to South Africa achieving its Millennium Development Goals, particularly MDGs 4 and 5. It is also an important part of the strategy to ensure the successful implementation of the African Union's Campaign for the Accelerated Reduction of Maternal, Neonatal and Child Mortality in Africa (CARMMA), to which South Africa is a signatory.

The revision of the contraception policy was deemed necessary to ensure up to date practice in South Africa, and reflects the changes over the last decade in the fields of HIV, contraceptive technology and related research. One of the most significant changes has been the expanded scope of the policy –to embrace both the prevention of pregnancy (contraception) and the planning for a healthy pregnancy (conception). The policy also reflects the Department of Health's focus on human rights, quality and integration. Drawing on the expertise of scientists, clinicians, health workers and practitioners, the revised policy provides a framework for a broad, forward looking contraception and fertility planning programme, with an emphasis on improved access as well as expanded contraceptive choice.

Now, more than ever, the successful implementation of this policy is of critical importance. We urgently need to deal more effectively with the challenges facing our country in terms of unacceptably high rates of HIV, teenage pregnancy, unintended pregnancies, infant and maternal mortality, and the elimination of mother-to-child transmission of HIV. Improved access to and use of contraception will result in a decreased demand for termination of pregnancies. Encouraging women to plan for healthy pregnancies, including timing and spacing, will improve health outcomes for both mothers and babies.

However, the realisation of a sound, innovative policy can only be measured by its successful implementation. To ensure that this happens, I call upon all health workers to prioritise the following five key actions:

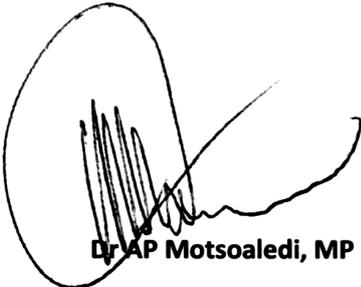
**(i) The provision of quality contraceptive health services:** We need to ensure that we have a robust health system so that we can provide the contraceptives and services we promise - this involves improved access, expanded choice, quality care, staff training and continuous and efficient commodity supply.

**(ii) Stimulating community awareness and demand:** We need to ensure that our communities understand the importance of contraception and planning for healthy pregnancies, the range of methods available and where they can be obtained - this requires advocacy and demand creation, underpinned by effective communication strategies which encourage informed decision-making and contraceptive use.

**(iii) Putting integration into practice:** We need to deal with the dual challenges of HIV and unwanted pregnancies, through the promotion of condom use and dual contraception as well as through the active promotion of integrated HIV and sexual and reproductive health services - we need commitment, creativity and flexibility to actively operationalise integration.

**(iv) Strategic multi sectoral collaboration:** We need to expand access beyond traditional clinical settings and strengthen provision. To this end, we need vibrant, responsive partnerships - with civil society, the private sector, and development and implementing partners.

**(v) Evidence guided planning and provision:** We need to ensure that the implementation of the policy is monitored, evaluated, and that international and local research informs decisions and planning.



**Dr AP Motsoaledi, MP**  
**Minister of Health**  
**Date:** 22/1/2013

# Acknowledgments

The revision of the Contraception Policy has been a collective effort and an extensive consultative process. The Department of Health would like to acknowledge and thank all those who have contributed to this process, through attending meetings, research, writing, commenting on the many drafts and, importantly, engaging in rigorous discussion and debate.

To all the organisations and individuals who contributed to the development of the policy (listed in Appendix 1) we extend our sincerest appreciation; without their contribution we would not have developed such a forward-looking, comprehensive and responsive policy.

In particular, the Department of Health would like to thank:

- Dr Aaron Motsoaledi (Minister of Health), Dr Yogan Pillay (Deputy Director General: HIV/AIDS, TB and MCWH), Professor Eddie Mhlanga (Chief Director: Maternal and Women's Health) and Dr Nonhlanhla Diamini (Chief Director: Child, Youth and School Health) for their leadership and stewardship in ensuring that reproductive health and rights remain a national health priority;
- National and Provincial Department of Health personnel, who commented on drafts, and contributed their hands-on experience to assist in the formulation of the policy and guidelines, and especially Dr Nat Khaole (Director: Women's Health and Genetics) for the overall coordination of the revision process;
- Wits Reproductive Health and HIV Institute for project managing the revision, in particular Professor Helen Rees for chairing the respective working groups, and Melanie Pleaner for overseeing the process from its inception to publication;
- University of Cape Town, particularly Professor Petrus Steyn and Dr Margaret Moss for convening the HIV and Contraception, and Method Mix working groups, and for their on-going contribution to the many drafts;
- United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID) for funding the process;
- International development partners who provided technical expertise to support the development of the policy and guidelines;
- FHI 360 for their on-going technical assistance and contribution to reviewing the document.

We hope that the interest, commitment and enthusiasm that drove the revision process will extend into ensuring the successful implementation of the revised contraception and fertility planning policy framework and guidelines.

# Abbreviations

AIDS	Acquired immunodeficiency syndrome	LARC	Long-acting reversible contraception
ART	Antiretroviral therapy or treatment	NET-EN	Norethisterone enanthate
ARV	Antiretroviral drugs/treatment	NNRTI	Non-nucleoside reverse transcriptase inhibitors
CHC	Combined hormonal contraception	NSAID	Non-steroidal anti-inflammatory drug
CIC	Combined injectable contraception	PE	Pulmonary embolism
COCs	Combined oral contraceptive pills	PI	Protease inhibitor
Cu IUD	Copper intrauterine device	PID	Pelvic inflammatory disease
DMPA	Depot medroxyprogesterone acetate	PMTCT	Prevention of mother-to-child transmission of HIV
DOH	Department of Health	POP	Progestogen-only pill
DVT	Deep vein thrombosis	POC	Progestogen-only contraceptive
ECP	Emergency contraceptive pill	SLE	Systemic lupus erythematosus
ETG	Etonogestrel implants	STI	Sexually transmitted infection
FAB	Fertility awareness-based methods	TB	Tuberculosis
HCT	HIV counselling and testing	TOP	Termination of pregnancy
HIV	Human immunodeficiency virus	UNFPA	United Nations Population Fund
HIV-RNA	HIV-ribonucleic acid (viral load)	USAID	United States Agency for International Development
HPV	Human papillomavirus	VTE	Venous thromboembolism
IEC	Information, education and communication	WHO	World Health Organization
IUD	Intrauterine device	WHO MEC	World Health Organization medical eligibility criteria for contraceptive use
IUS	Intrauterine system	WRHI	Wits Reproductive Health and HIV Institute
LAM	Lactational amenorrhoea method		
LGBTI	Lesbians, gay, bisexual, transgender and intersex persons		
LNG-IUS	Levonorgestrel releasing intrauterine system		

## UNITS

µg	microgram
mg	milligram

# Overview

The National Contraception Clinical Guidelines consists of four chapters relating to the clinical provision of contraceptive services.

- **Chapter 1** gives an overview of the World Health Organization’s medical eligibility criteria on which the Clinical Guidelines are based, and outlines key clinical practice issues within the South African context. Long-acting reversible contraception (LARC) is explained, and a summary of contraceptive effectiveness and continuation rates is presented.
- **Chapter 2** provides method-specific guidelines for contraception. Implicit in the guidelines is the concept that method provision includes contraceptive and fertility information and counselling, offered as part of a comprehensive HIV and sexual and reproductive health care package.
- **Chapter 3** provides guidelines for the provision of services for people with special needs: adolescents, menopausal women, women with physical and intellectual disabilities, and women with chronic conditions.
- **Chapter 4** considers issues relating to contraception and HIV, including HIV acquisition, transmission, disease progression and drug interaction. Guidance for the provision of specific methods within the context of HIV is provided.

**Annexes 1–10** outline the medical eligibility criteria for specific methods, based on the *Medical Eligibility Criteria for Contraceptive Use, fourth edition 2009*, published by the World Health Organization in 2010.

These contraception clinical guidelines are a companion to the *National Contraception and Fertility Planning Policy and Service Delivery Guidelines (DOH 2012)* which include the following sections:

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## CHAPTER 1

# Introduction to clinical guidelines for contraception

This chapter begins with an overview of the World Health Organization Medical Eligibility Criteria (WHO MEC) on which the clinical guidelines are based. This is followed by an outline of key clinical practice issues within the specific context of South Africa. The importance and relevance of long-acting reversible contraception (LARC) is also explained, followed by a summary of contraceptive effectiveness and continuation rates (Table 2).

## 1.1 Medical eligibility criteria for contraceptive use

In an attempt to update and standardise the safe provision of modern contraceptive methods and eliminate unnecessary restrictive practices and medical barriers, the World Health Organization (WHO) developed a set of medical eligibility criteria for contraceptive use (WHO MEC).<sup>1</sup> These are based on results of a collaborative review of all clinical, epidemiological and programmatic research on modern contraceptive methods. The suitability of using each method in the presence of specific factors, including medical conditions, was categorised by weighing the health risks against the benefits. The resulting medical eligibility criteria allow contraceptives to be prescribed in line with clients' personal preferences while maintaining an adequate margin of safety. This is a positive move towards ensuring that women and men (and their offspring) are adequately protected from possible health risks, while not being unnecessarily denied the contraceptive method of their choice. The WHO MEC classification categories are shown in Table 1.

These clinical guidelines are guided by WHO MEC<sup>1</sup> and WHO Selected Practice Recommendations for Contraceptive Use.<sup>2</sup> Any variations due to specific considerations in South Africa are noted. Other international guidelines based on WHO MEC with useful summaries or algorithms are also referenced.

**Table 1. WHO MEC classification categories**

	Classification	With clinical judgement	With limited clinical judgment
<b>Category 1</b>	A condition for which there is no restriction for the use of the contraceptive method	Use method in any circumstances	<b>Yes</b> (Use the method)
<b>Category 2</b>	A condition for which the advantages of using the method generally outweigh the theoretical or proven risks	Generally use method	
<b>Category 3</b>	A condition for which the theoretical or proven risks usually outweigh the advantages of using the method	Use of method not usually recommended unless more appropriate methods are not available or not acceptable	<b>No</b> (Do not use the method)
<b>Category 4</b>	A condition that represents an unacceptable health risk if the contraceptive method is used	Method not to be used	

## WHO's four cornerstones for family planning

WHO has developed a four part package, known as the four WHO cornerstones for family planning:

- Medical Eligibility Criteria for Contraceptive Use (4th edition, 2010).
- *Selected Practice Recommendations for Contraceptive Use* (2nd edition, 2004) and 2008 Update, the companion guideline to Medical Eligibility Criteria for Contraceptive Use, provides guidance on the safe and effective use of a wide range of contraceptive methods.
- *Decision-Making Tool for Family Planning Clients and Providers* (2005)
- *Family Planning: A Global Handbook for Providers* (Revised 2011 Update)

A useful accompaniment is the *WHO Medical Eligibility Criteria Wheel for Contraceptive Use* (WHO, 2009)

## 1.2 Key issues in clinical practice

The provision of contraception needs to be guided by the principles, policy framework and service delivery guidelines outlined in the companion to this document - the *Contraception and Fertility Planning Policy and Service Delivery Guidelines* (DOH, 2012). In addition, specific consideration needs to be given to the issues outlined below.

### Informed choice

Everyone should have access to accurate, unbiased information about all available methods in order to make an informed choice. Clients should be provided with the contraceptive method/s that they request, subject to meeting relevant medical eligibility criteria and availability, combined with an assessment of their circumstances.

### Client assessment and screening

- *History taking.* It is important to take a comprehensive personal medical history before clients select hormonal contraception, Cu IUD (copper intrauterine device) or sterilisation.
- *Fertility plans.* There should be a discussion about the client's future fertility plans and a risk assessment, as appropriate. Specific factors to be considered are listed below.
- *HIV screening.* HIV counselling and testing (HCT), and discussions relating to risk and prevention should be provided as a routine part of the consultation. The use of any contraceptive alone, without a male or female condom, offers no protection from STI/HIV and carries the risk of acquisition/ transmission. The frequency of an HIV test should be guided by possible exposure to HIV, for both the client and their sexual partners. A general guide is every six months. HIV staging assessment and a CD4 test should be offered if a client is diagnosed HIV-positive. CD4 levels need to be monitored subsequently to determine eligibility for ART (antiretroviral therapy or treatment).<sup>3</sup> In addition, there should be a discussion about the client's future fertility plans. HIV status, whether in a seroconcordant or serodiscordant relationship, and whether on ART are all factors to consider in terms of contraception and fertility planning.
- *STI screening.* This should be done according to the national Department of Health (DOH) guidelines,<sup>4</sup> with specific attention being given to the need to assess STI and HIV co-infection.
- *Tuberculosis (TB) screening.* Because of the high incidence of HIV and TB co-infection, the consultation is an opportunity to screen, provide information, treat or refer, as per the most recent DOH TB guidelines.
- *Blood pressure.* The measurement of blood pressure is essential for sterilisation. It is recommended that blood pressure is measured before and during the use of hormonal contraception. Where this is not possible, hormonal methods should not be denied providing there is no history of high blood pressure. (Where feasible, provision must be made to check blood pressure on a subsequent visit.)
- *Pelvic examination.* This is only essential before fitting an intrauterine contraceptive device/system or female sterilisation, unless the need for a pelvic examination is indicated in the history taking.
- *Breast and cervical screening.* Where possible, the consultation should serve as an opportunity to educate clients about breast self-examination and the purpose and value of cervical screening. This can be done on initiation of a contraceptive method or at a mutually agreed appointment. Pap smears should be done according to the most recent DOH national guidelines for the Cervical Cancer Screening Programme or when clinical history indicates this examination is required.

## HIV and STI prevention

There needs to be constant promotion of dual method use. Barrier methods, both male and female condoms, should be used in combination with all other contraceptive methods to effectively prevent HIV, STIs and pregnancy. Always emphasise consistent and proper condom use, combined with highly effective contraception.

## Follow-up visits

Follow-up visits should be scheduled according to sound medical reasoning; unnecessarily frequent follow-up visits should be discouraged. Recommendations for the timing of follow-up visits for each method are given in Chapter 2.

## High-dose combined oral contraceptive pills

Routine use of high-dose (>35 µg ethinyl estradiol) combined oral contraceptive pills (COCs) should be discontinued, unless specific medical indications exist. Clients using high-dose preparations should be switched to formulations containing ≤ 35 µg oestrogen, as soon as possible.

## Drug interactions with hormonal methods

See method-specific sections for most recent recommendations. Also see Chapter 4: Contraception and HIV.

## Injectable contraceptives

Progestogen-only injectables are currently the most commonly provided contraceptives in South Africa. Recent observational studies suggest that use of hormonal contraception (in particular progestogen-only injectables) might increase the risk of HIV acquisition and transmission.<sup>5, 6</sup> While there is need for further research, every effort must be made to emphasise the importance of *consistent and proper condom* use in conjunction with hormonal and other non-hormonal contraceptives for the prevention of HIV. Alternatives, such as low-dose hormonal contraceptives, and non-hormonal options, such as Cu IUDs, need to be explored with the client. The benefits of the injectable to prevent pregnancy need to be weighed against the possible risk of HIV acquisition.

## Re-injection within the grace period for late injections

In clients presenting late, the grace period for repeat injection (without the need to rule out pregnancy), is four weeks for depot medroxyprogesterone acetate (DMPA) and two weeks for norethisterone enanthate (NET-EN).<sup>7</sup> This does not mean that injections of DMPA and NET-EN should be routinely scheduled for 16 and 10 weeks – clients should still be encouraged to come for re-injection on time.

## Initiating contraceptive methods in non-menstruating women<sup>2, 7</sup>

Generally it is recommended to rule out pregnancy prior to initiation of most contraceptive methods. Traditionally, menstruation was considered to be a reliable indicator that a woman is not pregnant. However, it is not necessary to restrict initiation of the contraceptive method to menstruation. A woman can initiate contraception at any time in her menstrual cycle as long as the health care provider is reasonably sure that she is not pregnant.

In most cases pregnancy can be ruled out by asking a series of questions. Each of these questions describes a situation when pregnancy is highly unlikely (see Appendix 2: Pregnancy checklist).

Women in whom pregnancy has not been ruled out, should either wait until their next menses to initiate a method of contraception, or have a pregnancy test done if they miss their next period. Those who want to initiate oral contraceptive pills can be given a pack to take home with instructions to start on the first day of their next menses.

## Postpartum

- Women to be counselled about contraception and/or supplied with a suitable method of their choice at every opportunity, for example during antenatal visits, after delivery, at the six-week postpartum visit and subsequent visits for infant immunisation opportunities.
- Each client's/couple's needs for contraception should be discussed and assessed individually. For instance, couples intending to abstain from sexual activity for a period of time after childbirth, for religious or cultural reasons, may not require immediate postpartum contraceptive cover.
- Women who are not intending to breastfeed may start progestogen-only methods immediately. Non-breastfeeding women should delay initiation of combined hormonal contraceptives until three weeks postpartum when the risk of venous thromboembolism is reduced. If a woman has additional risk factors for thrombosis (for example smoking, immobility, transfusion at delivery, obesity, postpartum haemorrhage, pre-eclampsia), combined hormonal contraceptives should be delayed until six weeks postpartum.<sup>8</sup>
- Women who are intending to breastfeed should not use oestrogen-containing methods until six months postpartum, or when the infant is weaned (whichever occurs soonest).
- It is recommended that, ideally, initiation of progestogen-only injectables is delayed until six weeks postpartum. However, this puts women who do not fully breastfeed or discontinue breastfeeding before six weeks at risk of early conception (ovulation can start as early as 28 days postpartum).<sup>8,\*</sup> Thus, if no other methods are available or acceptable to the client, progestogen injectables could be initiated prior to discharge from the health facility.
- Female sterilisation (with full consent) may be performed immediately postpartum or within the first seven days. Otherwise it should be delayed until at least six weeks postpartum. Use of other contraception should be recommended in the interim. Priority should be given to ensuring that women requesting postpartum sterilisation have access to services (counselling and clinical).
- A Cu IUD may be inserted immediately postpartum (right after the delivery of the placenta), or within the first 48 hours, by providers trained in postpartum Cu IUD insertion. Otherwise it should be delayed until at least four weeks postpartum (sometimes until six weeks if the uterus takes longer to contract to its normal size).

## Lactational amenorrhoea method

Lactational amenorrhoea method (LAM) is not being actively promoted in South Africa due to the high prevalence of HIV infection and the local practice of early weaning in many parts of the country, which carries the risk of transmitting the virus from mother to child through breast milk. However, health care providers should be well informed about LAM in order to counsel effectively women who wish to use the method.

Women who are known to be HIV-positive should be counselled about all infant feeding options and the risks/benefits involved, so they can make an informed choice; they should also be supported in their decision. Currently the DOH guidelines recommend exclusive breastfeeding for the first six months.<sup>9</sup>

## Post-miscarriage and termination of pregnancy

After miscarriage or termination of pregnancy (TOP) all women should be offered counselling and be provided with a contraceptive method of their choice from the full range of available methods. Any method of the client's choice may be initiated immediately following uncomplicated miscarriage or TOP (at any gestational stage), provided that the medical eligibility criteria are met. Early initiation of contraception is advisable because ovulation occurs as early as two weeks post-TOP/miscarriage, so a woman can become pregnant almost immediately afterwards.

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\* This would be consistent with WHO MEC Category 3 and give providers option to initiate progestogen-injectables earlier than six weeks if needed.

## 1.3 Long-acting reversible contraception

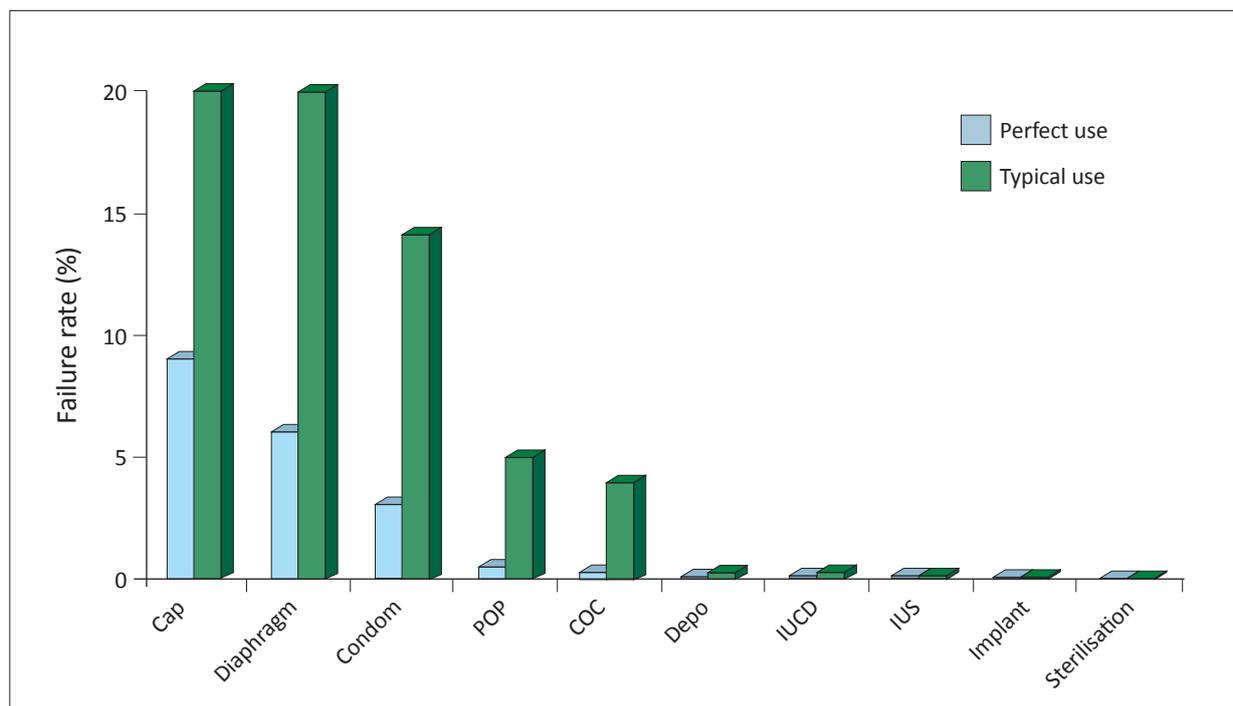
Of concern in South Africa is the problem of continuing high rates of unintended pregnancies, including among vulnerable groups (such as adolescents and women with HIV), as well as the growing number of women accessing TOP services, some repeatedly. Internationally, similar trends are seen and there has been increasing focus on LARC (long-acting reversible contraception), which are among the most effective contraceptive methods and have the greatest potential to reduce unintended pregnancies.

LARC are defined as methods that require administration less than once per cycle or month. The methods listed below fall within this definition.

- Intrauterine contraception:
  - CuT 380 IUD (registered in South Africa for 10 years but 12 years in other countries)
  - Levonorgestrel releasing intrauterine system (LNG-IUS) (5 years).
- Progestogen-only injectables:
  - DMPA (once every 12 weeks)\*
  - NET-EN (once every 8 weeks)
- Subdermal progestogen implants (single-rod for 3 years; two-rods for 4 or 5 years, depending on type).

LARC methods combine reversibility with highly effective contraception, as they do not rely on compliance and correct use in the same way as pills or barrier methods (see Box 1).<sup>10</sup>

**Box 1. Efficacy of various contraceptive methods comparing perfect use with typical use**



POP = progestogen-only pills  
IUS = intrauterine system

COC = combined oral contraceptive pills  
IUD = intrauterine contraceptive device

Source: Fleming CF, 2009<sup>10</sup>

\* It is noted that WHO and some countries interpret the interval as 13 weeks. In South Africa it is common practice to interpret the 3-month interval as 12 weeks, and this is reflected in local protocols and pharmaceutical job aids. For NET-EN it is 8 weeks.

With the exception of injections, LARC methods have superior continuation rates compared with short-term methods and, despite high initial costs (in particular with intrauterine systems and implants), in all instances are proven to be more cost effective in the long term.

There has been a lot of work done internationally to assess the cost effectiveness of LARC, looking at issues such as the costs of pregnancies averted, continuation rates, plus method and service delivery costs.<sup>11</sup> Findings include the following:

- all LARC methods are more cost effective than the combined pill at one year of use
- intrauterine devices/systems and implants are more cost effective than injectable contraceptives
- male and female sterilisation are only more cost effective than LARC at 15 years.

A comparison of methods in relation to effectiveness and continuation rates are summarised in Table 2.

**Table 2. Contraceptive effectiveness and continuation rates**

Effectiveness group	Method	Pregnancies per 100 women in first year		Percentage of women continuing at one year
		As commonly used	Used correctly and consistently	
Highly effective, do not rely on client's ability to use them correctly	Vasectomy	0.15	0.1	100
	Female sterilisation	0.5	0.5	100
	CuT 380 IUD	0.8	0.6	78
	LNG-IUS	0.2	0.2	80
	Implants	0.05	0.05	82
	Progestogen-only pills (during breastfeeding)	1	0.5	
Effective as commonly used. Very effective when used correctly and consistently	Progestogen-only injectables	3	0.3	56
	Combined injectables	3	0.05	56
	LAM	2	0.5	
	Combined oral contraceptive (plus Evra <sup>®</sup> Patch, Nuva Ring)	8	0.3	68
	Progestogen-only pills (not breastfeeding)	> 8	> 0.3	68
Only somewhat effective as commonly used. Effective when used correctly and consistently	Male condoms	15	2	53
	Coitus interruptus	27	4	51
	Diaphragm with spermicide	16	6	57
	Fertility awareness-based methods	25	5	
	Female condoms	21	5	49
	No method	85	85	

Source: Adapted from Trussell J, 2007<sup>12</sup>

**NOTE:** Emergency contraceptive pills initiated within 120 hours reduces risk of pregnancy by at least 75%.

Increasing use of LARC will reduce unwanted pregnancies in all groups of women, including:

- adolescents
- nulliparous women
- women who are breastfeeding
- women who have had a TOP or miscarriage
- women with HIV (need to encourage condom use for dual protection)
- women who have health conditions which make it unsafe to use oestrogen-containing methods (for example women with diabetes, migraines, or those taking drugs which affect liver enzymes).

Priority should therefore be given to expanding the range of LARC methods available in the public health sector. These have been clearly shown to be highly effective, have good continuation rates and are proven to be cost effective compared to other methods when used for longer than one year.

“Expanding the number of method choices offered can lead to improved satisfaction, increased acceptance and increased prevalence of contraceptive use.”

Source: *Medical eligibility criteria for contraceptive use*, WHO<sup>1</sup>



## CHAPTER 2

# Clinical guidelines for method provision

## Contraceptive methods discussed in this chapter

<b>Hormonal contraception</b>	Page 17
<b>Combined hormonal contraceptives</b>	Page 17
Low-dose combined oral contraceptive pills	
Combined hormonal methods not yet available in the public sector in South Africa	
<ul style="list-style-type: none"> <li>• Combined hormonal transdermal contraceptive patches (Evra®)</li> <li>• Combined hormonal vaginal ring</li> <li>• Combined injectables</li> </ul>	
Drug interactions and combined hormonal contraceptives	
<b>Progestogen-only contraceptives</b>	Page 25
Progestogen-only pills	
Progestogen-only injectables	
Subdermal implants	
Drug interactions and progestogen-only contraceptives	
Note: The levonorgestrel releasing intrauterine system although technically a progestogen-only method, is included in the section on intrauterine contraception	
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Copper intrauterine device	
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<b>Annexes</b>	Page 77
Outline the medical eligibility criteria for specific methods, based on the <i>Medical eligibility criteria for contraceptive use, fourth edition 2009</i> , published by the World Health Organization in 2010.	

## Overview

Chapter 2 provides method-specific information for contraception. These method-specific guidelines are intended to standardise and expand the range of methods available to women in South Africa. Although some of these methods are not yet available, it is recommended that they be incorporated into the Essential Drug List, and made available using a phased-in approach. Emphasis is placed on low-dose hormonal contraceptives, LARC and highly effective non-hormonal methods, such as the Cu IUD. Implicit in the guidelines is the concept that method provision includes contraceptive and fertility information and counselling, offered as part of comprehensive HIV and sexual and reproductive health care (see the companion to this document: the *National Contraception and Fertility Planning Policy and Service Delivery Guidelines (DOH 2012)*).

For each contraceptive method the following information is provided, where relevant.

- ◆ Key characteristics, which include, where applicable:
  - effectiveness
  - age limitations
  - parity limitations
  - mode of action
  - common side effects
  - non-contraceptive benefits
  - effect on STI and HIV risk
  - drug interaction
  - duration of use
  - return to fertility
- ◆ Procedures required for initiation and screening for medical eligibility (including HIV-related considerations and drug interaction where relevant)
- ◆ Timing of initiation
- ◆ Method-specific counselling
- ◆ Follow-up: schedule, content, management of common side effects
- ◆ Availability: the availability of the method in South Africa (as of 2012)
- ◆ Key recommendations for the future, in terms of increasing contraceptive choice in South Africa

For every method of contraception, discuss STI and HIV, as described in Box 2 below.

### **Box 2. STI and HIV counseling**

For every method of contraception, discuss STI and HIV.

- Risk assessment: with sensitivity, help the client assess her risk of exposure to STI and HIV, and that of her sexual partner/s.
- Explain the principles of safer sex (delayed sexual debut, limiting the number of sexual partners, mutual monogamy, correct and consistent condom use).
- Discuss and screen for STIs, treat if indicated; refer partner for treatment and advise condom use.
- Discuss HIV, HCT and explain the advantage of knowing one's own and one's partner's HIV status; discuss eligibility and adherence to ART (where appropriate).
- Encourage the client to use male or female condoms in addition to a non-barrier method of contraception (dual method use) if she is at risk of exposure to infection. Supply her with condoms, if appropriate.
- Explain that condoms are important for HIV prevention, but highly effective contraception is important to prevent pregnancy.

## 2.1 Hormonal contraception

### 2.1.1 Combined hormonal contraceptives

#### 2.1.1.1 Low-dose combined oral contraceptive pills

Low-dose COCs contain 35 µg or less of the synthetic oestrogen ethinyl estradiol and one of a range of synthetic progestogens (for example levonorgestrel). They are very effective in preventing pregnancy when taken regularly every day, and are safe for most clients. Many conditions that restrict the use of high-dose COCs do not apply to the low-dose formulations, but screening and careful instructions are required to ensure correct and consistent use. See Table 3 for key characteristics.

Information about drug interactions and COCs is given in Table 3

#### ◆ Key characteristics of low-dose COCs

**Table 3. Key characteristics of low-dose COCs**

<b>Effectiveness</b>	92% during the first year as commonly used; when used correctly and consistently the effectiveness is as high as 99.7%
<b>Age limitations</b>	No restrictions on use from menarche to age 40. After age 40 generally can use, but more careful follow-up may be required
<b>Parity limitations</b>	No restrictions
<b>Mode of action</b>	Works primarily by preventing ovulation. Other mechanisms, such as thickening of the cervical mucus (which reduces sperm transport) and altering the endometrium are considered secondary
<b>Common side effects</b>	Nausea and inter-menstrual spotting/bleeding are not uncommon in the first 3 months. Mild headaches, dizziness, breast tenderness, light periods, break through bleeding or occasionally amenorrhoea may occur. Medical management is not usually necessary or recommended, but the side effects should be discussed
<b>Non-contraceptive benefits</b>	Non-contraceptive benefits associated with COCs use include: <ul style="list-style-type: none"> <li>• Regular, lighter and less painful periods/menstruation</li> <li>• Prevention or improvement of iron-deficiency anaemia</li> <li>• Decrease in incidence of pelvic inflammatory disease (PID), ectopic pregnancy, ovarian and endometrial cancers and benign breast disease</li> <li>• Reduces symptoms of endometriosis and polycystic ovarian syndrome</li> <li>• Can improve or worsen acne (preparations containing cyproterone acetate or drospirinone as well as some other progestogens are particularly effective in management of acne)</li> <li>• Protection from risks associated with pregnancy</li> </ul>
<b>Effect on STI and HIV risk</b>	Not protective
<b>Duration of use</b>	Can use COCs safely throughout the reproductive years; there is no value in periodic discontinuation
<b>Return to fertility</b>	Fertility returns without a delay

#### ◆ Procedures required for the initiation of COCs

##### **Screening for medical eligibility**

- The vast majority of women can use COCs safely. Most of the conditions that may preclude women from the safe use of COCs are not very common in women of reproductive age and usually can be ruled out by taking appropriate medical history. See medical eligibility criteria for initiating combined hormonal contraceptives (Annexe 1).
- Thorough medical history taking is essential before the initiation of COCs.
- Whenever possible, blood pressure should be measured before initiating COCs; but a woman should not be denied COCs if her blood pressure cannot be measured, provided she has never been diagnosed with high blood pressure. Where possible, blood pressure should be measured within three months of commencing the method.

### ◆ Timing of initiation

COCs may be initiated at any time, as long as it is reasonably certain that the client is not pregnant. If pregnancy cannot be ruled out (see Appendix 2: Pregnancy checklist), the client should be advised to avoid sex or use condoms until her next period starts, and start taking COCs on day 1 of her period (but not later than day 5). If her next period is late, she should come back for a pregnancy test. See Table 4 for more guidelines.

**Table 4. Guidelines for timing of COC initiation**

Client's situation	When to start COCs
Having menstrual cycles	<ul style="list-style-type: none"> <li>• Within the first 5 days after the start of her monthly bleeding, protection is immediate; there is no need for a back-up method</li> <li>• Any other time in the cycle if it is reasonably certain that she is not pregnant (see Appendix 2: Pregnancy checklist). Advise to avoid sex or to use condoms for the next 7 days</li> </ul>
After childbirth if breastfeeding	<ul style="list-style-type: none"> <li>• After she stops breastfeeding or at 6 months postpartum – <i>whichever comes first</i>. Progestogen-only methods, Cu IUD, barrier methods or LAM can be used in the interim</li> </ul>
After childbirth if not breastfeeding	<ul style="list-style-type: none"> <li>• At 3 weeks after childbirth when there are no additional risk factors for thromboembolism</li> <li>• At 6 weeks after childbirth if there are additional risk factors for thromboembolism. Advise use of another method until this time</li> <li>• After 6 weeks, at any time if it is reasonably certain that she is not pregnant. (If she is sexually active before 6 weeks postpartum, she should use condoms or other back-up method for the next 7 days)</li> </ul>
After miscarriage or TOP	<ul style="list-style-type: none"> <li>• Immediately after uncomplicated first or second trimester miscarriage or TOP</li> <li>• Later at any time if it is reasonably certain that she is not pregnant (should use a backup method for 7 days if COCs are initiated more than 5 days after miscarriage or TOP)</li> </ul>
When changing methods	<ul style="list-style-type: none"> <li>• Immediately, as long as there was consistent and correct use of previous method</li> <li>• No need to wait for a period after using injectables but should initiate COCs before the window for re-injection expires</li> </ul>

### ◆ Method-specific counselling

- Appropriate method-specific counselling is essential.
- Provide the necessary information on key characteristics of the method, answer the client's questions, address fears and concerns respectfully, and instruct the client on correct method use.

When instructing the client on correct method use, cover the points outlined in the sections below.

#### **Explain routine pill taking**

It is important to give clear and practical instructions (see Box 3).

#### **Box 3. Recommended protocol for instructing a client on use of COCs**

- Hand the client a demonstration packet of the same pills that she will use.
- Explain:
  - which pills are active/contain hormones and which are inactive pills/placebos
  - how to take the first pill out of the packet
  - how to follow the directional arrows on the packet to continue taking the pills – one each day.
- Give instructions on starting COCs: no need to wait for menstruation, if reasonably certain that not pregnant.
- Emphasise the importance of taking one pill each day until the packet is empty. Encourage the client to link pill taking to some regular daily routine (for example teeth brushing) to assist with compliance.  
*Note: The daily intake of a COC pill is essential to achieve full contraceptive effectiveness.*
- Give her instructions on starting the next packet: with the 28-day pill packet, she should start a new packet of pills the day after she finishes the previous packet. If pills are taken correctly, she should always start a new packet on the same day of the week.
- Give instructions about what to do if pills are forgotten or vomiting occurs following pill taking.
- Ask her if she has any questions and request that she repeats the main information (to verify understanding).  
*Note: 21-pill packs require a 7-day break between the packs, however currently these 21-pill packs are not available in South Africa but may be being used by women visiting the country.*

#### **Discuss what to do if pills are missed**

Give the client instructions on what to do if she forgets to take a pill (see Boxes 4 and 5). If she frequently forgets to take pills, advise her to switch to a contraceptive method that does not require daily compliance and is acceptable to her.

**Box 4. Recommended protocol for missed COCs****What to do if you forgot to take one or more pills or started a pack late**

Missing pills or starting the pack late may make your pill less effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed.

A pill is **late** when you have forgotten to take it at the usual time.

A pill has been **missed** when it is more than 24 hours since the time you should have taken it.

In a 21:7 dosing regimen, the first 21 pills in a pack are active/hormonal pills and the last 7 are inactive/placebo pills. There are variations, for example, some packs have 24 active pills and only 4 inactive/placebo pills.

If you miss one active/hormone pill anywhere in your pack or start the new pack one day late, you will still have contraceptive cover.

However, missing **two or more active/hormone pills** or starting the pack **two or more days late** (more than 48 hours late) may reduce your contraceptive cover.

As soon as you realise you have missed any pills, take the most recently missed pill immediately.

Follow the advice below. If you are not sure what to do, continue to take your pill and use additional contraception, such as condoms, and seek advice as soon as possible.

If you have missed **one active/hormone pill**, anywhere in the pack:

- take the last pill you missed now, even if it means taking two pills in one day
- continue taking the rest of the pack as usual
- no additional contraception needed
- take your seven inactive/placebo pills as normal.

If you have missed two or more active/hormone pills (i.e. more than 48 hours late), anywhere in the pack:

- take the last pill you missed now, even if it means taking two pills in one day
- discard any earlier missed pills
- continue taking the rest of the pack as usual and abstain or use condoms for the next 7 days
- you may need emergency contraception (see below)
- you may need to start the next pack of pills without taking the inactive/placebo pills (see below).

**Emergency contraception**

If you have had unprotected sex in the previous 5 days and you have missed two or more active/hormone pills (i.e. more than 48 hours late) **in the first week of a pack**, you may consider emergency contraception. Get advice from your clinic, doctor or a pharmacist about this.

**Starting the next pack after missing two or more pills (more than 48 hours late)**

If **seven or more active/hormone** pills are left in the pack after the last missed pill:

- finish the pack as usual, including 7 days of inactive, placebo pills.

If **less than seven active/hormone** pills are left in the pack after the missed pill:

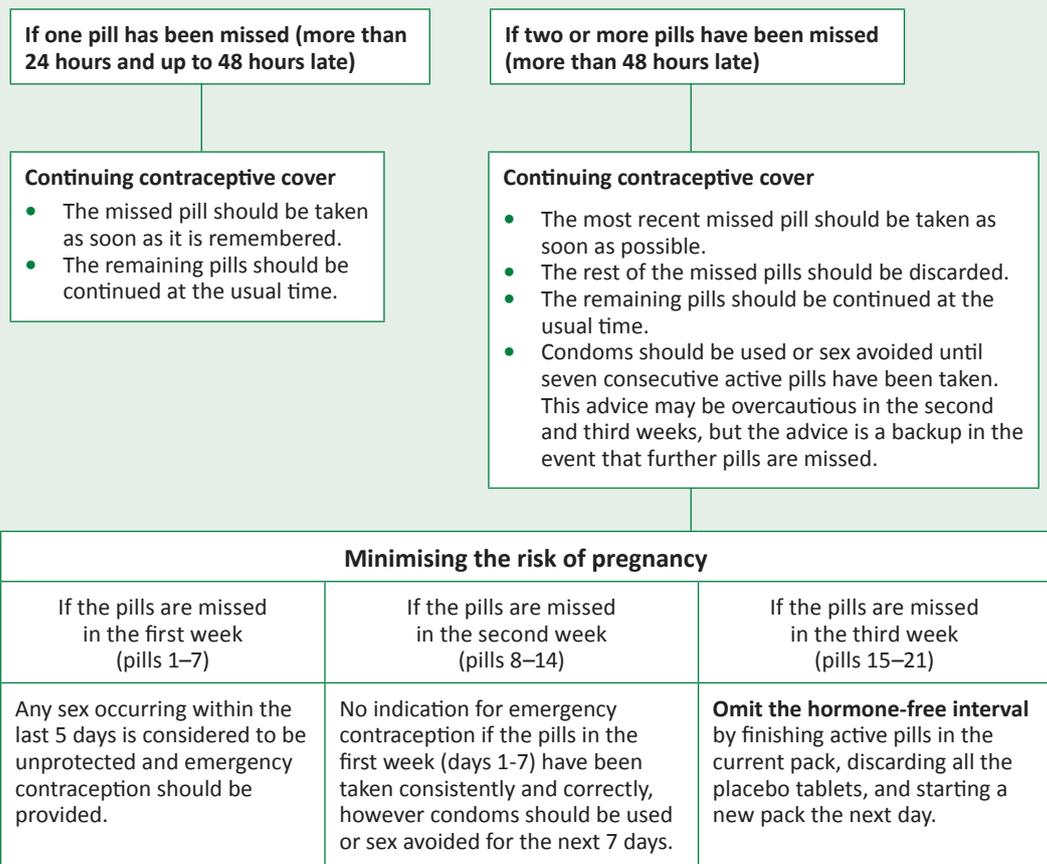
- finish the active pills in the pack, discard the seven inactive/placebo pills
- begin the first active pill from the next pack the following day.

If you forget any of the seven inactive/placebo pills this will not lead to risk of pill failure provided that no more than 7 days occur between the last active/hormone pill and the first active pill of the new pack. Discard the missed non-hormonal pills and keep taking the rest of the pills as usual.

If you **vomit** within two hours of pill taking you should take another pill. If vomiting persists resulting in two or more pills being 'missed' follow instructions for missed pills as above.

Source: Adapted from *Missed pill recommendations*, Clinical Effectiveness Unit, 2011<sup>1</sup>

**Box 5. Action that can be taken if COCs are missed**



Source: Adapted from *Missed pill recommendations*, Clinical Effectiveness Unit, 2011<sup>1</sup>

**Discuss common side effects and important warning signs of rare but serious complications (See Box 6 below)**

**Box 6. Side effects and warning signs of COCs**

**Common side effects of COCs**

- Describe common COC side effects (nausea, mild headaches, tender breasts, irregular bleeding or spotting, mood changes).
- Explain that these side effects are not signs of disease and usually become less or stop within three months of COC use; many women have none of these side effects.
- Explain how she can deal with some common problems.

**Warning signs of rare complications of COCs**

- **Describe the symptoms of serious COC-related complications (ACHES):**
  - Abdominal pain or jaundice
  - Chest pain or shortness of breath
  - Headaches that become severe, one-sided or are associated with:
  - Eye problems (such as brief loss of vision, seeing bright zigzag lines)
  - Severe pain or swelling in one leg (calf muscle)
- Reassure the client that serious complications are extremely rare, but if any of the above symptoms occur she should stop taking COCs, use a backup contraceptive method if needed and seek immediate medical attention.

**Discuss STI and HIV**

See Box 2 for guidelines.

**Arrange follow-up, provide method and written materials**

- Provide new acceptors with a three-months supply of COCs.
- Give clients appropriate IEC (information, education and communication) materials about their method and related issues (for example STI and HIV protection).
- Encourage clients to return to the clinic at any time if they have any questions or concerns about COCs or if they wish to switch to another method.
- Emphasise that they need to return to the clinic without a delay if they experience signs of complications (ACHES).

**◆ Follow-up****Schedule**

- Routine follow-up visits:
  - first follow-up visit should be scheduled before the end of the third packet of COCs;
  - at the first follow-up visit and at subsequent visits, 6–12-month supplies of COCs can be provided to clients in WHO MEC Category 1 and 2. (Category 3 clients should only receive COCs if prescribed by a doctor and they require careful medical follow-up.)

**Content**

- Counselling should cover client's questions, experiences with the method, satisfaction, side effects and health concerns.
- Where possible, blood pressure and weight should be measured and recorded at every visit.
- Management of side effects if needed (see Box 7).
- Invite the client to return again at any time if she has difficulties and ensure easy appointment system.
- Discuss STI and HIV risk, the need for dual protection and HCT.
- If the client is HIV-positive, monitor her CD4 count, assess her eligibility for ART and initiate or refer as appropriate

**Box 7. Management of common side effects of COCs****Nausea, dizziness, moodiness, mild headaches, tender breasts**

- Exclude pregnancy if suspected, using the pregnancy checklist in Appendix 2, or a pregnancy test.
- Reassure that these are common side effects and they usually diminish within three months of initiating use of COCs.
- Advise to continue taking the pills with meals, preferably just before going to bed. If problems persist try a different pill, switch to COCs with an oestrogen dose less than 35 µg (if available) or help her choose another method.
- Cyclical, premenstrual mood swings and/or breast tenderness that occur with use of triphasic pills often diminish if switched to a monophasic pill.

**Breakthrough bleeding or spotting, which is troublesome and/or persists beyond three months of COC use**

- Ask if the client was taking pills on schedule, without missing any pills.
- Exclude concomitant drug use, severe diarrhoea and vomiting.
- Examine to exclude pregnancy or other genital tract pathology, such as infection or cancer. If any pathology is identified manage or refer for treatment.

Switch to a different brand of low-dose pills. If this fails, switch to a higher dose oestrogen-containing pill (if available), or help her choose another method. Use of high-dose pill for three cycles often provides good cycle control, then the client should be switched back to a low-dose pill.

### ◆ Availability

- COCs are available at all levels of service provision. Routine use of high dose pills should be discontinued and replaced by formulations containing 35 µg oestrogen or less. High-dose COCs containing 50 µg oestrogen should not be used routinely but are appropriate in specific situations, such as for emergency contraception.
- Level of service delivery: COCs are available at all levels of service provision.

#### NOTE:

A COC containing 20 µg oestrogen should be made available at all levels of care, as second line management for clients who experience unacceptable side effects with pills containing 30–35 µg. These very low-dose options have particular applications for women with side effects, young or older women. However, these clients should be counselled that while lower dose COCs may reduce some common side effects (for example nausea, headaches and breast tenderness) associated with pills containing 30–35 µg oestrogen, they may increase menstrual side effects, such as irregular bleeding and spotting. Clients should be able to decide which side effects they are willing to tolerate.

### 2.1.1.2 Combined hormonal methods not yet available in the public sector in South Africa

The combined hormonal methods outlined below (contraceptive patches, the vaginal ring and injectables) are not yet available in the public sector and/or registered in South Africa, and so only a brief overview of each is provided. See Table 5 for information about drug interactions with these methods.

#### Combined hormonal transdermal contraceptive patches (Evra®)

- Small adhesive patches containing oestrogen and progestogen. Each patch is applied to the skin of the upper outer arm, buttocks, abdomen, back or thigh and remains in place for seven days continuously. A new patch is applied every week for three consecutive weeks, then no patch is used during the fourth week.
  - Low levels of hormones are released continuously and are absorbed through the skin and work in the same way as the COC by suppressing ovulation and result in cyclical withdrawal bleeds during the patch-free week.
  - Hormone levels are equivalent to COCs containing 20 µg ethinyl estradiol.
  - Transdermal administration avoids the first pass of hormones through the liver and thus may result in fewer oestrogen-related side effects than COCs. Compliance is simpler as it is limited to applying a patch once a week, compared to daily pill taking.
  - Until more data are available, patch efficacy, medical eligibility and side effect profiles are considered to be the same as for the COC.
  - Because of higher failure rates reported in women weighing over 90 kg the patch is not recommended for such clients.
  - The patch is highly effective in pregnancy prevention but provides no protection against STI and HIV. Additional use of condoms is advised for dual protection.
  - Contraceptive patches are currently only available in the private sector in South Africa. There are no plans currently to consider introducing this method for use in public sector services.

### Combined hormonal vaginal ring

- This consists of a flexible ring, which is placed high up in the vagina and remains in position for three weeks, followed by a week with no ring during which a withdrawal bleed occurs. A new ring is used for each cycle. The ring contains synthetic oestrogen and progestogen, which are released in small constant amounts throughout the three weeks. The hormones are absorbed through the vaginal mucosa and work in the same way as the COC, primarily by suppressing ovulation. Hormone levels are similar to those of COC containing 15 µg oestrogen.
- Transvaginal administration avoids the first pass of hormones through the liver and thus may result in fewer oestrogen-related side effects than pills, and the method does not require daily compliance.
- Until more data are available vaginal ring efficacy, medical eligibility and side effect profiles are considered to be the same as for the COC.
- Vaginal rings are registered, and it is expected that they will be marketed in the private sector in South Africa in the near future. There are no plans currently to consider introducing this method for use in public sector services.

### Combined injectables

- Injections containing a combination of oestrogen and progestogen are administered by intramuscular injection at intervals of 30 days. This induces cyclical bleeding patterns, however irregular/prolonged bleeding and amenorrhoea are not uncommon. The progestogen content is the same as that of the progestogen-only injectable contraceptives in combination with oestrogen (either estradiol cypionate or estradiol valerate), which is released during the first 8–11 days of each cycle at a level similar to that in a normal menstrual cycle.
- Combined injectables cause fewer oestrogen-related side effects than COCs because they avoid the first pass metabolism through the liver, oestrogen is present for a limited time in each cycle and natural oestrogen is less potent than the synthetic oestrogen in COCs.
- Failure rates of 0.2 to 0.4% are reported during the first year of use.
- Until further data are available, the same criteria for COC use are also used for combined injectables.
- Combined injectables are currently not registered or available in South Africa. Introduction of combined injectables to selected pilot sites may be considered in the future in order to expand contraceptive choice.

### 2.1.1.3 Drug interactions and combined hormonal contraceptives

Table 5 provides information about the interaction of combined hormonal contraceptives and other drugs.

**Table 5. Drug Interactions and combined hormonal contraceptives (COCs, patches, vaginal rings and combined injections)<sup>2-6</sup>**

Drug category	Drug	Type of interaction	Clinical recommendation
<b>Enzyme-inducing drugs</b>			
Anticonvulsants	<ul style="list-style-type: none"> <li>• Carbamazepine</li> <li>• Esiclarbazepine</li> <li>• Oxcarbazepine</li> <li>• Phenobarbital</li> <li>• Phenytoin</li> <li>• Primidone</li> <li>• Rifinamide</li> <li>• Topiramate (≥200mg daily)</li> </ul>	<ul style="list-style-type: none"> <li>• Enzyme inducer</li> <li>• Modest to marked (20–40%) reduction in ethinyl estradiol (EE) and progestogens</li> <li>• Possible reduced contraceptive efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• Use a method that is not affected by enzyme-inducing drugs</li> <li>• If client insists on using COCs, pills containing 30 to 35 µg EE should be used and client should be strongly encouraged to use condoms in addition to CHCs for enhanced pregnancy protection</li> <li>• Extend dosing regimen of 9–12 weeks active pills with hormone free interval of 4 days</li> </ul>
	Lamotrigine (as monotherapy)	Contraceptive efficacy unaffected BUT reduced seizure control (no adverse effects when used in combination therapy with sodium valproate)	Do not use CHCs with lamotrigine as monotherapy but can be used if lamotrigine is used in combined therapy
Herbal	St John's Wort	<20% reduction of hormone levels	See recommendations for anticonvulsants above
Anti-TB drugs	<ul style="list-style-type: none"> <li>• Rifampicin</li> <li>• Rifabutin</li> </ul>	Reduction EE>40% and progestogen. Markedly reduced contraceptive efficacy	Do NOT use CHCs
Antimicrobials	Broad spectrum antibiotics (excluding Rifampicin)	No significant effects on serum levels of hormones and no evidence of reduced contraceptive efficacy	<ul style="list-style-type: none"> <li>• There are no restrictions on the concurrent use of broad-spectrum antibiotics</li> <li>• Additional cover is not required</li> </ul>
<b>ART (antiretroviral therapy or treatment)*</b>			
Protease Inhibitors	Ritonavir or Ritonavir-boosted protease inhibitors	Significant >40% reduction in EE levels and some reduction in progestogens. Marked reduction in contraceptive efficacy	Do NOT use CHCs
Non-Nucleoside reverse transcriptase inhibitors (NNRTI)	<ul style="list-style-type: none"> <li>• Efavirenz</li> <li>• Nevirapine</li> </ul>	<ul style="list-style-type: none"> <li>• Slightly increased hormone levels</li> <li>• Modest reduction of EE (less than 30%)</li> </ul>	<ul style="list-style-type: none"> <li>• CHC can be used</li> <li>• CHC with oestrogen dose below 30 µg are not recommended. Clients should be strongly encouraged to use condoms in addition to CHCs for enhanced pregnancy protection</li> </ul>
Nucleoside reverse transcriptase inhibitors (NRTI)	<ul style="list-style-type: none"> <li>• Zidovudine</li> <li>• Stavudine</li> <li>• Tenofovir</li> <li>• Didanosine</li> <li>• Abacavir</li> </ul>		CHC can be used

\* For contraceptive interactions with ART drugs not listed above please consult an up-to-date medicines formulary.

## 2.1.2 Progestogen-only contraceptives\*

### 2.1.2.1 Progestogen-only pills

Progestogen-only pills (POPs) are oestrogen-free oral contraceptives containing very low doses of synthetic progestogen. A pill should be taken approximately at the same time every day. There are no inactive pills in the POP pack and no break required between packs.

POPs are appropriate for breastfeeding women and are a useful alternative for women who experience oestrogen-related side effects with COCs, or have health conditions that may preclude safe use of COCs. POPs are effective in preventing pregnancy, and their use does not affect breastfeeding or interfere with coitus. In common use, POP effectiveness is slightly less than that of COCs in non-breastfeeding women but, when compliance is good, POPs are very effective. They are also highly effective in breastfeeding women. POPs are safe for most women. Few conditions preclude safe POP use. See Table 6 for key characteristics.

#### ◆ Key characteristics of POPs

**Table 6. Key characteristics of POPs**

Effectiveness	In non-breastfeeding women: 90–92% as commonly used; when used consistently and correctly, POPs are more than 99% effective. In breastfeeding women: ≥99% effective
Age limitations	No restrictions on use for women from menarche to menopause
Parity limitations	No restrictions
Mode of action	Primarily thickens cervical mucus and so prevents sperm penetration (after 2 days of use). Also inhibits ovulation in 60% of cycles
Common side effects	Changes in menstrual bleeding (irregular bleeding, spotting or amenorrhoea), mild headaches, nausea, dizziness, mood changes and breast tenderness
Non-contraceptive benefits	None other than protection from risks associated with pregnancy
Effect on STI and HIV risk	Not protective
Duration of use	Can be used throughout the reproductive years
Return to fertility	Fertility returns without a delay

#### ◆ Procedures required for the initiation of POPs

##### **Screening for medical eligibility**

Most women can use POPs safely. POPs have fewer contraindications than COCs. Most of the conditions that may preclude safe use of POPs are not common in women of reproductive age and usually can be ruled out by taking appropriate medical history. (See Annexe 2 for WHO MEC.)

##### ◆ Timing of initiation

POPs may be initiated at any time provided it is reasonably certain that the client is not pregnant. If the possibility of pregnancy exists, a pregnancy test must be done, or the client advised to avoid sex/use condoms until her next menses, and begin pill taking from day 1 of the cycle.

\* Levonorgestrel releasing intrauterine system (LNG-IUS), although technically a progestogen-only method, is included in Section 2.2 on intrauterine contraception.

**Table 7. Guidelines for timing of POP initiation**

Client's situation	When to start
Having menstrual cycles	<ul style="list-style-type: none"> <li>• Within the first 5 days of the onset of menses, protection is immediate, no need for a backup method</li> <li>• Any other time in the cycle if it is reasonably certain that she is not pregnant</li> <li>• Advise avoiding sex or use condoms for the first 2 days of taking pills</li> </ul>
After childbirth if breastfeeding	<ul style="list-style-type: none"> <li>• Immediately if requested</li> <li>• Later at any time if it is reasonably certain that she is not pregnant</li> <li>• If her menses have returned, advise to avoid sex or use condoms for the first 2 days of taking pills</li> </ul>
After childbirth if not breastfeeding	<ul style="list-style-type: none"> <li>• Immediately or within the first 3 weeks postpartum; no backup protection needed</li> <li>• Later at any time if it is reasonably certain that she is not pregnant</li> <li>• Advise to avoid sex or use condoms for the first 2 days of taking pills</li> </ul>
After miscarriage or TOP	<ul style="list-style-type: none"> <li>• Immediately or within 5 days after first or second trimester miscarriage or TOP; no backup protection needed</li> <li>• Later at any time if it is reasonably certain that she is not pregnant</li> <li>• Advise avoiding sex or use condoms for the first 2 days of taking pills</li> </ul>
When changing methods	<ul style="list-style-type: none"> <li>• Immediately as long as there was consistent and correct use of previous method</li> <li>• No need to wait for a first period after using injectables</li> <li>• If using injectables, can start when repeat injection would have been given, or within the 2-week (NET-EN) or 4-week (DMPA) grace period</li> <li>• No additional contraceptive protection is needed</li> </ul>

### ◆ Method-specific counselling

Appropriate method-specific counselling is essential. Provide the necessary information on key characteristics of the method, answer the client's questions, address fears and concerns respectfully, and instruct the client on correct method use. For instruction on correct method use, cover the points below.

#### **Explain routine pill taking**

Clear and practical instructions are important.

##### **Recommended protocol for instructing clients on POP use**

- All pills look the same and all of them contain hormones. This means there are no inactive pills in the pack, no pill-free intervals and no days 'dedicated' to menstruation.
- Pills should be taken daily, preferably at the same time, but never more than 3 hours late. Clients should be counselled to take the pill at the same time every day, linking the pill to a daily routine activity.
- Pills are taken continuously: when the pack is finished, start the new pack the next day.
- When a woman stops breastfeeding, consider changing to COC, unless contraindicated, as POPs become less effective (unless very strict pill-taking regimen is followed).

#### **Discuss what to do if pills are missed**

Give the client instructions on what to do about missed pills. If she often forgets pills, it is better to choose another contraceptive method that does not require rigid compliance.

##### **Recommended protocol for missed POPs**

If a client is more than 3 hours late in taking a pill, she should take it as soon as possible, then keep taking one pill each day as usual and use condoms or avoid sex for the next 48 hours.

The same instructions apply if more than one pill is missed. Women who have monthly bleedings (regardless of their breastfeeding status) should consider using emergency contraception if they had sex in the past 5 days.

**Discuss common side effects**

These include changes in bleeding patterns (frequent/irregular/prolonged/no monthly bleeding), headaches, dizziness, mood changes, breast tenderness, nausea. For breastfeeding women, it may cause a longer delay of monthly bleeding after childbirth.

**Discuss STI and HIV**

See Box 2

**Arrange follow up, provide method and IEC materials**

- Provide new clients with a 3-months supply of POPs.
- Give clients appropriate IEC materials about their method and related issues (for example STI and HIV protection).
- Encourage clients to return to the clinic at any time if they have any questions or concerns about POPs or if they wish to switch to another method.

**◆ Follow-up****Schedule**

Routine follow-up:

- first follow-up visit to be before the end of the third packet of POPs
- at the first and subsequent follow-up visits, 6–12-month supplies can be provided to clients in WHO MEC Category 1 and 2. (Category 3 clients should only receive POPs if prescribed by a doctor and they require careful medical follow-up.) (See Annexe 2 for WHO MEC.)

**Content**

- Counselling should cover client's questions, experiences with the method, satisfaction, side effects and health concerns.
- Management of side effects if needed (see Box 8)
- Invite the client to return again at any time if she has difficulties and ensure easy appointment system.
- Discuss STI and HIV risk, the need for dual protection and HCT.
- If the client is HIV-positive, monitor her CD4 count, assess eligibility for ART and initiate or refer as appropriate.

**Box 8. Management of common side effects of POPs****Irregular bleeding or spotting**

- Reassure the client that irregular bleeding or spotting is to be expected and occurs commonly with POPs.
- Ask if she takes pills on time, had vomiting or diarrhoea, or started any medications, all of which could make POPs less effective.
- If there are reasons to suspect underlying condition (for example irregular bleeding became worse or started again after several months of normal bleeding) exclude pregnancy (intrauterine, ectopic) and other possible causes, such as incomplete miscarriage, genital tract infection and reproductive tract cancer. If pathology is identified or suspected, refer for management. If not, counsel, reassure and advise to continue using POPs.
- Management of irregular bleeding or spotting: for short-term relief, offer ibuprofen 800 mg 3 times a day for 5 days.
- If unacceptable bleeding persists and pathology has been excluded, advise client to change to another method.

**Amenorrhoea**

- Reassure the client that amenorrhoea is not uncommon in POP users. If there are reasons to suspect pregnancy (for example she forgets to take pills on time), rule it out by the means available (see Appendix 2: Pregnancy checklist). If pregnant, stop use of POPs and discuss on-going management including the option of TOP.
- If not pregnant, advise continued use of POPs with appropriate reassurance and counselling.

**Headaches**

- If mild and no cause is found, treat with analgesics. If she develops migraines with aura, stop POPs and offer her a choice of other appropriate methods (non-hormonal).

**Mood change**

- Counsel that mood changes may occur with POP use. If unacceptable, help her choose another method and if needed (for example if she has severe depression) refer for care.

## ◆ Availability

POPs are available at all levels of care.

### NOTE:

- When progestogen-only pills containing a daily dose of 75 µg desogestrel (Cerezette®) become available in South Africa it is recommended that they should be offered to women (especially non-breastfeeding women) as the preferred choice to currently available POPs.<sup>7</sup>
- Desogestrel-based POPs consistently suppress ovulation in addition to thickening cervical mucus, which makes their mechanism of action similar to that of COCs. As a result, they are more effective than other POPs and require less rigid pill taking requirements. This is particularly important for non-breastfeeding POP users as they do not benefit from the synergistic effect of lactation giving additional protection from pregnancy.<sup>8</sup>

### 2.1.2.2 Progestogen-only injectables

Progestogen-only injectables are a highly effective method of reversible contraception suitable for most women. They contain synthetic progestogens administered by deep intramuscular injection. There are two available and widely used progestogen-only injectables in South Africa: depot medroxyprogesterone acetate (DMPA), and norethisterone enanthate (NET-EN).

Injectables are popular among clients because they are highly effective, easy to comply with, require only periodic clinic visits, are private and no supplies need to be kept at home. See Table 8 for key characteristics.

## ◆ Key characteristics of progestogen-only injectables

**Table 8. Key characteristics of progestogen-only injectables**

Effectiveness	As commonly used, injectables are 94% effective. If used correctly (for example woman comes for reinjection on time), the effectiveness is as high as 99.7%
Age limitations	Overall no restrictions, but some caution may be warranted in adolescents younger than 18 years and women older than 45 years due to concerns about reduced bone mineral density. There are no data to deny the choice of either injectable on the grounds of age alone
Parity limitations	No restrictions
Mode of action	Primarily inhibits ovulation but also thickens cervical mucus and thereby prevents sperm penetration
Common side effects	Changes in menstrual bleeding (irregular, prolonged or/and heavy bleeding, amenorrhoea) and weight gain, are important issues to cover during counselling. Other possible side effects include headaches, dizziness, mood changes and decrease in sex drive
Non-contraceptive benefits	The use of injectable contraceptives provides the following additional health benefits: <ul style="list-style-type: none"> <li>• Prevention or improvement of iron deficiency anaemia</li> <li>• Decrease in occurrence of ectopic pregnancy, pelvic inflammatory disease, uterine fibroids and endometrial cancer</li> <li>• Reduction in the severity of sickle-cell crises among women with sickle-cell anaemia</li> <li>• Reduction in severity of symptoms of endometriosis</li> </ul>
Effect on STI and HIV risk	Not protective. Recent observational studies suggest that use of hormonal contraception, in particular DMPA, might increase risk of HIV acquisition. <sup>9,10</sup> While there is need for further research, every effort must be made to emphasise the importance of consistent and proper condom use in conjunction with hormonal and other non-hormonal contraceptives for the prevention of HIV. <sup>11</sup> Alternatives, such as lower dose hormonal contraceptives, and non-hormonal options, such as Cu IUDs, need to be explored with the client. The benefits of the injectable to prevent pregnancy need to be weighed against the possible risk of HIV
Duration of use	Can be used throughout a woman's reproductive years but perimenopausal women may not have enough time until menopause to regain bone density. Switching to another method after reaching 45 years may be considered
Return to fertility	Average delay of about 4–6 months depending on type of injectable. No permanent damage to fertility has been associated with injectables. Cover this issue when counselling

## ◆ Procedures required for the initiation of progestogen-only injectables

### **Screening for medical eligibility**

The vast majority of women can use injectables safely, provided condoms are used correctly and consistently to prevent HIV and STIs. Most of the conditions which may preclude safe use of injectables are not common in women of reproductive age and usually can be ruled out by taking appropriate medical history. See Annexe 3 for medical eligibility criteria for initiating progestogen-only injectable contraceptives.

### ◆ Timing of initiation

- If the first injection is given within the first seven days of the menstrual cycle, protection is immediate and no backup contraception is needed.
- The first injection can also be given at any other time during the menstrual cycle if it is reasonably certain that the client is not pregnant (refer to the pregnancy checklist in Appendix 2). If injectables are started after day 7, the client should avoid sex or use condoms for the next seven days after the injection.
- Initiation of injectables after childbirth, miscarriage, TOP and when changing methods is as for POPs above (only backup contraception, if applicable, should be used for seven days instead of two).
- Starting progestogen-only injectables should not be restricted to menstruation. This practice is unnecessary and acts as a barrier to access.

### ◆ Method-specific counselling

Appropriate method-specific counselling is essential. Provide the necessary information on key characteristics of the method, answer the client's questions, address fears and concerns respectfully, and instruct the client on correct method use. For instruction on correct method use, cover the points below.

#### **Discuss requirements for correct use**

The only requirement for the client is to attend for injection every 8 or 12 weeks\* depending on the type of injectable used.

#### **Discuss side effects and expected delay in return to fertility after method discontinuation**

Counselling about method-related side effects (see Box 9), prior to the initiation and during use of injectables *is essential* and reduces early method discontinuation because of side effects. Common client concerns about progestogen-only injectables are changes in menstrual bleeding patterns and weight gain.

#### **Box 9. Side effects related to progestogen-only injectables**

- Irregular, prolonged bleeding or spotting, and heavy bleeding are commonly associated with use of injectables. These may occur in one form or another, particularly in the first six months of use, but the frequency decreases progressively with duration of use.
- Conversely, the frequency of amenorrhoea increases progressively with duration of use and by the end of the second year about 80% of users of injectables develop amenorrhoea.
- Weight gain may be a problem for some clients and tends to increase with duration of use. This is mainly mediated through increased appetite. Clients should be advised that if they carefully monitor their diet they should be able to maintain their weight.
- Acne, headaches, mood changes and dizziness may also occur and be problematic for some clients.
- The anticipated delay in the return to fertility after method discontinuation must be discussed and women should be counselled accordingly – an average 4-month delay for NET-EN and 6-month delay for DMPA. This means that some women may conceive as soon as the effectiveness of the last injection wears off, and for some women it may take as long as 12–14 months to conceive. However, fertility is not permanently affected. Women should be able to decide if they want to discontinue injections 4–6 months before they want to conceive.
- Appropriate counselling on menstrual changes reduces the discontinuation rate. If a woman finds changes in bleeding unacceptable, she should be offered other available and suitable contraceptive options. However, she should understand that the effects of the injectables cannot be stopped immediately and side effects may continue until the blood level of the hormone reduces.

\* WHO and some countries interpret the interval as 13 weeks. In South Africa, the 3-month intervals are interpreted as 12 weeks, and this is reflected in local protocols and pharmaceutical job aids. For NET-EN it is 8 weeks.

**Discuss STI and HIV**

See Box 2

**◆ Administer the injection****Injection procedure**

- Administer by deep intramuscular injection into the buttock or upper arm depending on client's preference. The degree of obesity may make it difficult to inject the drug into the muscle of the buttocks and arm would be the preferred site of injection in such cases.
- Aseptic injection technique should be followed (i.e. the use of a sterile needle and syringe for each injection and their safe disposal).

**Arrange follow-up, provide method and IEC materials**

- Give clients appropriate IEC materials about their method and related issues (for example STI and HIV protection).
- Clients using DMPA should be seen every 12 weeks and those on NET-EN every 8 weeks for repeat injection.\*
- Encourage clients to return to the clinic at any time if they have any questions or concerns about their injectables or if they wish to switch to another method.

**◆ Follow-up****Schedule**

Clients using injectables require repeat injections: every 12 weeks for DMPA and every 8 weeks for NET-EN. Repeat injections may be given 2 weeks early for both NET-EN and DMPA (although this is not ideal) *or up to* 2 weeks late for NET-EN and up to 4 weeks late for DMPA. Guidelines for late injections are outlined in Box 10.

**Box 10. Late injections****If more than 2 weeks for NET-EN or more than 4 weeks for DMPA have elapsed since the due date for the repeat injection**

- It may be given if the provider can be reasonably certain that the client is not pregnant (for example she has not had sex since the end of her 2 or 4 weeks grace window for reinjection, or she was using condoms consistently and correctly, or she is protected by LAM).

**If the possibility of pregnancy cannot be excluded**

- She should be advised to use condoms, abstain from coitus or use POPs for 2 weeks. Then, if a pregnancy test is still negative, she can be given the injection and advised to abstain or use condoms for a further 7 days after injection.
- If she is unable to comply with the above, the injection may be given with an explanation that it will not abort or harm an existing pregnancy. She should be advised to use condoms or abstain from sex for the first 7 days after injection. An early follow-up appointment in 4–6 weeks should be given to exclude pregnancy
- Do **not** send her away without a method. It is not necessary to wait for menstruation to re-start the injectable.

**Content**

- Counselling should cover client's questions, experiences with the method, satisfaction, side effects and health concerns.
- Management of side effects if needed (see Box 11).
- Where possible, blood pressure and weight should be measured and recorded at every visit.
- Give next injection and date for next injection.
- Invite the client to return again at any time if she has difficulties and ensure easy appointment system.
- Discuss STI and HIV risk, the need for dual protection and HCT.
- If the client is HIV-positive, monitor her CD4 count, assess eligibility for ART and initiate or refer as appropriate.

\* WHO and some other countries interpret the interval as 13 weeks. In South Africa, the 3-month intervals are interpreted as 12 weeks, and this is reflected in local protocols and pharmaceutical job aids. For NET-EN it is 8 weeks.

**Box 11. Management of common side effects of progestogen-only injectables****Amenorrhoea**

- Reassure the client that amenorrhoea is normal among progestogen-only injectable users and not harmful. It does not mean that she is pregnant nor that menstrual blood is building up inside her body. Explain that amenorrhoea can improve her health by preventing anaemia.
- Lower dose injections of DMPA containing 30% less hormone, given by subcutaneous injections every 13 weeks, are available in some countries but are not yet registered or available in South Africa. Lower dosage may result in lower incidence of side effects without reducing efficacy, however, further research is still required regarding risk of HIV acquisition. Pre-loaded disposable systems make self-administration a possibility.

**Spotting or light irregular bleeding**

- Reassure her that this type of bleeding is very common during the first three to six months of injectable use, sometimes longer. It is not harmful.
- Light bleeding can usually be controlled with a low-dose COC, such as Nordette/Oralcon for 7 days or a non-steroidal anti-inflammatory drug (NSAID) but not aspirin, for example ibuprofen (400 mg 3 times a day for 3 days), if oestrogen is contraindicated.
- If there are reasons to suspect another gynaecological problem (for example bleeding continues or starts after several months of normal bleeding, or she has other symptoms as well as bleeding, or bleeding episodes are linked to the time of intercourse), examine and manage or refer as appropriate.

**Very heavy, prolonged or frequent bleeding (more than twice as long/as much as her usual period)**

- Reassure that some injectable users experience heavy or prolonged bleeding. Usually it is not harmful and diminishes with time.
- It may require attention, especially in women with anaemia. Advise iron-rich foods and iron supplements, if necessary.
- If there are reasons to suspect this bleeding may be due to reasons other than DMPA/NET-EN (see above), then examine and refer if necessary. If the other causes are excluded and oestrogen is not contraindicated, prescribe a high-dose COC pill, such as Biphasil, to be taken daily for 21 days followed by seven placebos during which time a normal withdrawal bleed will occur (it may be repeated for two cycles if necessary). An alternative to reduce the bleeding is a non-steroidal anti-inflammatory drug (NSAID) but not aspirin, for example ibuprofen (400 mg 3 times a day for 3 days), if oestrogen is contraindicated.
- If unacceptable bleeding recurs or persists advise change to another method.

**Severe headaches**

- Women who develop bad headaches, or whose headaches become worse after beginning injectable use, should be advised to switch to a non-hormonal method and be referred for assessment and management of the headaches if they do not settle.

**◆ Availability**

Progestogen-only injectables are widely available and utilised. Before beginning injectables, clients should be made aware of the full range of contraceptive options available to them. They should be thoroughly counselled about common side effects that may occur and how to manage them, in particular bleeding disturbances and amenorrhoea, delay in return to fertility and increase in appetite. Experience shows that such counselling facilitates informed method choice and reduces early discontinuation due to method dissatisfaction.

Recent observational studies, which suggest a possible increased risk of HIV acquisition and transmission with progestogen-only injectables, reinforce the need to emphasise consistent and correct condom use for HIV protection, and to promote alternative LARC methods.<sup>9–11</sup>

**Lower dose progestogen injections**

Lower dose injections of DMPA containing 30% less hormone, given by subcutaneous injections every 13 weeks, are available in some countries but are not yet registered or available in South Africa. Lower dosage may result in lower incidence of side effects without reducing efficacy, however, further research is still required regarding risk of HIV acquisition. Pre-loaded disposable systems make self-administration a possibility.

Introduction of these, in preference to current intramuscular DMPA, should be considered when such products become available in South Africa.

### 2.1.2.3 Subdermal implants<sup>12,13</sup>

Long-acting progestogen subdermal implants are proven to be highly effective and safe, and also have some additional non-contraceptive benefits (see Table 9 for key characteristics). Systems consisting of single rods containing etonorgestrel (Implanon NXT<sup>®</sup> used for 3 years) and two rods containing levonorgestrel (Jadelle<sup>®</sup> and Sino-plant<sup>®</sup> used for 5 and 4 years respectively) are available and utilised in many countries, including many in Africa. The older, six-rod system Norplant<sup>®</sup>, effective for 5 years, is no longer on the market, but there are still women who used this method in the past and plan to continue with it until expiration date.

The single-rod implant consists of a small plastic rod, about the size of a matchstick, placed just under the skin of the upper arm that releases small amounts of progestogen into the body. Implants contain no oestrogen and so are therefore suitable for most women, including those who are breastfeeding or cannot, or do not wish to, use oestrogen.

Implants have been shown to be the most effective form of contraception, with extremely low failure rates and high continuation rates. Despite high initial costs they have proved to be cost effective compared with pills and injections at one year.<sup>12</sup>

A trained health care provider (doctor or nurse) is required to insert and remove implants.

The blood levels of hormone released by implants are constant and much lower than with progestogen-only injectables, therefore side effects, whilst similar to those of injections, are less common and less pronounced and are rapidly reversed when the implant is removed. Implants have no effect on bone mineral density.

#### ◆ Key characteristics of progestogen-only implants

**Table 9. Key characteristics of progestogen-only implants**

Effectiveness	Implants are almost 100% effective. (With Implanon, one pregnancy occurs in 1000 women over a 3-year period)
Age limitations	No restrictions from menarche to menopause
Parity limitations	No restrictions
Mode of action	Primarily inhibits ovulation and thickens cervical mucus and thereby prevents sperm penetration
Common side effects	Changes in menstrual bleeding are common, including lighter bleeding, irregular bleeding, infrequent bleeding and amenorrhoea. Other side effects include headaches, nausea, dizziness, breast tenderness, mood changes and abdominal pain due to enlarged ovarian follicles
Non-contraceptive benefits	Prevention of symptomatic PID and iron-deficiency anemia
Effect on STI and HIV risk	Not protective
Duration of use	Can be used throughout the reproductive years
Return to fertility	Without a delay

#### Summary characteristics of subdermal implants

- Constant blood levels of hormone, much lower dose than progestogen-only injectable contraceptives
- Suppresses ovulation for the duration of use
- Efficacy greater than male or female sterilisation
- Common side effects include irregular bleeding and amenorrhoea, but both are less pronounced and/or frequent than with progestogen-only injectables
- Minimal effect on bone mineral density
- Minimal metabolic effects, no effect on blood pressure
- Rapidly reversible (undetectable blood levels seven days after removal)
- Single and two-rod systems much easier to insert and remove than older six-rod systems

#### ◆ Availability

Clients who have had implants inserted outside South Africa are seen at our services with increasing frequency. In these instances, referral systems need to be in place to deal with requests for implant removals. Implants are to be introduced into the public sector as soon as they are registered and procured. This requires a phased approach with service provider training and IEC promotion amongst the general public.

See Annexe 4 for medical eligibility criteria for initiating subdermal implants.

### 2.1.2.4 Drug interactions and progestogen-only contraceptives

Table 10 provides information about the interaction of progestogen-only contraceptives with other drugs

**Table 10. Drug Interactions with progestogen-only contraceptive methods (POCs)<sup>2-6</sup>**

Drug category	Drug	Type of Interaction	Clinical Recommendation
<b>Enzyme-inducing drugs</b>			
Anticonvulsants	Carbamazepine Esicarbazepine Oxcarbazepine Phenobarbital Phenytoin Primidone Rifinamide Topiramate(≥200mg daily)	Enzyme inducer  Modest to marked (20–40%) reduction of hormone blood levels for some progestogen-only methods  Possible reduced contraceptive efficacy	POPs NOT recommended (WHO MEC Category 3)  Progestogen injections DMPA (WHO MEC Category 1) and NET-EN (WHO MEC Category 2) can be used. Given at 12 and 8-week intervals respectively. No change to dosing intervals is necessary  Implants may be used (WHO MEC Category 2)
	Lamotrigine (as monotherapy)	No drug interactions with POCs	All POCs safe to use (WHO MEC Category 1)
Herbal	St John's Wort	<20% reduction of hormone levels	See recommendations for anticonvulsants above
Anti-TB drugs	Rifampicin Rifabutin	Enzyme inducers  Modest reduction of hormone blood levels for some progestogen-only methods may lead to reduced effectiveness	Do NOT use POPs (WHO MEC Category 3).  DMPA (WHO MEC Category 1)  NET-EN and Implant (both WHO MEC Category 2) can all be used. No change to dosing intervals needed
Antimicrobials	Broad spectrum antibiotics (excluding rifampicin)	No significant effects on serum levels of hormones and no evidence of reduced contraceptive efficacy	There are no restrictions on the concurrent use of broad-spectrum antibiotics and POCs  Additional cover is not required
<b>ART</b>			
Protease Inhibitors	Ritonavir or ritonavir-boosted protease inhibitors	Significant >40% reduction in hormone blood levels which may result in marked reduction in contraceptive effectiveness for some progestogen-only methods	Do NOT use POPs (WHO MEC Category 3)  DMPA (WHO MEC Category 1), NET-EN and implants (both WHO MEC Category 2) can be used. No change to dosing intervals needed
Non-nucleoside reverse transcriptase inhibitors (NNRTI)	Efavirenz Nevirapine	Reduces blood concentration level of hormone somewhat, but probably not enough to affect clinical outcomes. Use of condoms in addition to POCs for enhanced protection from pregnancy is recommended with all progestogen-only methods except DMPA	Generally can be used with POP and NET-EN (WHO MEC Category 2), no restrictions with DMPA (WHO MEC Category 1)
Nucleoside reverse transcriptase inhibitors (NRTI)		No interaction with progestogen-only contraceptives	All POCs can be used without restrictions

## 2.2 Intrauterine contraception

### 2.2.1 Copper intrauterine device

Cu IUDs are small, flexible contraceptive devices made of plastic and copper that prevent pregnancy when fitted into the uterus. The Cu IUD is a safe and highly effective method of long-acting reversible contraception suitable for most women. Cu IUDs do not affect breastfeeding, interfere with intercourse or have hormonal side effects. Some gynaecologic conditions and current PID or cervical infections preclude use of the method. The most widely used and most effective Cu IUD is the CuT 380A, which has copper bands around the arms and copper wire around the stem. The CuT 380A is currently registered in South Africa for 10 years of use, although WHO and many regulatory bodies consider it to be effective for 12 years continuous use. See Table 11 for key characteristics.

#### NOTE:

Cu IUDs must be inserted and removed by staff trained in the procedure (doctors and nurses) using an aseptic technique. Providers not trained in Cu IUD insertion and removal should be able to counsel suitable clients on the method and refer them if they wish to have a Cu IUD fitted.

#### ◆ Key characteristics of Cu IUDs

**Table 11. Key characteristics of Cu IUDs**

Effectiveness	99.2–99.4% for Cu IUDs in first year of use
Age limitations	Women of any age can use Cu IUDs
Parity limitations	No restrictions
Mode of action	Primarily prevents fertilisation by inhibiting sperm migration into the upper female genital tract. Secondary action prevents implantation through endometrial changes
Common side effects	Menstrual changes (bleeding may be heavier, longer and more cramps)
Non-contraceptive benefits	Provides some protection from endometrial cancer
Effect on STI and HIV risk	Not protective (See Box 13)
Drug interaction	None
Duration of use	Most women can use Cu IUDs safely throughout their reproductive years. The device should be removed one year after the cessation of menses (menopause). Duration of effectiveness: CuT 380 is currently registered for 10 years in South Africa* thereafter needs to be replaced. Dalcept is only registered for 5 years use
Return to fertility	Immediate upon removal

\* CuT 380A IUD is registered for 10 years in South Africa although already registered for 12 years elsewhere

#### ◆ Procedure required for initiation of Cu IUDs

##### Screening for medical eligibility

- The vast majority of women can use Cu IUDs safely. There are very few conditions that may preclude safe use of Cu IUDs. See Annexe 5 for WHO MEC for inserting Cu IUDs; and Annexe 6 for WHO guidelines related to Cu IUDs and STIs.
- Full history taking (including medical, obstetric, menstrual, gynaecological, contraceptive and sexual) is essential before insertion of a Cu IUD.
- Abdominal and pelvic exam (both bimanual and speculum) are essential prior to insertion.
- General examination, blood pressure measurement, pap smear, breast examination are not essential for safe insertion, but may be carried out if time and equipment permits.
- Special tests (for example haemoglobin estimation) should be done if clinically indicated.

**NOTE:**

If during assessment, a purulent cervical discharge is seen, or there is any suggestion of active PID the Cu IUD should *not* be inserted. The client and her partner/s should be treated appropriately and provided with another effective method to prevent pregnancy. A Cu IUD can be inserted after effective treatment, if there are no other contraindications for Cu IUD insertion. (Also see note on STI and HIV in Box 13)

**◆ Method-specific counselling**

- Providers who cannot themselves fit Cu IUDs should provide method-specific counselling *before* referring the client to an appropriate site for insertion.
- Providers should answer client concerns and cover the following: key characteristics of Cu IUDs; an outline of the procedure for Cu IUD fitting and removal; technique for self-checking Cu IUD threads, which is optional.
- Common side effects should be discussed, covering changes in bleeding patterns such as increased length and heaviness of menstrual bleeding, irregular bleeding, and more cramps at a time of monthly bleeding. Emphasise that not all women experience side effects and when they do, it is often limited to the first 3–6 months.

**Complications**

Warning signs of problems that require immediate medical attention include missed menstrual period/possible pregnancy (rare), possible expulsion of the Cu IUD, pelvic pain, purulent vaginal discharge and/or fever, excessive and/or abnormal bleeding.

**Discuss STI and HIV**

See Boxes 2 and 13

**◆ Insertion<sup>14</sup>****NOTE:**

Because prevalence of gonorrhoea and chlamydia infections is high in South Africa, and routine screening for asymptomatic infections is not available, prophylactic antibiotic use at time of insertion (a single dose of azithromycin 500 mg or doxycycline 200 mg, single dose) is recommended.<sup>14-16 \*</sup>

**Cu IUD routine insertion**

- A Cu IUD can be inserted within the first 12 days of the menstrual cycle (with day 1 being the first day of menstruation). There does not need to be active bleeding at the time of insertion. Limiting insertion to the days of menstrual bleeding is considered to be an unnecessary barrier that deters many women from using the method.
- A Cu IUD can be inserted at any other time of the cycle, if it is reasonably certain that the client is not pregnant (see the pregnancy checklist in Appendix 2).
- If pregnancy cannot be reasonably excluded, a pregnancy test should be done and/or insertion postponed until the next menses.
- If the client is discontinuing the use of one method in order to have a Cu IUD, the device can be inserted immediately on stopping the previous method as long as compliance has been good.

**Following uncomplicated first or second trimester miscarriage or TOP**

- The Cu IUD may be inserted immediately or within the first 12 days after miscarriage or TOP.

**After full-term pregnancy**

- Usually after normal vaginal delivery, the Cu IUD is inserted at 4–6 weeks postpartum. However, immediate/early postpartum insertion (up to 48 hours after delivery) may be performed by specially trained providers.
- At the time of Caesarean section by provider who performs C-section. Insertion 6 weeks after C-section by experienced staff only.

<sup>a</sup> The reason for recommending routine use of prophylactic antibiotics for insertion is due to the high background prevalence of STIs in South Africa. Research shows that whilst the routine use of antibiotics on insertion does not decrease incidence of clinical PID, it has shown to reduce the number of unscheduled clinic visits.

## ◆ Follow-up

### Schedule

- 3-6 weeks after insertion
- Thereafter client should be invited to return at any time if she has a problem related to the Cu IUD, wishes to discontinue because of side effects or to plan a pregnancy.
- The only essential return visit is when Cu IUD is due for replacement.
- Annual check-ups may be beneficial for general health purposes, but they are not required for the safe use of Cu IUD.

#### **Box 12. Management of common side effects and complications of Cu IUDs**

##### **Irregular or heavy vaginal bleeding**

- Reassure the client that Cu IUD users may experience these side effects. They are generally not harmful and usually diminish after a few months of Cu IUD use. Exclude cervical or pelvic infection, partial expulsion, intrauterine or ectopic pregnancy (rare) or other pathology. If no pathology is detected, counsel, treat with non-steroidal anti-inflammatory drugs (NSAIDs) other than aspirin (for example Ibuprofen) and follow-up. If bleeding is unacceptable, offer alternative contraception and remove the Cu IUD.

##### **Cramping and pain**

- Reassure the client that increased cramping and pain during menses is common in Cu IUD users and usually diminishes with time. Offer painkillers (NSAIDs) other than aspirin. If cramping and pain occur outside of monthly bleedings, exclude partial expulsion or perforation, evaluate for underlying pathology and treat or refer as appropriate. If cramping and pain are unacceptable to the client, counsel about other contraceptive options and remove Cu IUD.

#### **Management of problems and possible complications**

##### **Suspected pregnancy**

- Pregnancy may be suspected if a woman misses her period, has unexplained vaginal bleeding (for example after having regular menstrual cycles for a while with Cu IUD in place), or when Cu IUD strings are missing. Note that amenorrhoea may be related to previous use of injections, the effects of which take time to wear out. If not, exclude rarely occurring pregnancy (both intra- and extrauterine). If pregnant, inform the client and discuss management of pregnancy, including the option of TOP, if the pregnancy is not desired. If the pregnancy is desired, advise removal of Cu IUD if strings are visible and pregnancy <12 weeks. If strings are not visible or pregnancy >12 weeks, refer for further management (these women will require close follow-up throughout the pregnancy due to the increased risk of miscarriage which may be septic).

##### **Missing strings**

- May be due to:
  - threads cut short or drawn up into uterine cavity
  - expulsion (3–5%)
  - pregnancy (<1%)
  - perforation (<0.1%).
- Exclude pregnancy through history, examination and pregnancy testing if indicated.
- Enquire whether Cu IUD expulsion has been noticed.
- If not pregnant and expulsion has not been noted, probe the cervical canal and the uterine cavity and attempt to grasp the Cu IUD tail.
- If the Cu IUD is not found refer for ultrasound and/or X-ray to determine position of device. Advise condom use until investigation is complete. Consider emergency contraception if recent sexual activity was within 120 hours.

##### **Vaginal discharge or lower abdominal pain/suspected PID**

- Enquire about other symptoms of possible PID (for example fever, irregular bleeding or bleeding after intercourse, pain during intercourse or urination).
- Examine for genital tract infection and if client has a vaginal/cervical infection treat according to STI protocol. If PID is suspected, treat or refer as appropriate.
- Discuss safer sex practices and partner treatment or notification. There is no need to remove the Cu IUD if she wishes to continue using it. If symptoms do not improve after 2–3 days of antibiotics, removal of the Cu IUD might be considered and antibiotic treatment continued or reviewed.
- Arrange follow-up visit to check the response to treatment and treat partner/s.

##### **Cu IUD removal is recommended:**

- if the client requests removal for whatever reason (for example she finds side effects are unacceptable or wants to plan a pregnancy) providers should not refuse or delay removal unless medically indicated;
- for medical reasons (for example pregnancy, acute PID not responding to treatment, very heavy uterine bleeding);
- when the effective lifespan of the Cu IUD has expired according to the manufacturer's recommendation;
- when the user reaches menopause (one year after her last period if >age 50 years or two years if this occurs < age 50 years).

## Content

- Counselling should cover client's questions, experiences with the method, satisfaction, side effects and health concerns.
- Pelvic examination to check for expulsion of the device and infection.
- The client's checking of strings is not essential. Expulsions most commonly occur in the month following insertion. If Cu IUD is still in place during the first follow-up visit in 3–6 weeks after insertion, it is less likely that it will be expelled later.
- Manage side effects if needed (see Box 12).
- Invite the client to return again at any time if she has difficulties and ensure easy appointment system.\*
- Discuss STI and HIV risk, the need for dual protection and HCT (See Box 2).
- If the client is HIV-positive, monitor her CD4 count, assess eligibility for ART and initiate or refer as appropriate.

## ◆ Availability

- The DOH is prioritising the training and availability of the Cu IUD at all clinical levels of care.

### NOTE:

The Cu IUD is a highly effective, long-acting, reversible method of contraception. It is also highly cost effective but is grossly underutilised in South Africa. Cu IUDs should be actively promoted for use and to expand contraceptive choice for women. The CuT 380 which is effective for 10 years and equivalent to female sterilisation in efficacy, should be made available for women requiring long-term contraception and promoted to all clients, including postpartum, post-TOP, who require highly effective contraception to delay or space pregnancies or when family is complete.

### Box 13 A note on Cu IUDs and STIs/HIV

Cu IUDs, like hormonal methods, provide good pregnancy protection but do not protect against infection such as HIV. Previous concerns that some types of intrauterine devices were associated with upper genital tract infections have now been nullified by studies showing that slightly increased risk of infection is confined to the first few weeks after insertion and limited to a small number of women who had pre-existing asymptomatic gonorrhoea or chlamydia infection present at a time of insertion.

Inserting a Cu IUD through an infected cervix may introduce infection into the upper genital tract. Women with symptomatic cervical infection should be treated and counselled about using other methods. If they want a Cu IUD, it can be inserted after a full course of treatment for them (and preferably their partners).

Because many women with cervical infection are asymptomatic, careful history of sexual lifestyle should indicate clients at high individual risk of infection. These women should be counselled about safer sexual practices, including condoms for dual protection. For women at high risk of infection, full presumptive treatment prior to insertion should be considered.

Due to the high prevalence of gonorrhoea and chlamydia infections in South Africa, the recommendation is routine use of prophylactic antibiotics.<sup>†</sup> Clients should receive a single dose of azithromycin 500 mg or doxycycline 200 mg as prophylaxis at the time of insertion.

Also refer to Annexe 6 for WHO MEC for Cu IUD use in women with (or at risk of) STI and HIV.

Even amongst populations with high HIV prevalence, use of Cu IUDs or LNG-IUS by women at risk of HIV or HIV-positive women has not been associated with any increased risks of HIV acquisition, infection-related complications, disease progression or viral shedding (disease transmission).

Thus, the Cu IUD is considered a safe method for appropriately selected HIV-positive women (WHO MEC Category 2). The only group of women in whom Cu IUD/IUS insertion is not recommended is women with AIDS who are not clinically well on ART (WHO MEC Category 3). See Annexe 5 for WHO MEC.

\* CuT 380 IUD is registered for 10 years in South Africa although already registered for 12 years elsewhere.

† The reason for recommending routine use of prophylactic antibiotics for insertion is due to the high background prevalence of STIs in South Africa. Research shows that whilst the routine use of antibiotics on insertion does not decrease incidence of clinical PID, it has shown to reduce the number of unscheduled clinic visits.

## 2.2.2 Levonorgestrel releasing intrauterine system<sup>17-24</sup>

The LNG-IUS releases a constant, small amount of progestogen directly into the uterine cavity. Marketed under the brand name of Mirena<sup>®</sup>, it is highly effective, with a failure rate of 0.2% and a continuation rate of 80% at one year. It has fewer systemic hormonal effects than most of the other hormonal methods. Common side effects of LNG-IUS are similar to other progestogen-only hormonal contraceptives but are much less pronounced, including irregular bleeding, headaches, nausea and breast tenderness, and usually settle within the first couple of months. With continued use of the method, the majority of women will become amenorrhoeic. See Table 12 for key characteristics.

### ◆ Key characteristics of LNG-IUS

**Table 12. Key characteristics of LNG-IUS**

Effectiveness	Failure rate of 0.2% and a continuation rate of 80% at one year; as effective as male and more effective than female sterilisation
Age limitations	Safe for most women regardless of age
Parity limitations	None
Mode of action	Thickens cervical mucus and suppresses endometrial development
Common side effects	Side effects are less pronounced than with systemic hormonal methods. Light irregular bleeding and infrequent bleeding are common initially with increasing development of amenorrhoea later. At 12 months >90% reduction in blood loss
Non-contraceptive benefits	<ul style="list-style-type: none"> <li>• Reduces menstrual blood loss and thus protects from iron-deficiency anaemia</li> <li>• Protection against ectopic pregnancy</li> <li>• May reduce risk of PID in women exposed to STIs</li> <li>• Reduces menstrual cramps and symptoms of endometriosis, such as pelvic pain and excessive bleeding</li> <li>• It has practical applications other than contraception, such as: <ul style="list-style-type: none"> <li>• management of heavy menstrual bleeding (after evaluation)</li> <li>• hormone therapy in symptomatic perimenopausal women (as part of the regimen with unopposed oestrogen)</li> </ul> </li> </ul>
Effect on STI and HIV risk	None
Drug interaction	None
Duration of use	5 years
Return to fertility	No delay

### ◆ Availability

LNG-IUS is registered in South Africa for:

- contraception
- management of heavy menstrual bleeding
- endometrial protection during hormone therapy.

The method is currently only available to clients in the private sector and some secondary and tertiary institutions. It should be made more widely available for contraceptive use as a second line method in the public sector, for selected cases. Despite the apparently high initial costs involved, this method has been shown to be cost effective in comparison with other methods as early as one year of use.

See Annexe 5 for WHO MEC for LNG IUS. (Most classifications apply equally to Cu IUD and LNG-IUS but LNG-IUS has some additional contraindications and precautions due to the presence of hormones.)

## 2.3 Emergency contraception

Emergency contraception is the use of a contraceptive method following an episode of unprotected sexual intercourse (before pregnancy is established) in order to reduce the risk of pregnancy.

Emergency contraception can be used at any time in the menstrual cycle within 5 days of unprotected sexual intercourse. Unprotected intercourse includes situations when method fails (for example condom slips or breaks, or intrauterine device is expelled), situations when method was used incorrectly (for example missed pills, late for injection) or not used at all (for example, failure to use a condom as well as coercive sex or rape).

Knowledge about, access to, and use of emergency contraception can prevent many unwanted pregnancies following unprotected intercourse. It may be an especially useful method for young people, because in this group sexual activity is often unplanned and sporadic, and thus may be unprotected.

Two types of safe and effective emergency contraceptive methods are currently available in South Africa:

- hormonal, emergency contraceptive pills (ECPs) taken within 120 hours (5 days) of unprotected intercourse, the sooner the better;
- Cu IUD, inserted up to 120 hours (5 days) after unprotected intercourse.

Provision of ECPs is simpler and less invasive than emergency Cu IUD insertion. However, Cu IUD insertion is the most effective form of emergency contraception yet available and therefore should be offered to all women. If the Cu IUD is not acceptable to a woman as a method for on-going contraception, the Cu IUD can be inserted (under antibiotic cover if there is high risk of infection, for example following rape) and removed during the next menstrual period when a more suitable method of contraception can be initiated. Cu IUD insertion is particularly indicated in women who wish to use the method as on-going contraception, present late in the 120 hour time period, or vomit after taking ECPs.

It is important to note the following:

- For many women the risk of infection may be higher than the risk of pregnancy. All women presenting for emergency contraception should be screened for STIs if possible, and in cases of coercive sex or rape presumptive treatment for STIs as well as post-exposure HIV prophylaxis should be considered.
- The window for providing ECP has been extended from 72 hours (3 days) to 120 hours (5 days), however the sooner after unprotected intercourse the pills are taken, the more effective they are.<sup>25,26</sup> The efficacy of Cu IUD remains constantly high throughout the 120 hours.

### 2.3.1 Emergency contraceptive pills

ECPs are oral contraceptive pills (COCs or POPs) taken at higher dose and in a different way to those used for regular contraception (see Table 13 for key characteristics). The progestogen-only regimen is significantly more effective for emergency contraception than the COC regimen and has fewer side effects.<sup>26, 27</sup>

#### ◆ Key Characteristics of ECPs

**Table 13. Key Characteristics of ECPs**

<b>Effectiveness</b>	Within 5 days (120 hours) of unprotected intercourse: POP regimen is 58% to 95% effective depending on how soon after unprotected intercourse they are taken, COC regimen is 31% to 77% effective. Both regimens are most effective in the first 24 hours <sup>14</sup>
<b>Age limitations</b>	No restrictions
<b>Parity limitations</b>	No restrictions
<b>Mode of action</b>	Primarily inhibition or delay of ovulation; may also interfere with implantation. There is no evidence that ECPs cause abortion. They have no effect on already established pregnancy
<b>Common side effects</b>	Nausea and vomiting (more common with combined regimen). Sometimes dizziness, headaches and fatigue. Cycle irregularities
<b>Non-contraceptive benefits</b>	None
<b>Effect on STI and HIV risk</b>	Not protective
<b>Drug interaction</b>	In cases where the client is using enzyme-inducing drugs, a Cu IUD is the emergency contraceptive method of choice. If this method of emergency contraception is not suitable, ECPs may be used. It is recommended that the ECP dose is increased to 3 mg LNG stat, or 3 Ovral®/ Famynor® followed by 3 tablets 12 hours later, when the client is using enzyme-inducing drugs, such as rifampicin or ritonavir*
<b>Duration of use</b>	Intended for occasional 'emergency' use
<b>Return to fertility</b>	Immediate

\* Emergency contraception and enzyme-inducing drugs:

- "regular use of enzyme-inducing drugs (eg: many of the anticonvulsants and rifampicin-can include PI drugs such as ritoavir and lopinavir on this list also) may impair the contraceptive effect, it is suggested that the dose of emergency contraception be increased by 50%" Source: *South African Medicines Formulary*, 2012, page 244.<sup>28</sup>
- "Women who request oral EC [emergency contraception] while using enzyme-inducing drugs or within 28 days of stopping them, should be advised to take a total of 3 mg LNG (two 1.5 mg tablets) as a single dose as soon as possible and within 120 hours of unprotected sexual intercourse" Source: *Drug interactions with hormonal contraception*, Clinical Effectiveness Unit, 2011.<sup>2</sup>

## ◆ Procedures required for the initiation of ECPs

### Screening for medical eligibility

There are almost no contraindications to ECPs because hormones are administered for such a short time. Even women with contraindications to hormones can use them, exceptions to this are discussed later. There is no need to rule out pregnancy prior to ECPs. ECPs do not harm an established pregnancy. Unless a woman has already missed her period, she should be given ECPs.

Screening check should include:

- date of the last menstrual period
- time of the last episode of unprotected intercourse since the last menses to ensure that the client is within the 5-day (120-hour) treatment time frame. The importance of complete honesty about these dates should be emphasised to the client in a non-threatening way, so that the most appropriate management can be selected.

Recommended ECP regimens are given in Table 14.

**Table 14. Recommended ECP regimens\*<sup>‡</sup>**

Content of ECP	1st dose within 120 hours	2nd dose 12 hours later
<b>Combined oral contraceptives (COCs)</b>		
50 µg ethinyl estradiol, 250 µg levonorgestrel (e.g. Ovral®/Famynor®)	2 pills	2 pills
30 ethinyl estradiol, 150 µg levonorgestrel (e.g. Nordette® or Oralcon®)	4 pills	4 pills
<b>Progestogen-only pills (POPs)</b>		
1.5 mg levonorgestrel (e.g. Escapelle®)	1 pill, single dose	
0.75 mg levonorgestrel (e.g. Norlevo®)	2 pills, single dose	
30 µg levonorgestrel (e.g. Microval® or Hy-an®)	50 pills as a single dose, or 25 pills as divided dose	25 pills

\* Levonorgestrel as emergency contraception is registered for use as a single dose. This is simpler to use and just as effective as the divided dose and removes the risk of forgetting or delaying the second dose.

‡ ECPs are more effective the sooner they are used after the episode of unprotected intercourse.

## ◆ Method-specific counselling

Careful counselling is necessary for the initiation of ECPs. A request for emergency contraception is an opportunity to prevent an unwanted pregnancy and to provide counselling about future use of regular contraception. Clients who are treated without judgement and with respect when they consult for emergency contraception are more likely to return for long-term contraceptive advice and methods.

Clients should be counselled on the following:

- the correct regimen for ECP use: when to take the pills and how many to take;
- possible side effects (particularly nausea and vomiting) and how to manage them (take the pills with food and repeat the dose if vomiting occurs within two hours of taking it or offer Cu IUD);
- ECPs are intended for emergency contraception only and not for regular contraception because of the higher rate of failure and side effects. Hence clients should:
  - use condoms or abstain for the rest of the current menstrual cycle
  - consider a method for regular contraception that would suit them;
- when to expect the next menses (a few days earlier or later than normal);
- information and counselling concerning TOP should be provided in the event of method failure.

**Quick start a method**

(See Appendix 3. Bridging to on-going contraception).

On-going contraception may be started at the same visit as ECPs. This will reduce the possibility of pregnancy while waiting for the next menstruation. In event of ECP failure, oral and injectable hormones have not been shown to damage an early pregnancy. A pregnancy test should be advised if a normal period does not occur within a week after it was expected.

**Repeat use**

Whilst not ideal, ECPs may be given repeatedly. They should not be refused or rationed if requested within the accepted timeframe for provision (i.e. within 120 hours of unprotected coitus). Counselling about on-going contraception should accompany provision of each dose. Clients should be counselled that repeat use of ECPs is less effective than regular use of COCs, or other contraceptives and may cause more side effects. Clients requesting emergency contraception repeatedly should be encouraged to consider using the Cu IUD for both emergency contraception and on-going contraception.

Frequent and repeated use of ECPs (especially use of the combined ECP regimen) may be inappropriate for women who have contraindications for long-term hormonal use.

**Advanced provision**

The cost-effectiveness of widespread in-advance ECP provision has not been established. However, providers may supply clients with ECPs in advance after careful assessment of their individual situation and possible future needs.

**◆ Follow-up**

No routine follow-up visit is required for ECPs. Clients should be advised to come back if their next menses is delayed by more than one week in order to exclude pregnancy and to decide on appropriate further management. If the client is not pregnant and did not decide on a regular contraceptive planning method at the time of taking ECPs, she should be encouraged to choose a regular contraceptive as soon as possible.

**◆ Availability**

ECPs in the form of regular oral contraceptive pills are available at all levels of service delivery but require more extensive promotion.

Currently two types of progestogen-only ECP are registered and packaged specifically for emergency contraception in South Africa. Both are available over the counter in pharmacies. The registered product is simpler to take as it contains the full hormone dose required for emergency contraception in only one or two pills, which can be taken as one dose (compared to two doses of 4 low-dose COCs or two doses of 25 regular POPs). Because progestogen-only ECPs are more effective and have fewer side effects than combined contraceptive pills, they should be considered the preferred regimen for emergency contraceptive pills.

**2.3.2 Emergency Cu IUD insertion**

Cu IUDs provide highly effective emergency contraception. Emergency insertion can be performed by any service provider who is qualified to insert Cu IUDs and is aware of the timing restrictions for emergency Cu IUD insertion.

**Note:** LNG-IUS is **not** suitable for use as emergency contraception.

### ◆ Key characteristics of emergency Cu IUDs

The characteristics of emergency Cu IUDs are virtually the same as those of Cu IUDs for regular contraception (see Table 11) except for those shown in this table.

**Table 15. Key characteristics of emergency Cu IUDs**

Effectiveness	Treatment fails in <0.1% of cases
Mode of action	Depending on the timing of the emergency insertion in regard to ovulation, it can either prevent fertilisation or prevent implantation
Non-contraceptive benefits	None
Effect on STI and HIV risk	Not protective
Duration of use	The contraceptive effect lasts as long as the device remains in situ. It can continue to provide contraception for women who choose to use the method long term. Otherwise, the device may be removed at the next menses and an alternative contraceptive method started
<b>Note:</b> Emergency use of Cu IUD is not abortifacient (will not induce abortions) if used within the recommended time frame.	

### ◆ Procedures required for initiation of Cu IUD as emergency contraception

#### Screening for medical eligibility

As for regular Cu IUD provision (see section 2.2.1).

If the client selects Cu IUD as emergency contraception but not as on-going contraception, it can be inserted under antibiotic cover and then removed during the next menstrual period.

#### NOTE:

Because prevalence of gonorrhoea and chlamydia infections is high in South Africa, and routine screening for asymptomatic infections is not available, prophylactic antibiotic use at time of insertion (a single dose of azithromycin 500 mg or doxycycline 200 mg, single dose) is recommended.<sup>14-16 \*</sup>

### ◆ Timing

Cu IUDs provide highly effective emergency contraception if inserted:

- within 5 days (120 hours) of a single episode of unprotected intercourse; or
- up to 5 days after the earliest estimated date of ovulation in a regular cycle (i.e. up to day 19 of a normal 28-day cycle). When clients know their cycle length, enabling accurate estimation of the time of ovulation, the Cu IUD can be inserted beyond 5 days after intercourse, as long as this is not more than 5 days after ovulation;<sup>14</sup> or
- any time within the first 12 days of her menstrual cycle, whatever her cycle length, regardless of how many days have passed since unprotected sex.

### ◆ Method-specific counselling

Clients should receive the same information as provided to regular Cu IUD users about possible common side effects and how to manage them and when to come for follow-up. Clients should be instructed also to return to the clinic if menstruation has not occurred when expected for pregnancy evaluation and appropriate further management. They should also be counselled to come back immediately if they develop any signs of infection (for example fever, chills, low abdominal pain, abnormal vaginal discharge).

### ◆ Follow-up

If the emergency Cu IUD is not desirable or appropriate for long-term contraception, it should be removed at the next menses and a suitable method for regular contraception should be started as appropriate. If the client wishes to continue using the Cu IUD for long-term contraception, see section 12.2.1 on Cu IUD for the follow-up schedule and content of visits.

\* The reason for recommending routine use of prophylactic antibiotics for insertion is due to the high background prevalence of STIs in South Africa. Research shows that whilst the routine use of antibiotics on insertion does not decrease incidence of clinical PID, it has been shown to reduce the number of unscheduled clinic visits.

### ◆ Availability

Emergency Cu IUD insertion is an infrequently utilised emergency contraceptive option, because it is more invasive than ECPs and there is a lack of service providers trained and experienced in Cu IUD insertion. However, it is highly effective as an emergency contraceptive and should be offered more frequently.

## 2.4 Barrier methods

### 2.4.1 Male condom

The male condom is a sheath that covers the erect penis and prevents sperm from entering the female genital tract. It is usually made of latex. Condoms can be effective in preventing pregnancy when used *correctly* and *consistently*. Condoms provide the best protection against STI and HIV, second only to abstinence and mutual faithfulness with an uninfected partner. Condoms may be used alone for protection against both pregnancy and infection (dual protection), or with another more effective method of contraception (dual method use). See Table 16 for key characteristics.

The availability of emergency contraception for use when condoms are occasionally not used or there is method failure (such as breakage or slippage) may help to address concerns about contraceptive efficacy when only condoms are used for contraception.

Condoms do not affect breastfeeding nor do they have systemic side effects (as with hormonal methods, for example). They are accessible without prescription, immediately effective, user-controlled and need only be used when required.

### ◆ Key characteristics of male condoms

**Table 16. Key characteristics of male condoms**

Effectiveness	85-98% during first year of use – depends on correct and consistent use
Age limitations	No restrictions
Parity limitations	No restrictions
Mode of action	Creates a physical barrier to prevent sperm (or infections, including HIV) from entering the female genital tract
Effect on STI and HIV risk	Overall 80% effective protection from STIs, including HIV. Condoms are most effective in preventing STIs that are transmitted through bodily fluids, such as HIV, gonorrhoea and chlamydia. They are somewhat less effective against STIs transmitted through skin-to-skin contact, such as genital herpes and human papillomavirus (HPV), because the condom may not cover the entire affected area
Common side effects	None (allergy to latex may occur but it is extremely rare)
Non-contraceptive benefits	Use of male condoms provides significant protection against STIs (including HIV and to a lesser extent, HPV), and the possible consequences of STIs (e.g. PID, ectopic pregnancy, tubal infertility, cervical cancer)
Drug interaction	Should not be used with oil-based lubricants or vaginal/rectal creams as these damage the latex
Duration of use	Condoms can be used safely throughout the reproductive years and beyond if protection from infection is required
Return to fertility	Immediate

## ◆ Procedures required for the initiation of male condom use

### **Screening for medical eligibility**

Most users initiate and use condoms themselves, and do not need to undergo any screening.

- Eligibility to use male condoms may be restricted if there is erectile dysfunction or a severe allergy to latex (rare).
- Enquire about latex allergy in user and partner/s. In the event of proven latex allergy, plastic male condoms may be purchased, or advise use of the female condom made of polyurethane or synthetic rubber.

### ◆ Method-specific counselling

Thorough counselling is essential and should emphasise the need for *correct* and *consistent* condom use in order to achieve effective protection.

#### **Correct use**

- It is essential to demonstrate the proper technique of application (see Box 14).
- Oil-based lubricants should be avoided, use water-based lubricants such as KY Jelly.
- It is important to address concerns about condom use, both technical (how) and psychological (for example fear of loss of erection, embarrassment). Encourage clients new to condoms to practice using them on their own, to master both the technique and to build confidence.
- The male condom is recommended for one-time use only and should not be reused.

#### **Consistent use**

- Condoms are only effective if used each and every time intercourse occurs and are put on before any genital contact takes place.
- Provide information for the use of emergency contraception in case of condom non-use, breakage or slippage.
- Provide information about how/where to get more condoms (commercial and public sector).
- Explain that condoms protect against HIV, transmission and reinfection – for both partners
- Use the consultation as an opportunity to encourage dual method use.

#### **NOTE:**

Consideration should be given to the fact that the higher failure rate with condoms, as commonly used, compared to other contraceptive methods may represent a higher risk of unintended pregnancy. Dual method use (for example condoms plus oral contraceptive pills, injection, Cu IUD or implant) is advocated for women for whom accidental pregnancy is undesirable or would present a serious health risk, and for those who are also at risk of exposure to STI and HIV infection.

#### **Supply**

- Condoms should be supplied in quantities sufficient to prevent the need for frequent visits for re-supply.
- Condoms should be available and accessible to clients. This includes condom dispensers (which are regularly re-stocked), social marketing, HCT points. Condom distribution should be an integral part of community outreach work.

#### **IEC materials**

Leaflets on condoms, with diagrams to show correct use and other relevant issues (for example STIs and HIV prevention) should be provided, especially to new users.

#### **Considerations in terms of HIV**

#### **NOTE:**

Condoms are the only contraceptives that provide protection from HIV, if used correctly and consistently. Dual method use should be encouraged to maximise HIV and pregnancy protection.

**Discuss STI and HIV**

See Box 2 for guidelines.

**◆ Follow-up****Schedule**

- Routine follow-up visits are not necessary. Follow-up should be user-initiated.
- Users should be advised to contact a health worker or return to the clinic at any time if they have any health concerns, need help with correct condom use or partner negotiation, or want to initiate another method.

**Content**

- Counselling:
  - discuss problems or concerns experienced by the client and method satisfaction
  - check whether the client is using the condom correctly and consistently
  - discuss gender issues in terms of negotiating with a male partner to use a condom (correctly and consistently).
- Re-supply: provide the client with sufficient condoms for their needs.

**◆ Availability**

Male condoms are available, free of charge, at all levels of service delivery.

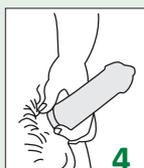
**NOTE:**

Condoms should be promoted for those who require dual protection, and especially for women and men who may be exposed to HIV. Always combine provision with information about contraceptive use and emergency contraception.

**Box 14. Step-by-step demonstration on male condom use**

**IMPORTANT:** Whenever possible, show clients how to put on a condom. Use a model of a penis, if available, or other item, like a banana, to demonstrate.

**Explain the 5 Basic Steps of Using a Male condom**

- |  |  |   |
|--|--|---|
| <p><b>1.</b> Use a new condom for each act of sex</p>  | <ul style="list-style-type: none"> <li>• Check the condom package. Do not use if torn or damaged. Avoid using a condom past the expiration date—do so only if a newer condom is not available.</li> <li>• Tear open the package carefully. Do not use fingernails, teeth, or anything that can damage the condom.</li> </ul>   |  <p><b>1</b></p> |
| <p><b>2.</b> Before any physical contact, place the condom on the tip of the erect penis with the rolled side out</p>              | <ul style="list-style-type: none"> <li>• For the most protection, put the condom on before the penis makes any genital, oral, or anal contact.</li> </ul>  |  <p><b>2</b></p> |
| <p><b>3.</b> Unroll the condom all the way to the base of the erect penis</p>  | <ul style="list-style-type: none"> <li>• The condom should unroll easily. Forcing it on could cause it to break during use.</li> <li>• If the condom does not unroll easily, it may be on backwards, damaged, or too old. Throw it away and use a new condom.</li> <li>• If the condom is on backwards and another one is not available, turn it over and unroll it onto the penis.</li> </ul> |  <p><b>3</b></p> |
| <p><b>4.</b> Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect</p> | <ul style="list-style-type: none"> <li>• Withdraw the penis.</li> <li>• Slide the condom off, avoiding spilling semen.</li> <li>• If having sex again or switching from one sex act to another, use a new condom.</li> </ul>   |  <p><b>4</b></p> |
| <p><b>5.</b> Dispose of the used condom safely</p>   | <ul style="list-style-type: none"> <li>• Wrap the condom in its package and put in the rubbish or latrine. Do not put the condom into a flush toilet, as it can cause problems with plumbing.</li> </ul>   |  <p><b>5</b></p> |

Source: Adapted from *Family Planning: A global handbook for providers (2011update)*, WHO/RHR, 2011.<sup>29</sup>

### 2.4.1 Female condom

The female condom is a sheath of thin, transparent, soft synthetic rubber that is inserted into the vagina before or at the time of intercourse to prevent pregnancy, STI and HIV. It has two flexible rings, an inner ring at the closed end assists insertion, and an outer ring at the open end covers the vulva and holds the condom in position.

The female condom can provide effective dual protection against pregnancy and the transmission of STIs and HIV when used *correctly* and *consistently*. It may be an acceptable option for women whose partners refuse to use male condoms or couples who are not able to use male condoms due to latex allergies.

Typical use method failure rates are high compared to many other contraceptive methods. Promotion and ease of access to emergency contraception for backup when female condoms are not used, or incorrectly used, may help reduce the incidence of accidental pregnancies.

The female condom may be used together with a more effective method of contraception (dual method use). This should be recommended, especially for women for whom accidental pregnancy is undesirable or would present a serious health risk, and who are at risk of exposure to STI and HIV. See Table 17 for key characteristics.

#### ◆ Key characteristics of female condoms

**Table 17. Key characteristics of female condoms**

<b>Effectiveness</b>	79-95% during first year of use, depending on correct and consistent use
<b>Age limitations</b>	No restrictions
<b>Parity limitations</b>	No restrictions
<b>Mode of action</b>	Creates a physical barrier to prevent sperm from entering the female genital tract
<b>Common side effects</b>	No side effects
<b>Non-contraceptive benefits and indications</b>	Use of female condoms provides significant protection against STIs (including HIV and HPV), and the possible sequelae* to STIs (e.g. PID, ectopic pregnancy, tubal infertility, cervical cancer)
<b>Effect on STI and HIV risk</b>	Offers significant protection against all STIs, including HIV. May provide somewhat better protection than male condoms from STIs transmitted by skin-to-skin genital contact (e.g. genital herpes, HPV)
<b>Drug interactions</b>	None. Not affected by oil-based lubricants
<b>Duration of use</b>	Short and long-term use throughout the reproductive years and beyond for infection protection
<b>Return to fertility</b>	Immediate

\* Pathological conditions as a result of another disease.

#### ◆ Procedures required for the initiation of female condom use

Check if the client is motivated and will be able to use the condom consistently and correctly.

##### **Screening for medical eligibility**

- There are no medical conditions which may preclude safe use of female condoms. However, consideration should be given to the fact that there is a higher typical failure rate with condoms compared to other methods and this may present an unacceptable risk of unintended pregnancy for certain clients. Hence, dual method use is advocated for clients who need very effective protection against pregnancy and are at risk of exposure to STI and HIV infection.
- Check if the client is at high risk for complications in pregnancy. If she is, weigh the health benefits against the risks. Discuss using an additional effective method of contraception.

### ◆ Method-specific counselling

Thorough counselling is essential and should include the need for correct and consistent condom use in order to achieve effective protection.

#### **Correct use**

- It is essential to demonstrate the proper technique of application (see Box 15).
- It is important to address concerns about condom use, both technical (how) and psychological (for example insertion into the vagina, self-consciousness during intercourse).
- Women may need some practice in order to learn how to insert a female condom into the vagina correctly.
- Encourage women to practice insertion at home and explain that practice will ensure proper insertion.
- It is important to dispel myths, such as the condom being pushed into the uterus.
- The female condom is recommended for one-time use only and should not be reused.
- The condom can be inserted up to eight hours before sex.

#### **Consistent use**

- Condoms are only effective if used for each and every intercourse.
- Provide information for the use of emergency contraception in case of condom non-use, breakage or slippage.
- Provide information about how/where to get more condoms (commercial and public sector).
- Explain that condoms protect against HIV transmission and reinfection, for both partners.
- Female condoms are female initiated but require male participation and cooperation.

Condoms are the only contraceptives that provide protection from HIV in addition to pregnancy, if used correctly and consistently. However, dual method use should be encouraged to maximise pregnancy protection

#### **Discuss STI and HIV**

See Box 1 for guidelines.

### ◆ Follow-up

#### **Schedule**

- Routine follow-up visits are not necessary. Follow-up should be user-initiated.
- Users should be advised to contact a health worker or return to the clinic at any time if they have any health concerns, need help with correct insertion of the condom, partner negotiation, or want to initiate another method.

#### **Content**

- Counselling:
  - discuss problems or concerns experienced by the client and method satisfaction
  - check whether the client is using the condom correctly and consistently
  - discuss gender issues in terms of partner support.
- Re-supply: with sufficient condoms for their needs.

### ◆ Availability

The female condom is available at selected public health facilities throughout the country. It is also available at some retail outlets.

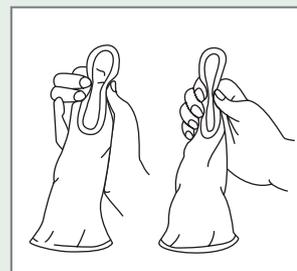
Female condoms should be promoted and be available at all levels of service provision for use by women who prefer a female-controlled method. Dual method use should be encouraged for those at risk of both pregnancy and STI/HIV.

**Box 15. Using female condoms**

**IMPORTANT:** Whenever possible, show the client how to insert the female condom. Use a model or picture, if available, or your hands to demonstrate. You can create an opening similar to a vagina with one hand and show how to insert the female condom with the other hand.

**Explain the 5 Basic Steps of Using a Female condom**

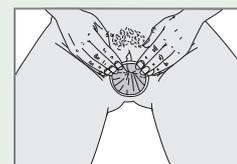
1. Use a new female condom for each act of sex
  - Check the condom package. Do not use if torn or damaged. Avoid using a condom past the expiration date – do so only if newer condoms are not available.
  - If possible, wash your hands with mild soap and clean water before inserting the condom.



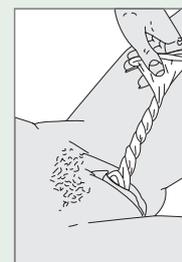
2. Before any physical contact, insert the condom into the vagina
  - Can be inserted up to 8 hours before sex. For the most protection, insert the condom before the penis comes in contact with the vagina.
  - Choose a position that is comfortable for insertion – squat, raise one leg, sit, or lie down.
  - Rub the sides of the female condom together to spread the lubricant evenly.
  - Grasp the ring at the closed end, and squeeze it so it becomes long and narrow.
  - With the other hand, separate the outer lips (labia) and locate the opening of the vagina.
  - Gently push the inner ring into the vagina as far up as it will go. Insert a finger into the condom to push it into place. About 2 to 3 centimetres of the condom and the outer ring remain outside the vagina.



3. Ensure that the penis enters the condom and stays inside the condom
  - The man or woman should carefully guide the tip of his penis inside the condom—not between the condom and the wall of the vagina. If his penis goes outside the condom, withdraw and try again.
  - If the condom is accidentally pulled out of the vagina or pushed into it during sex, put the condom back in place.



4. After the man withdraws his penis, hold the outer ring of the condom, twist to seal in fluids, and gently pull it out of the vagina
  - The female condom does not need to be removed immediately after sex.
  - Remove the condom before standing up, to avoid spilling semen.
  - If the couple has sex again, they should use a new condom.
  - Reuse of female condoms is not recommended



5. Dispose of the used condom safely
  - Wrap the condom in its package and put it in the rubbish or latrine. Do not put the condom into a flush toilet, as it can cause problems with plumbing.



Source: Adapted from *Family Planning: A global handbook for providers (2011 update)*, WHO/RHR, 2011.<sup>29</sup>

### 2.4.3 Diaphragm and spermicides

A detailed discussion on the use of the diaphragm and spermicide methods has not been included in the Policy and Guidelines as neither is available in the public sector. There is limited availability in the private sector. Diaphragms may provide some protection from cervical infection and PID, but should not be relied upon for STI/HIV prevention. Spermicides provide no protection from STI/HIV. Spermicides are also among the least effective forms of contraception and frequent use of spermicide containing nonoxynol-9 has the potential to increase the risk of HIV acquisition.

## 2.5 Voluntary sterilisation (voluntary surgical contraception)

### Forced (or coerced) sterilisation

Forced (or coerced) sterilisation is the permanent removal of an individual's ability to reproduce without their free and informed consent. It also occurs where there is a lack of proper counselling prior to the procedure to enable the user to make a fully informed decision for themselves.

The legislative framework makes sterilisation without informed consent illegal in South Africa. The Constitution of the Republic of South Africa of 1996 protects the rights of individuals as set out in the Bill of Rights (Sections 9, 10, 12, 27 and 32). The Sterilization Act 44 of 1998 (Section 2) prohibits the sterilisation of people without their informed consent. The Act provides that patients must fully understand the sterilisation procedure, risks, and the consequences thereof, before they are able to give informed consent.

HIV positive clients should be afforded the same rights and legal protection as all clients. A person's HIV status should not be a reason to recommend sterilisation.

The Sterilisation Amendment Act (Act No 3 of 2005) makes provision for clients not considered competent to make an informed decision and consent to surgery.

Getting informed consent is a process, and a signature on a consent form is not sufficient. A person giving consent to sterilisation needs to be in a physical and psychological state to understand the information, and make the decision without feeling pressured.

### 2.5.1 Female sterilisation

Female sterilisation, also called tubal occlusion or tubal ligation, is a permanent contraceptive method for women who do not ever want to have more children. The method entails a simple surgical procedure to block the fallopian tubes. The most common surgical approaches are: mini-laparotomy, laparoscopy or sterilisation at the time of Caesarean Section, performed under either general, local or spinal anaesthesia depending on the circumstances. Essure® – a technique of inserting a small device, which results in fibrosis, into each fallopian tube via hysteroscopy – has recently been introduced to South Africa but is only available in the private sector.

Female sterilisation does not affect breastfeeding and is free from the side effects of some of the temporary contraceptive methods. It is not the same as hysterectomy, and women continue to menstruate. The operation does not affect sexual desire or feelings and does not interfere with sexual intercourse. No medical condition makes a woman ineligible for sterilisation, but in some cases sterilisation has to be delayed or special arrangements may need to be made. See Table 18 for key characteristics.

In view of the fact that long-acting reversible methods (LARC) (such as CuT 380, LNG-IUS and implants) are as effective as female sterilisation and do not require surgery, LARC should be discussed with all women when sterilisation is requested.

#### ◆ Key characteristics of female sterilisation

*Table 18. Key characteristics of female sterilisation*

<b>Effectiveness</b>	99.5–99.8% in the first year after the procedure; 98.2% over 10 years of use
<b>Age limitations</b>	From a medical perspective, no restrictions for age or parity. However, incidence of regret is highest amongst women under 30 years of age and/or of low parity, so careful counselling is essential
<b>Parity limitations</b>	See above
<b>Mode of action</b>	Blocking of the fallopian tubes prevents the ovum and sperm from uniting. The woman is sterile from the time the procedure is completed
<b>Common immediate problems/complications</b>	Post-operative pain for a few days, wound infection, haematoma
<b>Non-contraceptive benefits</b>	Female sterilisation may provide some protection against PID and ovarian cancer
<b>Effect on STI and HIV risk</b>	Not protective
<b>Drug interaction</b>	None
<b>Duration of use</b>	Considered to be permanent and irreversible
<b>Return to fertility</b>	Never, unless the tubes are reconnected (either spontaneously or surgically, which is expensive and success is not guaranteed)

## ◆ Procedures required for initiation of female sterilisation

### *Screening for medical eligibility*

No medical condition prevents a woman from having a tubal ligation, but some conditions and circumstances call for a delay, referral or caution. (See Annexe 7 for medical eligibility criteria).

Screening procedures include careful history taking (personal, medical, drug and sexual), examination (general, cardiovascular, abdominal and genital examination, blood-pressure measurement) and, sometimes, special tests (for example haemoglobin).

### ◆ Method-specific counselling

Comprehensive counselling is essential for all clients considering sterilisation. Because sterilisation is essentially permanent, it must be ensured that consent to the procedure is voluntary and fully informed so that the client will be a satisfied user and there is no regret afterwards. Preferably, both partners should be included in counselling. But the partner's consent is not a prerequisite for the procedure. The client should be encouraged to ask questions and discuss fears and concerns.

Counselling should be done when the woman is able to focus on the issues and the decision, and not when she is under emotional/physical duress or pressure.

The following points should be covered during counselling.

- Review the client's reason for choosing sterilisation.
- Provide information on other available highly effective methods of contraception, which offer equivalent protection from pregnancy but are reversible and do not require intra-abdominal surgery (for example Cu IUD, LNG-IUS, or subdermal implants).
- Provide information about male sterilisation (vasectomy), which is a safer, simpler and more effective permanent procedure.
- Thoroughly discuss the client's feelings about not having any more children. This is particularly important for clients who are young, have no or few children, do not seem to be in a stable relationship, are not in complete agreement with their partner about the procedure, and/or show excessive interest about reversal procedures.
- Help the client to consider possible change in circumstances in the future, such as loss of one or more of her existing children, loss of partner through death or divorce and the possibility of remarriage and wanting more children with a new partner.
- Provide information on the key characteristics of female sterilisation, the procedure itself, risks and possible complications.
- Clarify any misconceptions about female sterilisation, including explaining that there is no change in sexual function and that menses will revert to the normal bleeding pattern without contraception.
- Emphasise that sterilisation offers no protection from STI and HIV, therefore use of condoms should be recommended.
- After counselling, the client should be given the opportunity to think about the information given before making a decision on whether to proceed. Backup contraception should be offered in the meantime. If a client decides to go ahead with the sterilisation, she should be referred to an appropriate facility.
- There should be no coercion and incentives should not be offered to clients who agree to sterilisation.
- HIV is not a reason to recommend sterilisation.
- Written informed consent must be obtained from all clients prior to sterilisation.

### ***Discuss STI and HIV***

See Box 2

### ◆ Timing

Female sterilisation can be performed at any time during a woman's reproductive life. The most common/convenient times are:

- in the immediate postpartum period – immediately or up to seven days after delivery. Priority should be given to ensuring that women requesting postpartum sterilisation have access to services;
- during Caesarean section (provided the decision was taken prior to the Caesarean section);
- immediately following an induced or spontaneous abortion;
- any time six weeks or more since the last delivery (when the uterus has returned to normal size) if it is reasonably certain that she is not pregnant.

The client needs to ensure correct and consistent use of an effective method of contraception or abstinence up to the time of the procedure.

### ◆ Follow-up

Women should be advised to return to the clinic at any time if they develop any complications (for example: infection, haematoma, superficial bleeding), have concerns, questions or need help.

#### **Management of complications/problems**

- *Skin/wound infection.* Treat with antibiotics.
- *Abscess.* Drain and treat as indicated.
- *Bleeding.* Control bleeding, determine the cause and manage appropriately.
- *Pregnancy.* Pregnancy following female sterilisation is rare but when it does occur it is more likely to be ectopic. Advise client to seek medical attention if she ever suspects that she might be pregnant.

### ◆ Availability

Female sterilisation services have deteriorated in recent years. In many areas services are inadequate being either non-existent, difficult to access or have long waiting lists.

#### **NOTE:**

Priority should be given to ensuring that women requesting postpartum sterilisation have access to services. Services should be strengthened and expanded to make interval\* sterilisation available at least at one service point per district as well as access to postpartum sterilisation when requested.

Condom use should always be encouraged for those at risk of STI and HIV.

\* Interval sterilisation is performed four or more weeks after delivery of a baby or after a pregnancy.

## 2.5.2 Male sterilisation

Male sterilisation, also called vasectomy, is a permanent surgical contraceptive method for men who do not want any more children. The method entails the simple surgical procedure, performed under local anaesthesia, of closing both vas deferens (two tubes that carry the sperm to ejaculatory duct) to prevent sperm from mixing with ejaculate.

Male sterilisation is not the same as castration. During vasectomy the testes are not removed. Vasectomy does not interfere with intercourse or affect a man's sexual desire, function or appearance. Male sterilisation is generally safer, somewhat more effective and less expensive than female sterilisation. It is a good way for men to share in the responsibility for contraception. See Table 19 for key characteristics.

If a man is not certain about ending fertility, other highly effective reversible methods for his partner can be discussed. In terms of informed decision-making, alternative LARC methods should be considered (according to availability) before a final decision is made.

## ◆ Key characteristics of male sterilisation

**Table 19. Key characteristics of male sterilisation**

<b>Effectiveness</b>	Over 99.8% in the first year after the procedure
<b>Age limitations</b>	From a medical perspective, no restrictions for age (although young men have a higher chance of regret later in life, so careful counselling is essential)
<b>Parity limitations</b>	From a medical perspective, no restrictions for parity (although incidence of regret is higher among men with few children so careful counselling is essential)
<b>Mode of action</b>	Surgical closure of both vas deferens (two tubes that carry the sperm to ejaculatory duct) to prevent sperm from mixing with ejaculate. Not effective immediately. Takes on average three months for vas deferens to be cleared of sperm
<b>Common immediate complications/problems</b>	Minor post-operative short-term effects (e.g. discomfort for a few days and scrotal bruising and swelling), bleeding from wound, haematoma, wound infection and, less frequently, chronic scrotal pain.
<b>Non-contraceptive benefits</b>	None other than protection for man's partner from risks associated with pregnancy
<b>Effect on STI and HIV risk</b>	Not protective
<b>Drug interaction</b>	None
<b>Duration of use</b>	Considered to be permanent and irreversible
<b>Return to fertility</b>	Never unless the vas deferens is reconnected (spontaneously or by surgery, which is expensive and does not guarantee success)

## ◆ Procedures required for initiation of vasectomy

### *Screening for medical eligibility*

- No medical conditions prevent a man from having a vasectomy. Some conditions and circumstances, however, call for delay, referral or caution. In general these conditions fall into three categories: abnormalities of the genitalia that make the procedure technically more difficult or increase its associated risks; infections that must be treated prior to the procedure; and certain systemic disorders that require special precautions or possible hospitalisation for the procedure. (See Annexe 8 for WHO MEC).
- Screening procedures: as for female sterilisation.

### ◆ Timing

Any time a man requests it (if there are no medical reasons to delay).

### ◆ Method-specific counselling

As for female sterilisation.

Providers should also inform clients that the procedure does not cause any change in sexual functioning or satisfaction, and does not affect the male hormones nor change one's physical appearance. If possible, arrange for them to talk with other men who have had a vasectomy.

### *Discuss STI and HIV*

See Box 2.

### ◆ Follow-up

- After undergoing a vasectomy, it takes about three months before the ejaculate becomes sperm-free (i.e. the man is sterile). Clients should be counselled to use an effective contraceptive method in the interim period (condom or his partner to use a contraceptive method). Semen analysis at 3 months (12–13 weeks) is recommended.
- Clients should be advised to return to the clinic at any time if they develop complications, have any health concerns, questions or need help.
- Sterilisation offers no protection from STI and HIV; therefore condoms should be used if at risk of exposure to STI and HIV.

### Management of complications

- *Bleeding.* Control the bleeding, determine its cause and manage as appropriate.
- *Haematoma.* Advise warm packs and analgesia.
- *Infection.* Determine whether there is infection or abscess. If there is infection, clean the infected area and treat with appropriate antibiotics. If an abscess is present, either drain it or refer for drainage, and treat with antibiotics.

### ◆ Availability

There are limited facilities that offer vasectomy.

Vasectomy needs to be actively promoted, with a focus on:

- raising public awareness and the understanding of vasectomy
- training staff to provide no-scalpel vasectomy services more widely with at least one service point per district.

## 2.6 Fertility awareness-based methods\*

Modern fertility awareness-based (FAB) methods can be used for both planning and avoiding pregnancy. They are based on the identification of naturally occurring signs and symptoms of the fertile and infertile phases of the menstrual cycle and the abstinence or use of condoms during the fertile phase. FAB methods are effective when both partners are motivated to abstain consistently from coitus (or use condoms) during the fertile phase of each cycle, and have been fully instructed by a specially trained teacher (lay or professional). See Table 20 for key characteristics.

In South Africa the most frequently used FAB methods are the Billing's Ovulation Method and the sympto-thermal method. These are based on observing the signs and symptoms of ovulation and have replaced methods that are based on keeping track of days in the menstrual cycle, such as the rhythm/calendar method.

### ◆ Key characteristics of modern FAB methods

**Table 20. Key characteristics of modern FAB methods (Billing's and sympto-thermal)**

<b>Effectiveness</b>	Depends on a woman's ability to identify her fertile window, as well as both partners' motivation and discipline to practise abstinence (or use condoms) when required. 95–97% effective during first year of <i>consistent and correct use but only 75% effective as commonly used</i>
<b>Age limitations</b>	No restrictions (but may be more difficult to interpret in adolescents and in women approaching menopause due to anovulatory cycles)
<b>Parity limitations</b>	No restrictions
<b>Mode of action</b>	Avoidance of sexual intercourse (or use condoms) during the woman's peri-ovulatory fertile time, as identified by the couple, and thereby preventing the entry of sperm into the woman's genital tract
<b>Common side effects</b>	FAB methods have no side effects and no medical conditions restrict the eligibility of clients to use them, however certain conditions can make it harder to use FAB effectively. Clients for whom pregnancy is contraindicated for medical reasons (e.g. severe cardiovascular disease, diabetes with complications, severe liver disease, TB, AIDS) should be advised to consider using more effective contraception
<b>Non-contraceptive benefits</b>	<ul style="list-style-type: none"> <li>• Can be used for pregnancy achievement</li> <li>• Empowerment of the man and woman with knowledge of reproduction</li> <li>• May increase communication between the couple and strengthen their relationship</li> </ul>
<b>Effect on STI and HIV risk</b>	Not protective
<b>Drug interaction</b>	None
<b>Duration of use</b>	Can be used throughout the reproductive years but may be difficult to interpret in adolescents and in perimenopause
<b>Return to fertility</b>	Fertility is never suppressed

\* previously known as natural family planning

## ◆ Procedures required for initiation of FAB methods

### **Screening for medical eligibility**

No medical conditions prevent safe use of FAB methods, but some conditions can make them harder to use effectively, thus caution or delay is recommended. (See Annexe 9 for WHO MEC.)

### **Screening procedures**

Thorough history taking covering medical, gynaecological and menstrual history to determine suitability of the method according to WHO MEC.

## ◆ Method-specific counselling and training

*Billing's Ovulation Method* is based on identification of changes in cervical mucus. During each cycle, fertile cervical mucus secretion leads to a wet, slippery sensation at the vulva and signifies impending ovulation and the fertile phase of a woman's cycle. After instruction by trained FAB teachers, clients can recognise fertile mucus characteristics. After ovulation the cessation of fertile cervical mucus results in a dry sensation at the vulva. The fertile phase is from the first sensation of vulval wetness to the fourth day of vulval dryness. Couples must abstain from intercourse during this entire time in each cycle.

The *sympto-thermal method* combines cervical mucous changes with temperature monitoring and other indicators of fertility, for example monitoring the texture, position and opening of the cervical os. Ovulation is accompanied by a persistently higher body temperature than the pre-ovulatory basal level. Couples wishing to use this method are taught to take accurate daily temperature readings, using fertility thermometers, prior to getting up each morning; to plot the readings on a graph and determine any temperature rise. The fertile phase ends three days after the woman's temperature has risen above her regular temperature. The post-ovulatory infertile phase of the cycle begins when both the fourth day of vulval dryness, and the third day of high temperature reading have occurred. Couples must abstain from intercourse from the first day of menstrual bleeding until both fertile criteria have been met in each cycle (some couples choose to have unprotected sex between the end of menstrual bleeding and the beginning of cervical secretions).

The effective use of FAB methods requires a sound understanding of the method of choice and how to use it correctly. Hence, FAB teachers require special training. Ideally both partners should be counselled and trained together but if this is not possible, the woman can be taught alone. Detailed training should be given on the identification of fertile and infertile phases of the cycle, using appropriate language for each couple/client. Appropriate practical training should be included, for example on the use of a thermometer, plotting readings on a graph and using the information to identify the fertile window of each menstrual cycle. For more information see Chapter 9 in the companion to this document - *Contraception Policy and Service Delivery Guidelines (DOH, 2012)*.

### **Discuss STI and HIV**

See Box 1 for guidelines.

## ◆ Follow-up

### **Schedule**

Clients should be seen regularly during the teaching phase in order to complete training, answer questions, deal with problems and monitor progress. Once the couple are using the method correctly and confidently, further follow-up appointments should be made at their request.

### **Content**

Counselling: discuss problems, concerns, questions, method satisfaction and correct method use, including consistent abstinence at the appropriate times. Clients should be advised to return to the clinic at any time if they have problems or concerns about the method or want to change methods.

### ◆ Availability

Clients who are interested in FAB methods are usually referred for counselling to trained FAB teachers linked with the Fertility Mastery Association of South Africa (FERMASA) or the Couple to Couple League (CCL) who specialise in these methods.

## 2.7 Lactational amenorrhoea method

The lactational amenorrhoea method (LAM) is a temporary method of contraception that can be used by fully-breastfeeding women. Unlike FAB methods it does not require abstinence. Breastfeeding-induced birth spacing has been practised throughout history and the health benefits of breastfeeding to both mothers and infants are well documented. It is only more recently, however, that the use of breastfeeding as a temporary method of avoiding pregnancy has been scientifically documented and guidelines for its effective use have been developed. See Table 21 for key characteristics.

LAM is a very effective method if the following three criteria are met:

- the woman is amenorrhoeic and
- the woman is fully breastfeeding (does not give the infant any supplementary feeds) and
- the baby is less than six months old.

### ◆ Key characteristics of LAM

**Table 21. Key characteristics of LAM**

Effectiveness	98–99% among amenorrhoeic, fully breast-feeding women during the first six months after childbirth
Age limitations	No restrictions
Parity limitations	No restrictions
Mode of action	Suppresses ovulation
Common side effects	No side effects
Non-contraceptive benefits	The use of LAM provides the following additional health benefits for mother and infant: <ul style="list-style-type: none"> <li>• Provision of the best source of nutrition for the infant</li> <li>• Protection of the infant from life-threatening diarrhoea</li> <li>• Provision of passive immunisation to diseases such as measles and pneumonia</li> <li>• Reduction in postpartum bleeding</li> <li>• Decreased risk of breast cancer</li> </ul>
Effect on STI and HIV risk	Not protective
Drug interaction	None; but to protect infant health, breastfeeding is not recommended for women who are on the following drugs: antimetabolites, bromocriptine, certain anticoagulants, high doses of corticosteroids, cyclosporin, ergotamine, lithium, mood altering drugs, radioactive drugs and reserpine
Duration of use	First six months after childbirth, effectiveness falls thereafter
Return to fertility	Once any one out of the three LAM criteria is not met, an additional method of contraception should be added to prevent pregnancy

### ◆ Procedure required for initiation of LAM

#### **Screening for medical eligibility**

There are no medical conditions that restrict the use of LAM, and there is no documented evidence of its negative impact on maternal health. But certain conditions or obstacles may make LAM a less suitable choice of contraception. (See Annexe 10.)

#### **Screening procedures**

History-taking and appropriate tests to identify conditions that prevent or limit breastfeeding. If any such conditions are identified, the risks and benefits of using LAM must be carefully considered and discussed with the client.

### ◆ Timing

A woman can start LAM immediately postpartum or at any time during the first six months, provided she has been fully breastfeeding her baby since birth and menstruation has not returned.

### ◆ Method-specific counselling

Informed, supportive, trained health personnel and lay people can teach a woman to use LAM effectively by giving her clear and practical information about LAM, including:

- strictly adhere to all three criteria for effective method use
- start another method of pregnancy prevention as soon as any of the three LAM criteria expires, or she does not want to rely on LAM for contraception.

### *Discuss STI and HIV*

See Box 2.

### ◆ Follow-up

Women should be advised to contact a health worker or return to the clinic at any time if they have any health concerns, problems with breastfeeding, need help and/or want to use another means of preventing pregnancy.

### ◆ Availability

LAM is not actively promoted due to the tendency towards early weaning in South Africa. It also may carry a risk of HIV transmission if the mother is HIV-positive. Nevertheless, health service providers should be well informed about LAM to enable them to effectively assist women who wish to use the method. Exclusive breastfeeding should be encouraged during the first six months of the baby's life and supplementary breastfeeding can be continued up to two years of age or beyond.

HIV-positive women should receive counselling on infant feeding options and the risk of mother-to-child transmission, to enable them to make informed choices about the option that is most suited for their circumstances. According to current policy on the prevention of mother-to-child transmission (PMTCT):

- HIV-positive mothers should receive appropriate ART intervention and should be encouraged to exclusively breastfeed for the first six months of the baby's life. When this is not possible, replacement feeding and avoidance of all breastfeeding by HIV-positive women is recommended;
- LAM may be practised but condoms should be used to prevent STI and HIV transmission or acquisition.

## 2.8 Abstinence

Abstinence or the avoidance of sexual intercourse is the most effective way to prevent pregnancy, STIs and HIV. Many other forms of sexual expression are permissible during sexual abstinence, such as hugging, kissing, body rubbing, masturbation and mutual masturbation. Abstaining from sexual intercourse has no ill effects on the health of males or females. The essential requirements for the method to be successful are high motivation, good self-control, assertiveness, positive self-esteem, shared values between partners, information on risk-free alternatives to sexual intercourse, commitment and partner communication and cooperation.

Abstinence also encourages couples to discuss and commit themselves to safe sex, and to explore alternative ways of sexual expression and pleasure.

The role of abstinence in pregnancy and HIV prevention must be recognised by service providers. Unbiased counselling on the subject should be regularly provided, in a non-judgemental way, including how to say 'No', and alternative forms of sexual intimacy. Counselling on abstinence should be provided to any adolescent seeking advice on fertility regulation.

Only counselling is necessary for the initiation of abstinence.

- Delaying sexual debut should be discussed as an option with young people who have not yet initiated sexual activity (and even for those who are already sexually active). It is an important option for those clients who are not ready for sexual intercourse and its associated risks.
- Counselling on abstinence must be done in a sensitive manner that is neither moralising nor judgemental. Clients should be encouraged to consider their personal reasons for and against a sexual relationship at that specific time in their life. Providers should support the client's choice and help them gain the necessary skills for coping with possible peer and partner pressure to have sexual intercourse.
- For many people abstinence may be difficult to practice, thus providers need to supply all clients who wish to practice abstinence with information on and access to reliable contraceptive options, particularly condoms and emergency contraception.

### **Discuss STI and HIV**

See Box 2.

## **2.9 Withdrawal**

Withdrawal, or coitus interruptus, requires the removal of the penis from the vagina and away from the external genitalia prior to ejaculation, thus preventing sperm from entering the female genital tract.

It has been used to prevent pregnancy for many centuries, and can be effective in clients who are well motivated and able to practice the method correctly and consistently with every act of intercourse, i.e. perfect use. However, as commonly used it is one of the least effective methods of contraception.

No medical condition restricts a client's eligibility for the use of withdrawal. It has no side effects, is always available, is cost-free and can be used as a backup for other methods. See Table 22 for key characteristics.

### **◆ Key characteristics of withdrawal**

**Table 22. Key characteristics of withdrawal**

Effectiveness	73% during first year of typical use, 96% if used consistently and correctly
Age limitations	No restrictions
Parity limitations	No restrictions
Mode of action	Prevents sperm from entering the vagina
Common side effects	None
Non-contraceptive benefits	None
Effect on STI and HIV risk	Not protective
Drug interaction	None
Duration of use	Can be used throughout the reproductive years
Return to fertility	Fertility never affected

### **Medical eligibility**

No medical condition restricts a client's eligibility for use of the withdrawal method, but the following conditions and situations can make using the method less effective or unsuitable:

- high risk of STI and HIV infection;
- conditions that make pregnancy an unacceptable risk (for example severe cardiovascular disease, diabetes with complications, severe liver disease, TB or AIDS, psychosocial and economic considerations);
- premature ejaculation;
- lack of sexual experience when men may not have sufficient control over ejaculation;
- repeated intercourse at short intervals, as some leftover ejaculate from previous intercourse can remain on a man's genitalia and be introduced into a woman's vagina.

### ◆ Method-specific counselling

Counselling should be sensitive, neither moralising nor judgemental. Clients should be supported in their method of choice, provided there are no contraindications to its use, and given the correct information on using the method effectively. Clients should be informed that modern methods of contraception are available, which are far more effective at pregnancy prevention.

Clients should be informed that withdrawal can be used at any time, and that partner cooperation and commitment is needed. The method must be used correctly and consistently with every act of intercourse in order to be effective. To increase effectiveness, clients may combine withdrawal with other methods, such as FAB.

For many people, withdrawal may be a difficult method to practice and so providers should supply all clients with information on and access to reliable backup contraceptive options, particularly condoms and emergency contraception.

#### ***Discuss STI and HIV***

See Box 2

### ◆ Follow-up

Clients should be advised to contact a health worker or return to the clinic at any time if they have any health concerns, need help and/or want to change to another contraceptive method.

Due to the high rates of unintended/unplanned pregnancies, STIs and HIV in South Africa and the availability of contraceptive methods in the public sector, withdrawal is not promoted as an effective, reliable contraceptive method.

## 2.10 Traditional methods

Traditional methods for the prevention of pregnancy include herbal mixtures, intercrural sex, breastfeeding and abstinence after childbirth. There has been very little research conducted and documentation of the traditional methods used by the different cultural groups in South Africa.

Providers should be aware that clients may be using a variety of different traditional methods of contraception, which are specific to their locality.

### Method assessment and counselling

- Clients using traditional methods are unlikely to come to the clinic for contraception. Counselling should be done during the antenatal visits, at the time of delivery and during the postnatal period and at visits for infant immunisation.
- During history taking about the client's use of contraception, enquire about any contraceptive methods they are using/have used and ask specifically about traditional methods. If the client admits to using a traditional method, respect the client's freedom of choice and avoid being critical and/or judgemental; find out which traditional method/s is/are being used; and assess the client's intentions for future pregnancies, or if she is high risk for pregnancy complications or STI and HIV exposure. Counsel the client accordingly.
- The client should be given information about more effective contraceptive methods. In particular, clients who do not want to be pregnant, and/or are at high risk for STI and HIV, should be encouraged to use condoms with another modern contraceptive for effective dual protection.
- If the traditional method being used is fairly effective when used correctly (for example intercrural sex), and the client is not high risk of STI and HIV, she should be advised on how to use the method as effectively as possible. Information about modern contraceptive methods and the risk factors for STI and HIV should also be given. She should be advised to return if she wishes to use a modern contraceptive and/or her risk status for STI and HIV changes.
- Harmful contraceptive practices, for example the use of quinine, should be actively discouraged.

The opportunity should always be taken to help the client to assess her/his risk for exposure to STI and HIV and discuss and promote reliable contraceptive methods, HIV testing and condom use.

## CHAPTER 3

# Contraception for special needs

## Adolescents, menopausal women, disabled women and women with chronic conditions

### 3.1 Adolescents

The WHO defines adolescents as young people between the ages of 12 and 19. High rates of unintended pregnancy and HIV among young people reflect an urgent need for effective appropriate sexual education and services. Good counselling, provided within the context of accessible ‘youth-friendly’ services, helps young people to make informed decisions regarding their fertility. No medical reason exists for denying any contraceptive method based on young age alone. However, many non-medical factors need to be considered and addressed through counselling. This is discussed in more detail in Chapter 6 in the companion to these guidelines - *Contraception and Fertility Planning Policy and Service Delivery Guidelines (DOH 2012)*. Additional clinical guidelines about contraceptives can be found in Chapter 2.

An overview of the suitability of particular methods of contraception for young people is given below.

#### Hormonal contraception

Young women rarely have health conditions that preclude safe use of hormonal methods. Oral contraceptives (COCs and POPs) are safe for almost all young clients but compliance, particularly with the POP method, may present a challenge for young women. Counselling involves careful instructions to ensure correct and consistent use. Providers should encourage young women to link pill taking to some daily routine (for example brushing teeth) to assist with compliance, and provide clear instructions on what to do if pills are missed. Because use of COCs often results in menses that are lighter, regular and less painful, they may benefit many young women who experience menstrual irregularities and menstrual cramps. Some women with acne may notice improvement on COCs. POPs are less effective than COCs in non-breastfeeding women, require more rigid compliance, and are more likely to cause irregular bleeding. Hence they should only be considered in the rare situations when oestrogen is contraindicated. Weight gain is not a side effect of either COC or POPs.

The rapid loss of contraceptive effect when pills are discontinued can be a problem for those in unstable relationships who stop pill taking when they are not having intercourse. Stopping and starting pill taking results in suboptimal contraceptive cover and an increase in side effects. Sexually active adolescents who choose to use COCs should be advised to use them without interruptions even if they go through phases when they are not sexually active.

#### Progestogen-only injectables

Progestogen-only injectables are popular among young women as they require only periodic visits to the clinic and are private – no supplies need to be kept at home. Both DMPA and NET-EN are safe, highly effective and equally suitable for young women. Injectables often result in irregular bleeding, spotting or amenorrhoea, which may worry some clients. A delay in return to fertility (4–6 months) is common after discontinuation. As with any method, clients need thorough counselling in advance about possible side effects in order to increase method satisfaction and continuation rates.

The link between DMPA and decrease in bone mineral density is of concern as this may affect young women achieving peak bone mass. The WHO have weighed the risks against the benefits and considered injection use by adolescents to be generally safe (WHO MEC Category 2).

Recent observational research suggests that DMPA use may increase the risk of HIV acquisition, particularly in young women. It is therefore important to offer a wider range of contraceptive options to young women at risk of exposure to HIV. Where injectables are the preferred choice, it is vital to counsel on consistent and correct condom use.<sup>1,2,3</sup>

### Subdermal contraceptive implants

Implants provide a long-acting, highly effective form of reversible contraception suitable for use by women of all ages, including adolescents. Implants deliver low doses of hormone that do not affect bone density. They are a useful addition to the method mix available to increase young women's options.

### Intrauterine contraception

There are no contraindications for use of this method based on age or parity alone. Young, nulliparous women may use Cu IUDs (WHO MEC Category 2 for <20 years).<sup>4</sup> Intrauterine devices are a highly effective form of long-acting reversible contraception. Clients should be counselled that there is a small possibility of device expulsion and be encouraged to return for a follow-up visit 3–6 weeks after insertion to check that the device is in position and that there is no sign of infection.

### Emergency contraception

For many young people, sexual activity can be sporadic, unplanned, and non-consensual. It is important for young people to know about, and have easy access to, emergency contraception. In addition, emergency contraception is very useful after contraceptive accidents, such as condom breakage or missed pills. It is an important method in terms of prevention of teenage pregnancy. Emergency contraception is not recommended as a regular contraceptive method, and does not protect against transmission of STIs and HIV. Condom use should be actively promoted.

### Condoms

The use of condoms should be encouraged. They are available without prescription, immediately effective, user-controlled and only need to be used when required. When used with another method, condoms add protection from STI/HIV (dual method use).

When used correctly and consistently, condoms are very effective in preventing pregnancy, however correct and consistent use may be hard to achieve. In typical use condoms are only moderately effective compared to many other contraceptive methods. Apart from abstinence and mutual monogamy with an uninfected partner, correct and consistent condom use provides the best protection against STI and HIV. Condoms can be used alone or in combination with other more effective methods of contraception (dual method use) to achieve optimal protection from pregnancy as well as STI and HIV.

There may be challenges for young people in terms of discovering their sexuality and using condoms correctly. For example, young men may be embarrassed and worry about losing their erection with male condoms, young women may feel uncomfortable about inserting the female condom. Successful condom use requires counselling and practice. Young people should be encouraged to practice condom use on their own, to learn to use them correctly and with confidence. Emergency contraception should be promoted and provided for backup in the event of incorrect/failed condom use.

*The risk of pregnancy needs to be explained, and the client should also be counselled on other less client-dependent and more effective methods of contraception and the benefits of dual method use.*

### Voluntary sterilisation

Sterilisation is seldom an appropriate method for adolescents or young adults because it is considered to be permanent and irreversible.

## Fertility awareness-based methods

FAB methods should be used with caution by adolescents, because of a greater frequency of anovulation and irregular menstrual cycles post menarche that make accurate identification of the fertile time difficult. In addition, many adolescents may not be in stable relationships and sexual activity is commonly sporadic and unplanned, making it difficult to practice periodic abstinence. There is therefore an increased risk of pregnancy, STI and HIV.

## Abstinence

Abstinence, or the avoidance of sexual intercourse, offers complete dual protection. Providers should appreciate the role of abstinence (or secondary abstinence for those already sexually active) in the prevention of pregnancy, STI and HIV as well as in the personal development of adolescents and young people. Unbiased, sensitive counselling about delaying sexual debut should be provided, in a non-judgemental way. This should include supporting clients who wish to abstain by assisting with negotiation skills on how to say 'No' and information about alternative forms of sexual expression and activity. All clients choosing to abstain should be encouraged and supported. *However, this should not preclude information on and access to reliable contraceptive options, particularly condoms and emergency contraception.*

### Box 16: Summary of contraceptive methods for young people

- Abstinence (including secondary abstinence)
- Delay sexual debut or
- Barrier method (strong reinforcement of condom use) with:
  - emergency contraception
  - highly effective contraception:
    - combined hormonal contraception
    - progestogen-only injection
    - Cu IUD
    - LNG-IUS
    - progestogen-only implant
- Emergency contraception to be promoted and accessible in the event of unprotected intercourse, method misuse or failure

## 3.2 Women with physical and intellectual disabilities

People with physical or intellectual disabilities face many barriers to accessing sexual and reproductive health services, particularly contraception and fertility planning. Health care providers, carers and family members often make assumptions about the sexual and reproductive health needs of the disabled in terms of, for example: their desires to become pregnant and have children; their ability to care for children; their sexual needs and their ability to make informed decisions.

Today greater recognition is given to the rights of all people to freely make informed sexual and reproductive choices; however, the contraceptive needs of those with disabilities are seldom adequately met.

Physical and intellectual disabilities vary enormously, and so it is vital that every client is treated as an individual, with respect for their dignity and rights. Their needs, capabilities and aspirations should be assessed, together with the client, as far as is feasible. Where possible and appropriate, family or carer involvement may be helpful; however, the client's rights must be respected, consent must always be sought from the client and the client's privacy and confidentiality upheld at all times.

In order to do this effectively, one of the first principles is making services accessible. This includes transport to health services, physical access for people with disabilities, plus assistance with communication (for example sign language or other translation) plus an enabling, supportive attitude from all staff rendering the service.

Health care providers need to take into account the following factors when considering the contraceptive options for the physically disabled:

- immobility and possible increased risk of blood clotting, degree of lack of physical sensation and limitation of manual dexterity;
- whether the condition is stable, and any possible drug interactions with current medication;
- the mental health of the person (such as signs of depression);
- problems the client has handling menstruation and menstrual hygiene;
- for the intellectually disabled, factors such as psychiatric condition and ability to use a method correctly is important;
- vulnerability to sexual abuse or exploitation.

Adolescents with disabilities require life skills education as for able-bodied people. This must include information on sexuality and other appropriate reproductive health services. Adolescents with disabilities may be as sexually active as their able-bodied counterparts, and may be at higher risk of sexual abuse or exploitation. For some women, depending on the nature of the disability, methods that are independent of client action and/or methods that reduce menstrual bleeding might be preferred options.

Below are key considerations for physically and intellectually disabled women in relation to contraception. The WHO MEC for contraceptive use also needs to be taken into account with all methods (see Annexe 1–10).

### 3.2.1 Physical disabilities

#### Hormonal contraception

Women with certain physical disabilities may find it difficult to use COCs correctly and consistently, or return to the clinic on time for progestogen-only injectables. The increased risk of venous thromboembolism, associated with impaired circulation and/or immobility, is a consideration for women with some physical disabilities who wish to use COCs. Risk of venous thrombosis is not increased by progestogen-only methods (oral, injectables, implants or LNG-IUS). Progestogen-induced amenorrhoea may be an extra benefit for those clients who have difficulty in coping with menstrual hygiene.

#### Intrauterine contraception

Cu IUDs can usually be fitted, unless clients have difficulty in coping with menstrual hygiene. Women who have severe anaemia may benefit from a method that reduces menstrual blood loss. Women with lower-body sensory loss are at risk of being unaware of signs of Cu IUD-related complications (for example symptoms of infection or expulsion) and so routine follow-up at 4–6 weeks is important. For some clients the LNG-IUS is a very acceptable contraceptive option, particularly because of the reduced bleeding over time.

#### Condoms

Condoms should be encouraged for all clients at risk of exposure to STI and HIV. Correct condom use, however, may be difficult for people with poor coordination and/or lack of manual dexterity. Where appropriate and possible, able-bodied partners should be encouraged to assist.

#### Voluntary surgical contraception

Male or female sterilisation may be appropriate if an individual with a physical disability personally requests it. However, as with any client requesting sterilisation, careful counselling should be provided to ensure a thorough understanding of the procedure, especially its permanence and irreversibility, as well as of the equally effective long-acting reversible methods of contraception. It is important to ensure that the client's rights are respected, and that the client with a disability is not coerced into sterilisation.

Health care providers should be aware of the necessary legal process that must be followed if the parents, guardian or curator request/s sterilisation for a client who is not considered competent to consent to surgery. The legal requirements are set out in the Sterilisation Act (No. 44 of 1998) and the Sterilisation Amendment Act (No. 3 of 2005). A team of professionals need to consider each case individually.

### Fertility awareness-based methods

Modern FAB methods can be used effectively by many people with physical disabilities, (for example blindness), especially if they have able bodied partners who can assist with daily observations. Careful training of the client/couple by an experienced FAB teacher, including consideration of her particular circumstances, is essential for optimal use.

### 3.2.2 Intellectual disabilities

People with intellectual disabilities, including psychiatric disturbances, require careful consideration regarding their contraceptive and fertility planning needs. The nature of their disability, level of function, ability to understand the consequences of sexual intercourse and make reproductive choices, as well as their long-term prognosis, must be taken into consideration.

#### Hormonal contraception

Hormonal methods are highly effective, but for a mentally disabled client the following need to be considered:

- the client's ability to comply with regular pill taking or ability to return for re-injection on time;
- the client's ability to cope with the irregular bleeding often caused by progestogen-only methods, particularly injectable contraceptives;
- benefits of progestogen-induced amenorrhoea for women unable to cope with menstrual hygiene (although it is important to remember that becoming amenorrhoeic may take time and clients should be able to cope with the irregular bleeding that frequently precedes amenorrhoea).

#### Intrauterine contraception

Cu IUDs provide very effective contraception without need for client compliance. LNG-IUS may be a better option as it will also reduce menstrual bleeding.

#### Condoms

Condoms should be promoted and made available whenever possible to protect against STIs and HIV. Compliance may present a major problem; and clients where pregnancy is undesirable should be encouraged to use more effective, client-independent contraceptive methods in addition to condoms to ensure dual protection.

### Fertility awareness-based methods

FAB methods are not suitable for this group of clients as the accurate identification and interpretation of fertility signs are likely to be difficult to learn and follow.

#### Voluntary sterilisation

Informed consent should be obtained if the client is capable of understanding the nature of the sterilisation procedure, and it is certain that they will not wish to conceive in the future.

Health care providers should be aware of the necessary legal process that must be followed if the parents, guardian or curator request/s sterilisation for a client who is not considered competent to consent to surgery. The legal requirements are set out in the Sterilisation Act (No. 44 of 1998) and the Sterilisation Amendment Act (Act No. 3 of 2005). A team of professionals need to consider each case individually.

### 3.3 Women approaching menopause

Menopause usually occurs by the age of 52 (within a range of 45–55). A woman is assumed to have reached menopause after 12 consecutive months without any menstrual bleeding (if not using any hormonal contraception) or if her follicle stimulating hormone (FSH) level is above the menopausal level specified by the laboratory.

The term 'perimenopause' describes the period, normally about three to five years, preceding menopause. This is characterised by changes in the menstrual cycle, with decreased or increased bleeding and menstrual irregularities. Sexually active women continue to be at risk of conception unless they use effective methods of contraception until menopause.

Pregnancy in perimenopausal women is usually unplanned and carries increased health risks for both the mother and child. All methods of contraception can be considered after careful health screening, subject to WHO MEC. Age itself does not restrict a woman from using any contraceptive method.

Providers should be aware that certain medical conditions that may make some methods unsuitable are more common in this age group (for example hypertension and other cardiovascular risk factors).

It is often assumed that older women are less at risk of STIs and HIV. However, perimenopausal women may be at the same risk of STIs and HIV as women of any age and need to use condoms to prevent HIV, unless they are in a mutually monogamous relationship with an HIV-negative partner.

#### 3.3.1 Contraceptive choices in the perimenopausal woman

Methods that can be used without restriction by perimenopausal women include Cu IUDs, LNG-IUS, progestogen-only pill, progestogen implants, barrier methods and sterilisation. The WHO MEC apply to these methods.

##### Hormonal contraception

Combined hormonal contraception (the combined pill, patch, vaginal ring or combined injection) is not contraindicated by age alone in perimenopausal women. However:

- it should not be used by women of 35 years or older who smoke 15 or more cigarettes a day, or who experience migraine over the age of 40 (WHO MEC Category 4);
- it is not usually recommended for women of 35 years or more who smoke less than 15 cigarettes a day, or who quit smoking less than one year ago (WHO MEC Category 3);
- where COCs are suitable, a pill containing 20 µg ethinyl estradiol is a good first choice if available;
- emergency contraception can be used by all perimenopausal women, even those who cannot use hormonal methods on a continual basis.

Progestogen-only injectables can be used without restriction up to the age of 45. In women over the age of 45, the benefits generally outweigh the risks. This relates particularly to the reduced bone mineral density and injections should be discontinued at 45 by women with any other risk factors for osteoporosis, for example low body mass index, smoking, long-term use of corticosteroids and genetic factors.

The non-contraceptive benefits of hormonal contraception can influence the choice of contraception for women with the conditions listed below.

- *Vasomotor symptoms (hot flushes)*. Combined hormonal contraception may reduce symptoms.
- *Osteoporosis*. Combined hormonal contraception may increase bone mineral density; while progestogen-only injectables can reduce bone mineral density.
- *Menstrual pain, bleeding and irregularity*. Combined hormonal contraception may reduce symptoms.
- *Menstrual pain*. Progestogen-only methods may reduce symptoms.
- *Heavy menstrual bleeding*. The LNG-IUS reduces menstrual bleeding and can cause amenorrhoea; COCs, injectables and POPs may also reduce bleeding if there are no other contraindications for use of these methods.

## Hormone therapy

Women using combined hormone therapy should not rely on this as contraception. A POP can be used with combined sequential hormone therapy to provide effective contraception. A POP used with oestrogen-only hormone therapy will not provide an adequate level of endometrial protection. Combined continuous hormone therapy regimens are not appropriate in this age group.

The LNG-IUS can be used as the progestogen component of hormone therapy for five years, and provides concurrent contraception.

## Fertility awareness-based methods

FAB methods are not generally recommended because irregular anovulatory menstrual cycles in the perimenopause make this method difficult to use effectively.

### 3.3.2 When should contraception be stopped at menopause?

The Cu IUD and the LNG-IUS can be retained longer during the perimenopause. In addition:

- women who have any Cu IUD inserted at or after the age of 40 may retain the device until they no longer require contraception;
- women who have an intrauterine system inserted at or after the age of 45 may retain the device until they no longer require contraception;

Stopping non-hormonal contraception (Cu IUD, condoms) at the menopause:

- women less than 50 years of age should continue contraception for two years after the last period
- women aged 50 years or more should continue contraception for one year after the last period
- condoms should be used into the menopause if protection against STIs and HIV is required.

Condoms should be used into the menopause if protection against STI and HIV is required.

Advice for stopping non-hormonal and hormonal contraception is described in Table 23.

**Table 23. Advice for women on stopping hormonal contraception**

Contraceptive method	Advice on stopping contraception	
	Age <50 years	Age ≥50 years
Non-hormonal	Stop contraception after 2 years of amenorrhoea	Stop contraception after 1 year of amenorrhoea
CHC	Can be continued to age 50 years*	Stop CHC at age 50 years and switch to a non-hormonal method or progestogen-only pill, then follow appropriate advice
DMPA	Can be continued to age 50 years*	Stop DMPA at age 50 years and choose from options below: <ul style="list-style-type: none"> <li>• switch to a non-hormonal method and stop after 2 years of amenorrhoea</li> <li>or</li> <li>• switch to the POP, implant or LNG-IUS and follow advice below</li> </ul>
Implant POP LNG-IUS	Can be continued to age 50 years or longer*	Continue method If amenorrhoeic either: <ul style="list-style-type: none"> <li>• check FSH levels and stop method after 1 year if serum FSH is ≥30 IU/L on two occasions 6 weeks apart</li> <li>or</li> <li>• stop at age 55 years when natural loss of fertility can be assumed for most women</li> </ul> If not amenorrhoeic, consider investigating any abnormal bleeding or changes in bleeding pattern, and continue contraception beyond age 55 years until amenorrhoeic for 1 year

\* If a woman wishes to stop hormonal contraception before age 50 years she should be advised to switch to a non-hormonal method and to stop once she has been amenorrhoeic for 2 years (or 3 years if switched from DMPA due to the potential delay in return of ovulation).

#### Key

CHC= combined hormonal contraception; DMPA= depot medroxyprogesterone acetate; FSH= follicle stimulating hormone; IU= international unit; LNG-IUS= levonorgestrel releasing intrauterine system; POP= progestogen-only pill

Source: *Contraception for women aged over 40 years*, Clinical Effectiveness Unit, 2010<sup>1</sup>

### 3.4 Chronic medical disorders

For many women with serious chronic medical disorders, the prevention of unwanted pregnancy is very important, because pregnancy may pose a major health risk to the mother and/or the fetus. The pregnancy itself may cause deterioration in the medical condition, and/or the necessary drug treatment for the condition may be harmful to the fetus.

Counselling clients with medical conditions about their fertility and contraceptive options should include a careful weighing of the benefits, risks, safety, acceptability and effectiveness of each method against the pregnancy-related risks for the client. So, for example, methods that have no or few side effects (such as barrier methods) but are less effective in typical use than other methods (such as voluntary sterilisation, COCs, Cu IUD, LNG-IUS, implants and injectables) can expose the user to an unintended high-risk pregnancy.

The use of certain contraceptives that may exacerbate the medical disorder or cause additional risk of complications must also be avoided. In addition, when selecting a suitable method careful consideration must be given to potential drug interactions.

Some of the more common medical disorders that require special attention in terms of contraceptive method provision are discussed below. For more detailed information on a broader range of conditions, refer to WHO MEC.<sup>1</sup>

#### Cardiovascular disease

Cardiovascular disease includes a wide range of conditions with various implications for contraception, as discussed below.

- *Hypertension*. If hypertension develops during COC use, the method should be discontinued and an alternative contraceptive method chosen. For women with blood pressure over 140/90 and those on antihypertensive treatment:
  - Methods containing oestrogen (combined pills, patches, vaginal rings and injectables) are not recommended because they increase the risk of serious complications, such as heart attacks and strokes;
  - POPs, injectables, implants, Cu IUD and LNG-IUS are safe alternative choices. However, injectables should not be initiated (or should be discontinued) in women with very high blood pressure levels (systolic  $\geq 160$  and/or diastolic  $\geq 100$ );
  - Vasectomy is the preferred method of sterilisation if the couple is sure that they do not wish to have any more children. Tubal ligation under local anaesthesia can be considered if the service is available.
- *Venous thromboembolism* – deep vein thrombosis and pulmonary embolism (DVT/PE).
  - Current or a past history of venous thromboembolism is an absolute contraindication to the use of oestrogen-containing contraceptives (combined oral, patch, vaginal ring or combined injectables).
  - POPs, injectables, implants and LNG-IUS are suitable choices for women with a history of DVT/PE, but should not be initiated or used by women with acute DVT/PE.
  - The Cu IUD may be used but concurrent use of anticoagulants may give rise to excessive bleeding.
  - Female sterilisation should be delayed until the condition has been stabilised on anticoagulant therapy (and preferably after treatment has been discontinued).
- *Arterial disease* – acute myocardial infarction, angina, cerebral haemorrhage or thrombosis, transient ischaemic attacks.
  - Arterial disease or high risk factors, including heavy smoking in women over 35 years of age, contraindicate the use of all oestrogen-containing methods (for example combined hormonal contraceptives, namely COCs, patches, vaginal rings or combined injectables).

- Progestogen-only injectables should not be used by women with these conditions. All other progestogen-only methods, including LNG-IUS subdermal implants and POPs, can be initiated or continued, but careful follow-up is required and the method should be discontinued if the condition worsens.
- The Cu IUD is safe and highly effective.
- There are associated anaesthetic risks with female sterilisation. Therefore vasectomy should be the sterilisation procedure of choice for couples who are sure that they do not wish to have any children in the future.

**NOTE:**

**Smoking** increases the risk of cardiovascular disease for all ages and should be discouraged.

- The use of COCs is not recommended in smokers of 35 years or older.
- Heavy smoking (more than 15 cigarettes per day) in women of 35 years or older is an absolute contraindication to oestrogen-containing contraceptives.
- Smokers can safely use progestogen-only methods, Cu IUDs and sterilisation.

- *Valvular heart disease* – uncomplicated cases. There are no absolute contraindications to the use of any contraceptive method, although combined hormonal contraceptives (WHO MEC Category 2) would require careful follow-up.
  - Combined hormonal contraceptives are absolutely contraindicated (WHO MEC Category 4) in the presence of complications, such as pulmonary hypertension, risk of fibrillation or history of subacute bacterial endocarditis.
  - Progestogen-only methods can be used safely.
  - In the presence of complicated valvular heart disease, Cu IUD or LNG- IUS can be inserted (WHO MEC Category 2), prophylactic antibiotics to prevent bacterial endocarditis advised.

**Diabetes mellitus**

- Women with diabetes (both non-insulin and insulin dependent) who do not have vascular complications can use any contraceptive method safely.
- Women with long-standing disease (more than 20 years) or those with vascular complications (neuropathy, nephropathy or retinopathy) should not use combined hormonal methods (COCs, patches, etc.) or progestogen-only injectables as they are in WHO MEC Category 4. They can safely use Cu IUDs, LNG-IUS, or other progestogen-only methods, such as POPs and implants.
- Female sterilisation has associated anaesthetic and surgical risks. Therefore, vasectomy is the sterilisation procedure of choice for couples, who are sure that they do not wish to have any children in the future. When alternative, highly effective long-acting reversible methods are unacceptable, female sterilisation can generally be performed in women with complicated diabetes if specialised settings, with a trained surgical team and adequate support equipment, are available (WHO MEC Category S\*).

**Epilepsy**

Epilepsy itself does not preclude the use of any contraceptive method. But some of the commonly used anticonvulsant drugs (namely phenytoin, carbamazepine, ethosuxamide, phenobarbitone and primidone) may reduce the efficacy of hormonal contraceptives and thus increase the risk of pregnancy.

**NOTE:**

Sodium valproate has been associated with various fetal congenital abnormalities. The risk occurs in the first trimester and the lowest dose possible and folic acid supplementation is advised. The risk–benefit ratio should be carefully considered as well as the danger of changing therapy during pregnancy. Prenatal diagnosis of valproate-induced spina bifida can be performed. Valproate use during pregnancy may also be associated with an increased risk of cognitive impairment in children.<sup>2</sup>

\* WHO S = procedure should be undertaken with experienced surgeon and staff.

- Progestogen-only injectables are effective, injection intervals do not need to be shortened.
- Cu IUDs, LNG-IUS or sterilisation may be a good choice for clients with epilepsy, if no specific contraindications to these methods are identified during appropriate screening.
- POPs should not be used.
- COCs generally should not be used by women taking anticonvulsants long term (WHO MEC Category 3). For women taking anticonvulsants short term, higher dose preparations containing 50 µg oestradiol (to a maximum 70 µg, this may require taking two pills each day) may be considered to counteract the potential reduced effectiveness of COCs. Extended dosing regimens of monophasic pills, i.e. three or four packs of active pills (9–12 weeks) followed by a hormone-free interval of only four days are recommended.
- Lamotrigine has no effect on contraceptive efficacy, but use of COCs are not recommended with this anticonvulsant in monotherapy as oestrogen reduces seizure control. If drug dose is increased to improve therapeutic effects, patients may then suffer lamotrigine toxicity during the placebo/hormone-free week. However, when lamotrigine is used in combination with sodium valproate COCs do not seem to have the any negative effects and can be used. Progestogen-only methods are safe and effective as are IUD/IUS.
- Women who are on anticonvulsants, or who took anticonvulsants that are enzyme-inducing drugs within 28 days of the act of unprotected sex, must be offered an intrauterine device for emergency and on-going contraception, if ECPs are used the dose should be increased by 50%.

### Tuberculosis

TB does not contraindicate the use of any method, except intrauterine devices in the presence of pelvic TB.

If the potent enzyme-inducing drugs, rifampicin or rifabutin are used in treatment, hormone levels are dropped by >40%, reducing efficacy of POPs and COCs (even high dose) significantly, therefore their use is not advised.

Progestogen-only injectables are suitable; injection intervals do not need to be shortened.

The Cu IUD, LNG-IUS or sterilisation can be used safely in women with the non-pelvic form of TB. Female sterilisation in women with pelvic TB can be considered, but only if specialised settings, with a trained surgical team and adequate support equipment, are available as per WHO MEC Category S.\*

### Women with malignant disease

- *Breast cancer.* Benign breast disease, undiagnosed breast lumps and a family history of breast cancer do not contraindicate the use of any specific method.
  - The Cu IUD is a safe choice as it has no hormonal effects.
  - Hormonal methods are contraindicated for women with current breast cancer (WHO MEC Category 4 for all hormonal contraceptives). For women with a history of breast cancer (no evidence of current disease for at least five years) hormonal methods are not generally recommended, although if nothing else is available or acceptable they may be allowed with approval from the attending oncologist and under careful medical supervision (WHO MEC Category 3 for all hormonal contraceptives).
  - Voluntary sterilisation is appropriate for women who are certain that they do not want to have children in the future.
  - Other methods require careful counselling as they generally carry a greater risk of contraceptive failure and pregnancy may exacerbate the disease.
- *Cervical and other genital-tract cancers.* HPV infection is the main cause of cervical cancer. The onset of sexual activity at a young age and multiple sexual partners increase risk of exposure to HPV and thus are associated with a higher risk of cervical cancer. Therefore, delay of sexual debut and safer sexual practices should be encouraged to reduce HPV infection. Introduction of HPV vaccines for adolescents should be considered as a strategy to reduce cancer of the cervix in South Africa.

\* WHO S = procedure should be undertaken with experienced surgeon and staff.

- *Cervical intraepithelial neoplasia*. If cervical intraepithelial neoplasia is diagnosed on the cervical (pap) smear, it must be managed appropriately. The condition does not preclude any form of contraception, including hormonal methods and intrauterine devices. Sterilisation would be suitable for women or couples who do not wish to have children in the future.
- *Invasive cervical and other genital tract cancers* – for example ovarian and endometrial. These cancers require treatment that generally results in sterility. Any contraceptive method can be initiated if needed while the woman awaits treatment. The only exception is the insertion of Cu IUD or LNG-IUS in the presence of cervical and endometrial cancer (WHO MEC Category 4), or ovarian cancer (WHO MEC Category 3). If a Cu IUD or LNG-IUS user is diagnosed with cervical cancer, the device can be kept in place while she awaits treatment (WHO MEC Category 2).
- Hormonal contraceptives provide protection from genital tract cancers. The use of hormonal contraceptives, both oral and injectables (and theoretically other hormone delivery systems, for example LNG-IUS, implants, patches and vaginal rings) have been shown to significantly reduce the risk of developing endometrial and ovarian cancer by as much as 50%. This protective effect increases with duration of use and extends up to 15 years after discontinuing the method.



## CHAPTER 4

# Contraception and HIV

There is a need to consider the various contraceptive methods in terms of their impact on HIV acquisition and, for HIV-positive women, their impact on transmission, disease progression and drug interaction.\* The recommendations in the Policy and Guidelines are drawn from expert consultations within South Africa, and an expert consultation hosted by WHO in Geneva, January 2012.<sup>3</sup>

## 4.1 HIV acquisition in HIV negative women

Twenty prospective studies assessed the risk of HIV acquisition among HIV-negative women using different hormonal contraceptives. Most higher-quality studies found no statistically significant association between oral contraceptive pill use and HIV acquisition. Evidence on progestogen-only injectables, specifically DMPA, was mixed; some higher-quality observational studies reported a significant increase in the risk of HIV acquisition (ranging from 48% to 100%) while other observational studies did not report such an association. These findings are of particular concern in the context of South Africa, where HIV incidence is very high among young women.

Reviewing the available evidence, the WHO expert committee agreed that the data were not sufficiently conclusive to advise HIV-negative women who are at risk of HIV infection to stop using progestogen-only injectables, but a strong clarification to current guidance was added. This stated that:

“Because of the inconclusive nature of the body of evidence on possible increased risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection is essential. These recommendations will be continually reviewed in light of new evidence.”

Source: *Hormonal contraception and HIV*, WHO, 2012<sup>3</sup>

## 4.2 HIV transmission from HIV-positive women to HIV-negative men

One recent observational study provided direct evidence on the relationship between female-to-male HIV transmission and oral contraceptive pills or injectable contraception. It suggested a two- to three-fold increased risk with use of injectable contraceptives, but not for oral contraceptive pills.

Indirect evidence on two possible mechanisms by which hormonal contraception may impact female-to-male HIV transmission, namely increased genital HIV viral shedding or altered plasma viral load, was also assessed. Findings from studies assessing hormonal contraceptive use and genital HIV viral shedding were inconsistent, but studies assessing hormonal contraceptive use and plasma viral load or viral load set point largely indicated no adverse effects.

As the evidence is limited and inconsistent, one cannot assume that women using hormonal contraceptives are more likely to transmit HIV to a HIV-negative partner than women not using hormonal methods. However, more research is required to clarify this question and future guidance will be refined based on the research outcomes. In any case, it is strongly recommended that all HIV-positive women with HIV-negative partners should continue using condoms at all times, even when they are relying on an effective contraceptive method for pregnancy prevention. Condom use by serodiscordant couples is critical for prevention of HIV transmission.

\* Two key sources have contributed to this chapter (a) Bekker L-G et al. Guideline on safer conception in fertile HIV-infected individuals and couples. *Southern African Journal of HIV Medicine*, 2011, 12(2):31;<sup>1</sup> and (b) *Family Planning: A global handbook for providers*, WHO/RHR and CCP, 2011<sup>2</sup>

### 4.3 Disease progression in HIV-positive Women

None of the 10 observational studies that examined use of various hormonal contraceptives and HIV disease progression (as measured by mortality, time to CD4+ cell count below 200 cells/mm<sup>3</sup>, initiation of ART, increased HIV-RNA viral load, or decreased CD4+ cell count) found a statistically significant association. An increased risk of a combined outcome of progression to AIDS, ART initiation or death was reported in one randomised controlled trial that compared hormonal contraceptive users with Cu IUD users; however, interpretation of this association is difficult due to high rates of method switching and loss to follow-up. At present this policy does not restrict the use of hormonal contraceptives among HIV-positive women.

### 4.4 Overall guidance for contraceptive use by HIV-positive women

#### Dual method

It is strongly recommended that all HIV-positive clients who wish to avoid pregnancy should consider dual method use – effective contraceptive method of their choice for pregnancy prevention and consistent use of male or female condoms – to prevent STI and HIV transmission between partners. If a woman does not want a pregnancy or a pregnancy could impact negatively on her health (for example a woman with CD4<200), a highly effective and, preferably, client-independent method should be considered in addition to condoms. If a woman chooses to rely on condoms for both pregnancy prevention and prevention of HIV transmission to her partner, then she should also be counselled about the use of emergency contraception in case condoms were not used consistently and/or correctly.

#### Hormonal contraceptives

Hormonal contraceptives can be used safely by the majority of HIV-positive women. Progestogen-only injectables and implants can be safely used and are highly effective contraceptives, with implants also being long acting. Some ART drugs (such as ritonavir or ritonavir-boosted protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) as well as TB drugs (rifampicin and rifabutin) can interact with implants and NET-EN. While interactions with these drugs are not expected to significantly affect the effectiveness of implants and NET-EN and they can be generally used by women on ART or TB treatment, concurrent use of condoms is also recommended for both dual protection purposes and enhanced protection from pregnancy (WHO MEC Category 2). Women who use DMPA can do so safely even if they receive ART or TB treatment because the effectiveness of DMPA is not affected by drug interactions (WHO MEC Category 1)

There are more concerns about women who are on ART or receive treatment for TB and are planning to use combined hormonal contraceptives or POPs. Blood levels of hormones in women who take COCs, combined injectables or POPs are significantly reduced as a result of drug interactions with ritonavir and ritonavir-boosted PIs as well as with the TB drugs rifampicin and rifabutin. WHO recommends that these should generally not be used together (WHO MEC Category 3). There are some lesser interactions with NNRTIs, which generally do not preclude use of combined hormonal methods and POPs, but adding a condom is appropriate for enhanced pregnancy protection (WHO MEC Category 2).

ECPs should be available to women with HIV. ART or TB medications are unlikely to reduce the effectiveness of ECPs because ECPs contain higher doses of hormones than daily COCs. There is currently no evidence to justify increasing the ECP dosage for women on ART or TB medication, although higher dose ECP regimens could be considered (see Section 13.4).

#### Intrauterine devices or systems

Intrauterine contraceptives (both Cu IUDs and LNG-IUS) are very effective long-acting reversible methods that can generally be used by most HIV-positive women, including those with AIDS, provided they are clinically well on ART (WHO MEC Category 2). Women with AIDS, who do not receive ART or those who are not clinically well on ART, generally should not initiate intrauterine devices or LNG-IUS (WHO MEC Category 3). At the same time, women who developed AIDS while using an intrauterine device or system, can continue to use it safely even if they are not on ART (WHO MEC Category 2).

## Sterilisation

Male or female sterilisation is appropriate only for individuals or couples who have been thoroughly counselled about the procedure and are certain that they never wish to have more children in the future and who have considered the implications thoroughly. The decision should be voluntary and fully informed, with clients being cognisant of their sexual and reproductive health rights. While HIV status may affect clients' decision to choose sterilisation, they should never be coerced into doing so.

## Condoms

Regardless of what method was chosen for pregnancy prevention, all women at risk of HIV and those living with HIV should be strongly encouraged to use condoms consistently and correctly (dual method use). They should also be counselled about additional HIV preventive measures, which include voluntary adult male medical circumcision, awareness of one's own and one's partner's HIV status, ART for treatment-eligible HIV-positive individuals, diagnosis and treatment of STIs, and a reduction in the number of sexual partners.

## 4.5 Summary of contraceptive methods and HIV\*

Below is a narrative summary of HIV-related eligibility for specific methods. An outline of the risks and drug interactions associated with each contraceptive method is provided in Table 24. A summary of contraception and HIV according to the WHO MEC is provided in Table 25.

### Combined hormonal contraceptives (COCs, patches, rings and combined injectables)

- Can be used safely by women who are living with HIV and AIDS (WHO MEC Category 1).
- Can be used by women on ART (WHO MEC Category 2) unless their therapy includes ritonavir or ritonavir-boosted PIs, as ritonavir may significantly reduce the effectiveness of combined hormonal contraceptives (WHO MEC Category 3).
- Combined hormonal contraceptives provide no protection in terms of STI and HIV transmission, and consistent and correct condom use in addition to combined hormonal method needs to be encouraged.

### Progestogen-only pills

- Can be used safely by women who are living with HIV and AIDS.
- Can be used by women on ART (WHO MEC Category 2) unless their therapy includes ritonavir or ritonavir-boosted PIs, as ritonavir may significantly reduce the effectiveness of POPs (WHO MEC Category 3).
- POPs provide no protection in terms of STI and HIV transmission; therefore consistent and correct condom use in addition to POPs needs to be encouraged.

### Progestogen-only injectables (DMPA and NET-EN)

- HIV-positive women and those who have AIDS, including those on ART, can safely use progestogen-only injectables (WHO MEC Category 1 for DMPA and Category 2 for NET-EN).
- Progestogen-only injectables provide no protection in terms of STI and HIV transmission; therefore consistent and correct condom use in addition to injectables needs to be encouraged.

### Subdermal implants

- Can be used by women who are living with HIV and AIDS, including those on ART (WHO MEC Category 2).
- Implants provide no protection in terms of STI and HIV transmission; therefore consistent and correct condom use in addition to implants needs to be encouraged.

\* This section has been adapted from *Family Planning: A global handbook for providers*, WHO/RHR and CCP, 2011<sup>2</sup>

### Intrauterine contraception

- Women living with HIV, but who do not have AIDS, can safely have the Cu IUD/LNG-IUS inserted (WHO MEC Category 2).
- Women who have AIDS but are on ART and are clinically well can safely have the Cu IUD/LNG-IUS inserted (WHO MEC Category 2).
- Women who have AIDS but who are not on ART, and those who are not clinically well while on ART, should not have the Cu IUD/LNG-IUS inserted (WHO MEC Category 3).
- If a woman develops AIDS while she has a Cu IUD/LNG-IUS in place, she can continue using the method. More careful monitoring may be required in such cases.
- Intrauterine devices and systems provide no protection in terms of STI and HIV acquisition or transmission; therefore consistent and correct condom use in addition to Cu IUD/LNG-IUS needs to be encouraged.

### Emergency contraceptive pills

- Women with HIV, AIDS, and those on ART can safely use ECPs, even when they have health conditions precluding them from using hormonal methods for regular, on-going contraception.
- ART or TB medications are unlikely to reduce the effectiveness of ECPs because ECPs contain higher doses of hormones than daily oral contraceptives. There is currently no evidence to justify increasing the ECP dosage for women on ART or TB medications, although such an approach may be considered. In this case, women on ART regimen containing ritonavir or taking rifampicin/ rifabutin for TB may be advised to increase the dose of ECPs (Ovral/Famynor 3 +3, Norlevo 3 tabs stat, Escapelle 2 tabs stat Microval/Hyan 38+38)

### Barrier methods

- Condom use, in addition to any other contraceptive method, should be promoted to prevent pregnancy, STI and HIV reinfection.
- Barrier methods should be combined with a LARC method if pregnancy is either contraindicated or not desired.

### Female sterilisation

- Women living with HIV, AIDS, or those on ART can safely undergo female sterilisation.
- Special arrangements are needed to perform female sterilisation on a woman with AIDS.
- Presence of an AIDS-related illness may require the procedure to be delayed until health improves.
- Sterilisation provides no protection in terms of STI and HIV transmission; therefore consistent and correct condom use needs to be encouraged in addition to sterilisation.
- Sterilisation should only be performed with the full consent of the client. No one, including HIV-positive women, should be pressurised or coerced into being sterilised.

### Vasectomy

- Men living with HIV, AIDS, or those on ART can have a vasectomy safely.
- Special arrangements may be needed to perform a vasectomy on a man with AIDS.
- Presence of an AIDS-related illness may require the procedure to be delayed until health improves.
- Vasectomy provides no protection in terms of STI and HIV transmission; therefore consistent and correct condom use needs to be encouraged in addition to vasectomy.
- Vasectomy should only be performed with the full consent of the client. No one, including HIV-positive men, should be pressurised or coerced into having a vasectomy.

Table 24. Summary of method safety and HIV: increased risk of progression, transmission and drug interaction

Contraceptive method	Impact on disease progression	Increased HIV transmission to partner	Interaction with ART regimens	Interaction with TB treatment
<b>Oral contraceptive pills (COCs and POPs)</b>	No conclusive evidence of harm: can use	No conclusive evidence of harm: can use	Drug interaction with ritonavir and ritonavir-boosted PIs: generally do not use (WHO MEC Category 3) Some interaction with NNRTIs: generally can use, but adding condom is appropriate for enhanced pregnancy protection (WHO MEC Category 2)	Drug interaction with rifampicin and rifabutin: generally do not use (WHO MEC Category 3)
<b>Injectable contraceptives (DMPA, NET-EN)</b>	No conclusive evidence of harm: can use	No conclusive evidence of harm. Recent observational studies suggest that use of DMPA might increase risk of HIV acquisition and transmission. More research is needed: can use (WHO MEC Category 1), but concurrent use of condoms should be strongly encouraged	No drug interaction with DMPA: can use without restrictions (WHO MEC Category 1). Some interaction between NET-EN and NNRTIs as well as ritonavir/ritonavir-boosted PIs: generally can use, but adding condom is appropriate for enhanced pregnancy protection (WHO MEC Category 2). No need to increase dose or shorten re-injection interval	No interaction with DMPA: can use without restrictions (WHO MEC Category 1). Some interaction between NET-EN and rifampicin/rifabutin: generally can use (WHO MEC Category 2), but adding condom is appropriate for enhanced pregnancy protection. No need to increase dose or shorten re-injection interval
<b>Implants</b>	No conclusive evidence of harm: can use	No conclusive evidence of harm: can use	Some interaction between Implants and NNRTIs as well as ritonavir/ritonavir-boosted PIs: generally can use, but adding condom is appropriate for enhanced pregnancy protection (WHO MEC Category 2)	Some interaction between Implants and rifampicin/rifabutin: generally can use (WHO MEC Category 2), but adding condom is appropriate for enhanced pregnancy protection
<b>Male condom</b>	None: may prevent reinfection	Barrier method protects from HIV transmission to partner	Not applicable	Not applicable
<b>Female condom</b>	None: may prevent reinfection	Barrier method protects from HIV transmission to partner	Not applicable	Not applicable
<b>Cu IUD</b>	No evidence that Cu IUD has any impact on disease progression: can use	Limited evidence showed no increased risk of HIV transmission to partner: can use	No interactions. Women with AIDS should not have a Cu IUD inserted unless they are on ART and are clinically well	No interactions
<b>LNG-IUS</b>	Limited evidence, but considered safe: can use	Limited evidence but extrapolating from Cu IUD: can use	No interactions. Women with AIDS should not have LNG-IUS inserted unless they are on ART and are clinically well	No interactions
<b>Male and female sterilisation</b>	No biological reasons to suspect any negative impact: can use	No biological reasons to suspect any negative impact: can use	Not applicable	Not applicable

**Table 25. Summary of contraception and HIV according to the WHO MEC for contraceptive use**

Condition	CHC	CIC**	POP	DMPA NET-EN	LNG/ETG implants	Cu IUD		LNG-IUS	
						I	C	I	C
High HIV risk	1	1	1	1	1	2	2	2	2
HIV-positive	1	1	1	1	1	2	2	2	2
AIDS (not on ART)	1	1	1	1	1	3	2	3	2
Not clinically well on ART	Decisions to initiate and use hormonal methods are not based on clinical status, but on possibility of drug interaction. See 'ART' categories below					3	2	3	2
Clinically well on ART						2	2	2	2
ART									
Nucleoside reverse transcriptase inhibitors (NRTIs)	1	1	1	DMPA=1 NET-EN=1	1	Cu IUD and LNG-IUS do not interact with ART drugs. Decisions to initiate and continue IUD/IUS are made based on woman's clinical status (clinically well on ART or not – see categories above).			
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2	2	2	DMPA=1 NET-EN=2	2				
Ritonavir-boosted protease inhibitors	3	3	3	DMPA=1 NET-EN=2	2				
Rifampicin or rifabutin therapy for TB 3	3	2	3	DMPA=1 NET-EN=2	2	1*	1*	1*	1*

\* IUD/IUS do not interact with TB drugs and can be used without restrictions unless woman has pelvic form of TB (in which case Cu IUD insertion is classified as WHO MEC Category 4 and should not be done)

\*\* Currently, CICs are not available in South Africa

#### Key

CIC= combined injectable contraception; CHC= combined hormonal contraception; IUD= intrauterine device; IUS= intrauterine system; ETG= etonogestrel implants

Source: Medical eligibility criteria for contraceptive use, WHO.<sup>4</sup>

#### NOTE:

According to the WHO MEC (2010):<sup>4</sup> "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). For up-to-date, detailed information on HIV drug interactions, it is recommended that the HIV Drug Interactions website: [www.hiv-druginteractions.org](http://www.hiv-druginteractions.org) is consulted."

See Appendix 4 for the full WHO statement: HIV and hormonal contraception

## ANNEXE

# Medical eligibility criteria

**Annexes 1–10** outline the medical eligibility criteria for specific methods, based on the *Medical eligibility criteria for contraceptive use, fourth edition 2009*, published by the World Health Organization in 2010.

## Annexe 1

*Medical eligibility criteria*

### Initiating combined hormonal contraceptives (CHCs)

(including low-dose combined oral contraceptives (COCs), combined injectables, transdermal patches and vaginal ring)

Note: Conditions not in the WHO MEC, but relevant to the South African context are marked with an asterisk and reference (\*<sup>1</sup>).

#### CHCs WHO MEC Category 1: USE METHOD IN ANY CIRCUMSTANCES

- *Age: menarche to <40 years*
- *Parity: Nulliparous/parous*
- *Non-migrainous headaches (mild or severe)*
- *Gynaecological/obstetric conditions*
  - Recent abortion/miscarriage, history of ectopic pregnancy
  - Irregular menstrual periods, severe dysmenorrhoea, heavy periods
  - Uterine fibroids, endometriosis, PID (history or current)
  - Benign breast disease, family history of breast cancer
  - Endometrial or ovarian cancer
  - History of gestational diabetes
  - Gestational trophoblastic disease
  - Non-breastfeeding postpartum >6 weeks
  - Cervical ectropion
- *Chronic disease/other conditions*
  - Varicose veins
  - Thyroid disease
  - Schistosomiasis
  - Chronic viral hepatitis or carrier
  - Mild cirrhosis
  - Use of broad spectrum antibiotics, antifungals or antiparasitics
  - Tuberculosis (unless taking rifampicin)
  - Malaria
  - Iron-deficiency anaemia
  - Depressive Disorders
- *Minor surgery without mobilisation*
- *STI and HIV risk (advise condom use in addition to CHCs)*
  - High risk of STI and HIV, HIV positive or AIDS (unless on ART therapy)

## Annexe 1 (continued)

### Initiating combined hormonal contraceptives (CHCs)

#### CHCs WHO MEC Category 2: GENERALLY USE THE METHOD

- Age 40 years or older
- Smoker under age 35 years
- Obesity  $\geq 30\text{kg/m}^2$  body mass index (BMI)
- Simple migraine without aura age  $< 35$  years
- Gynaecological/obstetric conditions
  - History of pregnancy-related cholestatic jaundice
  - History of pregnancy-related hypertension where current blood pressure is measurable and normal
  - Breastfeeding, over 6 months postpartum
  - Non-breastfeeding  $> 3$  weeks postpartum (if no additional risk factors for thrombosis)
  - Undiagnosed breast mass
  - Cervical intraepithelial neoplasia (CIN) or cancer awaiting treatment
  - Unexplained vaginal bleeding (before evaluation)
  - Breast disease; undiagnosed mass
- Cardiovascular conditions
  - Uncomplicated valvular heart disease
  - Superficial thrombophlebitis
  - family history of VTE (venous thromboembolism)
- Chronic diseases/other conditions
  - Diabetes without vascular complications (both insulin-/non-insulin dependent)
  - SLE (systemic lupus erythematosus) without antiphospholipid antibodies
  - Benign liver tumour: focal nodular hyperplasia
  - Migraines without aura under age of 35
  - Sickle cell disease
  - ART therapy (unless ARV drug regimen contains ritonavir or ritonavir-boosted PIs)
- Major surgery without immobilisation

#### CHCs WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED (unless other methods not available)

- Smoker ( $< 15$  cigarettes/day), age  $\geq 35$  years
- Migraine without aura, age  $\geq 35$  years
- Gynaecological/obstetric conditions
  - Breastfeeding ( $= 6$  weeks to  $< 6$  months postpartum)
  - Non-breastfeeding  $< 3$  weeks postpartum (if no additional risk factors for thrombosis)
  - Non-breastfeeding  $< 6$  weeks postpartum (if additional risk factors for thrombosis are present)
  - History of breast cancer and no evidence of disease in past 5 years
- Cardiovascular conditions
  - Elevated blood pressure levels (systolic  $\geq 140$ – $159$  or diastolic  $\geq 90$ – $99$  mmHg)
  - Adequately controlled hypertension
  - History of hypertension if blood pressure cannot be measured
  - Known hyperlipidaemias
  - Multiple risk factors for cardiovascular disease (e.g. increasing age, smoking, diabetes, obesity, hypertension strong family history)
- Chronic diseases/other conditions
  - Use of certain antibiotics (e.g. rifampicin or rifabutin) and anticonvulsants (e.g. phenytoin, lamotrigine)
  - Use of certain ARVs: ritonavir or ritonavir-boosted protease inhibitors
  - History of COC-related cholestasis
  - Current or medically treated gall bladder disease
  - Acute porphyria without previous crisis and latent or asymptomatic porphyria<sup>1\*</sup>

## Annexe 1 (continued)

### Initiating combined hormonal contraceptives (CHCs)

#### CHCs WHO MEC Category 4: METHOD NOT TO BE USED

- *Smoker ≥15 cigarettes/day, age ≥35 years*
- *Migraine with aura, any age*
- *Gynaecologic/obstetric conditions*
  - *Breastfeeding <6 weeks postpartum*
  - *Breast cancer (current)*
- *Cardiovascular conditions*
  - *Elevated blood pressure levels: systolic >160 or diastolic >100*
  - *Current/ history of thromboembolic disorders (deep venous thrombosis or pulmonary emboly) or stroke*
  - *Known thrombogenic mutation*
  - *Current/history of ischaemic heart disease*
  - *Current/history of complicated valvular heart disease (pulmonary hypertension, risk of atrial fibrillation, history of sub-acute bacterial endocarditis)*
- *Chronic disease/other conditions*
  - *Liver tumours (malignant and benign, except focal nodular hyperplasia)*
  - *Active viral hepatitis or severe cirrhosis*
  - *Diabetes with vascular complications (nephropathy, neuropathy, retinopathy) or >20 years duration,*
- *SLE with positive or unknown antiphospholipid antibodies*
- *Acute porphyria with history of crisis\*<sup>1</sup>*
- *Major surgery with prolonged immobilisation*

## Annexe 2

### Medical eligibility criteria

### Initiating progestogen-only pills (POPs)

Note: Conditions not in the WHO MEC, but relevant to the South African context are marked with an asterisk and reference (\*<sup>1</sup>).

Variation from WHO recommendations - extracted from UK-MEC 2009 are marked with an asterisk and reference (\*<sup>2</sup>).

#### POPs WHO MEC Category 1: USE METHOD IN ANY CIRCUMSTANCES

- *Menarche to menopause*
- *Smoker any age/number of cigarettes*
- *Nulliparous/parous*
- *Obesity =30kg/m<sup>2</sup> body mass index (BMI)*
- *Headaches, non-migrainous or migrainous with or without aura, any age*
- *Gynaecological/obstetric conditions*
  - Postpartum or post abortion
  - Breastfeeding\*<sup>2</sup>
  - Benign breast disease
  - History of pregnancy-related diabetes/cholestasis, gestational trophoblastic disease
  - Cervical ectropion/intraepithelial neoplasia (CIN, for short-term use)
  - Uterine fibroids, severe dysmenorrhoea, endometriosis
  - Endometrial or ovarian cancer, benign ovarian tumours
  - PID (history or current)
- *Cardiovascular conditions*
  - Varicose veins, Superficial thrombophlebitis
  - Valvular heart disease (complicated or uncomplicated)
  - Adequately controlled hypertension
  - Elevated blood pressure levels systolic 140–159 or diastolic 90–99
  - Minor surgery without immobilisation
  - Major surgery without prolonged immobilisation
- *Chronic diseases/other conditions*
  - Depressive disorders
  - Viral hepatitis (active, chronic or carrier)
  - Thyroid disease
  - Sickle-cell disease
  - Epilepsy
  - Schistosomiasis
  - Tuberculosis (not on rifampicin)
  - Malaria
  - Broad spectrum antibiotics, antifungals and antiparasitics drugs
  - Lamotrigine
  - Iron deficiency anaemia
- *STI/HIV risk (advise dual protection use)*
  - Increased risk of STI/HIV infection, HIV positive or AIDS (unless ARV regimen contains ritonavir or ritonavir-boosted PIs (protease inhibitors))

## Annexe 2 (continued)

### Initiating progestogen-only pills

#### POPs WHO MEC Category 2: GENERALLY USE THE METHOD

- *Migraine with aura at any age*
- *Gynaecological/obstetric conditions*
  - Irregular menstrual bleeding/ prolonged heavy bleeding patterns or unexplained vaginal bleeding (before evaluation)
  - Past ectopic pregnancy
  - Breast disease – undiagnosed mass
- *Cardiovascular condition*
  - Elevated blood pressure levels systolic  $\geq 160$  or diastolic  $\geq 100$
  - History of thromboembolic disorders (deep vein thrombosis (DVT)/pulmonary embolism (PE))
  - Current DVT, but established on anticoagulant therapy
  - Ischaemic heart disease, stroke
  - Known hyperlipidaemias
  - Multiple risk factors for cardiovascular disease
  - Major surgery with prolonged immobilisation
- *Chronic diseases/other conditions*
  - Diabetes with or without vascular disease of any duration, nephropathy/retinopathy/neuropathy (insulin or non-insulin dependent),
  - SLE negative for antiphospholipid antibodies
  - Gall bladder disease surgically or medically treated and asymptomatic
  - Liver tumour: focal nodular hyperplasia

#### POPs WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED (unless other methods not available)

- *Chronic diseases/ other conditions*
  - Liver tumours (malignant or benign other than focal nodular hyperplasia), severe cirrhosis
  - SLE with positive or unknown antiphospholipid antibodies
  - Past breast cancer with no evidence of recurrence for 5 years
  - Acute DVT/PE (if not on anticoagulant therapy)
  - Acute Porphyria without previous crisis and latent or asymptomatic porphyria\*<sup>1</sup>
  - Use of certain antibiotics (e.g. rifampicin) anticonvulsants (e.g. phenytoin) and ARVs (ritonavir and ritonavir-boosted Protease Inhibitors)

#### POPs WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED

- *Gynaecological/obstetric conditions*
  - Current breast cancer
  - Acute porphyria with history of crisis\*<sup>1</sup>

## Annexe 3

### Medical eligibility criteria

### Initiating progestogen-only injectables

Note: Conditions not in the WHO MEC, but relevant to the South African context are marked with an asterisk and reference (\*1).

#### Progestogen injectables WHO MEC Category 1: USE METHOD IN ANY CIRCUMSTANCES

- Age 18 years to 45 years
- Parous/nulliparous
- Smoker any age/number of cigarettes
- Obesity  $\geq 30\text{kg/m}^2$  Body mass index (BMI) and older than 18 years
- Obesity  $\geq 30\text{kg/m}^2$  Body mass index (BMI) and younger than 18 years (NET-EN only)
- Non-migrainous headaches
- Gynaecological/obstetric conditions
  - History of ectopic pregnancy, gestational trophoblastic disease, gestational diabetes
  - Postpartum (non-breastfeeding) or post abortion
  - Breastfeeding (>6 weeks postpartum)
  - Benign breast disease
  - Uterine fibroids, severe dysmenorrhoea, endometriosis, PID, benign ovarian tumours, endometrial or ovarian cancer
- Cardiovascular conditions
  - Valvular heart disease
  - Known thrombogenic mutation
  - Minor or major surgery without prolonged immobilisation
  - Varicose veins
- Chronic diseases/other conditions
  - Viral hepatitis (acute, chronic or carrier)
  - Mild cirrhosis
  - Thyroid disease
  - Sickle-cell disease
  - Epilepsy (if no significant drug interactions)
  - Schistosomiasis
  - Tuberculosis (if no significant drug interactions)
  - Malaria
  - Use of broad spectrum antibiotics, antifungals or antiparasitics
  - Iron deficiency anaemia
  - Depressive disorders
- STI/HIV risk (advise condom use in addition to progestogen-only injectables)
  - Increased risk of STI and HIV, HIV-positive or AIDS
  - AIDS on ART (if no significant drug interactions)

## Annexe 3 (continued)

### Initiating progestogen-only injectables

#### Progestogen injectables WHO MEC Category 2: GENERALLY USE THE METHOD

- Age < 18 years or >45 years
- Obesity  $\geq 30\text{kg/m}^2$  Body mass index (BMI) and younger than 18 years (DMPA only)
- Migrainous headaches with/without aura at any age (but if migraines with aura develop while using injectables, the method should be discontinued)
- Gynaecological/obstetric conditions
  - Irregular, prolonged or heavy menstrual bleeding patterns
  - Breast disease (undiagnosed mass)
  - Cervical intraepithelial neoplasia (CIN) or cancer
- Cardiovascular conditions
  - Adequately controlled hypertension
  - Elevated blood pressure levels systolic 140–159 or diastolic 90–99
  - Known hyperlipidaemias
  - History of VTE (DVT or PE) or current VTE established on anticoagulation therapy
  - Major surgery with prolonged immobilisation
- Chronic diseases/other conditions
  - Diabetes without vascular complications (insulin and non-insulin dependent) or less than 20 years duration
  - SLE negative for antiphospholipid antibodies
  - Benign liver tumour: focal nodular hyperplasia

#### Progestogen injectables WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED (unless other methods not available)

- Gynaecological/obstetric conditions
  - Breastfeeding (<6 weeks postpartum)
  - Past breast cancer and no evidence of disease for 5 years.
  - Unexplained vaginal bleeding (before evaluation).
- Cardiovascular conditions
  - Hypertension with vascular disease or severe hypertension (systolic  $\geq 160$  or diastolic  $\geq 110$ )
  - Current/history of ischaemic heart disease or stroke.
  - Multiple risk factors for cardiovascular disease (e.g. increasing age, smoking, diabetes, obesity, hypertension strong family history)
  - Acute DVT/PE (if not on established anticoagulant therapy)
- Chronic diseases/other conditions
  - Diabetes with vascular complications (nephropathy, neuropathy, retinopathy) or more than 20 years of duration
  - SLE positive (or unknown) for antiphospholipid antibodies
  - Liver tumours (malignant and benign other than focal nodular hyperplasia) or severe cirrhosis

#### Progestogen injectables WHO MEC Category 4: METHOD NOT TO BE USED

- Gynaecological/obstetric conditions
  - Current breast cancer
  - Acute porphyria with history of crisis\*<sup>1</sup>
  - Acute porphyria without previous crisis and latent or asymptomatic porphyria\*<sup>1</sup>

## Annexe 4

### Medical eligibility criteria

### Initiating subdermal implants

Note: Conditions not in the WHO MEC, but relevant to the South African context are marked with an asterisk and reference (\*<sup>1</sup>).

Variation from WHO recommendations - extracted from UK-MEC 2009 are marked with an asterisk and reference (\*<sup>2</sup>).

#### Subdermal implants WHO MEC Category 1: USE METHOD IN ANY CIRCUMSTANCES

- *Menarche to menopause (from <18 years to >45 years)*
- *Parous/nulliparous*
- *Smoker any age/number of cigarettes*
- *Obesity  $\geq 30\text{kg/m}^2$  body mass index (BMI) regardless of age*
- *Non-migrainous headaches*
- *Gynaecological/obstetric conditions*
  - *History of ectopic pregnancy, gestational trophoblastic disease, gestational diabetes*
  - *Postpartum or post abortion*
  - *Breastfeeding(\*<sup>2</sup>)*
  - *Benign breast disease*
  - *Uterine fibroids, severe dysmenorrhoea, endometriosis, PID, benign ovarian tumours, endometrial or ovarian cancer*
- *Cardiovascular conditions*
  - *Valvular heart disease*
  - *Known thrombogenic mutation*
  - *Minor or major surgery without prolonged immobilisation*
  - *Varicose veins or superficial thrombophlebitis*
  - *Adequately controlled hypertension or elevated blood pressure levels with systolic 140–159 and/or diastolic 90–99*
- *Chronic diseases/other conditions*
  - *Viral hepatitis (acute, chronic or carrier)*
  - *Mild cirrhosis*
  - *Thyroid disease*
  - *Sickle cell disease*
  - *Epilepsy (if no significant drug interactions)*
  - *Schistosomiasis*
  - *Tuberculosis (if no significant drug interactions)*
  - *Malaria*
  - *Depressive disorders*
  - *Iron deficiency anaemia*
  - *Use of broad-spectrum antibiotics, antifungals and antiparasitics.*
- *STI and HIV risk (advise condom use in addition to progestogen-only injectables)*
  - *Increased risk of STI/HIV, HIV-positive or AIDS*
  - *AIDS on ART (if no significant drug interactions)*

## Annexe 4 (continued)

### Initiating subdermal implants

#### Subdermal implants WHO MEC Category 2: GENERALLY USE THE METHOD

- *Migrainous headaches with/without aura at any age (but if migraines with aura develop while using implants, the method should be discontinued)*
- *Gynaecological/obstetric conditions*
  - Irregular, prolonged or heavy menstrual bleeding patterns
  - Breast disease (undiagnosed mass)
  - Cervical intraepithelial neoplasia (CIN) or cancer
- *Cardiovascular conditions*
  - Adequately controlled hypertension
  - Elevated BP levels with systolic >160 or diastolic >100
  - Vascular disease
  - Known hyperlipidaemias
  - History of VTE (DVT or PE) or current VTE established on anticoagulation therapy
  - Major surgery with prolonged immobilisation
  - Current/history of ischaemic heart disease or stroke (category 2 for initiation, however, if heart disease or stroke develop or become worse while using implants, the method should be discontinued).
  - Multiple risk factors for cardiovascular disease (e.g. increasing age, smoking, diabetes, obesity, hypertension, strong family history for cardiovascular disease)
- *Chronic diseases/other conditions*
  - Diabetes (insulin and non-insulin dependent) regardless of vascular complications and length of duration
  - SLE negative for antiphospholipid antibodies
  - Benign liver tumour: focal nodular hyperplasia

#### Subdermal implants WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED (unless other methods not available)

- *Gynaecological/obstetric conditions*
  - Past breast cancer and no evidence of disease for 5 years
  - Unexplained vaginal bleeding (before evaluation)
- *Cardiovascular conditions*
  - If pre-existing ischaemic heart disease or stroke becomes worse or develops while using implants (Category 3 for continuation)
  - Acute DVT/PE (if not on established anticoagulant therapy)
- *Chronic diseases/other conditions*
  - SLE positive (or unknown) for antiphospholipid antibodies
  - Liver tumours (malignant and benign other than focal nodular hyperplasia) or severe cirrhosis

#### Subdermal implants WHO MEC Category 4: METHOD NOT TO BE USED

- *Gynaecological/obstetric conditions*
  - Current breast cancer
  - Acute porphyria with history of crisis \*<sup>1</sup>
  - Acute porphyria without previous crisis and latent or asymptomatic porphyria \*<sup>1</sup>

## Annexe 5

### Medical eligibility criteria

### Copper intrauterine device (Cu IUD) insertion

Note: Most classifications apply equally to Cu IUD and LNG IUS, but some additional contraindications and precautions are relevant for LNG IUS due to the presence of the hormone. LNG-IUS categories can be found in *Medical eligibility criteria for contraceptive use, fourth edition 2009*. WHO: Geneva, 2010 (page 65).

#### Cu IUD WHO MEC Category 1: USE METHOD IN ANY CIRCUMSTANCES

- Age > 20 years
- Parous
- Smoking any age and number of cigarettes
- Headaches (migrainous and non-migrainous)
- Gynaecological/obstetric conditions
  - Breastfeeding
  - History of pre-eclampsia, ectopic pregnancy
  - Postpartum ≥ 4 weeks, post-abortion (first trimester)
  - Irregular menstrual patterns without heavy bleeding
  - Past PID (with subsequent pregnancy)
  - Breast disease (benign, undiagnosed mass, cancer)
  - Cervical intraepithelial neoplasia (CIN), cervical ectropion
  - Benign ovarian tumours
  - Prior pelvic surgery
  - Uterine fibroids without distortion of the uterine cavity
- Cardiovascular conditions
  - Thromboembolic disorders, uncomplicated valvular heart disease
  - Hypertension, vascular disease, ischaemic heart disease, stroke
- Chronic diseases/other conditions
  - Thyroid disease
  - Epilepsy
  - Diabetes (gestational, vascular/non-vascular disease, nephropathy, neuropathy)
  - Liver tumours (benign, malignant), hepatitis (active, carrier), cirrhosis (mild, severe)
  - Gall bladder disease
  - Schistosomiasis
  - Depression
  - Malaria
  - Non-pelvic tuberculosis

## Annexe 5 (continued)

## Copper intrauterine device (Cu IUD) insertion

**Cu IUD WHO MEC Category 2: GENERALLY USE THE METHOD**

*Menarche to <20 years*

- *Nulliparity*
- *Gynaecological/obstetric conditions*
  - Menstrual patterns with heavy or prolonged bleeding and/or severe dysmenorrhoea
  - Endometriosis
  - Past PID without subsequent pregnancy
  - Uterine/cervical anatomical abnormalities (other than fibroids) that do not distort the uterine cavity or interfere with IUD insertion
  - Postpartum <48 hours (provider must be specially trained to do this)
  - Post-abortion (second trimester)
- *Cardiovascular conditions*
  - Complicated valvular heart disease (prophylactic antibiotics to prevent bacterial endocarditis advised)
- *Chronic diseases/other conditions*
  - Sickle cell disease
  - Iron deficiency anaemia
- *Increased risk of STI and HIV or current infection*
  - Vaginitis (including trichomoniasis and bacterial vaginosis)
  - HIV-infected and AIDS if clinically well on ART

**Cu IUD WHO MEC Category 3: USE OF METHOD NOT RECOMMENDED (unless other methods not available)**

- *Gynaecological/obstetric conditions*
  - Postpartum between 48 hours and 4 weeks
  - Benign gestational trophoblastic disease if persistently elevated  $\beta$ HCG (or malignant disease)
  - Ovarian cancer
  - Systemic lupus erythematosus with severe thrombocytopenia
  - Very high individual risk of exposure to gonorrhoea and chlamydia
  - AIDS and either not on ART, or not clinically well on ART (Category 2 for continuation)

**Cu IUD WHO MEC Category 4: METHOD NOT TO BE USED**

- *Gynaecological/obstetric conditions*
  - Pregnancy
  - Puerperal sepsis or post-septic abortion
  - Current PID
  - Current purulent cervicitis or infection with gonorrhoea or chlamydia
  - Distorted uterine cavity (due to uterine fibroid or other anatomical abnormality) incompatible with insertion of IUD
  - Unexplained vaginal bleeding (before evaluation)
  - Malignant gestational trophoblastic disease
  - Cervical or endometrial cancer
- *Chronic diseases/other conditions*
  - Known pelvic tuberculosis

## Annexe 6

### Medical eligibility criteria

#### Summary: WHO MEC for IUD use in women with (or at risk of) STI and HIV

Condition	Cu-IUD/LNG IUS	
	I	C
<i>Current PID or purulent cervicitis or chlamydial infection or gonorrhoea</i>	4	2
<i>Past history PID with subsequent pregnancy</i>	1	1
<i>Past history PID without subsequent pregnancy</i>	2	2
<i>Other STIs (excluding HIV and hepatitis)</i>	2	2
<i>Vaginitis (including trichomonas and bacterial vaginosis)</i>	2	2
<i>Increased risk of STIs high local prevalence of chlamydia/gonorrhoea</i>	2	2
<i>Very high individual risk of exposure to chlamydia/gonorrhoea</i>	3	2
<i>At high risk of HIV</i>	2	2
<i>HIV infected</i>	2	2
<i>AIDS clinically well on ART</i>	2	2
<i>AIDS not on ARVs (or on ART, but not clinically well)</i>	3	2

Key: I= initiation; C=continuation

## Annexe 7

### Medical eligibility criteria

#### Female sterilisation

##### ACCEPT: no medical reason to deny or delay the procedure

- *Nulliparity or any parity*
- *Smoker – any age or number of cigarettes/day*
- *Migrainous/non-migrainous headaches*
- *Gynaecological/obstetric conditions*
  - History of ectopic pregnancy, gestational trophoblastic disease
  - History of pregnancy-related diabetes, pregnancy/COC-related cholestasis, or pregnancy-related hypertension
  - Postpartum (<7 days or > 42 days), post abortion (uncomplicated)
  - Mild pre-eclampsia
  - Breastfeeding
  - Heavy, prolonged or irregular menstrual bleeding, severe dysmenorrhoea
  - Past PID (with subsequent pregnancy)
  - Breast disease, except current breast cancer
  - Cervical ectropion/intraepithelial neoplasia (CIN)
  - Benign ovarian tumours
- *Cardiovascular conditions*
  - Minor surgery or major surgery without prolonged immobilisation
  - Superficial varicose veins, superficial thrombophlebitis
  - History of thromboembolic disorders
  - Known hyperlipidaemia
- *Chronic diseases/other conditions*
  - Thyroid disease (simple goitre)
  - Treated or asymptomatic gallbladder disease
  - Hepatitis (carrier, not active case)
  - Schistosomiasis (uncomplicated)
  - Malaria
  - Tuberculosis (non pelvic)
  - Vaginitis without purulent cervicitis
  - STIs (other than current gonorrhoea, chlamydia, or hepatitis)
  - Increased risk of STI and HIV or HIV-positive (no AIDS)

## Annexe 7 (continued)

### Female sterilisation

#### CAUTION: can be done in routine setting, but with caution

- *Young age\**
- *Obesity = 30 kg/m<sup>2</sup> body mass index (BMI)*
- *Gynaecological/obstetric conditions*
  - Past PID (without subsequent pregnancy)
  - Current breast cancer
  - Uterine fibroids
- *Cardiovascular conditions*
  - Adequately controlled hypertension
  - Elevated BP levels with systolic 140–159 or diastolic 90–99
  - History of ischaemic heart disease or stroke
  - Uncomplicated valvular heart disease (requires antibiotics)
- *Chronic diseases/other conditions*
  - Use of certain antibiotics or anti-epileptics MAY interact with anaesthetic
  - Diabetes (non-vascular disease, insulin or non-insulin-dependent diabetics)
  - Hypothyroid
  - Sickle-cell disease
  - Moderate iron deficiency anaemia (Hb between 7 and 10 g/dl)
  - Mild cirrhosis (compensated), liver tumours (benign or malignant)
  - Epilepsy
  - Schistosomiasis with fibrosis of liver
  - Diaphragmatic hernia
  - Kidney disease
  - Severe nutritional deficiencies
  - Previous abdominal or pelvic surgery
  - Concurrent elective abdominal surgery
  - Depressive disorders

#### DELAY: until condition evaluated and/or corrected

- *Gynaecological/obstetric conditions*
  - Pregnancy
  - Postpartum (anytime between day 7 and day 42)
  - Severe pre-eclampsia/eclampsia
  - Postpartum/post abortion infection, haemorrhage or fever, prolonged rupture of membranes (>24 hours)
  - Severe trauma to the genital tract at time of delivery or abortion
  - Unexplained vaginal bleeding
  - Current PID
  - Current purulent cervicitis, gonorrhoea or chlamydia
  - Cervical, endometrial, or ovarian cancer
  - Malignant gestational trophoblastic disease
- *Cardiovascular conditions*
  - Current thromboembolic disorders, ischaemic heart disease
  - Major surgery with prolonged immobilisation
- *Chronic diseases/other conditions*
  - Symptomatic, current gall bladder disease
  - Active viral hepatitis
  - Severe iron deficiency anaemia (Hb <7 g/dl)
  - Abdominal skin infection
  - Acute respiratory disease (bronchitis, pneumonia)
  - Systemic infections or gastroenteritis
  - Emergency abdominal surgery (when there is no time for appropriate counselling) or associated with infection

## Annexe 7 (continued)

### Female sterilisation

**SPECIAL: provide only in specialised clinical settings with experienced staff, equipment and back up that can handle potential problems**

- *Gynaecological/obstetric conditions*
  - Fixed uterus due to previous surgery or infection
  - Uterine rupture or perforation (postpartum or post-abortion)
  - Endometriosis
  - Hernia (abdominal wall or umbilical)
- *Cardiovascular conditions*
  - Elevated blood pressure levels systolic  $\geq 160$  or diastolic  $\geq 100$
  - Hypertension with vascular disease
  - Complicated valvular heart disease
- *Chronic disease/other conditions*
  - Severe cirrhosis (decompensated)
  - Hyperthyroid
  - Blood clotting disorders
  - Chronic respiratory diseases: asthma, bronchitis, emphysema, lung infection
  - Known pelvic tuberculosis
  - Diabetes, of >20 years duration or with vascular complications, such as nephropathy, neuropathy, retinopathy
  - AIDS

\* Because women of young age are more likely to regret sterilisation later.

## Annexe 8

### Medical eligibility criteria

#### Male sterilisation

##### **ACCEPT: no medical reason to deny or delay the procedure**

- Sickle-cell disease
- Anaemia
- HIV positive or high risk of HIV

##### **CAUTION: can be done in routine setting, but with caution**

- Young age\*
- Previous scrotal surgery or injury
- Large varicocele or large hydrocele
- Cryptorchidism
- Unilateral undescended testicle – perform vasectomy on normal side. Then, if any sperm is present in a semen sample after 3 months, the other side must be done
- Diabetes
- Depressive disorders

##### **DELAY/REFER: until condition evaluated and/or corrected**

- Local infections: scrotal skin infection, balanitis, epididymitis or orchitis
- Active STI
- Acute systemic infection or gastroenteritis
- Filariasis; elephantiasis
- Intrascrotal mass

##### **SPECIAL: provide only in specialised clinical settings with experienced staff, equipment and back up that can handle potential problems**

- Inguinal hernia (Should be repaired first or at the same time as vasectomy)
- Bilateral undescended testicles
- Blood clotting disorders
- AIDS

\* Because men of young age are more likely to regret sterilisation later.

## Annexe 9

### Medical eligibility criteria

#### Initiating FAB (other than LAM)

FAB methods do not protect against STI and HIV. If there is a risk of STI and HIV (including during pregnancy or postpartum), the correct and consistent use of condoms should be recommended, either alone or with another contraceptive method. Women with conditions that make pregnancy an unacceptable risk should be advised that FAB methods may not be appropriate because of the relatively high failure rates.

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

**ACCEPT:** *There is no medical reason to deny a particular FAB method to a woman in this circumstance*

- Postpartum non-breastfeeding  $\geq 4$  weeks

**CAUTION:** *The method is normally provided in a routine setting, but special counselling and support may be needed to ensure correct use of the method by a woman in this circumstance.*

- Post-menarche and perimenopausal.
- Breastfeeding  $\geq 6$  weeks postpartum and after menses begin
- Post-abortion
- Chronic diseases that elevate body temperature may make basal body temperature difficult to interpret, but there is no effect on cervical secretions

**DELAY:** *Use of this method should be delayed until the condition is evaluated or corrected. Alternative temporary methods of contraception should be offered.*

- Postpartum non-breastfeeding  $< 4$  weeks
- Breastfeeding  $< 6$  weeks postpartum
- Irregular vaginal bleeding
- Vaginal discharge
- Use of drugs that affect cycle regularity, hormones and/or fertility signs (e.g. tricyclic antidepressants, anti-anxiety therapies, certain antibiotics and anti-inflammatory)
- Acute diseases that elevate body temperature may make basal body temperature difficult to interpret, but there is no effect on cervical secretions

## Annexe 10

### *Medical eligibility criteria*

#### Initiating LAM

There are no medical conditions that restrict the use of LAM, and there is no documented evidence of its negative impact on maternal health. But certain conditions or obstacles may make LAM a less suitable choice of contraception.

These include:

- certain medication, such as mood-altering drugs, lithium, reserpine, bromocriptine, certain anticoagulants, radioactive drugs, antimetabolites, cyclosporin, high dose corticosteroids;
- conditions affecting the newborn baby (e.g. certain metabolic disorders, congenital deformities of the mouth).

# APPENDICES

## Appendix 1: Acknowledgements

In order to implement the revision of the Policy and Guidelines, the Chief Directorate of Maternal Child and Women's Health secured funding from the United Nations Population Fund (UNFPA), and the Wits Reproductive Health and HIV Institute (WRHI) was tasked with assisting with the revision.

Many people and organisations contributed to the revision process. A full list of contributors is provided in the Contraception Policy and Service Delivery Guidelines (DOH 2012). The main contributors to the Contraception Clinical Guidelines are listed below:

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## Appendix 2: Pregnancy checklist

### Pregnancy checklist

#### How do I know if a client is pregnant?

Ask the following questions to determine whether or not a client is pregnant.

- Have you given birth in the last four weeks?
- Are you less than six months postpartum and fully breastfeeding and free from menstrual bleeding since you had your child?
- Did your last menstrual period start within the last seven days?
- Have you had a miscarriage or abortion in the last seven days?
- Have you abstained from sexual intercourse since your last menstrual period (menses)?
- Have you been using a reliable contraceptive method consistently and correctly?

If the client answers 'No' to all questions, pregnancy cannot be ruled out. The client should be advised to abstain or use condoms until her next menses or do a pregnancy test to exclude pregnancy.

If the client answers 'Yes' to any one of these question and is free of signs or symptoms of pregnancy, provide her with her desired method of contraception.

Source: Adapted from Farrell B. *Family Planning-Integrated HIV Services: A framework for integrating family planning and antiretroviral services*. New York: Acquire Project/Engender Health, June 2007, page 11.

## Appendix 3: Emergency contraception - bridging to on-going contraception

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- All clients eligible for emergency contraception should be offered Cu Insertion which provides the most effective emergency contraception and can be used for on-going, regular contraception.
- If client prefers emergency contraception pills, discuss regular contraception and offer to quick-start combined oral contraceptives or injectables at time of visit.
- Advise client that there is no evidence that hormones in emergency contraceptive pills will harm the foetus if pregnant.
- Take emergency contraceptive pills today and start with COC the following day.
- Do a follow-up urine pregnancy test in two weeks if injection given, or if no withdrawal bleed occurs the end of the first cycle of COC.
- If negative, continue with method
- If positive, continue with counselling

*Source: DOH Provincial Contraception Guidelines. PGWP 2010/2011 Circular H151/2012*

## Appendix 4: WHO statement: HIV and Hormonal contraception

The following is an extract from the statement issued in response to recent research which indicated a possible link between hormonal contraceptives (especially progestogen-only injectable methods) and HIV transmission and or acquisition. (Source: WHO. *Hormonal contraception and HIV*. Technical Statement. Geneva: World Health Organization, 2012.)

### Hormonal contraception and HIV: Technical statement (WHO 2012)

Following new findings from recently published epidemiological studies, the World Health Organization (WHO) convened a technical consultation regarding hormonal contraception and HIV acquisition, progression and transmission. It was recognized that this issue was likely to be of particular concern in countries where women have a high lifetime risk of acquiring HIV, where hormonal contraceptives (especially progestogen-only injectable methods) constitute a large proportion of all modern methods used and where maternal mortality rates remain high. The meeting was held in Geneva between 31 January and 1 February 2012, and involved 75 individuals representing a wide range of stakeholders. Specifically, the group considered whether the guideline Medical eligibility criteria for contraceptive use, Fourth edition 2009 (MEC) should be changed in light of the accumulating evidence. After detailed, prolonged deliberation, informed by systematic reviews of the available evidence and presentations on biological and animal data, GRADE profile summaries on the strength of the epidemiological evidence, and analysis of risks and benefits to country programmes, the group concluded that the World Health Organization should continue to recommend that there are no restrictions (MEC Category 1) on the use of any hormonal contraceptive method for women living with HIV or at high risk of HIV. However, the group recommended that a new clarification (under Category 1) be added to the MEC for women using progestogen-only injectable contraception at high risk of HIV as follows:

Some studies suggest that women using progestogen-only injectable contraception may be at increased risk of HIV acquisition, other studies do not show this association. A WHO expert group reviewed all the available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection is essential. These recommendations will be continually reviewed in light of new evidence.

### Recommendations

All evidence was reviewed carefully, and there was extensive discussion of the interpretation and implications of the results. The group considered the strength of the epidemiological and biological data, possible implications for country programmes, taking into account the need for HIV prevention, and the risk of unintended pregnancy on maternal mortality and pregnancy related morbidity. Most concern focused on the relationship between progestogen-only injectable contraception and risk of HIV acquisition in women. In considering the totality of available evidence, the group determined that currently available data neither establish a clear causal association with injectables and HIV acquisition, nor definitively rule out the possibility of an effect. The group agreed that use of hormonal contraceptives should remain unrestricted if a strong clarification was added to the MEC, which reflected the difficulties the group had with the data, the need for an enhanced message about condom use, for both male and female condoms, and other HIV prevention measures, and the need for couples to have access to as wide a range of contraceptive methods as possible. A clear recommendation was also made on the need for further research on this issue and an undertaking to keep emerging evidence under close review. Thus, the expert group determined that women at high risk of HIV or living with HIV, can continue to use all existing hormonal contraceptive methods (Category 1) (oral contraceptive pills, contraceptive injectables, patches, rings, and implants), but that a strong clarification (as detailed above) relating to the use of progestogen only injectables be added for women at high risk of HIV. Overall, women should receive correct and full information from their health-care providers so that they are in a position to make informed choices.

### Recommendations for women at high risk of HIV infection

- Women at high risk of HIV can continue to use all existing hormonal contraceptive methods without restriction.
- It is critically important that women at risk of HIV infection have access to and use condoms, male or female, and where appropriate, other measures to prevent and reduce their risk of HIV infection and sexually transmitted infections (STIs).
- Because of the inconclusive nature of the body of evidence on progestogen-only injectable contraception and risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to also always use condoms, male or female, and other preventive measures.
- Condoms must be used consistently and correctly to prevent infection.

### Recommendations for women living with HIV infection

- Women living with HIV can continue to use all existing hormonal contraceptive methods without restriction.
- Consistent and correct use of condoms, male or female, is critical for prevention of HIV transmission to non-infected sexual partners.
- Voluntary use of contraception by HIV-positive women who wish to prevent pregnancy continues to be an important strategy for the reduction of mother-to-child HIV transmission.

*For more information:* [http://www.who.int/reproductivehealth/topics/family\\_planning/hc\\_hiv/en/index.html](http://www.who.int/reproductivehealth/topics/family_planning/hc_hiv/en/index.html)

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