



National Family Planning Guidelines for Service Providers

Updated to reflect the 2009 Medical Eligibility Criteria of the World Health Organization



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DIVISION OF REPRODUCTIVE HEALTH
Revised January 2010



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FOR SERVICE PROVIDERS

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LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Virus
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral Drug
BBT	Basal Body Temperature
BCC	Behaviour Change Communication
BCS+	Balanced Counseling Strategy Plus
BMI	Body Mass Index
BP	Blood Pressure
BTL	Bilateral Tubal Ligation
CBD	Community Based Distributor
CCC	Comprehensive Care Centre
CHEW	Community Health Extension Worker
CHW	Community Health Worker
CI	Contraceptive Implant
CIC	Combined Injectable Contraceptive
CIN	Cervical Intraepithelial Neoplasm
COC	Combined Oral Contraceptive
CPR	Contraceptive Prevalence Rate
Cu-IUCD	Copper- IUCD
CVA	Cerebral Vascular Accident
CVD	Cardiovascular Disease
DMPA	Depot Medroxyprogesterone Acetate

DMPA-SC	Subcutaneous DMPA
DRH	Division of Reproductive Health
DVT	Deep Vein Thrombosis
EBF	Exclusive Breastfeeding
EC	Emergency Contraception
ECN	Enrolled Community Nurse
ECP	Emergency Contraception Pill
EE	Ethinyl Estradiol
ETG	Etonogestrel
FAM	Fertility Awareness-Based Method
FANC	Focused Antenatal Care
FHI	Family Health International
FHOK	Family Health Options Kenya
FP	Family Planning
FS	Female Sterilisation
FSH	Follicle Stimulating Hormone
GA	General Anaesthesia
GTD	Gestational Trophoblastic Disease
GTZ	Gesellschaft für Technische Zusammenarbeit
HBC	Home Based Care
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling Centre
HTSP	Healthy Timing and Spacing of Pregnancies
IDP	Internally Displaced Person
IHD	Ischaemic Heart Disease

IEC	Information Education and Counselling
IM	Intramuscular
IP	Infection Prevention
IUCD	Intrauterine Contraceptive Device
KAIS	Kenya AIDS Indicator Survey
KEMWA	Kenya Medical Women's Association
KCS	Kenya Catholic Secretariat
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
KEMWA	Kenya Medical Women Association
KEPH	Kenya Essential Package of Health
KMA	Kenya Medical Association
KMTC	Kenya Medical Training College
KNH	Kenyatta National Hospital
KOGS	Kenya Obstetrical and Gynaecological Society
KQM	Kenya Quality Model
LAM	Lactational Amenorrhoea Method
LAPMs	Long Acting and Permanent Methods
LH	Lutenizing Hormone
LMP	Last Menstrual Period
LNG	Levonorgestrel
IUS	Intrauterine System
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MEC	Medical Eligibility Criteria
MOH	Ministry of Health

MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MTCT	Mother-to-Child Transmission
NASCOP	National AIDS and STD Control Programme
NCAPD	National Coordinating Agency for Population and Development
NCK	Nurses Council of Kenya
NET-EN	Norethisterone Enthanate
NFP	Natural Family Planning
NGO	Non-governmental Organization
NHSSP	National Health Sector Strategic Plan
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRHP	National Reproductive Health Policy
NSAID	Non-steroidal Anti-inflammatory Drug
OI	Opportunistic Infection
OVC	Orphans and Vulnerable Children
Pap	Papanicolaou Stain
PC	Population Council
PE	Pulmonary Embolism
PID	Pelvic Inflammatory Disease
PMTCT	Prevention of Mother-to-Child Transmission
PNC-FP	Postnatal Family Planning
PEP	Post-exposure Prophylaxis
PHO	Public Health Officer
PHT	Public Health Technician
PI	Protease Inhibitor

POP	Progestin-only Oral Pill
POIC	Progestin-only Injectable Contraceptive
PSA	Protein-specific Antigen
PSI	Population Services International
PwD	People with Disabilities
SDM	Standard Days Method
SDP	Service Delivery Point
SLE	Systemic Lupus Erythematosus
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TB	Tuberculosis
TBA	Traditional Birth Attendant
TDM	Two-Day Method
TFR	Total Fertility Rate
TL	Tubal Ligation
USAID	United States Agency for International Development
VIA	Visual Inspection with Acetic Acid
VILI	Visual Inspection with Lugol's Iodine
VS	Vasectomy
VSC	Voluntary Surgical Sterilisation
WHO	World Health Organisation
WHO/AFRO	WHO Regional Office for Africa
WHO/RHR	WHO Department of Reproductive Health and Research

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The Family Planning Guidelines Review Committee members represented the following organizations and institutions:

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- Capacity Kenya and IntraHealth International
- Caritas Nurses Association of Kenya
- Clinical Officers Council
- Division of Reproductive Health
- EngenderHealth
- Essential Health Services
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- Family Health Options Kenya (FHOK)
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- Gesellschaft für Technische Zusammenarbeit (GTZ)
- Jhpiego, an affiliate of John Hopkins University
- Kenya Catholic Secretariat (KCS)
- Kenya Medical Association (KMA)
- Kenya Medical Training College
- Kenya Medical Women Association (KEMWA)
- Kenya Obstetrical and Gynaecological Society (KOGS)
- Kenyatta National Hospital
- National AIDS and STD Control Programme (NASCOP)
- National Coordinating Agency for Population and Development (NCPD)
- Nursing Council of Kenya (NCK)
- Population Council
- Population Services International (PSI)
- University of Nairobi, Department of Community Health
- University of Nairobi, Department of Obstetrics and Gynaecology
- World Health Organization (WHO)

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FOREWORD

The practice of family planning (FP) in Kenya has increased steadily since the early 1980s, with the contraceptive prevalence rate (CPR) for all FP methods reaching 46 percent in 2008¹. Use of modern contraceptives among married women rose from 32 percent to 39 percent between 2003² and 2008. At about the same time, Kenya witnessed a historic decline in fertility: The total fertility rate (TFR) decreased from 8.1 births per woman in 1978 to 4.6 births per woman in 2008. Indeed, Kenya's FP programme has been among the most successful in sub-Saharan Africa.

Several challenges still need to be addressed:

- Kenya still has a large unmet need for FP services, estimated at around 25 percent in 2008.
- Nearly 42 percent of Kenya's population (16.5 million) is under 15 years of age, and an estimated 100,000 young people turn 16 every year. This pattern will continue for more than a decade, and it is likely to put a heavy demand on reproductive health (RH) services, including FP.
- Despite a notable increase in the use of injectable contraceptives, the 2008 Kenya Demographic and Health Survey (KDHS) showed a decline in the utilisation of long-acting and permanent methods (LAPMs), such as intrauterine contraceptive devices (IUCDs) and both female and male sterilisation.

¹Kenya Demographic and Health Survey (KDHS) 2009.

²Kenya Demographic and Health Survey (KDHS) 2003.

- The continuing HIV/AIDS epidemic poses several serious challenges, including its impact on available resources for RH programmes, particularly FP services.

The HIV/AIDS epidemic has resulted in a large population of HIV-positive women and men who have a substantial degree of unmet need for FP, estimated at 60 percent in the 2007 Kenya AIDS Indicator Survey (KAIS)³. Therefore, it is imperative that the MOPHS, through the Division of Reproductive Health (DRH), and the Department of Obstetric Services in the MOMS, address this new challenge. Through the integration of FP and HIV services, these departments must ensure not only that all service providers are adequately trained in the special needs of HIV-positive clients, but that all service providers intensify the fight against stigma, discrimination, and other barriers so that all HIV-positive individuals have easy access to reproductive health (RH) and FP services throughout the country.

Finally, a challenge arises from the need to ensure equitable access to RH services, including FP, by all persons who need them, including groups with special needs. Providing services to persons with disabilities (PwD) and hard-to-reach populations will require special planning and approaches to improve access to quality services for all. The hard-to-reach populations include pastoral or nomadic communities, migrant workers in industries and farms, refugees, and internally displaced persons (IDPs).

It is obvious that these emerging challenges require sound and evidence-based knowledge and principles of practice.

³National AIDS and STI Control Programme, Ministry of Health, Kenya. July 2008. Kenya AIDS Indicator Survey 2007: Preliminary Report. Nairobi, Kenya.

Consequently, there is a need to review and update guidelines and manuals to ensure that service providers are informed of breaking and emerging developments. It is for this reason that a revised edition of the *National Family Planning Guidelines for Service Providers* is necessary. This fourth edition reflects the current policy and training guidelines for providing FP services, especially with regard to the integration of FP and the various RH and HIV/AIDS programmes and services. The fourth edition incorporates the most up-to-date information on Medical Eligibility Criteria (MEC) for the use of various contraceptives, and covers a wide range of medical conditions as published by the WHO (2009). These guidelines will equip FP service providers with the tools required to provide consistently high-quality, client-sensitive professional services.

These guidelines provide the most current and up-to-date information on the methods of contraception currently approved by the MOPHS and MOMS. This information covers the advantages and limitations of contraceptive methods, MEC, management of common side effects, and how to obtain contraception services. These guidelines also discuss the scope of FP service delivery: quality of care; infection prevention; counselling; client assessment; the effectiveness and safety of FP methods; and the integration of services for FP and RH, including HIV/AIDS and cancers of reproductive organs.

The guidelines are designed to help service providers maintain comprehensive care for clients who are seeking FP. In using these guidelines, it is important to remember that contraceptives are highly effective when they are used correctly; however, method failure, although rare, can occur. In the case of method failure, the client should receive counselling and referrals for appropriate care and management.

We hope that this fourth edition of the *National Family Planning Guidelines for Service Providers* will meet the expectations of all clients and provide a solid foundation on which service providers can reactivate and improve FP services. The MOPHS and MOMS also encourage health managers and policy-makers to follow these guidelines and use them as resource material in pre- and in-service training courses.

The preparation of these guidelines has been a collaborative initiative between the MOPHS, the MOMS, and other FP stakeholders who have participated at various stages in the review process. The MOPHS and MOMS gratefully acknowledge their valuable contribution.



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INTRODUCTION TO THE FOURTH EDITION

Since the launch of the third edition of *Family Planning Guidelines for Service Providers* in early 2005, several important developments have taken place in the reproductive health (RH) arena. Key among these is the recognition of the central role of family planning (FP) in the achievement of national and international goals, including the Millennium Development Goals (MDGs). This is clearly seen in the 2005 revision of MDG 5 with the addition of Target 5.B: “Achieve, by 2015, universal access to reproductive health.” Target 5.B lists two direct FP indicators, 5.3 *Contraceptive Prevalence Rate (CPR)* and 5.6 *Unmet Need for FP*. These revisions reflect a renewed interest in FP both globally and nationally, which has been supported by new strategies, such as the Repositioning Family Planning Initiative (launched by USAID⁴), whose goal of persuading clients, providers, governments, and donors to recognise that FP is critical to the health and development of the people and nations of sub-Saharan Africa. The WHO’s Regional Office for Africa (WHO/AFRO) has approved the *Framework for Accelerated Action 2005-2014* as a strategy for repositioning FP in RH services.

In Kenya, several policies and strategies have been developed with the goal of strengthening the demand for and supply of FP services. The second *National Health Sector Strategic Plan*⁵ (NHSSP II)

⁴www.usaid.gov/cgi-bin/keyword.cgi?keyword=Repositioning (Last Updated on: June 02, 2009).

⁵Ministry of Health. The Second National Health Sector Strategic Plan (NHSSP II) 2005-2010.

for the period 2005-2010 recognises RH (including FP) as an essential priority in the *Kenya Essential Package for Health* (KEPH). In addition, the *Plan* has a Community Strategy⁶ to strengthen the interface between level 1 (the community) and levels 2 (dispensary) and 3 (health centre) of the health care system. The goal of this strategy is to enhance the functional effectiveness of community health workers (CHWs), including community-based distributors (CBDs) under the supervision of community health extension workers (CHEWs). This strategy has provided a mechanism through which RH services, including FP, can be extended down to the grassroots level.

*The National Reproductive Health Policy (NRHP) 2007*⁷ lists FP among the priority RH components, and has identified priority actions that must be taken to attain national and international goals. The objectives of the revised National Reproductive Health Strategy 2009-2015 are to reduce the unmet need for FP, reduce unplanned births, and narrow the socioeconomic disparities in the Contraceptive Prevalence Rate (CPR). Among the proposed key strategies for achieving these objectives are to:

1. Increase advocacy and policy dialogue to improve the policy environment for delivering FP services, including the involvement and support of policy-makers and concerned groups and individuals.

⁶Ministry of Health/ Health Sector Reform Secretariat. Taking the Kenya Essential Package for Health to the Community: A Strategy for the Delivery of Level One Services, 2005.

⁷Republic of Kenya Ministry of Health. National Reproductive Health Policy: Enhancing reproductive health status for all Kenyans, 2007.

2. Promote the integration of FP into other RH programmes, especially in maternal and newborn health services (antenatal care, postpartum, and postnatal⁸ care services) and HIV and AIDS services⁹ (integrated FP/HIV Testing and Counselling [HTC] and prevention of mother-to-child transmission [PMTCT] of HIV).
3. Improve commodity logistics and management systems¹⁰ in order to ensure uninterrupted and affordable supplies of contraceptives, especially in the disadvantaged areas and among groups with special needs.
4. Improve quality of care and promote a balanced method mix of contraceptive options that will emphasise the use of LAPMs¹¹ in Kenya, thereby changing the current pattern of predominantly short-acting methods.

The third (2005) edition of *National Family Planning Guidelines for Service Providers* was developed against the backdrop of deteriorating RH indicators, as reported in two KDHSs (1998 and 2003). Both KDHSs showed that CPR had stagnated at around 39 percent between 1998 and 2003. The surveys also showed a pattern of declining use of two long-term methods: IUCDs and female sterilization. The provision of these methods suffers most

⁸See Mwangi A., Warren C., Koskei N., and Blanchard H. 2008. *Strengthening Postnatal Care Services Including Postpartum Family Planning in Kenya*. FRONTEERS Final Report, Washington DC, Population Council.

⁹National Reproductive Health and HIV&AIDS Integration Strategy- (Draft May 2009); and *Integration of Reproductive tract infections/ sexually transmitted infections (RTIs/STIs) services in Family Planning Services*, MOPHS/DRH.

¹⁰The National Contraceptive Commodities Security Strategy 2007-2012.

¹¹Ministry of Public Health and Sanitation/Division of Reproductive Health. Strategy for Improving the Uptake of Long-acting and Permanent Methods of Contraception in the Family Planning Program 2008-2010.

from deterioration in standards and quality of clinical services, provider attitudes, and skills. The 2008 KDHS¹² showed a decline in total fertility rate (TFR) to 4.6 births per woman, which indicates that Kenya's fertility could be returning to the declining trend that was observed from the mid-1970s to the late 1990s.

Current fertility rates differ for urban and rural areas and across the provinces in Kenya. The TFR in rural areas (5.2 births) is significantly higher than in urban areas (2.9 births). These urban-rural differences in fertility rates are evident throughout all age groups, including adolescents, which illustrates the need to address the unmet need for FP among rural adolescents and youths. There has been a sizeable increase in contraceptive use, from 39 percent of married women in 2003 using any method, to 46 percent in 2008-09. Analysis of trends by method shows that the overall CPR is fueled by the increased use of modern methods. Between 2003 and 2008, use of modern methods increased from 32 to 39 percent of married women, while use of traditional methods over the same time period actually decreased from eight to six percent of married women. Despite the overall increase in CPR, the level of unmet need for FP remains high, estimated at 25 percent.

Therefore, this fourth edition of the *National Family Planning Guidelines for Service Providers* emphasizes improving access to quality FP services. It recognises that reproductive and sexual health care, including FP information and services, is not only a key intervention for improving the health of women, men, and children but also a human right. Everyone has the right to access, choice, and the benefits of scientific progress in the selection of FP methods. A rights-based approach to the provision of contraceptives assumes

¹²Kenya Demographic and Health Survey 2008-09 Preliminary Report.

a holistic view of clients, which includes taking clients' sexual and reproductive health care needs into account and considering all appropriate eligibility criteria in helping clients choose and safely use an FP method. In addition to updating the MEC, the *National Family Planning Guidelines for Service Providers* addresses several other issues in the appropriate provision of contraceptive methods, such as task shifting, new strategies to increase access (e.g., Community Strategy [see above]); postpartum FP packages, including postabortion contraception; services for persons with special needs; integration of FP with other RH services, including HIV and AIDS and screening for cancers of reproductive organs; new contraceptive choices; and male involvement.

These guidelines have been updated to reflect the latest WHO MEC (2009) for selecting methods of contraception, particularly for the following FP methods: low-dose combined oral contraceptives (COCs), progestogen-only pills (POPs), emergency contraceptive pills (ECPs), Depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel (LNG) and etonogestrel (ETG) implants, copper intrauterine devices (Cu-IUCDs), levonorgestrel-releasing systems (LNG-IUSs), female and male sterilisation, barrier methods (male and female condoms), lactational amenorrhoea method (LAM), fertility awareness-based methods (FAM), and coitus interruptus.

The DRH plans to update the guidelines at least every five years, but important new evidence may be communicated on an as-needed basis. Besides printed copies, the guidelines will also be accessible on the DRH website (www.drh.go.ke), where interim updates will be posted.

WHAT IS NEW IN THE FOURTH REVISED EDITION?

In order to ensure familiarity for existing users, the fourth edition follows the same format and layout that was used in the third edition, overall. Some of the major changes from the 2005 version are listed below.

WHO Medical Eligibility Criteria (MEC) 2009

These guidelines have been updated to include the latest WHO MEC of 2009. The 2009 MEC contain changes that have been incorporated in these guidelines in connection with the following conditions (see in the text for details):

- Postpartum period
- Deep venous thrombosis (DVT) and pulmonary embolism (PE)
- Systemic lupus erythematosus (SLE)
- Gestational trophoblastic disease (GTD)
- Viral hepatitis
- Liver tumours
- Drug interactions

New Sections

New sections of the guidelines have been added to address the following:

- Male involvement

- Postpartum FP
- FP/HIV service integration at various levels
- Integration of screening for reproductive organ cancers in FP services
- FP services for people with special needs (e.g., PwD, displaced persons, and women near menopause)
- Strengthening FP services at Level 1 through the Community Strategy

Also, two new appendices have been added:

- “How to Identify Migraine Headaches and Auras” (Appendix 3)
- “Signs and Symptoms of Selected Serious Health Conditions” (Appendix 4)

Section Significantly Modified

The section on infection prevention has been edited to address aspects that are relevant to the provision of FP services.

Categories of Service Providers

The following changes pertain to categories of service providers:

- The Community Midwife has been added to the list of providers of FP services.
- Trained CHWs (CBDs) can, in most cases, initiate oral contraceptives in women with MEC category 2 conditions, and then refer the women to clinicians for evaluation.

Method-Specific Changes

Combined Oral Contraceptive (COC) Pills

Only monophasic pills are considered in detail. Biphasic and triphasic pills are not widely used in Kenya.

Combined Contraceptive Patches and Ring

The combined contraceptive (skin) patch (Evra) and combined contraceptive vaginal ring (NuvaRing) are mentioned in these guidelines.

More Recently Registered Methods

These guidelines contain information on more recently registered methods in Kenya, (e.g., Sino-implant 11, which is registered as ZARIN).

Timing of Initiating the Use of Progestin-Only Methods among Breastfeeding Women

This timing has been brought down to four weeks postpartum, which is in line with the updated PNC-FP orientation package that requires mothers to come for a postnatal follow-up between four and six weeks.

DMPA Reinjection Grace Period

The DMPA grace period for a repeat injection of DMPA has been extended to four weeks without requiring additional contraceptive protection. For NET-EN, the repeat injection can be given up to two weeks late without requiring additional contraceptive protection.

Management of Bleeding or Spotting while Using Progestogen-only Injectables

Two non-steroidal anti-inflammatory (NSAID) drugs, mefenamic acid and valdecoxib, were added to the currently available recommendations for women experiencing and concerned with either spotting or light bleeding, or heavy or prolonged bleeding related to the use of progestogen-only injectables.

Postpartum Timing for IUCD Insertion

The postpartum timing for the insertion of the IUCD has been clarified. The copper IUCD (Cu-IUCD) can be inserted up to 48 hours after delivery, including immediately after delivery of the placenta. If the delivery is by caesarean section, the Cu-IUCD can be placed near the fundus after delivery of the placenta before closing the uterus. In non-breastfeeding women, the LNG-IUS can be inserted as specified above for the Cu-IUCD.

Diaphragms, Cervical Caps, and Spermicides

Discussions of diaphragms, cervical caps, and spermicides have been omitted in these guidelines because: (a) the diaphragm and cervical cap have been used very little for FP purposes in Kenya, and they are not available in public health facilities here; and (b) spermicides are among the least effective methods; and (c) the use of nonoxynol-9 spermicide has been shown to increase the risk of HIV transmission.

Fertility Awareness-based Methods (FAMs)

A new fertility awareness method, the Two-day Method (TDM), has been added. The rhythm method has been omitted, leaving only the Standard Days Method (SDM) as a calendar-based method.

Chapter One

THE SCOPE OF FP SERVICE DELIVERY

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Introduction

Family planning (FP) is not only a key intervention for improving health; it is also a key strategy for the achievement of national and international development goals, including the Millennium Development Goals (MDGs). Identified as a priority component in the National Reproductive Health Policy (Ministry of Health, 2007), FP is a human right. All individuals have the right to access FP, including all FP-pertinent data regarding benefits and scientific progress made in the area of contraception. A rights-based approach to the provision of contraceptives assumes a holistic view of clients, which includes taking into account clients' sexual and RH care needs and considering all appropriate eligibility criteria and practice recommendations in helping clients choose and use an FP method.

Many factors contribute to the gap between access to FP services and the actual use of services. These factors include logistical, social, and behavioural barriers to meeting the contraceptive needs and wishes of individuals and couples, as well as obstacles that stem from the organisation of the services. Removal of the barriers that impede free access to FP information and services is critical to improving access to and coverage of FP services, especially for the youth; the unmarried; people with disabilities (PwDs); the poor; and hard-to-reach individuals, including pastoralists, refugees, and

internally displaced persons (IDPs). The major restrictive barriers include distance, cost, religion, culture, provider bias, and legal and medical regulations.

On many occasions, medical barriers such as menstrual requirements, unnecessary examinations, and the inability to visit health centres for resupply often restrict or prohibit access to contraceptive services. In addition, complicated instructions could create unnecessary obstacles to contraceptive uptake and continuance (e.g., instructions pertaining to initiating use of hormonal contraceptives and managing missed pills or injections). This fourth edition of the *National Family Planning Guidelines for Service Providers* addresses these challenges by incorporating the latest evidence from research in the instructions for administration and use of the various contraceptive methods.

Overview of Essentials of FP Service Provision

Successful delivery of FP services requires the proper coordination of activities at the various stages in the service delivery chain. The goal of these activities is to ensure the sustained demand for and predictable availability and continued use of services.

Increasing Demand for FP Services

Understanding and responding to the issues of a community is key to bridging the gap between the community's access to FP services and its actual use of those services. Service providers should develop communication strategies that facilitate advocacy for the use of FP services among the communities they wish to serve. Specifically, service providers should:

- Dispel the various myths and misconceptions related to specific methods
- Enhance the image of SDPs within the target communities
- Provide information about specific methods and services—their health benefits, potential side effects, and where they can be obtained
- Enhance community linkage and support systems (see Community Strategy below)

Increasing Availability and Utilization of Services

The Community Strategy within the National Health Sector Strategic Plan II (NHSSP) provides mechanisms for increased coverage of RH (including FP) services at the community level. Through a strengthened interface between the community (level 1) and health facilities (levels 2 and 3), the functional effectiveness of the Community Based Distributors (CBDs) and Community Health Workers (CHWs) is enhanced to be able to screen and, as appropriate, provide services or refer clients that require clinical attention. The Community Health Extension Workers (CHEWs) (See Table 1.1) serve as supervisors for CHWs, and provide the bridge between the community and health facilities. This arrangement should facilitate timely access to time-sensitive services (e.g., post-rape care, provision of ECPs, and post-HIV-exposure prophylaxis [PEP]); and provide a mechanism to ensure that most clients with category 2 conditions (see MEC below) can be initiated with COCs and POPs by the CBDs. At that stage, clients could be referred to levels 2 and 3 with minimal delay. Application of e-health technologies, especially mobile phones, should further improve the efficiency of the referral systems.

Counselling (see also page 36)

Counselling is an important prerequisite for the initiation and continuation of an FP method. Counselling is an interactive process between the service provider and client; it allows for information exchange and support, so that clients can make decisions, design a plan, and take action to improve their health.¹³ There should be no incentives or coercion to adopt FP practices or to use any particular method of contraception. If a woman is able to make an informed choice (preferably with her partner), she is more likely to be satisfied with the method she has chosen and continue to use it.

Service providers should be competent in counselling for all methods of FP and should have basic counselling skills appropriate to individual client needs. Service providers who are counselling for and providing FP might encounter clients who are coming for FP services, but have other needs as well. Adolescents, PwDs, or clients living with HIV and AIDS are examples of individuals that might require additional support. In particular, service providers should be prepared to counsel clients about sex and sexuality, fertility, childbearing, prevention of HIV and other STIs, and PMTCT of HIV.

Dual Protection

Dual protection is protection against STIs (including HIV/AIDS) and unplanned pregnancy; it can be achieved either by the consistent and correct use of condoms, or the use of one method to protect against unplanned pregnancy (e.g., a hormonal method or IUCD) and a second method to protect against STIs and HIV (a male or

¹³ *Counselling for Maternal and Newborn Health Care: A Handbook for Building Skills*. WHO 2009.

female condom). Dual protection is also implied in the avoidance of risky sex (i.e., in mutual monogamy between uninfected partners combined with a contraceptive method for those wanting to avoid pregnancy). Male involvement is crucial to the success of dual protection.

All FP clients should receive counselling about dual protection, specifically regarding the importance of the correct and consistent use of condoms. FP service providers must adopt a more positive attitude towards the condom as an effective method of contraception; and condoms must be available, affordable, and of good quality.

Provision of Contraceptives

Contraceptives should be provided to clients in accordance with approved method-specific guidelines and job-aids, by providers who have been trained to provide that method. A “supermarket” approach should be adopted; that is, clients should have a wide range of methods (method mix) from which to choose. These guidelines recognise task-shifting as an important mechanism for increasing access to services (especially at levels 1, 2, and 3), and specify which cadre of service providers may provide which method, subject to appropriate training (see Table 1:1).

Follow-up and Referral System

All clients who choose an FP method must be informed of the appropriate follow-up requirements and encouraged to return to the service provider if they have any concerns. Clients that require or choose a method that is not available at a facility must be advised where they can obtain the method. Providers should follow the established referral system.

Record Keeping

All FP providers should maintain proper records on each client and the distribution of contraceptives. Non-governmental organizations (NGOs) and the private sector also should follow the Ministry of Health's record-keeping and service provision guidelines.

Supervision

Supervision is an essential component of programme monitoring and evaluation; it ensures that guidelines are being followed and clients' needs are being met. Facilitative (supportive) supervision should be encouraged, and the supervisor should be seen as a team member who motivates staff and guarantees the rights of providers and clients. Supervision activities should extend to private-sector facilities.

Logistics

Service providers are expected to have a consistent supply of methods available in order to offer a choice to clients. The Kenya Medical Supplies Agency (KEMSA) is responsible for the procurement, storage, and distribution of contraceptive commodities through warehouses that are located at the district level. Service providers should make monthly returns to KEMSA with details on methods used and stocks remaining in order to avoid both under-stocking and over-stocking of commodities. In addition, this information enables KEMSA to develop an accurate picture of stocks in the country, thereby supporting advance planning and commodity security. Increasing adoption of e-health approaches should enhance efficiency in logistics management.

Cost Considerations for Clients

The service provider must keep in mind that provision of FP services involves both financial and opportunity costs. The cost to the client includes the time taken off work to visit the SDP; transport costs; and the direct cost of services, which includes the cost of the contraceptive commodity and the professional services that are required to obtain it. The service provider must consider the client's financial circumstances and ensure that the client is aware in advance of any ongoing expenses (e.g., returning frequently for reinjections, especially when transportation costs are significant). If the cost of a method will impose a major hardship on the client, then the provider should discuss an alternative contraceptive or a means of obtaining the desired contraceptive less expensively.

Service providers should be prepared to discuss the cost-effectiveness of various available contraceptive methods with the client. For example, some methods might be highly priced at the onset (e.g., an IUCD or contraceptive implant), but the unit cost is low over time because the duration of effectiveness is long. On the other hand, a less expensive method that has shorter duration of effectiveness and requires more frequent visits to the SDP (e.g., COCs, injectables, and condoms) will have a higher yearly unit cost. In addition to the direct costs at the SDP, there is also the cost to the national programme related to human resources, procurement of commodities and consumable supplies, logistics, and supervision and monitoring.

Categories of FP Service Providers

Many categories of people can be involved in the provision of FP services after they have received the necessary training and instruction. Similarly, FP services can be provided at various levels of the health care system (e.g., from community to tertiary care levels) and within facilities that are operated by varying providers (e.g., public, faith-based, private). However, certain standards must be met before providers can offer a particular FP method.

Table 1.1
Provision of FP methods by different categories of service providers¹

Provider/ method	Male condom	Female condom	LAM	Pills (COC, POP)	Injectable	IUCD	Implant	Standard Days Methods (SDM) ⁶	Other FAMs (Two Days Method, Ovula -tion)	Female and male steril- isation
Medical doctor	Trained medical doctors can provide full services related to the above.									
Nurse midwife	Trained nurse-midwives (including community midwives) can provide full range of services related to the above.									
Clinical officer	Adequately trained Registered Clinical Officers (RCOs) can provide full range of services related to the above ³ .									
CHW ²	CHEWs provide an interface between CHWs and SDPs.									
CHW ³	Counsel, provide	Counsel, Provide	Counsel, support, provide, refer	Counsel, provide, refer	Counsel, refer	Counsel, refer	Counsel, refer	Counsel, provide, refer	Counsel, refer	Refer
Phar- -macy ⁴	Counsel, provide	Counsel, provide	Counsel, refer	Counsel, provide	Counsel, sell, refer for injection	Counsel, sell, refer	Counsel, sell, refer	Counsel, provide, refer	Counsel, refer,	Refer
Social market -ing outlets	Promote, sell, refer	Promote, sell, refer	Promote, refer	Promote, sell	Promote, sell, refer	Promote, sell, refer	Promote, sell, refer	Counsel, provide, refer	Refer	Refer

¹ All of these are subject to appropriate training and availability of specified requirements for the particular method.

² CHWs include appropriately trained Public Health Technicians (PHT), Enrolled Community Nurses (ECN), or Community Midwives.

³ CHWs include CBDs and TBAs.

⁴ This category includes pharmacists and pharmaceutical technologists.

⁵ These are RCOs with post-basic training in reproductive health.

⁶ The SDM has been widely offered at the community level (especially in North-Eastern Kenya), as well as in pharmacies and in social marketing outlets.

For example, whereas condoms and oral contraceptives can be provided anywhere, special conditions must be fulfilled before surgical methods can be provided in a health facility. These guidelines specify the conditions for each method.

Table 1.1 shows the range of FP methods that each category of service provider working in Kenya may provide. The service providers are grouped according to their basic training into two main categories, “Clinician” and “Non-clinician.”

Values and Attitudes

Attitudes, opinions, and beliefs (including misconceptions among health service providers) can affect the way providers interact with clients. Everyone has a right to her or his own beliefs, but health care providers have a professional obligation to provide care in a respectful and non-judgmental manner. Every interaction between health care staff and clients—from the moment clients enter the health care setting until they leave the facility—affects the clients and has an impact on their:

- Willingness to trust and to share personal information and concerns
- Ability to listen and to retain important information
- Capacity to make decisions that accurately reflect their situation, needs, and concerns
- Commitment to adopt new health-related behaviours
- Willingness to continue using the facility
- Ability to be agents of positive change in the community

Strict adherence to job aids (see below) can improve interactions between the service provider and the client. A friendly and unbiased service provider who listens to a client’s concerns and gives clear and practical information about proper method use and known side effects will help the client practice contraception with success and satisfaction.

Quality of Care

Service providers at all levels—whether public, mission, or private—must strive to provide quality services based on the Kenya Quality Model (KQM),¹⁴ and other quality improvement models. Poor quality services result in fewer people using the services, less benefit to clients, and waste of health resources.

The fundamentals of care are based on clients’ rights and the staff’s needs for quality services. The “Clients’ Rights and Staff’s Needs” framework¹⁵ can be applied to service delivery.

Clients’ Rights

Information

Service providers should ensure that clients receive adequate information regarding the services provided. Clients need to be informed about the workings of the SDPs—their opening hours, services provided, and costs involved (if any). Clients interested in a particular method need to know how it works and how to obtain/use it, the importance of follow-up, information about potential side

¹⁴Ministry of Health Kenya Quality Model, 2004.

¹⁵www.acquireproject.org/.../fs-app-f-session-a-june2008.ppt.

effects and how to manage them, warning signs, and the protection from STIs (including HIV/AIDS) that it may or may not offer. Clients also need to be informed about how to switch to another method if they so desire.

Access to Services

All clients, including adolescents and PwDs, have the right to FP services at all levels of care. The SDPs should be clean, well organised, and adequately supplied with quality contraceptives. Clients should not have long waiting times and should be able to obtain the contraceptive of their choice.

Informed Choice

Clients should be counselled on the range of contraceptive options and methods that are available at all levels of care, and should be provided with accurate and complete information to enable them to make an informed decision.

Safety of Services

Service providers should adhere to infection-prevention practices and client instructions for effective use of the contraceptive method.

Privacy and Confidentiality

Care should be individualised and discrete. Clients should be protected from both auditory and visual exposure. Client information should be protected from access by anyone who is not directly involved in his or her care.

Dignity, Comfort, Expression of Opinion

Clients should be treated with dignity and friendliness. Precautions should be taken to ensure minimal discomfort. Clients' opinions should be sought and their wishes and perspectives respected.

Continuity of Care

The clients' records and follow-ups should be accurately and completely documented to ensure appropriate client management and clinical safety.

Provider Staff's Needs*Supportive Supervision and Management*

The work environment and facilitative supervisory system should be supportive and emphasise mentoring and joint problem solving. The system should help staff provide the best possible FP services.

Information, Training, and Development

Staff should be knowledgeable and skilled in providing FP, and have ongoing opportunities for training to update and maintain a high level of performance.

Supplies, Equipment, and Infrastructure

Staff should have sufficient and appropriate supplies, instruments, and logistics infrastructure to ensure uninterrupted FP services and the safety of service providers.

FP Services in the Postnatal Period

Women are much more likely to take up FP if they have made a decision before going into labour. The foundation for postpartum FP should be established during the antenatal period. FP information and services or referral should be a key component of the postnatal consultation package, along with other maternal and neonatal care services.

The MOPHS¹⁶ recommends that the postpartum woman and her infant receive at least three assessments by a skilled attendant within the first six weeks of childbirth. The first assessment should occur within 48 hours; the second within one to two weeks (preferably within the first week); and the third between four and six weeks (see **Table 1.2**). An additional visit between four and six months (i.e., when they bring their infant for Vitamin A and growth monitoring) can help women transition to another FP method if they have been practising LAM. This method, as discussed later in these guidelines, might be a good contraceptive choice for women who are exclusively breastfeeding, who have not resumed their menses, and who are less than six months postpartum. Counselling and support for early and exclusive breastfeeding (EBF) are key to the success of LAM. During the visits, the service provider should counsel clients on their return to sexual activity and fertility, and introduce them to the concept of Healthy Timing and Spacing of Pregnancies (HTSP). (See PNC-Job Aid.¹⁷)

¹⁶ Ministry of Public Health and Sanitation, Road Map for accelerating the attainment of the MDGs related to Maternal and Newborn health in Kenya. Division of Reproductive Health, December 2008.

¹⁷ MOH, JHPIEGO- ACCESS-FP, October 2006.

Table 1.2

FP counselling and services during the continuum of care from the antenatal through postpartum periods

Timing of visit or assessment ¹⁸	FP services for the mother
Antenatal	Counselling on all methods
Intrapartum	Advise on LAM Counselling on intrapartum female sterilisation (FS) and IUCD during caesarean section
Within 48 hours after birth	Focused physical exam Counselling on LAM; postpartum FS and IUCD
Within one or two weeks (preferably within one week) after birth	Focused physical exam Counselling on: LAM and HTSP, return to sexual activity, return to fertility and condoms, when to initiate FP methods based on breastfeeding status
At four to six weeks after birth	Focused physical exam For LAM users: supportive counselling on transition to other FP methods, HTSP messages, return to fertility, and sexual activity Counselling and provision of, or referral for, all other FP methods as appropriate (based on breastfeeding status, other eligibility criteria, and woman's choice); counselling on dual method use Screening for cervical cancer using visual inspection with acetic acid (VIA) and visual inspection with Lugol's iodine (VILI) screening techniques
Between four and six months	Reassess fertility desires For LAM users: supportive counselling on transition to other FP methods (preferably initiated before LAM expires) Counselling and provision of, or referral for, all other FP methods based on breastfeeding status

¹⁸Not necessarily a visit; she might still be in hospital and not all women attend all within the expected order.

Services for Adolescents and Youth

Adolescents are defined as persons between the ages of 10 and 19, and youths are defined by WHO as persons between the ages of 15 and 24. Adolescents and youth in Kenya constitute 26 percent and 36 percent, respectively, of Kenya's population,¹⁹ which has major demographic, social, and economic implications. Achievement of optimal health for the adolescent population of Kenya will increase their productive capacity to contribute to the nation's development.²⁰ Among the strategic actions that have been identified for promoting the health of adolescents and youth is to acknowledge their right to reproductive services and to increase their access to these services. Denying reproductive rights to young people has a negative effect on their general wellbeing.

Service providers can encourage adolescents and youth to use FP services by adopting positive attitudes, ensuring privacy and confidentiality, and providing convenient hours of service.²¹ Service providers need to ensure that adolescents have easy access to the range of FP services they need.

Adolescents in need of contraceptive services can safely use any of the temporary methods included in these guidelines. Adolescents living with HIV and AIDS can safely use most of the currently available methods of contraception.

¹⁹ According to the 1999 Population and Housing Census.

²⁰ Adolescent Reproductive Health and Development Policy (2003).

²¹ See Ministry of Health, Guidelines for Youth Friendly Services Provision 2006.

Services for Clients with Special Needs

FP service providers have a duty to ensure equitable access to services for all, including groups with special needs. These guidelines focus on three categories of clients that are considered to have special needs: PwDs; displaced persons, especially IDPs; and women in the perimenopausal period.

People with Disabilities (PwDs)

The WHO has estimated that disability affects 10 percent of every population. In Kenya, about five percent of the people experience some form of disability.²² The most common forms of disability are physical (35 percent), visual (30 percent), hearing (11 percent), mental (seven percent), and speech (four percent). PwDs encounter discriminatory practices and stigma within the society, as well as within health facilities. All discrimination constitutes a denial of human rights. FP service providers must ensure that women and men living with disabilities have access to counselling on sexuality and access to appropriate FP options.

Service providers need to be familiar with the special needs of PwDs and be prepared to address them with a positive attitude that is devoid of discrimination and stigma. In this regard, health facilities should be more accessible to PwDs (i.e., by providing wheelchair ramps, adjustable examination couches, and/or staff who are trained in sign language).

²²The *Preliminary Report of the Kenya National Survey for Persons with Disabilities* (March 2008).

Advice on contraception should take into account the nature of an individual's disability, her specific needs, and the nature of the method. Service providers must ensure that clients make decisions on contraceptive methods based on informed choice.

Special consideration should be given to individuals who are mentally challenged or those with psychiatric disorders²³ who might require specialised counselling or referral for treatment before they make a decision on contraception. Where the nature of the condition does not allow for informed choice (e.g., severe mental challenge), an FP method should be provided only after full discussion with all parties, including guardians or care-givers. The reproductive rights of the individual must be considered in any such decisions.

Internally Displaced Persons (IDPs)

Increasing access to RH services, including FP, for IDPs (as well as other displaced persons) needs special attention because a large proportion of them are women and children, and IDP camps are often located far from existing health facilities. RH needs of IDPs include the prevention of unintended pregnancies; the reduction of the transmission of STIs, including HIV; and the prevention and management of the consequences of sexual violence.

The *Family Planning Services* package for IDPs should include the following:

- Counselling services that ensure confidentiality and privacy as much as possible. Counselling on dual protection is particularly important for persons living in IDP situations.

²³ There is no evidence to show hormonal contraceptives increase depressive symptoms in women with depression compared to baseline or to nonusers.

- Provision of contraceptive methods, including EC, as appropriate. Some of the clients might be new, but others might already be on a method and could require management of missed doses as described for individual methods in these guidelines.
- Provision of a medical response to survivors of sexual violence, including EC and PEP anti-retroviral therapy, as appropriate.
- Referrals for other methods, if necessary.

Women Near Menopause

A woman has reached menopause when her ovaries stop releasing eggs (ovulating). Menopause usually occurs between ages 45-55, and about half of women reach menopause by age 50. A woman is assumed to have reached menopause if she has gone 12 consecutive months without having any bleeding, or if her follicle stimulating hormone (FSH) level is more than 30-40 mIU/ml.

The term *perimenopause* describes the period around the time of menopause, normally about three to five years before actual menopause sets in. Sexually active women in this age group continue to be at risk for unintended pregnancy unless they use effective methods of contraception until menopause. Perimenopausal women can use any method of FP, subject to MEC guidelines. By itself, age does not restrict a woman from using any contraceptive method.

Described below are situations that could have contraindications for specific methods:

- Women who are over 35 years of age and have migrainous headaches (with or without aura) should not receive COCs, monthly injectables, skin patches, or vaginal rings.

- Women who have migrainous headaches with aura should not receive oestrogen-containing methods, regardless of age.
- Women who are over 35 years of age and use tobacco products should not receive COCs, monthly injectables, skin patches, and/or vaginal rings.
- Women over 35 years of age are more likely to have conditions that require delay, referral, and caution for tubal ligation (female sterilisation).
- Women who have irregular cycles during their perimenopausal phase have difficulty using FAM reliably.

When Contraception Is No Longer Needed

Menstruating women can discontinue contraception when they reach menopause (i.e., if 12 months have elapsed without any noticeable bleeding). In the case of women who have been using injectable contraceptives such as DMPA and are amenorrhoeic, the following guidelines apply:

- Where hormone levels can be measured, an elevated value of FSH (more than 30-40 mIU/ml) on two occasions, one month apart, is indicative of menopause.
- Appearance of symptoms and signs associated with oestrogen deficiency, (e.g., vaginal dryness or hot flashes), are suggestive, but not an absolute indication, of menopause.
- After switching to a method that is not associated with amenorrhoea and no bleeding occurs after 12 months, menopause may be assumed.

Male Involvement

FP service providers should take the following steps to promote male involvement:

- Encourage women clients to bring their male partners with them to the clinic.
- Create male-friendly FP clinics by providing suitable waiting rooms for men and displaying information, education and communication (IEC) materials.
- Introduce male FP clinics and organise FP outreaches that target males at their places of work.
- Promote male FP methods.
- Promote research on male FP methods.
- Maintain flexible opening hours at FP clinics.
- Add services that are beneficial to men, (e.g., prostate cancer screening, and male circumcision—see integration of services section below).

Integrating FP and Other RH (Including STI and HIV/AIDS) Services

Rationale

Any client who is visiting an FP clinic could have a need for services other than FP. Service providers should take advantage of the opportunity to discuss matters related to sex and sexuality while counselling clients about FP methods. Clients should be assessed for risks of STIs, HIV, and reproductive cancers (e.g., cervical, breast, and prostate). They should be offered screening for these conditions, and counselled on dual protection (e.g., against

pregnancy, STIs, and HIV). FP service providers should play a leading role in risk assessment, screening, diagnosis, treatment, and referrals related to STIs (including HIV) and cancer. They should be able to provide clients with the necessary information and skills to assess and reduce their risk of acquiring these conditions. In addition, clients who are living with HIV and attending ART centres should be counselled and offered FP methods (or referred for such services).

Specific reasons for integrating FP services with other RH services, including STIs, HIV, and reproductive cancers services, include the following:

- Both cater to a similar clientele—women and men of reproductive age who are sexually active.
- The same providers can be oriented with minimal inputs to serve in both areas.
- FP programs are effective entry points for most of the STI, HIV, and reproductive cancer services, and vice versa. Providers in both areas should be able to assess the relevant needs of clients and to direct them accordingly.
- Integrated services are a good approach to access hard-to-reach clients, including men and youth.
- Integrated services can overcome the challenge posed by the stigma that is often associated with stand-alone services (whether HIV/AIDS or FP) and encourage more male participation.

Prevention of STIs, Including HIV/AIDS, and Cancers of Reproductive Organs in FP Settings

Visits to FP clinics offer clients an opportunity for detection and management of RTIs/STIs, and provide a mechanism for

early detection and referral for management of cancers of the reproductive organs. FP service providers are expected to integrate these services into their FP counselling. When a client is at risk of contracting or transmitting an STI or HIV, it is important that service providers strongly recommend and make accessible to the client dual protection methods—either the simultaneous use of condoms with other methods, or the consistent and correct use of condoms alone—for both pregnancy prevention and disease prevention.

- Service providers at FP clinics can help prevent the transmission of STIs and the occurrence of cancer of the reproductive organs by adopting the following practices:
- Provide clients with information on modes of transmission, especially the risk of contracting STIs and HIV/AIDS through high-risk sexual behaviour.
- Educate clients on common reproductive cancers and the importance of early detection and treatment of premalignant lesions.
- Screen clients for cervical cancer using VIA/VILI.
- Promote the use of condoms (male and female) for clients who are at risk of acquiring STIs, even if they are using other methods of FP (see dual protection, above).
- Educate all clients about:
 - High-risk sexual behaviours
 - The protective benefits of male and female condoms
 - The need to have the sex partner(s) evaluated and treated if a client is found to have an STI
 - The importance of knowing one’s HIV status and information on where HTC services may be obtained

Service providers should be familiar with specific job aids that will guide them through counselling and risk assessment for RTI and STIs (including HIV) and reproductive cancers among clients visiting FP clinics. CHWs should be trained to recognise STIs and ophthalmia neonatorum and to make appropriate referrals. Treatment of clients with STIs using syndromic approach can be done by trained FP service providers at the SDP.

All service providers offering treatment should follow contact-tracing guidelines.

Integration of FP with HIV Counselling and Testing Services

Health professionals should enable HIV-positive women to plan their pregnancies or limit the size of their families by counselling them and providing them with the appropriate contraception at the time of HIV diagnosis (and during follow-up). Clients who test positive for HIV should be referred to Comprehensive Care Centres (CCC), post-test clubs, and other appropriate services. Additional recommendations include the following:

- The *National Guidelines for Voluntary Counselling and Testing*²⁴ requires that basic FP information should be incorporated into all HIV-counselling sessions, for both HIV-positive and HIV-negative clients.
- FP services, including referrals, should be provided at the HIV testing and counselling sites, whenever possible.
- HIV/AIDS services, especially HIV testing, counselling, and referrals, should be provided at all FP SDPs whenever possible;

²⁴ MOH/NASCOP/NACC: National Guidelines for Voluntary Counseling and Testing (VCT), 2001

otherwise, FP clients with HIV/AIDS needs should be referred accordingly.

- Counsellors should emphasise dual protection as a strategy to prevent both STI/HIV transmission and unintended pregnancy through the use of condoms alone, the use of condoms combined with other methods (dual method use), or by practicing abstinence.
- Counsellors need to explain to HIV-positive clients the risk of MTCT, as well as the benefits of FP.
- Both men and women should be encouraged to use FP services to make informed decisions about pregnancy and contraceptive measures appropriate to their HIV status. Family practice service providers should be able to discuss safer ways to get pregnant (i.e., minimizing the risk of transmitting infection to both child and partner).
- FP service providers should maintain confidentiality of HIV test results and treat all FP and HIV clients with respect.

Table 1.3 presents the Essential Package for Integrated Family Planning and HIV/AIDS Services. This table shows the areas of service delivery for each level, and aspects of FP and HIV services that offer the potential for integration. Program managers should determine the essential areas that can be considered for integration, depending on their local context.

Table 1.3
Service delivery levels, service areas, and potential integrated services²⁵

Service delivery level	Services areas and service providers	Potential areas for integration of FP and HIV services
Level 1 (Community)	<p>Services: Community-based RH services, community home-based care, and OVC services</p> <p>Providers: CHWs, CHEWs, and community midwives</p>	<p>HIV services: psychosocial support; drug treatment adherence; HIV counselling and referrals; behaviour change communication</p> <p>FP services: counselling and provision of condoms and referral for other methods;²⁶ encouraging male involvement; record keeping and reporting.</p> <p>Home based care (HBC), Behaviour change communication (BCC), FP counselling, condoms and referral</p> <p>Postnatal care: PMTCT</p> <p>Post-abortion care</p>

²⁵ Extracted from National Reproductive Health and HIV&AIDS Integration Strategy (May 2009).

²⁶ CBW (who are CBDs) should be able to also provide pills to clients with HIV unless they are on ARVs, particularly a regimen containing Ritonavir.

Table 1.3

Service delivery levels, service areas, and potential integrated services (cont.)

Level 2 (Dispensary)	Services: MCH FP services; STI services; HIV counselling and testing services; HBC services Providers: Nurse/ midwife, public health technician, CHEWs	FP and HTSP counselling and provision of condoms, pills and injectables, and implants, IUCD in some facilities (subject to training) and referral for other methods. STIs: risk assessment and screening; Focused Antenatal Care (FANC) – PMTCT HIV: counselling and testing and referral; HBC outreach services. Postnatal care: PMTCT Post-abortion care Cervical cancer screening
Level 3 (Health Centre, Maternity Home, Nursing Home)	Services: MCH/ FP/HTSP services; STI services; HIV counselling and testing services; HBC services Providers: Doctor (outreach Clinical Officer Nurse/midwife Public Health Technician CHEWs	FP and HTSP counselling and provision of condoms, pills and injectables, implants, IUCD in some facilities (subject to training), BTL/VS as outreach service, referral for other methods STIs: risk assessment and screening FANC – PMTCT HIV: counselling and testing and referral; PEP HBC outreach services Postnatal care: PMTCT Post-abortion care Cervical cancer screening.

Table 1.3

Service delivery levels, service areas, and potential integrated services (cont.)

<p>Level 4 (primary hospital, sub-district hospitals, district, and mission hospitals)</p>	<p>Services:</p> <p>MCH/FP/HTSP services</p> <p>STI services</p> <p>HIV counselling and testing services, ART</p> <p>HBC services</p> <p>Providers:</p> <p>Doctors Clinical Officer Nurse/midwife Public Health Officer or Technician</p>	<p>FANC: PMTCT, ART, and OI prophylaxis, STI and TB screening</p> <p>FP /HTSP: FP counselling and provision of full range of FP methods</p> <p>CCC: FP Counselling and provision of pills, condoms, injectables, and implants.</p> <p>Postnatal care: PMTCT</p> <p>Post-abortion care</p> <p>Cervical cancer screening</p> <p>Screening for breast and prostate cancers</p>
<p>Level 5 and above (secondary, provincial, and referral hospitals)</p>	<p>Services:</p> <p>FP/ HTSP services</p> <p>STI services</p> <p>HIV counselling and testing services, ART</p> <p>Providers:</p> <p>Doctors (including specialists) Clinical Officer Nurse/midwife</p>	<p>FANC – PMTCT, ART, and OI prophylaxis, STI and TB screening</p> <p>FP /HTC – FP counselling and provision of full range of FP methods.</p> <p>CCC– FP Counselling and provision of full range of FP methods.</p> <p>Postnatal care: PMTCT</p> <p>Post-abortion care:</p> <p>Full screening, investigation, and management of cancers of reproductive organs.</p>

FP Services for People Living with HIV

Persons living with HIV and AIDS have just as much need for FP services as the non-infected persons, and there is evidence that they have an unmet need for FP. FP service providers must ensure that safe and effective contraception is accessible to women who are HIV-positive in order to help them not only plan their future childbearing patterns, but also to prevent the births of HIV-positive children. FP is among the core interventions for PMTCT. The service provider should refer to the particular sections in these FP guidelines for eligibility criteria for use of different methods by persons living with HIV and AIDS. Most of the currently available methods can be used safely by such clients.

Drug Interaction and Hormonal Contraception

Both oestrogen (e.g., in COCs and CICs) and some forms of progestin (e.g., in COCs and POPs) are metabolised in the liver. Some drugs increase or reduce the metabolism of these hormones through effects on the liver enzymes, thereby interfering with their contraceptive efficacy. Similarly, some anti-epileptics, anti-TB drugs, antifungals, and certain antiretrovirals can affect the efficacy of hormonal contraceptives (see **Table 1.4**). Use of alternative contraceptives should be encouraged for women who are long-term users of any of these drugs.

Table 1.4
Drugs that might reduce efficacy of hormonal contraceptives

Conditions	Drugs known to reduce efficacy of hormonal contraceptives
	<p>Note: DMPA effectiveness is not affected.</p> <p>When a COC is chosen, a preparation containing a minimum of 30 µg EE should be used.</p>
Epilepsy	Phenytoin, Carbamazepine, Barbiturates, Primidone, Topiramate, and Oxcarbazepine Lamotrigine
Tuberculosis	Rifampicin or rifabutin
HIV infection	<p>Some NNRTIs, such as Nevirapine, reduce hormonal levels in blood somewhat, but not enough to significantly reduce effectiveness of hormonal contraceptives. Condom use in addition to hormonal methods may be recommended.</p> <p>On the other hand, the NNRTI Efavirenz has the opposite effect of increasing hormonal levels in blood. Therefore, it does not reduce efficacy of hormonal contraceptives.</p> <p>Only ritonavir and other ritonavir-boosted protease inhibitors (PIs) (e.g., Lopinavir with Ritonavir) reduce blood hormonal levels low enough to affect hormonal contraceptives other than DMPA and NET-EN.</p> <p>Note: Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs) are classified as category 2 for COCs, POPs, Implants and NET-EN, and category 1 for DMPA.</p> <p>Ritonavir and ritonavir-boosted PIs are category 3 for pills, category 2 for implants and NET-EN, and category 1 for DMPA (see MEC, pp. 62 ff).</p>

Infection Prevention (IP) in the Clinic

The procedures to prevent infection are simple, effective, and inexpensive. Infectious organisms that are of concern in the clinic include bacteria (e.g., staphylococcus), viruses (particularly HIV and hepatitis B), fungi, and parasites. In the clinic, infectious organisms can be found in blood, body fluids with visible blood, or tissue (i.e., feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomit are not considered potentially infectious unless they contain blood). The organisms can be passed through mucous membranes or broken skin, such as cuts and scratches, needlesticks with used needles, and other puncture wounds. Infectious organisms can pass from clinics to communities when waste is not properly disposed of, or staff members do not wash their hands properly before leaving the clinic.

Infection prevention in RH and health care facilities has two primary objectives: (1) To prevent major post-operative infections when providing clinical contraceptive methods (e.g., IUCDs, injectables, implants, and male and female voluntary sterilisation); and (2) To prevent the transmission of serious diseases, such as hepatitis B and HIV, not only to clients, but also to service providers and staff

The following are recommended IP practices for service providers:

- Consider every person (client or staff) potentially infectious.
- Wash hands. This is the most practical procedure for preventing cross-contamination (person to person).
- Wear gloves before touching anything wet, such as broken skin, mucous membranes, blood, or other body fluids (secretions or excretions); soiled instruments; and other items.

- Use safe work practices, such as not recapping or bending needles, safely passing sharp instruments, and properly disposing of medical waste.
- Isolate patients only if disease is contagious and secretions (airborne) or excretions (urine or faeces) cannot be contained.
- Get vaccinated for hepatitis B virus (HBV).

Hand Washing

Hand washing might be the single most important procedure for preventing the spread of infections. Wash hands before and after examining or treating each client. Hand washing is not necessary if clients do not require an examination or treatment. Follow these recommendations:

- Use clean water and plain soap, and rub hands for at least 10-15 seconds. Be sure to clean between the fingers and under fingernails.
- Wash hands after handling soiled instruments and other items, or after touching mucous membranes, blood, or other body fluids.
- Wash hands before putting on gloves, after taking off gloves, and whenever hands get dirty.
- Wash hands when you arrive at work, after you use the toilet or latrine, and when you leave work.
- Dry hands with a paper towel or a clean, dry cloth towel **that no one else uses**, or air-dry.

Experience has shown that the most effective way to increase hand washing is to have senior health workers or other respected

individuals (role models) consistently wash their hands and encourage others to do the same.

The supervisor should work with facility management to ensure provision of soap and continued supply of clean water.

Gloves

Wear gloves in all of the following circumstances:

- When performing a procedure in the clinic or operating room
- When handling soiled instruments, gloves, and other items
- When disposing of contaminated waste items (cotton, gauze, or dressing)

A separate pair of gloves must be used for each client to avoid cross-contamination.

Cleaning and Decontamination

Wipe surfaces with chlorine solution. Wipe examination tables, bench tops, and other surfaces that come in contact with unbroken skin with 0.5% chlorine solution after each client.

Process instruments that will be reused. High-level disinfect or sterilise instruments that touch intact mucous membranes or broken skin. Sterilise instruments that touch tissue beneath the skin.

For injections, use new, auto-disable syringes and needles (where available); otherwise, use standard single-use disposable syringes and needles, which are safer than sterilising reusable syringes and needles. Dispose of single-use equipment and supplies properly and safely, and use personal protective equipment—goggles, mask, apron, and closed protective shoes—when handling wastes.

Follow these additional rules and procedures:

- Needles and syringes meant for single use must not be reused. Do not take apart the needle and syringe. Used needles should not be broken, bent, or recapped. Put used needles and syringes immediately into a puncture-proof container for disposal. If needles and syringes will not be incinerated, they should be decontaminated by flushing with a 0.5% chlorine solution before they are put into the puncture-proof container. The puncture-proof sharps container should be sealed and either burned, incinerated, or deeply buried when three-fourths full.
- Dressings and other soiled solid waste should be collected in plastic bags and, within two days, burned and buried in a deep pit. Liquid wastes should be poured down a utility sink drain, in a flushable toilet, or into a deep pit and buried.
- Clean waste containers with detergent and rinse with water.
- Remove utility gloves and clean them whenever they are dirty (and at least once every day).
- Wash hands before and after disposing of soiled equipment and waste.

Needle-Stick Injuries

Health care providers could be exposed to HIV through needle sticks or through contact with mucous membranes or broken skin, but the risk of infection is low (the average risk of HIV infection after a needle-stick exposure to HIV-positive blood is only three infections per 1,000 needle sticks). The risk after exposure of the eye, nose, or mouth to HIV-positive blood is estimated to be about one infection per 1,000 exposures.

Individuals who are most likely to get needle-stick injuries are the following:

- Surgeons, who are most often stuck by needles in theatre by accidentally sticking themselves during suturing
- Nurses, who are most often stuck by needles in hospitals, either by accidentally sticking themselves while handling hypodermic needles and syringes, or being accidentally stuck by surgeons
- Cleaning and housekeeping staff, when processing soiled instruments or disposing of waste material such as used needles

In the event of a needle-stick injury, PEP should be initiated as soon as possible as prescribed in the National guidelines for Post-Exposure Prophylaxis, and preferably within 24-36 hours after injury.

Make infection prevention a habit, and always follow universal precautions to avoid workplace exposure to HIV and other fluid-borne infections:

- Decontaminate instruments, gloves, and other objects to kill infectious organisms, such as HIV and hepatitis B, and to reduce risk for people who clean them.
- High-level disinfect or sterilise instruments or supplies that touch intact mucous membranes or broken skin, such as vaginal specula, uterine sounds, and gloves for pelvic examinations, by boiling, steaming, or using chemicals (i.e., to kill all infectious organisms except some bacterial endospores—a dormant, resistant form of bacteria).
- Sterilise to kill all infectious organisms, including bacterial endospores, with a high-pressure steam autoclave, a dry-

heat oven, chemicals, or radiation. Sterilise instruments such as scalpels and needles that touch tissue beneath the skin. If sterilisation is not possible or practical (e.g., for laparoscopes), instruments must be high-level disinfected.

- Store instruments and supplies to protect them from contamination (i.e., in a high-level disinfected or sterilised container in a clean area away from clinic traffic). The equipment used to sterilise and high-level disinfect instruments and supplies must be guarded against contamination, too.

NOTE:

Service providers must be competent in the safe handling of hypodermic needles, syringes, scissors, and other sharp items; in the withdrawal of medication from sterile multi-dose vials without contamination; and in disposal of wastes, including used syringes, needles, and gloves (see Infection Prevention Manual).

Waste Disposal

The purpose of waste disposal is to prevent the spread of infection both to the clinic personnel who handle the waste and to the local community, and also to protect those who handle waste from accidental injury.

Proper handling of contaminated wastes (i.e., items contaminated with blood or body fluid) is required to minimise the spread of infection. Proper handling refers to the following:

- Wearing utility gloves
- Transporting solid contaminated wastes to the disposal site in covered containers
- Depositing all sharp items in puncture-resistant containers
- Carefully pouring liquid waste down a utility drain or a flush toilet
- Decontaminating utility gloves and any containers used
- Washing hands

Counselling

Counselling is a vital part of RH care, and it should be a part of every interaction with the client. The role of FP counselling is to support a woman and her partner in choosing the method of FP that suits them best, and to support them in solving any problems that could arise in the process of selecting or using their chosen method.

Information Provided through Counselling

Effective counselling is important in order for a woman or couple to understand their reproductive options, choose an FP method that best meets their needs, and use the chosen method safely and effectively. Counselling also offers service providers the opportunity to dispel myths that might discourage the uptake and continued use of FP methods. These myths could be of a general nature, (e.g., that family planning encourages promiscuity or unfaithfulness) or they might target specific FP methods, as in the following:

- Use of hormonal methods causes infertility or child malformations.

- An IUCD will migrate to the brain or prick the man during intercourse.
- Vasectomies cause impotence.
- Tubal ligation interferes with libido.
- Condoms are laced with viruses.

Counselling should also include information on warning signs of the various side effects of different methods of contraception.

Who Provides Counselling

Information and counselling will commonly come from more than one source, but they should include service providers who are trained in FP counselling and who are knowledgeable about all available contraceptive methods.

Essentials of Good Counselling

A good counsellor is trained to:

- Understand and respect the client's rights.
- Earn the client's trust.
- Understand the benefits and limitations of all contraceptive methods.
- Understand the cultural and emotional factors that affect a client's (or a couple's) decision to use a particular contraceptive method.
- Encourage the client to ask questions.
- Use a nonjudgmental approach, which shows respect and consideration to the client.
- Present information in an unbiased, client-sensitive manner.

- Actively listen to the client’s concerns.
- Understand the effect of nonverbal communication.
- Recognise when she or he cannot sufficiently help a client and refer the client to someone who can.

To be effective, counselling must be based on the establishment of trust and respect between the client and counsellor. All clients have certain rights, including:

- The right to decide whether to practice FP
- The freedom to choose which method to use
- The right to privacy and confidentiality
- The right to refuse any type of examination
- The freedom to choose where to seek services

Also, while many contraceptive methods are highly effective, method failure can occur. In the case of method failure, the client should be counselled, informed about the options available, and referred for appropriate services.

The Counselling Process

When discussing contraceptive options with clients, service providers should briefly review all available methods of FP. Service providers should be aware of a number of factors about each client that could be important when selecting a method. These factors might include:

- The reproductive goals of the woman or couple (i.e., the spacing, timing, or limiting of births)

- Personal factors, including the time, travel costs, pain, or discomfort likely to be experienced
- The need for protection against STIs and HIV

Steps in FP Counseling

Several approaches to counselling have been used, including “Greet, Ask, Tell, Help, Explain, and Return” (GATHER); “Rapport, Exploration, Decision making, and Implementation of decision,” (REDI); and, more recently, The Balanced Counselling Strategy Plus (BCS+),²⁷ which incorporates counselling, screening, and services for STIs, including HIV, within routine FP consultations. In general, counselling can be divided into three phases:

- Initial counselling on arrival. The provider describes all methods and helps the client to choose the method appropriate for him or her.
- Method-specific counselling prior to and immediately following service provision. The provider instructs the client on using the method and discusses common side effects with him or her.
- Follow-up counselling during the return visit. The provider discusses with the client the use of the method, the client’s satisfaction with the method, and any problem that the client might have experienced.

Within the context of HIV/AIDS, FP counselling should address the following concerns:

- Whether the chosen FP method protects against STIs, including HIV.

²⁷ Raney, Laura, Saiqa Mullick, Wilson Liambila, Mantshi Menziwa, Doctor Khoza, and Ian Askew, 2008. *Balanced Counselling Strategy Plus User’s Guide*, part of the *Balanced Counselling Strategy Plus: A Toolkit for Family Planning Service Providers Working in High STI/HIV Prevalence Settings*. Mullick et al. Washington, DC: Population Council.

- Safety of the FP method when used by a person living with HIV/AIDS.
- Interactions between contraceptive methods and some drugs used in treatment for HIV/AIDS, including ARVs, and anti-TB drugs (see **Table 1.4**).
- Knowledge and guidance on dual protection practices, with emphasis on the consistent and correct use of condoms or abstinence as the most effective means of protection. In this regard, appropriate counselling messages depend on the HIV status of the client or couple, as suggested in **Table 1.5**.

Table 1.5

Key counselling messages based on HIV status

HIV status of couple	Key counselling messages and emphases
Concordant HIV-negative	Use effective contraception. Be faithful.
Discordant (one partner HIV-positive)	Use effective contraception. Use condoms for protection of partner. Get medical care and support.
Concordant HIV-positive	Use effective contraception. Be faithful. Use condoms to avoid infection with new HIV variants. Get medical care and support.

NOTE:

Both HIV and FP counsellors should be qualified to counsel clients about sex and sexuality, fertility desires, childbearing, and PMTCT of HIV. The possibility or reality of a positive HIV test makes HIV testing and counselling emotionally charged, and counsellors need to be able to address clients' feelings and emotions about HIV.

Recommended Job Aids

The Balanced Counselling Strategy Plus: A toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings. Population Council 2008.

Client Assessment

Objectives of Client Assessment

The primary objective of assessing clients prior to providing FP services is to determine the medical status of the client:

- Is the client pregnant?
- Does the client have any conditions that require additional evaluation or care, or that make the client ineligible to use a particular method?
- Does the client have any special problems that require further assessment, treatment, regular follow-up, or referral? Does the client require HIV/AIDS services? If so, either provide the services or arrange appropriate referral.

Client Assessment Process

This process usually can be accomplished by asking a few key questions. Unless specific problems are suspected, the safe provision of most contraceptive methods, except IUCDs and voluntary sterilisation, does not require performing a physical or pelvic examination (see below and method-specific FP checklists). Where resources are limited, it is not justifiable to require medical evaluation and or laboratory testing (e.g., blood sugar and haemoglobin) before providing modern contraceptive methods. Where demand for FP services is high, medical requirements that are not essential to the provision of specific contraceptives, act as

a major barrier to contraceptive choice and access to services. To enable clients to obtain the contraceptive method of their choice, only those procedures that are essential and mandatory for all clients in all settings should be required.

Importance of Selected Procedures for Use of FP Methods

Where health services are not readily accessible, FP clinics might present the only opportunity for a first medical examination for some women. So, FP service providers should endeavour to offer women as many services as possible through the FP clinics, including counselling, health screening examinations or tests, and referrals, as appropriate. Persons with known medical conditions, or persons in whom medical conditions are detected, should be handled as per MEC. Where resources are limited, service providers should use the following classifications to prioritise examinations and tests:²⁸

- Class A: Examination or testing is essential and mandatory in all circumstances for the safe and effective use of the contraceptive method (e.g., pelvic and genital examinations are essential before the insertion of an IUCD, or before female or male sterilisation).
- Class B: Examination or testing contributes substantially to the safe and effective use of the contraceptive method (e.g., checking a client's haemoglobin before inserting an IUCD). However, if the test or examination cannot be done, the risk of not performing it should be weighed against the benefits of making the contraceptive method available.

²⁸ Adapted from FP Global Handbook.

- Class C: Examination or testing does not contribute substantially to the safe and effective use of the contraceptive method. Many of the routine examinations and tests fall into this category.

Specific Examinations or Tests

Specific examinations and tests that the provider might perform include the following:

- Breast examination
- Pelvic and genital examination
- Cervical cancer screening
- Routine laboratory tests
- Haemoglobin test
- STI risk assessment: medical history and physical examination
- STI/HIV screening: laboratory tests
- Blood pressure screening

Whether the provider performs the examination or test depends on the MEC.

How to Be Reasonably Sure a Client Is Not Pregnant

You can be reasonably sure a client is not pregnant if at least one of the following situations applies:

- She has had a baby less than six months ago, is fully or nearly fully breastfeeding, and has had no menstrual period since then.
- She has abstained from sexual intercourse since her last menstrual period or delivery.
- She has had a baby in the last four weeks.

- Her last menstrual period started within the past seven days (or within the past 12 days if she plans to use an IUCD).²⁹
- She has had a miscarriage or abortion in the past seven days (or within the past 12 days if she plans to use an IUCD).
- She has been using a reliable contraceptive method consistently and correctly.

A pelvic examination is seldom necessary, except to rule out pregnancy of more than six weeks—measured from client’s last menstrual period (LMP)—or to screen for cervical cancer.

Pregnancy testing is not essential except in the following cases:

- The woman answered “no” to all questions on the pregnancy checklist.
- It is difficult to confirm pregnancy (i.e., it is six weeks or less from the LMP).
- The results of the pelvic examination are equivocal (e.g., the client is overweight, making it difficult to size the uterus).

In these situations, a sensitive urine pregnancy test or ultrasound scan might be helpful if it is readily available and affordable. If pregnancy testing is not available, counsel the client to use barrier methods or abstain from intercourse until her menses occurs or pregnancy is confirmed.

Client Screening for STIs and HIV

FP service providers have a responsibility to assess the risk of STIs and HIV/AIDS in all clients seeking FP services (see “Prevention of

²⁹ Unlike other methods that take time to become effective in preventing pregnancy, the IUCD is effective immediately.

STIs, including HIV/AIDS and Cancers of Reproductive Organs, in FP Settings” above). Service providers should be familiar with and competent to apply appropriate job aids, including BCS+. In most cases, effective screening does not require the use of complicated clinical or laboratory investigations.

It is essential that the service providers:

- Be knowledgeable about high-risk sexual practices and behaviours
- Be aware of the signs and symptoms of common STIs
- Be aware of the common STIs in the client population they serve, and carefully evaluate clients in whom STIs are suspected based on their medical history or physical examination findings
- Be familiar with the current protocols for diagnosis and treatment of common STIs
- Know where to refer clients that require a higher level of care
- Ensure clients are counselled on dual protection, including the use of dual methods

Service providers should ask clients the following questions to screen for risk of STIs (including HIV and AIDS):

- Do you have a vaginal discharge that is especially unusual for you?
- Do you have itching of the vagina or the genital area?
- In the previous year, have you had a genital tract problem, such as an unusual vaginal discharge, ulcers, or skin lesions in your genital area?
- In the last three months, has your sex partner been treated for a genital tract problem, such as discharge from the penis or swollen groin glands?

- Do you know whether (or think that) your sex partner has other sex partners?
- Are you or your partner in a profession that puts you at high risk (e.g., commercial sex worker, long-distance truck driver)?
- Have you had more than one sex partner in the last two months?
- Do you think that you might have an STI (including HIV and AIDS)?

Client Screening for Cancers of Reproductive Organs

FP service providers have a responsibility to assess the risk of reproductive organ cancer in all clients who are seeking FP services, and should be familiar with (and competent to apply) appropriate job aids concerning reproductive organ cancer screening. Screening for these cancers should be integrated in the counselling services, and arrangements should be made for referral of positive cases for appropriate management. **Table 1.6** shows the types of services that can be provided at the various levels of the health care system.

Table 1.6
Screening for reproductive organ cancers in clients seeking FP services

Cancer type	Level of care			
	Level 2 (dispensary, clinic)	Level 3 (health centre, nursing home)	Level 4 (district hospital)	Level 5 (general hospital and above)
Cervical	VIA/VILI; refer if positive	VIA/VILI; refer if positive	VIA/VILI, Pap smear; biopsy; refer if positive	Pap smear; biopsy; definitive treatment
Breast	History taking (family), breast palpation for lumps; refer suspicious lumps	History taking (family), breast palpation for lumps; refer suspicious lumps	History taking (family), breast palpation for lumps; mammo-gram; refer if positive	History taking (family), breast palpation for lumps; mammo-gram; biopsy; definitive treatment
Prostate	History of pattern of micturition; refer if not normal	History of pattern of micturition; rectal exam; refer if not normal	History of pattern of micturition; rectal exam and PSA; refer if not normal	History of pattern of micturition; rectal exam and PSA; definitive treatment

Method Effectiveness and Safety

The ideal contraceptive would be 100-percent effective, entirely safe and without side effects, affordable and available to everyone, instantly reversible, and easy to use without interfering with intercourse in any way. Also, it would not require any consultation with health providers. It is unlikely such a method will be found, but clients can choose a method based on the characteristics they

deem most important. Often, the two most important considerations for clients choosing a method are effectiveness and safety.

Effectiveness

Service providers should be prepared to respond to clients' questions regarding the effectiveness of various contraceptive methods. **Appendix 1** gives estimates (based on research data) of the effectiveness of the most common methods when used consistently and correctly (i.e., perfect use), as well as the effectiveness for the method when it is not used consistently and correctly, as is more typical, (i.e., user-effectiveness). In practice, the effectiveness of a method depends largely on the way it is used; this depends on the kind of counselling and the information clients receive from service providers.

Safety

No contraceptive can be said to be 100-percent safe as defined above. While contraceptive methods in general are safe for the vast majority of women, a small number of women might be exposed to some risks if they use certain methods in the presence of certain medical conditions. For example, COC use by a woman with hypertension could increase her risk of stroke or heart attack; IUCD insertion in a woman with a cervical infection could increase her risk of pelvic inflammatory disease (PID). There are also risks associated with pregnancy should the method fail.

Usually, selecting a contraceptive method requires weighing the advantages and disadvantages of specific methods based on one's individual circumstances, perceptions, and interpretations. For example, someone might ask how often pregnancy occurs with a given method. **Appendix 3** shows medical conditions that expose

a woman to increased risk as a result of unintended pregnancy. Women with these conditions should be counselled to choose contraceptive methods that are known to be most effective in typical use in preventing pregnancy.

The WHO MEC and their Application in Kenya

The WHO's expert Working Groups periodically review the latest scientific information on the safety of contraceptive methods and make recommendations on criteria for their use in different situations. In 2009, WHO published a new set of recommendations³⁰ which have been incorporated in the present guidelines.

The WHO groups medical conditions into these four categories:

1. Conditions for which there is no restriction on the use of the contraceptive method.
2. Conditions for which the advantages of using the method generally outweigh the theoretical or proven risks. In most situations, the method can be used freely, but careful follow-up might be required.
3. Conditions for which the theoretical or proven risks usually outweigh the advantages of using the method. In this case, use of the method is not usually recommended unless other more appropriate alternative methods are not available or acceptable.
4. Conditions that present an unacceptable health risk if the contraceptive method is used, (i.e., the method should not be used).

³⁰WHO Medical Eligibility Criteria for Contraceptive Use 2009. Fourth edition.

Considering that FP services in Kenya are provided in diverse settings that differ in resource availability and levels of provider training and skills, the eligibility criteria must be adapted to the local situation, taking into consideration levels of clinical judgement. Consequently, in Kenya, the above four categories should be interpreted as follows:

- Category 1. Conditions for which there is no restriction on the use of the contraceptive method. Recommendation: Use the method.
- Category 2. Conditions for which the advantages of using the method generally outweigh the theoretical or proven risks. Recommendation: Where clinical judgement is adequate, use the method with care—close follow-up might be required in some cases; but where clinical judgement is NOT adequate, initiate the method and refer the client for evaluation as soon as possible.³¹
- Category 3. Conditions for which the theoretical or proven risks usually outweigh the advantages of using the method. Recommendation: Use of method is not usually recommended unless other more appropriate alternative methods are not available or not acceptable. Where clinical judgement is adequate, help the client choose an alternative method OR use the method with extreme care (ensure access to continuous clinical services). Where clinical judgement is NOT adequate, do not use the method. Refer the client or help her choose an alternative method.
- Category 4. Conditions that present an unacceptable health risk if the contraceptive method is used. Recommendation: Do not use the method.

³¹ Note: In a few conditions only, evaluation may be necessary before initiating method.

Table 1.7 shows an adaptation of the WHO MEC categories for use in the Kenyan setting. **Table 1.8** gives an example of a woman with uncomplicated diabetes who chooses to use oral contraceptive pills. Whereas a clinician will generally provide the method to such a client, it is expected that the CHW will initiate the method and refer the client for evaluation as soon as possible.³² **Table 1.9** gives the WHO MEC categories and provider actions for female sterilisation and vasectomy.

Table 1.7

Classification of criteria for medical eligibility for temporary contraceptive methods (adapted for use in Kenya from WHO, 2008)

WHO category	Where clinical judgement is possible	Where clinical judgement is not possible or is limited (e.g., level 1, CHW)
No restriction on the use of the contraceptive method	Method can be used in any circumstances.	Method can be used in any circumstances.
Advantages of using the method generally outweigh the theoretical or proven risks.	Generally use the method, but with care. Careful follow-up may be needed in some cases.	Initiate method and refer for evaluation as soon as possible ³³ .
Theoretical or proven risks usually outweigh the advantages of using the method.	Generally advise suitable alternative. Method may be used only if no others are available or acceptable to the client and careful follow-up can be assured.	Do not use the method. Refer as needed.
4. Conditions that present an unacceptable health risk if the contraceptive method is used	Method should not be used. The condition represents an unacceptable health risk if method is used.	Do not use the method. Refer as needed.

³² CHWs should ensure that clients who come for resupply on a subsequent visit have been evaluated.

³³ In a few conditions only, evaluation may be necessary before initiating method.

Table 1.8

Example of actions by service providers in relation to MEC category 2 conditions

Situation	Clinical judgement possible	Clinical judgement not possible or is limited (e.g., CBD)
Woman with uncomplicated diabetes chooses COC pill Classification: MEC 2	Generally provide. Advise follow-up.	Initiate method then refer for evaluation as soon possible. Re-supply as needed.

Table 1.9

Classification of criteria for medical eligibility for surgical contraception methods (adapted for use in Kenya from WHO, 2008)

WHO category	Definition
Accept (Category A)	No medical reason prevents performing the procedure in a routine setting.
Caution (Category C)	The procedure can be performed in a routine setting, but with extra preparation and precautions.
Delay (Category D)	Delay the procedure. Condition must be treated and resolved before the procedure can be performed. Provide temporary methods in meantime.
Special—Refer (Category S)	Special facilities and equipment are needed for surgical procedure, including experienced surgeon and staff, general or regional (spinal) anaesthesia and specialist medical support. Otherwise Refer. Provide temporary methods in meantime.

Return to Fertility

The use of contraceptive methods, with the exception of male and female sterilisation, does not result in an irreversible change in

fertility. Also, return to fertility is prompt with all methods except for DMPA and NET-EN. For the latter methods, the median delay in a return to fertility is 10 and six months, respectively, measured from the date of the last injection, regardless of the duration of their use. Male and female sterilisation should be regarded as permanent methods, and all those considering these methods should be counselled accordingly. Other than sterilisation, no other methods directly result in permanent infertility.

Chapter Two

2

HORMONAL CONTRACEPTIVE METHODS

Chapter 2

HORMONAL CONTRACEPTIVE METHODS

Hormonal contraceptives are among the most widely used FP methods worldwide. In Kenya, nearly 75 percent of all women using modern contraceptives choose hormonal methods, with 32 percent and 61 percent choosing the Pill and injectable contraceptives, respectively.³⁴ Hormonal contraceptives are highly effective (if used correctly), safe, and convenient. They can be taken in the form of oral pills, injectables, implants, skin patches, or hormone-releasing intrauterine systems.

Hormonal contraceptives contain synthetic hormones (i.e., a combination of oestrogen and progestin, or progestin alone), which work primarily by preventing ovulation and making the cervical mucus too thick for sperm penetration. These methods are very effective, but they vary in terms of the side effects associated with their use. Methods containing oestrogen are not advisable for women who are breastfeeding because these methods can suppress lactation. On the other hand, progestin-only methods do not have this limitation, and they are ideal for breastfeeding mothers. The updated PNC-FP orientation package specifies that mothers should come for postnatal follow-up between four and six weeks. In that case, progestin-only pills can be provided to breastfeeding women from four weeks postpartum.

³⁴ KDHS 2003.

Methods containing oestrogen are not advisable for women who have risk factors for cardiovascular disease (CVD), but women with these risk factors may use progestin-only methods if careful monitoring and care is available. Some progestin-only contraceptives might increase the risk of thrombosis in women with pre-existing risk factors, although this increase is substantially less than with the combined oral contraceptive (COC) pill that contains both oestrogen and progestin.

Hormonal methods do not protect women against STIs, including hepatitis B and HIV. Therefore, at-risk individuals should use a barrier method for dual protection against pregnancy and STIs.

The following hormonal methods are commonly available in Kenya:

- Combined oral contraceptives (COCs)
- Progestin-only contraceptive pills (POPs)
- Progestin-only injectable contraceptives (DMPA, NET-EN)
- Progestin-only contraceptive implants (Jadelle, Implanon, Zarin)
- Hormone-releasing intrauterine systems (LNG20-IUS)
- Dedicated products for emergency contraception

These methods are less commonly available in Kenya:

- Combined injectable contraceptives (see Injectable Contraceptives below).
- Combined contraceptive (skin) patch (Evra), which releases a daily dose of ethinylestradiol 20µg and a progestogen (norelgestromin 150µg) transdermally when applied to the

buttocks, torso, abdomen, or upper arm. This patch prevents pregnancy by inhibiting ovulation. Its contraceptive effect compares well to COCs with similar hormone formulations in terms of safety and effectiveness.

- Combined vaginal contraceptive ring (NuvaRing), which releases a daily dose of ethinylestradiol 15 µg and a progestogen (etonogestrel 120 µg) when the ring is placed high up in the vagina. The contraceptive ring prevents pregnancy by inhibiting ovulation. Its contraceptive effectiveness compares well to COCs with similar hormone formulations in terms of safety and effectiveness.

The guidelines that follow focus primarily on the methods that are commonly available in Kenya.

Combined Oral Contraceptive Pills

Combined oral contraceptives are pills that contain synthetic oestrogen and progesterone (progestins), which are similar to the natural hormones produced in a woman's body. These are the contraceptives commonly referred to as *The Pill*. COCs must be taken daily to prevent pregnancy. Apart from contraception, COCs also have other significant health benefits. In some cases, they are used purely for these benefits, even where contraception is not required. For example, COCs are frequently prescribed to alleviate menstrual disorders, including dysmenorrhoea (painful periods), irregular cycles, and premenstrual mood syndrome. They are prescribed to treat acne or hirsutism, as well.

Over the years, the amount of the oestrogen hormone in COCs has decreased to lower and safer levels, which has decreased the

occurrence of side effects. High-dose COCs are now defined as those containing 50 micrograms or more of oestrogen, and low-dose pills contain 30-35 micrograms of oestrogen. The ultra low-dose COCs contain 20 micrograms ethinyl oestradiol. Low-dose pills are the most commonly available COCs in Kenya.

COCs are highly effective (see **Appendix 1**) in preventing pregnancy by suppressing ovulation and thickening the cervical mucus, which prevents the sperm from penetrating the cervix.

Note: None of the hormonal methods are effective once pregnancy is established. COCs do NOT disrupt an existing pregnancy.

Types of COCs

The Pill comes in packets of 21 or 28 tablets. In the 28-pill packet, only the first 21 pills are active pills (i.e., they contain hormones). The remaining seven pills are not active and usually contain iron.

The low-dose pill comes in three types:

- **Monophasic:** Each active pill contains the same amount of oestrogen and progestin. Examples include Microgynon, Lo-Femenal, Nordette, Marvelon, and Yasmin.
- **Biphasic:** The active pills in the packet contain two different dose combinations of oestrogen and progestin. For example, in a cycle of 21 active pills, 10 may contain one combination, while 11 contain another. Examples include Biphasil, Ovanon, and Normovlar.
- **Triphasic.** The active pills contain three different dose combinations of oestrogen and progestin. Out of a cycle of 21 active pills, six might contain one combination, five pills contain another combination, while 10 pills contain other

combinations of the same two hormones. Examples include Logynon and Trinordial.

NOTE:

Although Biphasic and Triphasic contraceptive pills are available in Kenya, they are not in common use. These guidelines address Monophasic pills only. The service provider should verify the type of COC that the client is taking and give her appropriate instructions.

Advantages of COCs

Contraceptive Benefits

As a method of contraception, COCs have many benefits:

- COCs are highly effective and are effective immediately when started within the first five days of the menstrual cycle (see “Limitations and Side Effects” below).
- COCs are safe for the majority of women.
- COCs are easy to use.
- COCs can be provided by trained non-clinical service providers.
- A pelvic exam is not required to initiate use if COCs.

Non-contraceptive Health Benefits

COCs offer several non-contraceptive benefits, too:

- Reduction of menstrual flow (lighter, shorter periods)
- Decrease in dysmenorrhoea (painful periods)

- Reduction of symptoms of endometriosis
- Improvement and prevention of anaemia
- Protection against ovarian and endometrial cancer
- Possible protection from symptomatic pelvic inflammatory disease
- Treatment for acne and hirsutism

Limitations and Side Effects of COCs

COCs must be taken daily to be effective, preferably at the same time each day. Effectiveness of COCs might be decreased when certain drugs are taken concurrently (e.g., certain anti-tuberculosis, anti-epileptic, and antiretroviral drugs). Clients should refer to MEC for possible interactions. Also, effectiveness could be lowered in the presence of gastroenteritis, severe vomiting, and diarrhoea. COCs offer no protection against STIs, including hepatitis B and HIV. Therefore, at-risk individuals should use condoms to ensure protection against STIs.

Use of COCs could be associated with minor and major side effects. Minor side effects include the following:

- Nausea (more common in the first three months)
- Spotting or bleeding in between menstrual periods, especially if a woman forgets to take her pills or takes them late (more common in the first three months)
- Mild headaches
- Breast tenderness
- Slight weight gain
- Mood change

- Amenorrhoea (some women see amenorrhoea as an advantage)

The following major side effects or complications are rare, but possible:

- Myocardial infarction
- Stroke
- Venous thrombosis or embolism, or both

Eligibility for Using COCs

COCs are safe and appropriate for many women. Other women might take COCs with additional monitoring or care; and some women should not take COCs at all, or only in very limited circumstances.

Women Who Can Use COCs without Restrictions (Includes MEC Category 1)

This method is recommended and acceptable with no restrictions for sexually active women of reproductive age (from menarche to menopause). It is acceptable in all of the following specific circumstances:

- Women of any parity, including women who have never given birth (the nulliparous)
- Women who want highly effective protection against pregnancy and who feel they can follow a daily routine of pill taking
- Post-abortion women (should begin within five days of abortion for immediate effectiveness)
- Women with severe dysmenorrhoea
- Women with a history of ectopic pregnancy

- Women who suffer from headaches (can initiate pill use [category 1]; but if headaches continue, eligibility changes to category 2)
- Women on antibiotics that do not affect effectiveness of COCs (see **Table 1.4**)
- Women with AIDS but not on antiretroviral (ARV) therapy, or those receiving ARVs that do not interfere with effectiveness of COCs (see **Table 1.4**)
- Women at increased risk of STIs, or with a very high individual risk of exposure to STIs
- Women at high risk of HIV, or those already infected with HIV
- Women with any of the following conditions:
 - Malaria
 - Non-pelvic TB
 - Thyroid disease
 - Iron-deficiency anaemia
 - Benign breast disease
 - Endometrial or ovarian cancer
 - Cervical ectropion, uterine fibroids without cavity distortion or endometriosis
 - Abnormal vaginal bleeding patterns: irregular, heavy, or prolonged bleeding
 - Chronic hepatitis, carrier state or mild cirrhosis
 - Vaginitis, current purulent cervicitis, chlamydia or gonorrhoea or current PID
 - Other STIs excluding HIV and hepatitis B

Women Who Can Use This Method with Extra Care (Includes MEC Category 2)

Table 2.1

Conditions that warrant extra precautions

Condition	Suggested Action	
	When clinical judgement is possible	When clinical judgement is not possible or is limited (e.g., CHW with FP training-CBD)
Women over 40 years of age	Initiate method. Age by itself does not restrict use of any method.	Initiate and re-supply method.
Women who have unexplained vaginal bleeding	Initiate method. Evaluate bleeding, including VIA/VILI or Pap Smear.	Initiate method and refer for evaluation as soon as possible. Re-supply as needed.
Women who have migraines without aura and are less than 35 years of age (See Appendix 3)	Initiate method and follow-up closely.	Initiate method and refer for evaluation as soon as possible. Re-supply if migraine is not getting more severe.
Women who suffer from obesity, i.e., weight equal or greater than 30kg/m ² Body Mass Index (BMI)	Use the method, but counsel about small risk and symptoms of thrombosis. Advise follow-up.	Initiate method and refer for evaluation as soon as possible. Re-supply as needed.
Women with gall-bladder disease who are currently asymptomatic or have been treated by cholecystectomy	Use the method, follow-up, and discontinue if symptoms develop. (Note: Women on medical treatment for this disease fall in category 3).	May initiate and re-supply as needed, especially where cholecystectomy has been performed.

Table 2.1
Conditions that warrant extra precautions (cont.)

	Suggested Action	
Condition	When clinical judgement is possible	When clinical judgement is not possible or is limited (e.g., CHW with FP training-CBD)
Women with undiagnosed breast lumps	Initiate method and evaluate the lump or refer as appropriate as soon as possible. After evaluation, women with benign breast disease fall into category 1; women with breast cancer fall into category 4, and COCs should be discontinued.	Refer for evaluation before initiating method.
Women with sickle cell disease	Initiate method and advise regular follow-up.	Initiate method and refer for evaluation as soon as possible if symptoms start. Re-supply as needed.
Women who smoke and are less than 35 years of age	Initiate method and recommend follow-up. Discontinue if symptoms or signs of CVD appear (category 3 or 4).	Initiate method and refer for evaluation as soon as possible. May re-supply as needed.
Uncomplicated diabetes (no vascular disease or diabetes of less than 20 years duration)	Generally use the method and recommend follow-up.	Initiate method and refer for follow-up, as soon as possible. Re-supply as needed.

Table 2.1

Conditions that warrant extra precautions (cont.)

	Suggested Action	
Condition	When clinical judgement is possible	When clinical judgement is not possible or is limited (e.g., CHW with FP training-CBD)
Women with superficial venous thrombosis	Initiate method and arrange for investigations to rule out deep vein thrombosis (DVT).	Initiate method and refer for follow-up as soon as possible. Re-supply as needed.
Women with a family history of DVT (first-degree relatives)	Initiate method and counsel about DVT symptoms. Warn client to come back as soon as possible if symptoms arise (Note: Women with a personal medical history of DVT fall into category 4).	Initiate method and refer for evaluation as soon as possible. Re-supply as needed.
Women who have had major surgery but without prolonged immobilization	Initiate method and arrange close follow-up. Discontinue if symptoms of DVT appear.	Initiate method and refer for evaluation as soon as possible. Re-supply as needed.
Women with Systemic Lupus Erythematosus (SLE) who have severe thrombocytopenia or who are on immunosuppressive therapy.	If woman is known to be negative for antiphospholipid antibodies, initiate method and arrange for close follow-up, including referral as appropriate. If antibodies are positive or unknown, these women fall into category 4.	Refer for evaluation before initiating method.

Table 2.1
Conditions that warrant extra precautions (cont.)

Condition	Suggested Action	
	When clinical judgement is possible	When clinical judgement is not possible or is limited (e.g., CHW with FP training-CBD)
Women with liver tumour	<p>If a woman is known to have focal nodular hyperplasia, initiate method.</p> <p>If the type of liver tumour is not known, evaluate or refer for evaluation prior to initiation. (Women with tumours other than focal nodular hyperplasia are classified as category 4).</p>	Refer for evaluation before initiating method.
Women taking ARVs other than ritonavir or ritonavir-boosted PIs	Initiate method; continue use if not on ritonavir or ritonavir-boosted protease inhibitors (use of ritonavir falls in category 3). Ensure COC preparation contains a minimum of 30 mcg EE. Advise consistent condom use to prevent HIV and to compensate for any possible reduction in COC effectiveness.	Initiate method and refer for review as soon as possible. Re-supply as needed.

Women Who Should Not Use COCs (Includes MEC Categories 3 and 4)

This section outlines circumstances that would absolutely prohibit a woman from using COCs (category 4), as well as circumstances that generally prohibit a woman from using COCs, but would allow it if these three criteria are met: no other method is available or acceptable, clinical judgement is possible, and careful follow-up can be assured (category 3). **Table 2.2** designates these conditions as either category 3 or 4.

Table 2.2

Conditions that qualify as MEC Categories 3 and 4

Condition	MEC category
Breastfeeding mothers before six weeks postpartum	4
Breastfeeding mothers before six months postpartum or non-breastfeeding mothers before three weeks postpartum	3
Women with current or history of ischaemic heart disease, complicated valvular heart disease or stroke	4
Women with a history of hypertension (where blood pressure [BP] cannot be measured), or moderate hypertension (BP is between 140/90 to 159/99)	3
Women with severe hypertension with BP equal or higher than 160/100, or hypertension complicated by vascular disease	4
Women with diabetes mellitus that is complicated by vascular disease or that is longer than 20 years in duration	4
Women who smoke (less than 15 cigarettes a day) and are 35 years of age or older	3
Women who smoke (more than 15 cigarettes a day) and are 35 years of age or older	4
Women with a history of or current breast cancer	4
Women with symptomatic gall bladder disease including those on medical treatment (who have not undergone cholecystectomy)	3

Table 2.2
Conditions that qualify as MEC Categories 3 and 4 (cont.)

Condition	MEC category
Women with current or previous history of DVT or pulmonary embolism (PE), acute DVT/PE, DVT/PE and on anticoagulant therapy, or known thrombogenic mutations	
Women who have had major surgery with prolonged immobilization	4
Women with SLE and positive (or unknown) for antiphospholipid antibodies	4
Women with acute viral hepatitis or flare	3 or 4 (depending on severity)
Women with severe (decompensated) cirrhosis	4
Women with hepatocellular adenoma or malignancy (hepatoma)	4
Women on ARV therapy who are receiving ritonavir or ritonavir-boosted protease inhibitors	3
Women on certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, or Lamotrigine)	3
Women on TB therapy who are on Rifampicin or Rifabutin	3

Method Prescription and Use

Providers can give COCs to women at any time to start later. If pregnancy cannot be ruled out, but the woman is otherwise medically eligible to receive COCs, a provider may give her one or more packs of pills to take later (i.e., when her monthly period begins). This eliminates the need for clients to return at menstruation to receive pills. While it is recommended that clients be given as

many as 13 packs of COCs during their visit, only three cycles of pills can be provided in Kenya at this time because of limited contraceptive supplies.

Providers should refer to MEC and appropriate manual and job-aids for instructions on pill usage.

For greatest effectiveness, a woman must take one pill every day and start each new pack of pills on time. Any missed pill should be taken as soon as possible. Missing pills increase the risk of pregnancy and could exacerbate some side effects.

Service providers should ensure that clients are aware of known complications that can be associated with COC use, pointing out that although these complications are rare, clients should return immediately if they experience any of the following symptoms (ACHES):

- Abdominal pains
- Chest pain or shortness of breath
- Headaches
- Eye problems
- Severe calf muscle pain

Bleeding changes are common, but not harmful. Irregular bleeding typically occurs during the first few months, followed by lighter and more regular bleeding.

Management of Common Side Effects of COCs

The following table describes how to manage some of the common side effects a client may encounter while using COCs. CBDs should

be instructed to refer all clients with side effects to a health facility for further evaluation, advice, and management by a clinician.

Table 2.3
Management of common side effects of COCs

Side effect	Management
Nausea and dizziness	<p>Assess for pregnancy.</p> <p>Reassure client that this is a common side effect in COC users and may diminish in a few months.</p> <p>Advise client to take pills with meals or at bedtime.</p>
Spotting	<p>Assess for pregnancy.</p> <p>Reassure client that irregular spotting is a harmless and common side effect in COC users, especially during the first three months.</p> <p>Assess for other illnesses if appropriate</p> <p>Encourage client to take pills at the same time each day.</p> <p>If spotting persists and is unacceptable for client, prescribe 800 mg ibuprofen three times a day for five days (or other NSAID, except aspirin). If this does not offer relief, help client to choose another FP method.</p>
Amenorrhoea	<p>Assess for pregnancy. If client is not pregnant, explain that this is one of the possible side effects of COC use.</p>

When to Start

A woman can start using COCs at any time if it is reasonably certain she is not pregnant.

- If she begins using COCs within five days after the start of her monthly bleeding, she will not need a back-up contraceptive method.

- If she begins using COCs more than five days after the start of her monthly bleeding, during the first seven days when she takes COCs she should also use a backup method.

What to Do in the Case of Missed Pill(s)

If a woman misses one or more hormonal pills, the primary advice is to take the missed pill as soon as possible and keep taking pills as usual, one each day. She may take two pills at the same time or on the same day. Specific instructions are provided in the table below.

Table 2.4
Making up missed pills with 30–35 µg oestrogen (Monophasic Pills)

Pills missed	Action and consequence
One or two days missed or started new pack one or two days late	Take a pill as soon as possible. Little or no risk of pregnancy.
Three or more days in a row missed in the first or second week, or started new pack three or more days late	Take a pill as soon as possible. Use a backup method for the next seven days. If client had sex in the past five days, she can consider ECPs. FP counselling might be needed.
Three or more days in a row missed in the third week	Take a pill as soon as possible, finish all hormonal pills in the pack (if 28-pill packs are used, throw away the 7 last non-hormonal pills) and start a new pack the next day without a break. Use a backup method for the next seven days. Also, if client had sex in the past five days, she can consider use of ECPs. FP counselling might be needed.
Severe vomiting or diarrhea	If she vomits within two hours after taking a pill, she should take another pill from her pack as soon as possible, then keep taking pills as usual. If she has vomiting or diarrhea for more than two days, follow instructions for one or two missed pills, above.

NOTE:

These instructions apply to pills containing 30–35mcg EE. For pills with 20mcg oestrogen or less, women missing one pill or starting a new pack one day late should follow the same guidance as for missing one or two 30–35mcg pills. Women missing two or more pills in a row or starting a new pack two or more days late should follow the same guidance as for missing three or more 30–35mcg pills.

Obtaining This Method

COCs can be provided at all SDPs:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing and maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)
- Level 1 (outreach, including CHWs and mobile services), pharmacies

COCs can be obtained from the following clinical providers:

- Medical doctors
- Nurses or midwives
- Clinical officers

COCs can be obtained from non-clinical providers, such as the following:

- Trained pharmacists or pharmaceutical technologists

- Trained CHEWs (nurses or midwives, Public Health Officers (PHOs), Public Health Technicians (PHTs))
- Trained CHWs, including CBDs

NOTE:

Non-clinical providers should supply no more than three cycles before a client is evaluated by a clinical provider. Women with category 3 and 4 conditions should not receive COCs from non-clinicians. Non-clinical providers can identify such clients by use of the approved MOH checklist which is based on MEC guidelines.

After review by a clinical provider, non-clinical providers may re-supply as many as six cycles per visit (subject to availability). They should ensure that the client will keep drugs in safe custody and return all unused pills to the provider if she changes to another method. However, all clients should be encouraged to attend a clinic for any problems or concerns. Providers should ensure that any unused pills that are returned by clients are destroyed to avoid re-issue to other clients.

Recommended Job Aids for Providers Dispensing COCs

- *How to Be Reasonably Sure a Client is Not Pregnant* (MOH/FHI)
- *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives* (includes questions from Pregnancy Checklist) (MOH/FHI)

- *Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use* (FHI)
- The MEC wheel (WHO)
- *A Guide to Effective and Efficient Provision of Combined Oral Contraceptives*
- *Family Planning: A Global Handbook for Providers*, (WHO: Geneva, 2008) (see section titled, “If You Miss Pills”)

Progestin-Only Pills (POPs)

As the name suggests, the Progestin-only pills (POPs) contain only one hormone—progestin; they do not contain any oestrogen. Therefore they do not cause many of the side effects associated with COC use. Progestins do not suppress production of breast milk, which makes POPs an ideal contraceptive method for breastfeeding women (see Appendix 1 for effectiveness). POPs prevent pregnancy by thickening the cervical mucus, which prevents the passage of sperm, and suppressing ovulation in about 50 percent of cycles.

Types of POPs

The brands commonly available in the public sector and the local market include Microlut, Micronor, Microval, Ovrette, Norgeston, and Noriday.

Advantages of POPs

As a method of contraception, POPs have many benefits:

- They are effective.
- They are safe (POPs have no known health risks).
- Women return to fertility immediately upon discontinuation.

- A pelvic exam is not required to initiate use.
- They can be given to a woman at any time to start later. If pregnancy cannot be ruled out, a provider can give her pills to take later, when her monthly bleeding begins.
- Taking POPs does not affect milk production or breastfeeding. It is safe for breastfeeding women and their babies.
- POPs add to the contraceptive effect of breastfeeding. Together, they provide effective pregnancy protection. Typically, pills lengthen the time during which breastfeeding women have no monthly bleeding.
- Taking POPs does not increase blood clotting.

Limitations and Side Effects of POPs

The limitations associated with POPs include the following:

- They provide a slightly lower level of contraceptive protection than COCs.
- They require strict daily pill-taking, preferably at the same time each day.
- They do not protect against STIs, including hepatitis B and HIV/AIDS. Therefore, at-risk individuals should use a barrier method to ensure protection against STIs and HIV/AIDS.
- They may lower effectiveness when certain drugs are taken concurrently (e.g., certain anti-tuberculosis, anti-retroviral and anti-epileptic drugs).

Use of POPs could be associated with some side effects, which include:

- Irregular spotting or bleeding, frequent or infrequent bleeding,

prolonged bleeding, amenorrhea (less common). Bleeding changes are common, but not harmful.

- Headaches, dizziness, nausea.
- Mood changes.
- Breast tenderness (although less common than with COCs).

Eligibility for Using POPs

Although POPs are safe and appropriate for the majority of women, eligibility depends on each individual's specific circumstances.

Women Who Can Use This Method without Restrictions (Includes MEC Category 1)

This method is acceptable for the following sexually active women of reproductive age:

- Women of any parity, including women who have never given birth (nulliparous women)
- Women immediately postpartum, if they are not breastfeeding
- Breastfeeding mothers from four weeks postpartum
- Women of any age who are cigarette smokers
- Women who cannot use COCs as a result of oestrogen-related contraindications
- Post-abortion clients (no additional protection needed if method is initiated within five days after abortion)
- Women with any of the following conditions:
 - Hypertension
 - Sickle cell disease
 - Benign breast disease

- Viral hepatitis, acute or chronic, or mild (compensated) cirrhosis
- Gestational trophoblastic disease (GTD)
- Migraine without aura
- Obese women and girls (individuals whose BMI is greater than 30 kg/m²)
- Women with a family history (first-degree relatives) of DVT or PE, and those who have had minor or major surgery without prolonged immobilization

Women Who Can Use This Method with Extra Precautions (Includes MEC Category 2)

Women who have one or more of the conditions in the following table should proceed with care if they choose to use POPs.

Table 2.5
Conditions that require extra care when taking POPs

Client's Condition	Suggested Action	
	Where clinical judgement is possible	Where clinical judgement is not possible or is limited (e.g., CBD)
History of ectopic pregnancy	Method can be used, but advise clients to report to the clinic without delay if she develops any symptoms suggestive of ectopic pregnancy.	Can initiate and re-supply method but refer for evaluation any client with abdominal pain.

Table 2.5
Conditions that require extra care when taking POPS (cont.)

Client's Condition	Suggested Action	
	Where clinical judgement is possible	Where clinical judgement is not possible or is limited (e.g., CBD)
Currently receiving ARV treatment	Method can be used unless ritanovir or ritanovir-boosted PIs are used. For all other regimens, advise condom use, which prevents HIV transmission and compensates for any possible reduction in effectiveness.	Initiate and refer for review as soon as possible. Woman should be advised to use condoms in addition to POPS at least until a clinician confirms that she is not receiving ritanovir in any form. (Note: Generally all women on ART, regardless of drug regimen, should be counselled to use condoms in addition to POPS to compensate for any possible reduction in effectiveness). Re-supply when needed.
Diagnosis of SLE with or without severe thrombocytopenia or receiving immunosuppressive therapy	Method can be used (unless they have positive or unknown antiphospholipid antibodies). Ensure regular follow-up at clinic and discontinue method use if symptoms get worse.	Refer for evaluation before initiating method.

Table 2.5

Conditions that require extra care when taking POPS (cont.)

Client's Condition	Suggested Action	
	Where clinical judgement is possible	Where clinical judgement is not possible or is limited (e.g., CBD)
Migraine without aura at any age	Method can be initiated. Ensure regular follow-up at clinic. Discontinue method use if symptoms get worse.	Initiate method, but refer client for evaluation. Re-supply as needed.
History of DVT and Pulmonary Embolism, or prolonged post-op immobilization.	Method can be initiated. Ensure regular follow-up at clinic.	CBD should initiate method, but refer for evaluation from time to time. Re-supply as needed.
Gall bladder disease: asymptomatic, medically treated, or after cholecystectomy.	Method can be initiated. Ensure regular follow-up at clinic	CBD should initiate method Refer for evaluation from time to time. Re-supply as needed.
At risk for cardiovascular disease: current and history of ischaemic heart disease and stroke (CVA)	Method can be initiated. Ensure careful evaluation in consultation with responsible clinician and regular follow-up at clinic. Discontinue if condition worsens.	CBD should initiate the method and refer for evaluation from time to time (refer immediately if woman complains of chest pain or severe headaches). Re-supply as needed.
Women with irregular, heavy or unexplained vaginal bleeding	Initiate method. Client should be evaluated (including VIA/VILI and Pap Smear).	Initiate method and refer for evaluation as soon as possible. Resupply when needed.

Table 2.5
Conditions that require extra care when taking POPS (cont.)

Client's Condition	Suggested Action	Where clinical judgement is not possible or is limited (e.g., CBD)
	Client's Condition	
Women with diabetes (including those with vascular complications) and hypertension (BP higher than 160/100).	<p>May initiate method use followed by careful evaluation in consultation with responsible clinician.</p> <p>Ensure regular follow-up at clinic.</p>	Can initiate the method and send for evaluation. Resupply when needed.
Undiagnosed breast lumps	Initiate method and evaluate the lump or refer as appropriate as soon as possible. After evaluation, women with benign breast disease fall into category 1; women with breast cancer fall into category 4 and POPS should be discontinued.	Refer for evaluation before initiating method.

Women Who Should Not Use POPS (Includes MEC Categories 3 and 4)

This section outlines circumstances that would absolutely prohibit a woman from using this method (category 4), as well as circumstances that generally prohibit a woman from using POPS, but would allow it if these three criteria are met: no other method is available or acceptable, clinical judgement is possible, and careful follow-up can be assured (category 3).

These circumstances include the following:

- Breastfeeding women less than four weeks postpartum
- Women who have breast cancer or a history of breast cancer
- Women with severe (decompensated) cirrhosis, and liver tumours (benign hepatocellular adenoma and malignancy hepatoma)
- Women with acute DVT or PE
- Women on any of the following:
 - ARV regimen with ritonavir or ritonavir-boosted protease inhibitors
 - Anticonvulsants, such as phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine
 - Rifampicin or rifabutin therapy for TB
- Women with SLE with positive or unknown antiphospholipid antibodies

Method Prescription and Use

POPs can be given to a woman at any time to start later. If pregnancy cannot be ruled out, a provider can give her pills to take later, when her monthly bleeding begins. Clients should take one pill every day. POPs must be taken at the same time every day (+/- two hours) to avoid pregnancy and minimise side effects. When one pack is finished, client should begin the next pack with no break in between packs.

An estimated 48 hours of POP use is usually required to achieve the contraceptive effects on cervical mucus.

All clients with relevant medical conditions should have regular follow-up and treatment of the medical condition while taking POPs.

A woman can initiate use of POPs under the following circumstances:

- If she is breastfeeding and has not resumed her menses, initiate any time between four weeks and six months after childbirth.
- After childbirth and she is not breastfeeding, initiate within the first four weeks (no back up method needed) or any other time if it is reasonably certain that the client is not pregnant. If initiated after four weeks postpartum, non-menstruating women and women whose menses started more than five days ago should use a back-up method (condom) or abstain for two days after initiating method use.
- After a miscarriage or abortion, initiate within the first five days after an abortion, POPs can be initiated without the need for back-up protection. After five days, a condom should be used as a back-up method for two days.
- If client is having menstrual cycles, initiate any time if it is reasonably certain that she is not pregnant. If method is initiated within five days after her menstrual cycle, client does not need to use a back-up method. Otherwise, a back-up method (i.e., condom) should be used for the next two days.

NOTES:

Pregnancies among consistent users of POPs are few, especially during breastfeeding. However, when pregnancy occurs, as many as one in every 10 pregnancies are ectopic (extra-uterine). Ectopic pregnancy is a life-threatening condition that requires immediate treatment.

For women who have had an ectopic pregnancy, POPs will not effectively prevent another pregnancy because they do not consistently suppress ovulation, but their risk for ectopic pregnancy would still be much less than for women not using contraception.

For women who have had problems with ovarian cysts, POPs will not protect against the development of future ovarian cysts.

New Problems That Might Require Switching Methods

The following problems might occur and require the client to switch methods. These problems might or might not be related to the use of this method.

Unexplained Vaginal Bleeding

This condition needs evaluation, diagnosis, and treatment as appropriate. A client with this medical condition can continue using POPs while her condition is being evaluated. If the bleeding is caused by an STI or a PID, she can continue using POPs during treatment.

Starting Treatment with Anticonvulsants, Rifampicin, Rifabutin, or Ritonavir

If these medications involve long-term treatment, a client may need help to choose a different method. If treatment is short-term, the client can use a backup method along with POPs.

Migraine Headaches (see how to identify migraine in Appendix 3)

For migraine headaches without aura, a client can continue to use POPs if she wishes. For migraine headaches with aura, a client should stop taking POPs, and the provider should help her choose a method without hormones.

Certain Serious Health Conditions

These might include DVT or PE, liver disease, ischemic heart disease or stroke, breast cancer, or SLE with positive antiphospholipid antibodies. If the condition becomes worse after the client starts using POPs, she should stop immediately. The provider should help her choose a method without hormones. Give her a backup method to use until the condition is evaluated. Refer her for diagnosis and care if she is not already under care.

Suspected Pregnancy

Assess the client for pregnancy, including ectopic pregnancy. Inform the client whether pregnancy is confirmed, and instruct her to stop taking POPs.

There are no known risks to a fetus conceived while a woman is taking POPs.

Management of Common Side Effects of POPs

CBDs should be instructed to refer all clients with side effects to a health facility for evaluation by a clinician. The table below describes how service providers should manage typical side effects that clients might encounter.

Table 2.6
Management of common side effects of POPs

Side effect	Management
Spotting	<p>Reassure client that this is common with POP use.</p> <p>Determine if client had vomiting or diarrhoea recently or is taking any drugs that might interact with POPs. If bleeding starts after several months of normal or no monthly bleeding, or there are other reasons to suspect pregnancy (e.g., client has missed pills), assess for pregnancy or other underlying conditions. Manage condition or refer client to appropriate level.</p>
Heavy or prolonged bleeding (twice as much as usual or longer than eight days)	<p>Reassure client that some POP users experience this type of bleeding, but it is generally not harmful.</p> <p>For modest relief prescribe 800 mg ibuprofen three times a day for five days (or other NSAID except aspirin).</p> <p>If no relief, suggest other type of POPs if available or help to choose another method.</p>
Amenorrhoea	<p>If client is breastfeeding, reassure her that it is normal not to have monthly bleedings while breastfeeding.</p> <p>If client is not breastfeeding, reassure her that some women stop having monthly bleeding while taking POPs.</p> <p>If there are reasons to suspect pregnancy (e.g., the woman has missed pills), assess for pregnancy. If client is pregnant, advise her to stop using POPs and refer for antenatal care (ANC). If she is not pregnant, reassure her to continue POPs.</p>

Table 2.6
Management of common side effects of POPS (cont.)

Side effect	Management
Headache or dizziness	Determine cause. If no cause is found, counsel client and recommend common painkillers. If headaches worsen while using POPS (e.g., she develops migraines with aura), help client select alternative method. Refer if need be.
Abnormal suspicious vaginal bleeding	Evaluate client by history and pelvic examination (refer as necessary), including VIA/VILI and Pap Smear. Treat or refer for treatment as necessary.
Mood changes or nervousness	Counsel client. If condition worsens, help client select alternative methods.
Severe pain in lower abdomen	Rule out ectopic pregnancy directly or through immediate referral.

What to Do in the Case of Missed Pill(s)

If a woman misses one or more hormonal pills, the primary advice is to take the missed pill as soon as possible and keep taking pills as usual, one each day. She may take two pills at the same time or on the same day. Specific instructions are provided in the table below.

CBDs should be instructed to refer clients that miss pills to a health facility for evaluation and advice by a clinician.

Table 2.7

Action to take if client misses a pill

Missed POP	Suggested action
Client's menses have returned and she misses one or more pills by more than three hours (or 12 hours in the case of the 75 µg desogestrel-containing pill), regardless of whether or not she is breastfeeding.	<p>Take one pill as soon as possible and continue taking the pills as usual, one each day.</p> <p>Abstain from sex or use a back-up method (e.g., a condom) for the next two days.</p>
Client is breastfeeding and is amenorrhoeic, and she misses one or more pills by more than three hours (or 12 hours in the case of the 75 mcg desogestrel-containing pill).	<p>Take one pill as soon as possible and continue taking the pills as usual, one each day.</p> <p>If she is less than six months postpartum, no back up method is needed.</p>

NOTE:

Inconsistent or incorrect use of pills is a major cause of unintended pregnancy. It is important to ensure POPs are taken at approximately the same time each day. An estimated 48 hours of POP use is deemed necessary to achieve the contraceptive effects on cervical mucus.

Obtaining This Method

Women can obtain POPs at all SDPs:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)

- Level 1 (outreach, including CHWs and mobile services, pharmacies, and household level CBDs)

The following clinical providers can dispense POPs to clients:

- Medical doctors
- Nurses or midwives
- Clinical officers

The following non-clinical providers can dispense POPs to clients:

- Trained pharmacists or pharmaceutical technologists, PHO, PHT, Trained CHWs, and CBDs
- Social marketing networks, shopkeepers

Non-clinical providers (pharmacists and community-based distribution workers) can:

- Initiate use of POPs and re-supply, using the approved MOH Checklist for MEC category 1 conditions.
- Except where otherwise stated, trained CHWs (CBDs) may initiate supply to clients with MEC category 2 conditions, and refer them for evaluation as soon as possible, as in the case of COCs (see above). They should not initiate supply to clients with conditions falling in category 3 or 4.
- Supply not more than three cycles to women with category 2 conditions before evaluation by a clinical provider. After evaluation non-clinical providers may re-supply up to three cycles per visit.

Service providers should ensure that clients keep the pills in safe custody and return all unused pills to the provider if they change to another method. Clients should be encouraged to attend a clinic for any problems or concerns. Providers should ensure that any unused pills returned by clients are destroyed to avoid re-issue to other clients.

Recommended Job Aids for Providers Dispensing POPs

- The MEC wheel (WHO)
- *How to Be Reasonably Sure That a Client Is Not Pregnant (MOH/FHI)*
- *Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use (FHI)*

Emergency Hormonal Contraceptive Pills (ECPs)

Description

Emergency contraception (EC) refers to the use of certain contraceptive methods by women to prevent pregnancy after unprotected sexual intercourse. Hormonal ECPs must be taken within 120 hours of intercourse, however, the sooner they are taken, the more effective they are. ECPs provide a second chance for preventing pregnancy after unprotected sex, either accidental or coerced sex, or rape.

It should be emphasised that EC should not be used on a regular basis (from month to month) because it is less effective than other methods.

Depending on the regimen used and number of hours passed since unprotected intercourse, ECPs seem to prevent between 75-95 percent of pregnancies that would otherwise have occurred. The average chance of pregnancy resulting from one act of unprotected intercourse in the second or third week of the menstrual cycle is estimated at 8 percent; after emergency oral contraception, it is 1-2 percent.

ECPs work in various ways to prevent pregnancy, largely depending on the time in a woman's cycle when she has sexual intercourse. ECPs do not cause abortion because they work before implantation. Thus ECPs prevent pregnancy by:

- Preventing or delaying ovulation
- Inhibiting or slowing down transportation of the egg and sperm through the fallopian tubes, which prevents fertilization and implantation

ECPs do not work once a woman is pregnant—women and girls who are already pregnant should not take ECPs.

The success of EC depends on the awareness and knowledge of its availability and efficacy prior to an unprotected, unplanned act. The method is only effective if potential users are aware of the method by prior information and counselling.

Types of ECPs and Dosage

Combined Oral Contraceptives (Yuzpe Method)

These contain the hormones oestrogen and progestin, and they prevent about 75 percent of expected pregnancies. Two standard dosage options are available:

- 50 mcg oestrogen pills (e.g., Eugynon): Two tablets to be taken as soon as possible after unprotected intercourse, but within 120 hours. Repeat the same dose in 12 hours. A total of four pills are required.
- 30 mcg oestrogen pills (e.g., Microgynon): Four tablets to be taken as soon as possible after unprotected intercourse, but within 120 hours. Repeat the same dose in 12 hours. A total of eight pills are required.

Progestin-only Oral Contraceptives

These dedicated ECPs contain the same progestin hormone (levonorgestrel) as some other progestin-only pills, although in higher doses. They are more effective than the combined pills, preventing up to 95 percent of expected pregnancies. Examples of brands of dedicated ECPs that are available in Kenya are Postinor 2, Pregnon, Smart lady, ECee2, and Truston2.

The standard dosage is as follows:

- One 750 mcg levonorgestrel pill to be taken as soon as possible after unprotected intercourse, but within 120 hours. Repeat the same dose in 12 hours. A total of two pills are required; or
- Two 750 mcg levonorgestrel pills to be taken as a single dose as soon as possible after unprotected intercourse, but within 120 hours. This regimen is to be preferred because it easier to comply with the one-dose regimen compared to the two-dose regimen
- Regular progestin-only pill (POP) may be used: 20 tablets taken within 120 hours after unprotected intercourse. Repeat the same dose in 12 hours. A total of 40 pills are required.

Table 2.8
Pill formulations and dosing

Pill type	Common brand names	Tablets per dose	Number of doses	Total number of tablets	Timeframe for administration of dosage
a) Combined oral contraceptive pills					
50 mcg oestrogen pills	Eugynon	2	2	4	First dose should be given within 120 hours after unprotected sex, second dose 12 hours later.
30 mcg oestrogen pills	Microgynon	4	4	8	
b) Progestin-only dedicated ECPs					
750 mcg levonorgestrel pill	Postinor 2,	1	2	2	First dose should be given within 120 hours after unprotected sex, second dose 12 hours later.
	Pregnon,	1	2		
	Smart lady,	1	2		
	Ecee2,	1	2		
	Truston2	1	2		
1.5 mg (1500mcg) levonorgestrel pill**	Postinor 2,	2	1	2	Single dose should be given within 120 hours after unprotected sex.
	Pregnon,	2	1		
	Smart lady,	2	1		
	Ecee2,	2	1		
	Truston2	2	1		

** This regimen is preferred because it improves compliance (Source: Family Planning: A Global Handbook for Providers (WHO: Geneva, 2008) and Emergency Contraception: Health Care Providers Quick Reference Guide (MOPHS, DRH 2008).

Table 2.8

Pill formulations and dosing (cont.)

Pill type	Common brand names	Tablets per dose	Number of doses	Total number of tablets	Timeframe for administration of dosage
c) Regular progestin-only pill (POP)					
Regular progestin-only pill (POP)	Microlut	20	2	40	First dose should be given within 120 hours after unprotected sex, second dose 12 hours later.

Advantages and Benefits of ECPs

EC provides emergency protection (prevents pregnancy) for about 75-95 percent of those at risk. EC can reduce unwanted pregnancies that might lead to child neglect, abandonment, and unsafe abortions (the latter are a major cause of maternal death in Kenya). EC is an important element in post-rape care and in the PMTCT of HIV, and it is an essential component of quality FP service provision. EC offers the following benefits:

- It is safe, effective, and easy to use.
- No medical examination or pregnancy tests are necessary or required.
- It can be used at any time during the menstrual cycle.

- ECPs are available in government, private, and NGO health facilities; and over the counter at pharmacies.

Limitations and Side Effects of ECPs

ECPs have the following limitations:

- ECPs are only effective if used within 120 hours of unprotected intercourse.
- They are not to be used as a regular method.
- ECPs do not protect against STIs, HIV, or AIDS.
- They can cause nausea (more common for the COC regimen).

Eligibility for Using EC

ECPs are safe and appropriate for all women. Some women might take ECPs with additional monitoring or care (see Table 2.9).

Women Who Can Use ECPs

Any woman can use ECPs, however emergency oral contraception should not be used in place of regular FP methods. It should be emphasised that ECPs contain a much higher dose of hormones compared to the regular hormonal contraceptive methods. Therefore, it should be used only in emergency situations such as the following:

- Sex took place without contraception, and the woman wants to avoid pregnancy.
- A woman has run out of oral contraceptives, has missed two or more POPs, or is more than four weeks late for her DMPA injection, and has had unprotected intercourse.
- A woman has had coerced sexual intercourse, such as rape.

- A condom has broken.
- An IUCD has come out of place.

Women Who Can Use ECPs with Some Precautions (Includes MEC Category 2)

The following table describes conditions that would warrant giving ECPs to women who generally would not be eligible for ongoing use of oral contraceptive pills according to MEC. Extra precautions should be taken in these cases.

Table 2.9
Conditions that warrant caution when using ECPs

Condition	Suggested action
Women with a history of severe cardiovascular complications (e.g., IHD, CVA, or other thromboembolic conditions)	They should be given the regimen without delay; they may need follow-up after they have taken the pills. Any delay may take them to the point beyond 120 hours when ECPs are not effective anymore.
Woman with Angina Pectoris	Pregnancy poses much more risk for these women than ECPs do.
Women suffering from migraine	The duration of the use of ECPs is less than that of the regular use of COCs or POPs and thus would be expected to have less clinical impact.
Women with severe liver disease (including jaundice)	

Women Who Should Not Use ECPs (Includes MEC Categories 3 and 4)

EC is not to be used as a regular method. Recurrent demand for ECPs is an indication that the woman requires further counselling to use other contraceptive options.

- Frequently repeated EC use may be harmful for women with conditions classified as “Who should not use” (MEC categories 3 and 4) for hormonal methods.
- ECPs should not be given to women who are known to be pregnant, but if ECPs are accidentally used by a woman who is pregnant, there is no known harm to the woman, the course of her pregnancy, or the baby.

Method Prescription and Use

EC pills should be started as soon as possible, but within 120 hours of unprotected sex. The sooner ECPs are used after unprotected intercourse, the more effective they are in preventing pregnancy. (See the section above titled “Types of ECPs and Dosage.”)

Management of Common Side Effects of ECPs

The following table outlines the management of possible side effects of ECPs.

Table 2.10
Management of ECP side effects

Side effects	Management
Nausea and vomiting (more common with COC regimen)	<p>Women should be counselled (at the time of ECP supply) about the possible occurrence of nausea. For women using combined pills or POPs for EC, an anti-emetic may be used before the pills are taken.</p> <p>If vomiting occurs within two hours, the woman should repeat the previous ECP dose orally as soon as possible.</p> <p>If she vomits again, give the dose vaginally, placing the needed dose high up in the vagina.</p>

Table 2.10

Management of ECP side effects (cont.)

Condition	Suggested action
Slight irregular bleeding	<p>Reassure women that this is not a sign of pregnancy or other condition.</p> <p>Irregular bleeding due to ECPs is common and will stop without treatment.</p>
Change in timing of next monthly bleeding	<p>Explain that it is not unusual for the next monthly bleeding to start a few days earlier or later than expected.</p> <p>Assess for pregnancy if woman's next monthly bleeding is more than one week later than expected.</p>

Obtaining This Method

Women can obtain ECPs at all SDPs:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)
- Level 1 (outreach, including CHWs, CBDs, and mobile services), pharmacies and chemists, SGBV centres, and any site with a trained provider

The following clinical providers can dispense ECPs:

- Medical doctors
- Nurses and midwives
- Clinical officers

The following non-clinical providers can dispense ECPs:

- Trained pharmacists and pharmaceutical technologists and assistants
- Trained Community Health Extension Workers (CHEWs), nurses and midwives, Public Health Officers (PHOs), Public Health Technicians (PHTs)
- Trained peer counsellors
- Trained Community Health Workers (CHWs), including Community-based Distributors (CBDs)

Starting FP Methods after EC

The following table describes contraceptive methods for use following EC.

Table 2.11
Contraceptive methods and when to begin using them after EC

Method	When to start
Condoms	Start immediately after EC; use also for dual protection.
Oral contraceptive pills (COCs, POPs)	Start the next day after second ECP dose or one to seven days after menses.
Injectables	Start within the first seven days after the start of her next period (12 days for IUCD).
IUCDs	
Implants	
Voluntary sterilization (VSC)	
Fertility-awareness methods (FAM)	

Bridging EC Users to Other RH Services

EC providers are expected to explain the mode of action of ECPs to the client, including the fact that EC is not 100-percent effective at preventing pregnancy. Unless in the case of rape (and woman is not sexually active), providers are expected to discuss the use of a regular FP method and emphasise that ECPs are for emergency use only. All providers are supposed to inform users of all FP methods available and that the FP methods (except condoms) do not protect women against STIs, including HIV/AIDS. Many women who need EC also need protection from STIs and HIV. Counselling on EC is an opportunity to discuss the risks and prevention options for STIs, including HIV/AIDS, and the need for counselling and testing services. Refer client for FP and other RH services. Women who have been raped or traumatised need also to be referred for more comprehensive medical and psychosocial care, including PEP.

Common Questions Women Have about ECPs

- *What are the effects of ECPs on my periods?* ECPs do not cause periods to start immediately. They will come around the normal time, but could be delayed or early by two or three days.
- *Can ECPs protect me for the rest of the cycle?* It will not, and any further unprotected acts put the woman at risk. Women should use a regular method of FP or condoms for further protection.
- *When can I resume or start a regular FP method after taking EC?* A woman can resume or start method, such as pills or condoms, immediately. She has to wait until her next period to begin using injections, IUCDs, and implants.
- *Can I use ECPs every time I have sex?* Women and girls should not use ECPs as a regular method. ECPs should be used only in emergency situations. ECPs are less effective than many regular FP methods.

- *What if I had sex multiple times before taking ECPs?* A woman can still use ECPs if the last time she had sex was within five days. If a woman is already pregnant from an earlier act of unprotected sex, the ECPs will not have any effect.

Recommended Job Aids

Mambo Matatu unayostahili kujua: *Three things to know about ECPs* (Population Council)

Injectable Contraceptives

Description

Injectable contraceptives contain one or two contraceptive hormones and provide protection from pregnancy for one, two, or three months (depending on the type) following an injection. About 61 percent of all women in Kenya who use modern contraceptive methods choose injectable contraceptives. The most widely used injectable methods contain only a progestin (Progestin-only Injectable Contraceptives or POIC). Less common methods are those that contain both progestin and oestrogen (Combined Injectable Contraceptives or CIC).

Progestin-Only Injectable Contraceptives (POICs)

The most widely available injectable contraceptives are the three-month-interval (13 weeks) Depo Provera (Depot-medroxyprogesterone acetate-DMPA) and the two-month-interval Noristerat (Norethisterone enanthate-NET-EN). Both of these injectables are given by an intramuscular (IM) injection. DMPA has also been formulated for sub-cutaneous injection at three-month intervals (DMPA-SC). Because they all contain only progestin,

they do not have oestrogen-associated side effects. In addition, because progestins do not suppress production of breast milk, these injectables can be used by breastfeeding women after four weeks postpartum (see Appendix 1 for effectiveness). Progestin-only injectables prevent pregnancy mainly by suppressing ovulation, but also by thickening cervical mucus and thereby preventing sperm from passing through it, and by thinning the endometrium, which could theoretically prevent implantation.

The dosages for the different injectables are provided below:

- Depot-medroxyprogesterone acetate (DMPA): Depo-ProveraR, Megestron 150mg is given every three months (13 weeks), but it can be given as much as two weeks (14 days) earlier or four weeks (28 days) later.
- Norethisterone enanthate (NET-EN): NoristeratR 200mg is given every two months, but it can be given as much as two weeks (14 days) earlier or two weeks (14 days) later.
- Depo-subQ provera 104 (also called DMPA-SC) is a new, lower-dose formulation of DMPA that is injected sub-cutaneously instead of intramuscularly. It contains 104 mg of DMPA instead of the 150 mg in the IM formulation. Like the IM formulation, DMPA-SC is given at three-month intervals.

Combined Injectable Contraceptives (CICs)

The CICs consist of a natural oestrogen plus a progestogen. They prevent pregnancy mainly through the inhibition of ovulation.

Types of CICs

Two CIC formulations, both given at four-week intervals, are on the market: Cyclofem/ Cyclo-Provera, which contains

Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg; and Mesigyna/Norigynon, which contains Norethisterone enanthate 50mg plus estradiol valerate 5mg.

In both preparations, the natural oestrogens might be less potent compared to the synthetic oestrogens of COCs. In addition, the intramuscular administration of CICs eliminates the first-pass effect of the hormones on the liver. As a result, the type and magnitude of oestrogen-related side effects associated with CICs might differ from those experienced by COC users. For many conditions, the WHO MEC has assigned categories for CICs somewhere between those for COCs and POPs.

The dosages for these injectables are provided below:

- Cyclofem/Cyclo-Provera, containing Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg, is given once every 30 days, but it could be given as much as three days earlier or later.
- Mesigyna/Norigynon, containing Norethisterone enanthate 50mg plus estradiol valerate 5mg, is given once every 30 days, but it could be given as much as three days earlier or later.

NOTE:

The guidelines below refer to progestin-only injectables.

Advantages of Injectable Contraceptives

Contraceptive Benefits

As a method of contraception, injectables have many benefits:

- They are highly effective and safe.
- A pelvic exam is not required to initiate use.
- They contain no oestrogen, so they do not have the cardiac and blood-clotting effects, which are associated with oestrogen-containing pills and injectables.
- These are long-acting methods:³⁵ each injection provides protection for two or three months, depending on the type.
- Confidentiality

Non-contraceptive Health Benefits

Other, non-contraceptive benefits include the following:

- Amenorrhea, which might be beneficial for women with (or at risk of) iron-deficiency anaemia
- Decrease in sickle cell crises
- Reduction of symptoms of endometriosis
- Protection against endometrial cancer
- Protection against uterine fibroids
- Possible protection from symptomatic pelvic inflammatory disease
- Possible prevention of ectopic pregnancy

³⁵ Technically injectables are not part of a long-acting methods group (which includes IUCDs, Implants, and sterilization), but they act longer than pills.

Limitations and Side Effects of Injectable Contraceptives

The limitations associated with Injectable contraceptives include the following:

- Return of fertility may be delayed for about four months or longer after discontinuation.
- They offer no protection against STIs, including hepatitis B and HIV; individuals at risk for these should use condoms in addition to injectable contraceptives.
- This method is provider-based, so a woman must go to a health care facility regularly.
- Use of injectables could be associated with the following side effects:
 - Menstrual changes, such as:
 - irregular bleeding
 - heavy and prolonged bleeding
 - light spotting or bleeding
 - amenorrhea, especially after one year of use
 - Weight gain
 - Headache
 - Dizziness
 - Mood swings
 - Abdominal bloating
 - Decrease in sex drive

Eligibility for Using Injectable Contraceptives

Injectable contraceptives are safe and appropriate for the majority of women. Other women might use them with additional monitoring or care; and a few women should not use injectable contraceptives at all, or only in very limited circumstances.

Women Who Can Use Injectables without Restrictions (Includes MEC Category 1)

Both DMPA and NET-EN are acceptable for all women between the ages of 18-45 with established menses who fall into MEC category 1:

- Women who had children or have never given birth (nulliparous women)
- Women who want highly effective, long-term protection against pregnancy
- Mothers who are breastfeeding (after four weeks postpartum)
- Mothers who are not breastfeeding (immediate postpartum)
- Women with fibroids, endometrial cancer, or benign breast disease
- Women who cannot remember to take the pill everyday
- Post-abortion clients
- Women with anaemia, sickle cell disease, and thyroid disease
- Women with STIs and PID
- Women with family history (first-degree relatives) of DVT or PE and those that have had minor or major surgery without prolonged immobilization
- Women with gestational trophoblastic disease

- Women with viral hepatitis (acute/flare, carrier, or chronic) and those with mild (compensated) cirrhosis.
- Women with obesity (i.e., BMI greater than 30 kg/m²)

Women in the following situations can use DMPA, but not NET-EN, which falls under MEC category 2:

- Women receiving anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, or lamotrigine)
- Women with HIV and AIDS and who are receiving treatment with NRTIs, NNRTIs, and Ritonavir-boosted protease inhibitors.
- Women receiving Rifampicin and Rifabutin for TB.

Women Who Can Use Progestin-Only Injectables, with Extra Precautions (Includes MEC Category 2)

Clinicians may provide injectable contraceptives to women with conditions that put them in category 2, but they may need to follow up with these women, evaluate them periodically, and make referrals, as appropriate.

Category 2 conditions are as follows:

- Women who are younger than 18 or older than 45.
- Decreased bone density
- Heavy or irregular vaginal bleeding patterns. Consider evaluating for an underlying condition, such as cervical cancer, after method initiation.
- CIN or cervical cancer awaiting treatment. The treatment might render the woman sterile.
- Migraine without aura.

- History of DVT or PE, current DVT or PE and established on anticoagulant therapy, known thrombogenic mutations and hyperlipidaemias, or major surgery with prolonged immobilization.
- SLE with negative antiphospholipid antibodies, on immunosuppressive treatment and those without severe thrombocytopenia. If a woman has positive or unknown antiphospholipid antibodies, she would fall into category 3.
- History of hypertension, adequately controlled BP, or BP between 140/90 and 159/99.
- Diagnosis of AIDS and under treatment with ARVs, including ritonavir. This applies to NET-EN only; DMPA is category 1.
- Rifampicin or rifabutin for TB. This applies to NET-EN only; DMPA is category 1.
- Anticonvulsants such as phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine. This applies to NET-EN only; DMPA is category 1.
- Gall bladder disease, symptomatic or asymptomatic.
- Uncomplicated diabetes.
- Focal nodular hyperplasia (benign liver tumour).

Women Who Should Not Use Progestin-only Injectable Contraceptives (MEC Categories 3 and 4)

NOTE:

For category 3 only in cases where clinical judgement is possible, clinicians may provide injectable contraceptives if no other method is available or acceptable to the client and careful follow-up can be assured. Otherwise, as in the case of category 4 conditions, injectable contraceptives should not be used.

Table 2.12
Conditions that qualify as MEC categories 3 or 4

Condition	MEC category
Breastfeeding women less than four weeks postpartum	3
Women with severe liver cirrhosis	3
Women with benign (Hepatocellular adenoma) or malignant liver tumour (hepatoma)	3
Women with unexplained abnormal vaginal bleeding before evaluation	3
Women with multiple risk factors for arterial cardiovascular disease (various combinations of older age, smoking, diabetes, and hypertension)	3
Women with a current case of or history of ischaemic heart disease	3
Women with diabetes mellitus complicated by vascular disease	3
Women whose blood pressure is equal to or higher than 160/100, and women with vascular disease	3
Women with a history of CVA or stroke	3

Table 2.12

Conditions that qualify as MEC categories 3 or 4 (cont)

Condition	MEC category
Women with current (acute) DVT or PE	3
Women with SLE and positive or unknown antiphospholipid antibodies or severe thrombocytopenia, or both	3
Women with a current diagnosis or history of breast cancer	4 (current) 3 (history)

Management of Common Side Effects of Injectable Contraceptives

The following table outlines the management of some possible side effects that can be associated with taking injectable contraceptives.

Table 2.13
Management of side effects of injectable contraceptives

Side effects	Management
<p>Spotting or light bleeding between monthly periods</p>	<p>Spotting or light bleeding is common during use of injectable contraceptives, particularly during the first 6-8 months of use. It is not harmful.</p> <p>In women with persistent spotting or bleeding, and in women with bleeding after a period of amenorrhoea, assess for pregnancy or incomplete abortion; exclude gynaecological problems when clinically warranted, such as infections, uterine fibroids, and cervical polyps; and treat according to the cause or refer.</p> <p>If client is pregnant, stop the injectable, counsel, reassure, and refer accordingly. If STI or PID is diagnosed, client can continue the method while receiving treatment. Counsel on abstinence or condom use.</p> <p>If no serious gynaecologic problems are found and client finds the bleeding unacceptable, short-term treatment with ibuprofen or other nonsteroidal anti-inflammatory drugs (except aspirin) might be helpful (e.g., ibuprofen, mefenamic acid, or valdecoxib).</p> <p>If client decides to discontinue the injectable, help her choose another method.</p>

Table 2.13

Management of side effects of injectable contraceptives (cont.)

Side effects	Management
<p>Heavy or prolonged bleeding (lasting more than eight days or twice as long as her usual menstrual period)</p>	<p>Explain that heavy or prolonged bleeding is common in women using injectables, particularly during the first 6-8 months of use.</p> <p>If heavy or prolonged bleeding persists, evaluate as above.</p> <p>If a gynaecologic problem is identified, treat or refer client for care.</p> <p>If the bleeding becomes a threat to the health of the woman, or is not acceptable to her, discontinue the injectable. Help her choose another method.</p> <p>To prevent anaemia, provide haematinics and advice on diet. In the interim, short-term treatment with either ethinylestradiol (or COCs) or nonsteroidal anti-inflammatory drugs other than aspirin, might be helpful.</p> <p>If no cause of the bleeding is obvious and it is less than 8 weeks from the last dose (injection), one or more of the following approaches may be tried:</p> <ul style="list-style-type: none"> • NSAIDs such as Ibuprofen and Mefenamic acid (Ibuprofen 400-800 mg tds for 7-14 days) • COC, one active pill daily up to 1-3 cycles (or 50mcg pill where bleeding is continuing), or ethinyl oestradiol 30-50 mcg daily for 7-21 days • Injection Estradiol cypronate 5mg IM or combined injectable contraceptive <p>However, these approaches may be short-term or no relief at all.</p> <p>If client presents when it is 8 weeks or more from the last dose, give another dose of injectable contraceptive and set a new return date based on the current injection. This schedule could speed up the development of amenorrhea, which would stop the bleeding.</p>

Table 2.13
Management of side effects of injectable contraceptives (cont.)

Side effects	Management
Amenorrhoea	<p>By the end of the first year on injectables, amenorrhea develops in the majority of clients. Normally amenorrhoea does not require any medical treatment. Counselling and reassurance are sufficient. If in doubt, assess for pregnancy, and manage as above.</p> <p>If client is bothered by lack of menses despite reassurance, discontinue injectable, and help her choose another method.</p>
Headache or dizziness	<p>If mild, treat with analgesics and reassure.</p> <p>Check blood pressure. If it is normal and headaches persist, discontinue injectable and refer for evaluation.</p> <p>Help client choose another method.</p>

When to Start

A woman can start injectables at any time if it is reasonably certain she is not pregnant.

- If she starts using an injectable within seven days after the start of her monthly bleeding, she will not need a back-up method.
- If she starts using an injectable more than seven days after her monthly bleeding, she should use a backup method for the first seven days after injection.

Switching from Another Method to Injectables

The following table describes the process of switching a woman from another method to injectables.

Table 2.14

Switch from another method to injectables

Method switching from	When first injection can be given
<p>Another hormonal method to progestin- only injectable (DMPA, NET-EN)</p>	<p>Give immediately if client has been using her hormonal method consistently and correctly, or if you are reasonably certain she is not pregnant. (Use checklist to rule out pregnancy). There is no need to wait for her next menstrual period, or to use a back-up method.</p> <p>If previous method was one of the other injectables, client should receive the new injectable when the repeat injection would have been given. No backup contraceptive protection is needed.</p>
<p>Non-hormonal method (other than IUCD)</p>	<p>Give immediately if reasonably certain client is not pregnant. There is no need to wait for her next menstrual period.</p> <p>If she is within 7 days of the start of her menstrual bleeding, no backup contraception is needed.</p> <p>If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use a back-up method for the next 7 days after injection.</p>

Table 2.14
Switch from another method to injectables (cont.)

Method switching from	When first injection can be given
IUCD (Including hormonal)	<p>Give within 7 days after the start of menstrual bleeding. No back-up contraceptive protection is needed. The IUCD can be removed at the same time.</p> <p>Can also be given at any other time if it is reasonably certain that she is not pregnant.</p> <p>If she has been sexually active in this menstrual cycle, and it has been more than 7 days since the menstrual bleeding started, the IUCD should remain in place after injection is given and be removed at the time of her next menstrual period.</p> <p>If she has not been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, she will need protection for the next 7 days after injection is given, if the IUCD is removed at that time. Otherwise she should retain the IUCD for removal at the time of her next menstrual period.</p>
Switching between DMPA and NET-EN	<p>Using DMPA and NET-EN interchangeably is not recommended.</p> <p>If it becomes necessary to switch from one to the other (e.g., because of stockouts), the switch should take place at the time the repeat injection would have been given.</p>

Missed Appointments

The following table describes what should be done if the client does not return to the clinic at the appropriate time for her injection.

NOTE:

All clients should be encouraged to come back to the clinic, regardless of how much time has passed since the missed appointment.

Table 2.15
When client misses appointment for injection

Client arrives	Suggested action
Too soon for her next injection	The repeat injection for both DMPA and NET-EN can be given up to two weeks early.
Late for her injection, up to 4 weeks for DMPA and 2 weeks for NET-EN	The repeat injection for DMPA can be given up to 4 weeks late; and for NET-EN, up to 2 weeks late without requiring additional contraceptive protection.
Late for her injection, more than four weeks for DMPA and more than two weeks for NET-EN or NET-EN	<p>If client is more than 4 weeks late for a DMPA repeat injection, she can have the injection, if it is reasonably certain she is not pregnant (Note: DMPA users may develop amenorrhoea without pregnancy so pregnancy test or pelvic exam might be needed to rule out pregnancy).</p> <p>If she is more than 2 weeks late for a NET-EN repeat injection, she can have the injection if it is reasonably certain she is not pregnant.</p> <p>She will need to abstain from sex or use additional contraceptive protection for the next 7 days after injection.</p> <p>She should consider using emergency contraception if appropriate (e.g., the only sexual intercourse she had since the end of re-injection window was not more than 120 hours ago).</p>

Giving the Injection

Providers should follow these guidelines for giving injectable contraceptives:

- Use disposable syringes and needles.
- Do not reuse disposable syringes and needles.
- Observe proper handling and disposal of needles and syringes (refer to section on infection prevention).
- Do not massage the injection site, and instruct the client not to massage or rub the site, as this could cause DMPA to be absorbed too fast.

Obtaining This Method

Injectable contraceptives can be provided at all SDPs:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing and maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)
- Level 1 (outreach, including CHWs and mobile services), and home-based care (provided by a nurse or midwife)

Injectable contraceptives can be obtained from the following clinical providers:

- Medical doctors
- Clinical officers
- Nurses and midwives

Recommended Job Aids

- *How to Be Reasonably Sure a Client is Not Pregnant* (MOH)

- *Checklist for Screening Clients Who Want to Initiate DMPA (or NET-EN)(MOH)*
- *Job Aid for Providing Services to Clients Returning for DMPA Re-Injection (MOH)*
- *Job Aid for Providing Services to Clients Returning for NET-EN Re-Injection(MOH)*
- *Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use (FHI)*

Contraceptive Implants

Description

Contraceptive implants are small rods that are inserted under the skin of a woman's upper arm to release the hormone progesterin slowly and prevent pregnancy. Contraceptive implants, which are also called sub-dermal implants, do not contain oestrogen; therefore, they are free from the side effects associated with that hormone. The latest implant to be registered in Kenya is the two-rod Sino-implant-II (Zarin).

Contraceptive implants prevent pregnancy primarily by making cervical mucus too thick for sperm to pass through it, and they also suppress ovulation in many cycles.

Types of Contraceptive Implants

The following table provides information about the implants that are in common use in Kenya.

Table 2.16
Descriptions of contraceptive implants

Device	Design	Hormone	Duration of effectiveness
Jadelle	2 rods	Levonorgestrel 75 mg/rod	5 years
Implanon	1 rod	Etonogestrel 68 mg/rod	3 years
Sino-implant [ZARIN] 75 mg/rod	2 Rods	Levonorgestrel	4 years (possibly 5)

Advantages and Benefits of Using Contraceptive Implants

Contraceptive Benefits

As a method of contraception, contraceptive implants are highly effective and safe, and they have significant benefits:

- Contraception is immediate if inserted within the first seven days of menstrual cycle, or within the first five days for Implanon.
- There is no delay in return to fertility.
- They offer continuous, long-term protection

Non-contraceptive Health Benefits

Other benefits are as follows:

- Implants do not affect breastfeeding.
- They reduce menstrual flow.
- They help prevent ectopic pregnancy (but do not eliminate the risk altogether).
- They protect against iron-deficiency anaemia.
- They help protect from symptomatic PID.

Limitations and Side Effects of Contraceptive Implants

This contraceptive method has the following limitations:

- Contraceptive implants must be inserted and removed by trained providers. This requires a minor surgical procedure with appropriate infection prevention practices.
- Common side effects of using implants include menstrual changes, such as irregular light spotting or bleeding, prolonged bleeding, infrequent bleeding, and amenorrhea.
- Non-menstrual side effects include headache, dizziness, nausea, breast tenderness, mood changes, weight change, and mild abdominal pain.
- Contraceptive implants do not protect against STIs, including hepatitis B and HIV. Individuals at risk should use condoms in addition to the implants.

Eligibility for Using Contraceptive Implants

Contraceptive implants are safe and appropriate for the majority of women. Some women might use contraceptive implants with additional monitoring or care; and a few women should not use contraceptive implants at all, or only in very limited circumstances.

Women Who Can Use Contraceptive Implants without Restrictions (includes MEC Category 1)

This method is acceptable with no restrictions for women of reproductive age, from menarche to menopause, with or without children, including the following:

- Breastfeeding mothers after four weeks postpartum, or immediate postpartum if not breastfeeding

- Women who prefer not to use or have contraindications to contraceptives that contain oestrogen or have developed oestrogen-related complications while taking COCs
- Women with STIs and PID
- Women with HIV and AIDS, unless they are on ARV therapy
- Women with adequately controlled or moderate hypertension (BP is less than 160/100) and those with history of hypertension during pregnancy
- Women who have had major and minor surgery without prolonged immobilisation, or varicose veins
- Women who take broad-spectrum antibiotics, antifungals or antiparasitics
- Women with any of the following conditions:
 - Valvular heart disease
 - Sickle cell disease
 - Non-migrainous headache or depressive disorders
 - Endometriosis, severe dysmenorrhoea, benign ovarian tumours, fibroids
 - Benign breast tumours, endometrial and ovarian cancer
 - Goitre
 - Viral hepatitis (acute/flare, carrier, or chronic) or mild (compensated) cirrhosis

*Women Who Can Use Contraceptive Implants with Extra Precautions
(Includes MEC Category 2)*

Clinicians may provide contraceptive implants to women with the conditions listed below (category 2), and thereafter arrange for any necessary follow-up, evaluation and referral, as appropriate:

- Irregular, prolonged or heavy bleeding patterns
- Diabetes without or with vascular complications
- Woman with multiple risk factors for cardiovascular disease (e.g., more than 35 years of age, cigarette smoking, diabetes, and hypertension)
- Women with ischemic heart disease or stroke (can initiate implants, but will have to discontinue if they develop these conditions while using the method)
- History of hypertension where BP cannot be measured
- Severe hypertension (BP of 160/100 or higher); or with vasculopathy
- Migraine with or without aura
- History of DVT/PE or DVT/PE and established on anticoagulant therapy; major surgery with prolonged immobilisation; known thrombogenic mutations
- Gall bladder disease, symptomatic or asymptomatic
- Diagnosed CIN or cervical cancer (risk of sterility)
- Undiagnosed breast mass (prompt evaluation needed—breast cancer is category 4)
- SLE who are negative for antiphospholipid antibodies, including women with severe thrombocytopenia or on immunosuppressive treatment
- Receiving treatment with certain ARVs, anticonvulsants, and anti-TB drugs that may reduce blood concentration of contraceptive hormones to some degree

Women Who Should Not Use Contraceptive Implants (Includes MEC Category 3 or 4)

For category 3 only, where clinical judgement is possible, clinicians may provide contraceptive implants if no other methods are available or acceptable to the client and careful follow-up can be assured. Otherwise, as in the case of category 4 conditions, contraceptive implants should not be used. The following table lists conditions that fall into MEC categories 3 and 4.

Table 2.17
Conditions that represent MEC Categories 3 and 4

Condition	MEC category
Breastfeeding women less than four weeks postpartum	3
Women who have severe cirrhosis or liver tumours (hepatocellular adenoma or hepatoma)	3
Women who have unexplained vaginal bleeding suspicious for serious underlying condition (before evaluation)	3
Women who have breast cancer or women with a history of breast cancer	4
Women who currently have DVT, or who developed ischaemic heart disease or stroke while using implants	3 (Note: DVT is category 3 for both initiation and continuation; ischaemic heart disease or stroke is category 3 for continuation only)
Women whose migraine with aura became worse while using implants	3 (for continuation)

Timing for Implant Insertion

Table 2.18

Timing for implant insertion

Situation	Suggested action
The woman is having her menstrual cycles.	<p>Insert implant within 7 days after the start of her menstrual bleeding (within the first 5 days for Implanon). No additional contraceptive protection is needed.</p> <p>Insert implant any other time if it is reasonably certain that she is not pregnant (see checklist). If it has been more than 7 days since menstrual bleeding started (within the first 5 days for Implanon), she will need additional contraceptive protection for the next 7 days (e.g., condoms, FAM, or Coitus Interruptus).</p>
The woman is amenorrhoeic.	<p>Insert implant any time if it is reasonably certain that she is not pregnant. She will need additional contraceptive protection for the next 7 days.</p>
The woman is breastfeeding.	<p>Between 4 weeks and 6 months postpartum and she is amenorrhoeic, insert implant any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed (see LAM).</p> <p>If she is more than 4 weeks postpartum and her menstrual cycles have returned, she can have the implant inserted as advised for other women having menstrual cycles.</p>
The woman is switching from another hormonal method.	<p>The implant can be inserted immediately if she has been using her hormonal method consistently and correctly, or if it is reasonably certain she is not pregnant. There is no need to wait for her next menstrual period.</p> <p>If her previous method was an injectable, she should have the implant inserted when the repeat injection would have been given. There is no need for additional contraceptive protection.</p>

Table 2.18
Timing for implant insertion (cont.)

Situation	Suggested action
<p>The woman is switching from a non-hormonal method (not IUCD).</p>	<p>The implant can be inserted immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her menstrual period.</p> <p>If she is within 7 days of the start of her menstrual bleeding (within 5 days for Implanon), no additional contraception is needed.</p> <p>If it has been more than 7 days since menstrual bleeding started (5 days for Implanon), she will need to abstain from sex or use additional contraceptive protection for the next 7 days.</p>
<p>The woman is switching from an IUCD (including hormonal).</p>	<p>The implant can be inserted within 7 days after the start of menstrual bleeding (5 days for Implanon). No additional contraceptive protection is needed. The IUCD can be removed at that time.</p> <p>The implant can also be inserted at any other time, if it reasonably certain she is not pregnant.</p> <p>If she has been sexually active in this menstrual cycle, and it has been more than 7 days since the menstrual bleeding started (5 days for Implanon), it is recommended that the IUCD should remain in position to be removed at the time of her next menstrual period.</p> <p>If she has <i>not</i> been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started (5 days for Implanon), she will need protection for the next 7 days, if the IUCD is removed at that time. Otherwise she should retain it for removal at the time of her next menstrual period.</p> <p>If she is amenorrhoeic or has irregular bleeding, she can have the implant inserted as advised for other amenorrhoeic women</p>

Instructions to Women

After Insertion

Counsel women to expect some soreness or bruising (or both), after anesthetic wears off. This is common and does not require treatment. She should be counselled and given these instructions:

- Keep insertion area dry for four to five days.
- Remove the gauze bandage after one or two days, but leave the adhesive plaster in place for an additional five days.
- Return to the clinic if the rods come out or if soreness develops after the removal of the adhesive plaster.
- Return to the clinic if she experiences pain, heat, pus, or redness at the insertion site, or if she sees a rod come out.

The service provider should emphasise that implants must be removed by the due date, and he should give her in writing the type of implant she has, the date of insertion, and the month and year when the implant will need to be removed.

The service provider should ensure that the woman knows where to go in case of problems with the implants.

Instructions for Clients Following Removal of Implants

After a client has had her implant removed, she should be counselled and instructed as follows:

- Keep removal area dry for four to five days.
- Remove the gauze bandage after one or two days, but leave the adhesive plaster in place for an additional five days.
- Return to the clinic if swelling and pain develops after the removal of the adhesive plaster.

The service provider should also discuss subsequent contraceptive options with the woman at this time.

Management of Side Effects of Contraceptive Implants

The following table lists some side effects that a woman might experience when using contraceptive implants and how the service provider should treat them or counsel the woman.

Table 2.19
Management of side effects of contraceptive implants

Side effect	Management
Amenorrhoea	<p>Reassure her that this is a common occurrence while using implants, and it is not harmful.</p> <p>Amenorrhoea does not require any medical treatment. Counselling is sufficient.</p> <p>If suspicious, assess for pregnancy as per Checklist. If she is pregnant, remove the implants. If she is not pregnant, reassure her and continue method.</p>
Irregular spotting or light bleeding	<p>Spotting or light bleeding is common during implant use, particularly in the first year; clients should be counselled and reassured that this problem usually decreases over time.</p> <p>If a woman has persistent spotting or bleeding, or bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer client for care.</p> <p>If STI or PID is diagnosed, she can continue using implants while receiving treatment (syndromic approach) and be counselled on condom use.</p>

Table 2.19

Management of side effects of contraceptive implants (cont.)

Side effect	Management
Irregular spotting or light bleeding	<p>If no gynaecologic problems are found and she desires treatment, non-hormonal (NSAIDs other than aspirin) and hormonal (COCs or Ethinyl Estradiol) options are available (see below).</p> <p>If she does not desire treatment or the treatment is not effective, and she finds the bleeding unacceptable, the implants should be removed. Help her choose another method.</p>
Heavy or prolonged bleeding (more than eight days or twice as much as her usual menstrual period)	<p>Reassure client that some women using implants experience heavy or prolonged bleeding. It is generally not harmful.</p> <p>Exclude gynaecologic problems when it is clinically warranted. Treat the condition or refer client for care.</p> <p>If no underlying condition exists and she desires treatment, non-hormonal (NSAIDs other than aspirin) and hormonal (COCs or ethinyl estradiol) options are available.</p> <p>If she does not desire treatment or treatment is not effective, and the bleeding becomes a threat to her health or is unacceptable to her, the implants should be removed. Help her choose another method.</p>
Recurrent and persistent headaches especially with blurred vision	<p>Assess for other causes. Reassure client if symptoms are mild. If severe, remove implants and refer client for treatment.</p> <p>Assist client to select another method.</p>
Implant expulsion	<p>In the case of two-rods (Jadelle) or one rod (Implanon) implants, a new set should be inserted.³⁶ Insert a new set in the other arm or in the reverse direction in the same arm, or help the client to select an alternative method.</p>

³⁶ In case of Jadelle, when one rod is expelled, it is sufficient to insert just one and not remove the one that remains in place.

Treatment for Light or Heavy Bleeding

If a woman experiences light or heavy bleeding while using contraceptive implants, there are a number of possible treatments:

- Treatment with NSAIDs
 - Ibuprofen: 800 mg three times a day for five days
 - Mefenamic acid: 500 mg twice a day for five days
- Hormonal management
 - Low-dose COCs: 30 µg ethinylestradiol 150 µg levonorgestrel a day for 21 days
 - COCs: 50 µg ethinylestradiol 250 µg levonorgestrel a day for 21 days
 - Ethinylestradiol: 50 µg a day for 20 days
- Hemostatics: Transnexamamic acid 500mg three times a day for five days or Sylate 500mg three times a day for five days

Obtaining Contraceptive Implants

Contraceptive implants can be provided at all SDPs:

- Level 5 and above (provincial hospitals and others)
- Level 4 (district hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)
- Level 1 (outreach, mobile services)

Contraceptive implants should be obtained from specially trained providers:

- Medical doctors
- Clinical officers

- Nurses or midwives

Recommended Job aids

- *How to Be Reasonably Sure a Client is Not Pregnant* (MOH)
- *Checklist for Screening Clients Who Want to Initiate Contraceptive Implants* (MOH)
- Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use (FHI)
- Samples of the implant
- Arm model

Chapter Three

INTRAUTERINE CONTRACEPTIVE DEVICES (IUCDs)

3

Chapter 3

INTRAUTERINE CONTRACEPTIVE DEVICES (IUCDs)

Description

The IUCD is a flexible device that is inserted into the uterine cavity by a trained service provider. It is a safe and highly effective, long-acting contraceptive method.

Types of IUCDs

There are two broad categories of intrauterine contraceptive devices (IUCDs): the copper-based and the hormone-releasing devices.

Copper-Based Devices

Copper-based devices release copper and work mainly by preventing fertilization. Several studies have shown that copper IUCDs reduce the number of viable sperm that reach the fallopian tubes, where fertilization normally takes place. In studies in which the uterine cavity and fallopian tubes were flushed after exposure to semen, no fertilised eggs were found in IUCD users. This is an indication that prevention of fertilization is so effective in women using copper IUCDs that other possible mechanisms, such as prevention of implantation, are not significant. In Kenya, the most widely used copper-bearing IUCD is Copper T380A, which is made of plastic with copper sleeves on the arms and copper wire wound

around the stem. It provides protection from pregnancy for as long as 12 years. Other relatively less utilised copper devices and their duration of effectiveness are shown in the table below.

Hormone-Releasing IUCDs

The hormone releasing IUCDs are less widely available in Kenya. They are devices made of plastic and work by releasing a progestin, levonorgestrel, during a period of five years. They work by suppressing ovulation in some (but not all) cycles, thickening cervical mucus, and making the endometrium thin. They are also referred to as Intra-Uterine Systems (IUS). Mirena, the LNG-20 IUS, is the most widely used hormone-releasing intrauterine system in use in Kenya. Also, there is a generic version of Mirena that is available in the Kenya market, and it goes by the name of Lingus.

Table 3.1
Types of IUCDs and their duration of effectiveness

Device	Duration of effectiveness
Copper based devices:	
Copper T 380A	As long as 12 years
TCu380S	8 years
Copper T200	8 years
Gynefix	8 years
NOVA T	5 years
Multiload- MLCu-375	5 years
Multiload- MLCu-250	3 years
Copper T 220	3 years
Hormone-releasing IUCDs:	
Mirena (LNG-20IUS),	5 years
Lingus ³⁷ - (LNG-IUS)	5 years

³⁷ A generic form of Mirena.

Myths and Misconceptions about the IUCD

IUCDs do not prevent pregnancy by causing an abortion. The devices might cause a miscarriage if accidentally inserted in a pregnant woman, or in the highly unlikely event of a woman getting pregnant with an IUCD in place. However, because the IUCD is highly effective in preventing fertilization, risk of abortion is almost non-existent if pregnancy is ruled out in all clients prior to insertion.

IUCDs are very safe; they do not cause PID in low-risk couples. Risk of infection is very low when the IUCD is inserted using the “no-touch” technique in women who have no cervical infection. But if the client already has gonorrhoea or chlamydia at the time of insertion, or if the service provider inserts the IUCD without maintaining sterility, there is a small risk of pelvic infection in the first four weeks after insertion. Prophylactic antibiotics are generally not recommended for Cu-IUCD insertion unless the risk for cervical, gonococcal, and chlamydial infections is high and facilities for STI screening are inadequate. In these cases, such prophylaxis might be considered. In any case, clients in these circumstances should be counselled to watch for symptoms of PID, especially during the first month of insertion, and to return immediately if symptoms develop.

Almost all brands of IUCDs have one or two strings, or threads, tied to the lower end. The strings hang through the opening of the cervix into the vagina. After insertion, it is advisable to cut the strings short, to about 3cm long from the cervix’s external os, or coil the strings around the fornix (postpartum insertion).

Advantages and Benefits of IUCDs

Contraceptive Benefits

IUCDs offer the following contraceptive benefits:

- High effectiveness and safety
- Immediate effectiveness
- Long-acting protection
- Immediate return of fertility upon removal of device

Other Benefits

IUCDs offer other advantages and health benefits, as well:

- IUCDs do not interfere with intercourse.
- Women who are breastfeeding can use IUCDs.
- IUCDs help prevent ectopic pregnancies.
- Women can use IUCDs immediately after delivery (to use LNG-IUS, breastfeeding women should wait till four weeks postpartum).
- IUCDs, including the Cu-IUCDS, might help protect from endometrial cancer.
- LNG-IUS do not increase bleeding as Cu-IUCDS do; they may reduce menstrual bleeding or cause amenorrhoea.

Eligibility for Using an IUCD

IUCDs are safe and appropriate for the majority of women. Some women might use an IUCD with additional monitoring or care; and a few women should not use an IUCD at all, or only in very limited circumstances.

Women Who Can Use an IUCD without Restrictions (Includes MEC category 1)

NOTE:

MEC for LNG-IUS generally considers both its effects as an intra-uterine device and its effects as a hormonal (progestin-only) method.

Women are eligible to use IUCDs based on the classifications in the table below.

Table 3.3
Eligibility conditions for MEC category 1

Conditions that apply to both Copper IUCD and LNG-IUS	Conditions that apply to Cu-IUCD only	Conditions that apply to LNG-IUS only
Women 20 years of age or older	Blood pressure of 160/100 or higher	Heavy or prolonged menstrual bleeding (regular or irregular patterns): initiation only (see continuation under category 2)
Parous women of any parity	History or acute DVT/PE, including those on anticoagulant therapy	Endometriosis or severe dysmenorrhoea. (LNG-20 IUS may have a beneficial effect on endometriosis and dismenorrhoea)
Women who want long-term, highly effective protection against pregnancy	Major surgery with prolonged immobilization	
Breastfeeding or non-breastfeeding if at least four weeks postpartum	SLE without severe thrombocytopenia	

Table 3.3
Eligibility conditions for MEC category 1 (cont.)

Conditions that apply to both Copper IUCD and LNG-IUS	Conditions that apply to Cu-IUCD only	Conditions that apply to LNG-IUS only
After first trimester abortion or ectopic pregnancy	Positive or unknown antiphospholipid antibodies (initiation and continuation)	Anaemias, such as iron deficiency anaemia, sickle cell disease, thalassaemia LNG-20 IUS users are more likely to experience light bleeding or even amenorrhoea, which is beneficial for women with anaemia. ³⁸
Smoking at any age	Immunosuppressive treatment (continuation only)	
Blood pressure between 140/90 to 159/99	Severe (decompensated) cirrhosis of the liver	
Family history of DVT or PE	Any type of liver tumours (benign or malignant)	
Major surgery without prolonged immobilization	Multiple risk factors for CVD	
Superficial venous thrombosis	Women with current IHD, DVT/PE, or stroke	
Uncomplicated valvular heart disease	Hypertension of 160/100 or higher, including with vascular complications	
Non-migrainous headaches	Uncomplicated or complicated diabetes	
Irregular menstrual bleeding patterns without heavy bleeding	Migraines with or without aura at any age	
Benign ovarian tumours or benign breast disease		

³⁸ French R, Van Vliet HHAAM, Cowan F, Mansour DD, Hughes DD, Robinson AA, Proctor TT, Summerbell CC., Logan S, Helmerhorst FM, Guillebaud J. Hormonally impregnated intrauterine systems (IUSs) versus other forms of reversible contraceptives as effective methods of preventing pregnancy. Cochrane Database of Systematic Reviews 2004, Issue 2. Art. No.: CD001776. DOI: 10.1002/14651858.CD001776.pub2.

Table 3.3
Eligibility conditions for MEC category 1 (cont.)

Conditions that apply to both Copper IUCD and LNG-IUS	Conditions that apply to Cu-IUCD only	Conditions that apply to LNG-IUS only
<p>Family history of breast cancer</p> <p>Non-pelvic TB</p> <p>Viral hepatitis (acute or flare, carrier or chronic) or mild (compensated) cirrhosis of the liver</p> <p>Anticonvulsants and antimicrobials including TB therapy</p> <p>Thyroid disorders</p> <p>Cervical ectropion (erosion) or uterine fibroids without distortion of uterine cavity</p> <p>History of PID in women who have subsequently conceived</p> <p>Obesity (BMI greater than 30 kg/m²)</p>	<p>Gall bladder disease</p> <p>Undiagnosed breast tumour or breast cancer</p>	<p>Anaemias, such as iron deficiency anaemia, sickle cell disease, thalassaemia LNG-20 IUS users are more likely to experience light bleeding or even amenorrhoea, which is beneficial for women with anaemia.³⁸</p>

Women Who Can Use IUCDs with Caution (Includes MEC Category 2)

Women who have any of the conditions listed in Table 3.4 below, should proceed with caution if they choose to use the IUCD. Careful counselling is required, and follow up may be necessary.

Table 3.4
Conditions that fall into MEC category 2 with advice for use with these conditions

Condition	Suggested action for Cu-IUCD	Suggested action for LNG-IUS
Menarche, younger than 20 years of age, and nulliparity	Generally provide after careful counselling on range of methods available. There is concern both about the increased risk of IUCD expulsion because of nulliparity and the risk of STIs because of sexual behaviour in younger age groups. Ensure follow-up.	Proceed as for Cu-IUCD.
Less than 48 hours postpartum	Generally provide and counsel the woman about a slightly higher risk of expulsion compared to interval insertion.	Proceed as for Cu-IUCD (if not breastfeeding).
Following second-trimester abortion (where there is no sepsis)	Generally provide. Follow-up is needed because of higher chance of expulsion compared with after first-trimester abortion.	Proceed as for Cu-IUCD.

Table 3.4

Conditions that fall into MEC category 2 with advice for use with these conditions (cont.)

Condition	Suggested action for Cu-IUCD	Suggested action for LNG-IUS
Past PID without subsequent pregnancy	Generally provide, but client needs careful counselling regarding safe sexual practices and STIs risk. Careful follow-up is needed.	Proceed as for Cu-IUCD.
Increased risk of STIs including HIV (see category 3/4 if woman has very high likelihood of exposure to STIs)	Generally provide, but counsel client that IUCDs do not protect against STIs including HIV. Advise use of dual protection (i.e., condom).	Proceed as for Cu-IUCD.
HIV infected, as well as those with AIDS who are clinically well on ARVT	Generally initiate use or continue use. Careful follow-up needed. There is no known interaction between ARVT and IUD use.	Proceed as for Cu-IUCD.
Women having heavy or prolonged vaginal bleeding patterns, or both (could be regular or irregular)	Heavy or prolonged bleeding patterns are category 2, i.e., IUCD may be inserted, but some follow-up may be required. Counsel woman that her bleeding may become even heavier after Cu-IUCD is inserted. (If woman considers bleeding unusual for her, evaluate prior to initiation—see category 4).	Can initiate without restrictions (see above category 1), but may need additional follow-up if bleeding becomes worse while using LNG-20 IUS (category 2 for continuation)

Table 3.4
Conditions that fall into MEC category 2 with advice for use with these conditions (cont.)

Condition	Suggested action for Cu-IUCD	Suggested action for LNG-IUS
Women with endometriosis or severe dysmenorrhoea	Use of Cu-IUCD could intensify dysmenorrhoea, including that associated with endometriosis. Generally provide method and follow-up carefully. Provide analgesics if necessary.	No restrictions (see category 1 above) ³⁹
Anaemias: iron-deficiency anaemia, sickle cell disease, thalassaemia	There is concern about an increased risk of blood loss with Cu-IUCD. Generally provide method and follow-up carefully. Advise use of haematinics.	No restrictions (see category 1 above) ⁴⁰
Women with valvular heart disease (complicated by pulmonary hypertension, risk of atrial fibrillation, and those with history of SBE)	Generally provide method, but give prophylactic antibiotics to prevent endocarditis during insertion. Needs careful counselling, follow-up, and referral.	Proceed as for Cu-IUCD.

³⁹ Cochrane systemic reviews of IUD trials: lesson learned. *J.Contraception* 2006.12.004.

⁴⁰ French R, Van Vliet HHAAM, Cowan F, Mansour DD, Hughes DD, Robinson AA, Proctor TT, Summerbell CC., Logan S, Helmerhorst FM, Guillebaud J. Hormonally impregnated intrauterine systems (IUSs) versus other forms of reversible contraceptives as effective methods of preventing pregnancy. *Cochrane Database of Systematic Reviews* 2004, Issue 2. Art. No.: CD001776. DOI: 10.1002/14651858.CD001776.pub2.

Table 3.4

Conditions that fall into MEC category 2 with advice for use with these conditions (cont.)

Condition	Suggested action for Cu-IUCD	Suggested action for LNG-IUS
Women with a history of DVT or PE, or currently diagnosed with DVT or PE and established on anticoagulant therapy; or major surgery with prolonged immobilization	No restrictions (see category 1 above).	LNG-IUS can be provided; arrange close follow-up.
Women with SLE who have no severe thrombocytopenia and are receiving immunosuppressive treatment	Generally initiate, but some follow-up might be warranted. Women who develop severe thrombocytopenia while using IUCD can generally continue, but not initiate IUCD use.	Generally can initiate and continue use of LNG-IUS regardless of the presence of thrombocytopenia, unless she has positive or unknown antiphospholipid antibodies (see category 3).
Women with benign liver focal nodular hyperplasia	No restrictions (see category 1).	May initiate and continue use; arrange careful follow-up.
Migraines with or without aura, at any age	No restrictions (see category 1 above).	Generally initiate, but follow-up might be warranted. Discontinue if migraines become worse while using LNG-IUS (see category 3).
Current or history of IHD	No restrictions (see category 1 above).	Generally initiate, but follow-up might be warranted. Discontinue if IHD symptoms become worse while using LNG-IUS (see category 3).

**Women Who Should Not Use IUCD (Cu IUCD and LNG –IUS)
(Includes MEC Categories 3 and 4)**

This section outlines circumstances that would absolutely prohibit a woman from using IUCD (category 4), as well as circumstances that would allow use of the method only if no other method is available or acceptable, clinical judgement is possible, and careful follow-up can be assured (category 3).

Whether a woman has a condition that makes her ineligible for using an IUCD could depend on which type of IUCD she is using (or wants to use). The following table outlines conditions that would prohibit or restrict a woman from using either type of IUCD, and conditions that would prohibit or restrict her from using the LNG-IUS type of IUCD.

Table 3.5
Conditions that fall into categories 3 or 4 for IUCDs

Conditions that apply to both Cu-IUCD and LNG-IUS	Conditions that apply to LNG-IUS only
<p>Women who are pregnant.</p> <p>Postpartum women after 48 hours and before the end of 4 weeks.</p> <p>Women with puerperal sepsis or immediately post-septic abortion.</p> <p>Women with unexplained vaginal bleeding before evaluation. Method should not be initiated before evaluation (category 4), but a woman who already is using IUCD can continue with it pending findings of the evaluation (category 2).</p>	<p>Women with acute DVT or PE.</p> <p>Women with severe (decompensated) cirrhosis or liver tumours (hepatocellular adenoma or hepatoma).</p> <p>Women with current breast cancer or a history of it.</p> <p>Women with SLE with positive or unknown antiphospholipid antibodies.</p>

Table 3.5

Conditions that fall into categories 3 or 4 for IUCDs (cont.)

Conditions that apply to both Cu-IUCD and LNG-IUS	Conditions that apply to LNG-IUS only
<p>Women with gestational trophoblastic disease: with decreasing or undetectable β-hCG levels (category 3) or persistently elevated β-hCG levels or malignant disease (category 4).</p> <p>Women with pelvic cancer (cervical, endometrial, and ovarian cancers).</p> <p>Women with fibroids distorting the uterine cavity.</p> <p>Women with anatomical abnormalities of the uterus and cervix that interfere with insertion and retention of IUCD.</p> <p>Women with current PID or current purulent cervicitis. After treatment (Syndromic approach and refer), she can have an IUCD inserted (category 2). Women who develop PID while using an IUCD can be treated with IUCD in place (category 2 for continuation).</p> <p>Women who have high individual likelihood of exposure to gonorrhea or chlamydia, e.g., women who have multiple sexual partners or whose partners have multiple sexual partners (Note: increased risk of STI is category 2, only high individual risk is category 3).</p>	<p>Women with migraine headaches with aura that got worse while using LNG-IUS (continuation only).</p> <p>Women with current diagnosis or a history of IHD (continuation only).</p> <p>Breastfeeding women before 4 weeks postpartum.</p>

Table 3.5

Conditions that fall into categories 3 or 4 for IUCDs (cont.)

Conditions that apply to both Cu-IUCD and LNG-IUS	Conditions that apply to LNG-IUS only
<p>Women who are known to have pelvic TB</p> <p>Women living with HIV who have AIDS are category 3 for initiating method, but category 2 for continuation.</p>	

When Can an IUCD Be Inserted?

The IUCD insertion is categorised as postpartum, postabortal, and interval.

- Postpartum insertion (does not apply to LNG-IUS if the woman intends to or is breastfeeding. Breastfeeding women can have LNG-IUD inserted at four weeks):
 - Trans-caesarean (i.e., following a caesarean delivery): The IUCD can be inserted before the uterus is sutured.
 - Post-placental: The IUCD can be inserted within 10 minutes after expulsion of the placenta following a vaginal delivery.
 - Immediate postpartum: The IUCD can be inserted after the post-placental window, but within 48 hours of delivery. If IUCD is not inserted within 48 hours, wait until four weeks after delivery.
- Postabortion where there are no complications. Following first or second trimester abortion, insert the IUCD immediately or within 12 days. Insertion of the IUCD should be undertaken

only after genital tract infection has been ruled out. If there is suspicion of infection, or there is significant injury to the genital tract, insertion should be delayed until after appropriate treatment (see interval insertion).

- Interval: Insert IUCD within the first 12 days after the start of menstrual bleeding or any other time of woman's menstrual cycle if provider is reasonably sure she is not pregnant.

NOTE:

Postpartum IUCD is contraindicated in situations that increase the risk of infections.

These situations include:

- Prolonged rupture of membranes
- Prolonged labour
- Puerperal genital infection
- Puerperal sepsis

Post-insertion Follow-Up

Arrange a follow-up visit three to six weeks after insertion. If IUCD strings cannot be felt on bimanual examination, refer client for ultrasound scan or X-Ray to confirm whether the device is still in situ. Advise the woman to use a back-up contraceptive method in the meanwhile.

Obtaining This Method

IUCDs should be provided within facilities that follow appropriate infection prevention practices:

- Level 5 and above (provincial hospitals and others)
- Level 4 (district hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 2 (dispensaries, private clinics)
- Level 1 (outreach by trained clinicians)

IUCDs can be obtained from service providers with appropriate training:

- Medical doctors
- Nurses or midwives
- Clinical officers

Limitations, Problems, and Side Effects with the Use of IUCDs

IUCDs have the following restrictions, limitations, or side effects:

- An IUCD requires a trained provider to insert and remove the device.
- Appropriate infection-prevention practices must be observed during insertion and removal.
- Cu-IUCDs might increase menstrual bleeding and cause cramping, more commonly during the first few months of use (LNG-IUs do not increase menstrual bleeding).

- IUCDs do not protect against STIs or HIV/AIDS.
- An IUCD could be expelled or translocated.
- Perforation of the uterus could occur, but this is rare.

Table 3.2

Management of common problems associated with IUCD use

Problem or side effect	Management
<p>A woman using an IUCD experiences abnormal bleeding patterns, such as spotting or light bleeding between menstrual periods and heavier or prolonged menstrual bleeding.</p>	<p>Bleeding problems are common during the first 3-6 months of Cu-IUCD use. Clients should be counselled and reassured that this problem usually decreases over time. If she requires treatment, a short course of NSAIDs, e.g., ibuprofen 800mg, 3 times a day for 5 days; or Indomethacin 25 mg, twice a day for 5 days; or Tranexamic acid (a haemostatic agent) may be given during the days of bleeding. Do not use aspirin as it may increase bleeding.</p> <p>In women with persistent spotting and those with heavy or prolonged bleeding, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.</p> <p>If no gynaecologic problems are found, and she finds the bleeding unacceptable, especially if there are clinical signs of anaemia, remove the IUCD and help her choose another method or refer (referral protocol to next level).</p>

Table 3.2
Management of common problems associated with IUCD use (cont)

Problem or side effect	Management
<p>A woman using an IUCD is found to be pregnant.</p>	<p>Exclude ectopic pregnancy with an ultrasound scan where available — otherwise, with careful clinical monitoring.</p> <p>Explain that she is at risk of second trimester miscarriage (which might be a septic miscarriage), and pre-term delivery if the IUCD is left in place. Advise her that it is best to remove the IUCD because removal of the device reduces these risks, although the procedure itself entails a small risk of miscarriage.</p> <p>If the IUCD cannot be removed or the woman refuses to have it removed, but she wishes to continue the pregnancy, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever. Ensure careful clinical monitoring (directly or through referral).</p> <p>If she does not wish to continue the pregnancy, counsel her accordingly.</p> <p>If the woman wants her IUCD to be removed and the IUCD strings are visible or can be retrieved safely from the cervical canal, remove the IUCD by pulling gently on the strings.</p> <p>Explain that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.</p>

Table 3.2

Management of common problems associated with IUCD use (cont)

Problem or side effect	Management
	<p>If the woman wants her IUCD to be removed, but the IUCD strings are not visible and cannot be safely retrieved: (1) where ultrasound is available, determine if the IUCD is still in the uterus. If the IUCD is not located, this may suggest that an expulsion of the IUCD has occurred; (2) if ultrasound is not available or if the IUCD is determined by ultrasound to be inside the uterus, make clear to her the risks and advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.</p>
<p>A woman experiences abdominal cramps, pain, and severe dysmenorrhoea.</p>	<p>All women should be counselled on potential changes in menstrual cycle before the IUCD is inserted.</p> <p>Examination should rule out partial expulsion of the IUCD, ectopic pregnancy, or PID (see below).</p> <p>Treat dysmenorrhoea with analgesics. If persistent, rule out pelvic pathology (refer and manage as appropriate-referral protocol).</p>
<p>A woman using an IUCD is diagnosed with PID.</p>	<p>Treat the PID using appropriate antibiotics. There is no need to remove the IUCD if she wishes to continue its use.</p> <p>If symptoms do not improve after a few (2-3) days of antibiotics, removal of the IUCD might be considered and antibiotic treatment continued or reviewed.</p>

Table 3.2

Management of common problems associated with IUCD use (cont)

Problem or side effect	Management
A woman using an IUCD is diagnosed with PID.	<p data-bbox="538 331 918 464">If she does not want to keep the IUCD, remove it <i>after</i> antibiotic treatment has been started, and have the woman complete a full course of antibiotics.</p> <p data-bbox="538 496 874 576">After the IUCD is removed, help the client to choose another contraceptive method.</p> <p data-bbox="538 608 893 687">In all cases, the woman should be closely monitored until the PID is fully resolved.</p>

Recommended Job Aids

- *Checklist for Screening Clients Who Want to Initiate Use of the Copper IUCD* (MOH)
- *How to Be Reasonably Sure a Client is Not Pregnant* (MOH)
- *Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use* (FHI)
- Sample of IUCD
- Hand-held uterine model

Chapter Four

VOLUNTARY SURGICAL CONTRACEPTION

4

Chapter 4

VOLUNTARY SURGICAL CONTRACEPTION

Introduction

Voluntary Surgical Contraception (VSC) includes female and male sterilisation procedures⁴¹ that are intended to provide permanent contraception. As such, special care must be taken to assure that every client who chooses this method does so voluntarily and is fully informed about the permanence of this method and the availability of alternative, long-acting, highly effective methods. Caution must be taken when the following individuals choose permanent methods: nulliparous women; youth; men who have not fathered a child; and persons with mental health problems, including depressive disorders.

Sterilisation does not protect against STIs, including hepatitis B and HIV/AIDS. If the client is at risk of contracting one of these, the correct use of condoms is recommended following sterilisation.

Recommendations for MEC for VSC Methods

There is no medical condition that would absolutely restrict a person's eligibility for sterilisation, although some conditions and

⁴¹For details on the actual procedures, refer to relevant manuals.

circumstances require that certain precautions are taken, including those where the recommendation is C (Caution), D (Delay), or S (Special). In some circumstances, when special requirements for clients with certain medical conditions cannot be met, a long-acting, highly effective contraceptive method might be a preferable alternative. An example of such a case would be a woman with complicated valvular heart disease who does not have access to a facility with an experienced surgeon, back-up medical support, and the necessary equipment that might be needed to manage complications that might arise during the sterilisation procedure.

The following categories are used for recommending VSC (see also **Table 1.7**):

- **Accept (Category A):** There is no medical reason to deny sterilisation to a person with this condition.
- **Caution (Category C):** The procedure is normally conducted in a routine setting, but with extra preparation and precautions.
- **Delay (Category D):** The procedure is delayed until the condition is evaluated and corrected if need be. Alternative temporary methods of contraception should be provided.
- **Special (Category S):** The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the provider must be able to decide on the most appropriate procedure and anaesthesia regimen. Alternative temporary methods of contraception

should be provided if referral is required or there is otherwise any delay.

NOTE:

- No incentives are to be given to clients to accept any form of contraception or to providers to recruit clients and perform the surgical procedure.
 - The client is free to change her mind anytime prior to the procedure.
 - Multiple caesarean sections and grand multiparity are not absolute indications for female sterilisation.
 - Informed consent must be obtained and the client must sign a standard consent form for the procedure. Spousal consent is not mandatory, but counselling should be provided to both partners and consent obtained from both, if possible, and where appropriate (see **Appendix 5**).
-

Female Voluntary Surgical Contraception

Description

Female voluntary surgical contraception, also referred to as female sterilisation or tubal ligation (TL), is a minor surgical operation that involves cutting and tying the fallopian tubes in order to prevent the sperm from fertilising the ovum that was released from the ovary, and reaching the uterine cavity. In Kenya, nearly 14 percent of users of modern methods of contraception rely on female

sterilisation.⁴² It is a highly effective method of contraception, with a pregnancy rate of less than one percent of women in the first year after surgery. TL can be performed on a conscious client using local anaesthesia, and it is generally a safe procedure when performed by a trained provider. Few women experience side effects or complications. Overall rates of complications are in the range of 0.4 to 2.0 percent.

TL is a permanent FP method (reversal cannot be assured). Hence, a client needs thorough and careful counselling before she decides to have this procedure. A consent form must be signed by the client in all cases before the procedure is undertaken. In the case of a mentally challenged client, the surgeon may, after consultation with a professional colleague, obtain the written consent of the parent or guardian (see **Appendix 5**).

Types of TL

There are several ways to perform a TL:

- Minilaparotomy (postpartum, postabortion,⁴³ or interval)
- Laparoscopic tubal ligation (interval)
- In conjunction with a caesarean section or other abdominal surgery

Advantages of TL

Contraceptive Benefits

TL is a highly effective, immediate, and safe form of contraception that offers the following benefits:

⁴² Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya], and Macro. 2004. Kenya Demographic and health Survey 2003. Calverton, Maryland: CBS, MOH, and ORC Macro. (KDHS 2003).

⁴³ After an uncomplicated abortion.

- TL does not change sexual function and does not interfere with intercourse.
- TL is permanent.
- TL has few known side effects (see “Limitations and Side Effects of TL”).
- TL does not affect breastfeeding.

Other Benefits

Women who have TLs have a decreased risk of getting ovarian cancer and have a possible decreased risk of PID.

Limitations and Side Effects of TL

The limitations and side effects of TL are listed below:

- TL is generally irreversible—the success of reversal surgery cannot be guaranteed.
- Side effects include:
 - Minimal risks and side effects of anaesthesia
 - Risks associated with surgical procedures
 - Some pain for several days after the procedure
- In rare cases when pregnancy occurs, it is more likely to be ectopic (although overall, female sterilisation greatly reduces the risk for ectopic pregnancy compared to women who use no contraception).
- TL is not provided at all SDPs.
- Only a trained provider can perform the procedure.
- TL does not protect against STIs, including HIV/AIDS and hepatitis B.

Women Who Can Use TL (Includes MEC Category A)

TL is considered appropriate and safe for the following:

- Women of reproductive age.
- Women who are certain that they have achieved the desired family size.
- Clients in whom pregnancy would pose a serious health risk.
- Women who understand and voluntarily consent to the procedure. In certain situations the procedure may be performed on a mentally-challenged person after consultation with a professional colleague, and with the written consent of a responsible parent or guardian.
- Women who want a permanent method.
- Women who are less than seven or more than 42 days postpartum.
- Women who have had uncomplicated abortions.
- Women of any reproductive age who are smokers.
- Women with a history of DVT or PE, a family history of DVT or PE, or who have had major or minor surgery without prolonged immobilization.
- Women with superficial venous thrombosis.
- Women with headaches, with or without aura.
- Women with irregular, heavy, or prolonged bleeding patterns or women with severe dysmenorrhoea.
- Women with benign ovarian tumours, benign gestational trophoblast disease, cervical ectropion, or cervical intraepithelial neoplasia.

- Women with an undiagnosed breast lump, benign breast disease, or a history of breast cancer.
- Women with previous history of PID and STIs who have had a subsequent pregnancy.
- Women at high risk of HIV or who are already HIV-positive (use of condoms is strongly recommended following sterilisation).
- Women with non-pelvic tuberculosis.
- Women with gall-bladder disease (asymptomatic or symptomatic and treated by either cholecystectomy or by medications).
- Women who are viral hepatitis carriers.
- Women with chronic viral hepatitis, benign focal nodular hyperplasia and mild (compensated) cirrhosis.

Classification of Medical Conditions According to Precautionary Measures Needed for Female Sterilisation

Table 4.1
Conditions that require caution, delay, or special requirements for TL

(C) CAUTION Procedure can be conducted in a routine setting, but with extra preparation and precautions.	(D) DELAY Delay procedure until condition is evaluated and corrected. Provide alternative temporary contraception.	(S) SPECIAL Procedure requires experienced surgical team, equipment for GA, and other medical support. Provide alternative temporary contraception if referral is required or there is otherwise any delay.
Obesity Hypertension adequately controlled and BP less than 160/100 History of ischaemic heart disease History of stroke Uncomplicated valvular heart disease Current breast cancer Epilepsy or depressive disorders Uterine fibroids Uncomplicated Diabetes	Young age and women with no living children. Because of the high risk of regret, counsel client very carefully about the permanency of the procedure and availability of alternative long-acting highly effective methods. Delay up to one month if need be to assured of informed decision. Delay postpartum procedure to permit careful evaluation and adequate treatment in women with the following conditions: <ul style="list-style-type: none"> • Prolonged rupture of membranes • Puerperal sepsis or post-abortal sepsis or pyrexia 	Uterine rupture or perforation Fixed uterus due to previous surgery, PID, endometriosis, or possibility of pelvic adhesions: avoid use of endoscopic methods. Abdominal wall or umbilical hernia Known pelvic TB Multiple factors for CVD BP 160/100 or higher Hypertension complicated by vascular disease

Table 4.1

Conditions that require caution, delay, or special requirements for TL
(cont.)

<p>(C) CAUTION</p> <p>Procedure can be conducted in a routine setting, but with extra preparation and precautions.</p>	<p>(D) DELAY</p> <p>Delay procedure until condition is evaluated and corrected. Provide alternative temporary contraception.</p>	<p>(S) SPECIAL</p> <p>Procedure requires experienced surgical team, equipment for GA, and other medical support. Provide alternative temporary contraception if referral is required or there is otherwise any delay.</p>
<p>Hypothyroid</p> <p>Mild cirrhosis</p> <p>Liver tumours ((benign and malignant)</p> <p>Anaemias</p> <p>Previous abdominal or pelvic surgery, diaphragmatic hernia</p> <p>Kidney disease</p> <p>SLE without complications</p> <p>Severe nutritional deficiencies</p> <p>Previous history of PID without subsequent pregnancy</p>	<ul style="list-style-type: none"> • Severe APH, PPH, or post-abortal haemorrhage • Severe trauma to genital tract, including uterine perforation. Severe pre-eclampsia or eclampsia • Peritonitis <p>Delay interval procedure to ensure careful evaluation and treatment in women with the following conditions (and arrange follow-up):</p> <ul style="list-style-type: none"> • Current DVT or major surgery with prolonged immobilization or PE • Current ischaemic heart disease • Unexplained vaginal bleeding before diagnosis <p>Procedure should be delayed to ensure investigations and definitive management are undertaken. The treatment could render the woman sterile:</p>	<p>Complicated valvular heart disease</p> <p>Diabetes with vascular complications</p> <p>Hyperthyroid</p> <p>Endometriosis</p> <p>Severe cirrhosis</p> <p>Coagulation disorders</p> <p>DVT/PE if established on anticoagulant therapy</p> <p>SLE with positive (or unknown) antiphospholipid antibodies, severe thrombocytopenia, and those on immunosuppressive treatment</p> <p>Chronic respiratory disease</p>

Table 4.1

Conditions that require caution, delay, or special requirements for TL
(cont.)

<p>(C) CAUTION</p> <p>Procedure can be conducted in a routine setting, but with extra preparation and precautions.</p>	<p>(D) DELAY</p> <p>Delay procedure until condition is evaluated and corrected. Provide alternative temporary contraception.</p>	<p>(S) SPECIAL</p> <p>Procedure requires experienced surgical team, equipment for GA, and other medical support. Provide alternative temporary contraception if referral is required or there is otherwise any delay.</p>
	<ul style="list-style-type: none"> • Malignant gestational trophoblastic disease • Cervical, endometrial or ovarian cancer Other conditions that may necessitate delay: • Current PID or purulent cervicitis • Current gall bladder disease • Active viral hepatitis • Severe anaemia (Hb <7gm) • Sickle cell disease • Local infection (abdominal skin) • Acute respiratory disease • Systemic infection or gastroenteritis 	<p>AIDS (Note: The presence of an acute AIDS-related illness could require delay of the procedure).</p> <p>Reported allergy to local anaesthetics</p>

Women Who Should Not Use TL

Providers should not perform TL on certain women:

- Women who are uncertain of their desire for future fertility
- Women who cannot withstand surgery
- Women or girls who do not give voluntary informed consent

Management of Common Side Effects

Table 4.2

Management of common side effects

Side effects	Suggested action
Pain at incision site	Determine presence of infection and treat; if no infection, reassure and provide analgesics.
Wound infection, fever	If skin is infected, clean, dress, and treat with antibiotics; if abscess is present, incise and drain; treat with antibiotics for 7-10 days.
Haematoma	Apply warm, moist packs on site, observe for a few days; if increasing, evacuate.
More serious injuries e.g., bladder or bowel injury	Give appropriate management or refer for competent care in a hospital.

Ectopic Pregnancy after Female Sterilization

Pregnancy following TL is rare, but when it does occur, it is more likely to be an ectopic than uterine pregnancy. Ectopic pregnancy is life threatening and requires immediate treatment. Health service providers must be prepared to ensure early diagnosis and management or referral of cases without undue delays. Following the procedure, advise the client to seek help without delay if she ever suspects a pregnancy.

Obtaining This Method

Tubal ligations can be performed by doctors or RCOs with post-basic training in RH. The procedure can be performed at any of the following:

- Any health facility with a minor theatre, appropriate equipment, the ability to observe infection-prevention measures, and the drugs and equipment to handle emergencies, including an effective and efficient referral system.
- Outreach services must be linked to health facilities where complications can be referred.
- Level 4 and above (district hospitals and above).
- Level 3 (health centres, nursing or maternity homes).
- Level 1 (outreach services only).

All appropriate infection-prevention practices, counselling, and follow-up must be adhered to regardless of the facility (static or outreach).

One surgeon should perform no more than 15 procedures in a day, and no more than 30 procedures should be performed in one operating room.

Recommended Job Aids

- *How to Be Reasonably Sure a Client is Not Pregnant* (MOH)

Male Voluntary Surgical Contraception (Vasectomy)

Description

Vasectomy, or male sterilization, is the surgical process of cutting and tying the vas deferens in order to prevent spermatozoa from mixing with semen. Consequently, when ejaculation occurs, the semen will not have any sperms. The operation is performed under a local anaesthetic, and it is one of the most effective methods of contraception—it has a reported failure rate of about 0.1 percent. Still, vasectomies are not often performed in Kenya. According to KDHS 2003, less than 1 percent of married women had ever relied on male sterilization (CBS, 2004). The option of a vasectomy would be a good solution when a woman has medical conditions that hinder use of all female methods.

Correcting Myths and Misconceptions about the Vasectomy

Vasectomy is *not* synonymous with castration, and it does not affect a man's sexual ability or desire.

A vasectomy does *not* become effective immediately. The client should be instructed to use condoms or another FP method for three months after the operation to be completely safe.

Reversal surgery *cannot* be assured. Thorough and careful counselling is needed before making a decision in order to avoid future regret. The procedure must be considered permanent.

Types of Vasectomy

There are scalpel and non-scalpel vasectomy techniques.

Advantages and Benefits of Vasectomy

Contraceptive benefits of vasectomies include the following:

- The procedure is highly effective and safe.
- There is no change in sexual function—the procedure does not interfere with sexual intercourse.
- It is permanent.

Limitations and Risks

A vasectomy has some limitations and risks:

- The procedure is virtually irreversible (i.e., success of reversal surgery cannot be guaranteed).
- There are minimal risks and side effects of local anaesthesia.
- There are risks associated with surgical procedures.
- A vasectomy does not protect against STIs, including HIV/AIDS.
- Only a trained provider can offer a vasectomy.
- There is a delay in effectiveness after the procedure has been performed.

NOTE:

Informed consent must be obtained and a standard consent form signed by the client for the procedure (see **Appendix 5**).

No incentives should be given to clients to accept VSC, or to providers to recruit clients and perform the surgical procedure.

The client is free to change his mind at any time prior to the procedure.

Men Who Can Use Vasectomy (Includes MEC Category A)

Vasectomies are recommended and safe for men of reproductive age who have achieved their desired family size and who understand and voluntarily give informed consent for the procedure. This includes men who are infected with or at risk of HIV or who have sickle cell disease.

Classification of Medical Condition According to Precautionary Measures Needed for Male Sterilisation

Table 4.3

Conditions that require caution, delay, or special requirements for vasectomies

<p>(C) CAUTION</p> <p>Procedure can be conducted in a routine setting, but with extra preparation and precautions.</p>	<p>(D) DELAY</p> <p>Delay procedure until condition is evaluated and corrected if necessary. Provide alternative temporary contraception.</p>	<p>(S) SPECIAL</p> <p>Procedure requires experienced surgical team, equipment for GA, and other medical support. Provide alternative temporary contraception if referral is required or there is otherwise any delay.</p>
<p>Single men, men with no living children, men below 18 years of age: counsel carefully and allow extra time if needed to make informed decision</p> <p>Depressive disorders</p> <p>Diabetics could have increased risk of postoperative wound infection. Follow-up and treat with antibiotics if any signs of infection are present.</p> <p>Inguinal hernia: vasectomy can be performed at the time of hernia repair. (C/S)</p>	<p>Local skin infection: treat prior to procedure</p> <p>Any local infection, including active STI, balanitis, epididymitis or orchitic: treat prior to procedure</p> <p>Systemic infection or gastroenteritis: treat prior to procedure</p> <p>Filariasis, elephantitis: if condition involves the scrotum, it may be difficult to palpate the spermatic cord. Delay until treated and corrected</p>	<p>Coagulation disorders present increased risk of bleeding and postoperative hematoma: might need additional medical support</p> <p>AIDS (see below): might require special care depending on the man's health status. Also delay might be warranted in the presence of acute AIDS-related illness (D/S)</p> <p>Previous scrotal injury, large varicocele, large hydrocele: might require an extensive surgery to locate the vas</p> <p>Cryptorchidism (undescended testicle): might require an extensive surgery to locate the vas</p> <p>Intra-scrotal mass: might be difficult to palpate the spermatic cord. Rule out underlying disease; delay procedure until treated and corrected. (D/S)</p>

Men Who Should Not Have Vasectomies

Vasectomies are not the appropriate choice for every man. Men who should not have vasectomies include the following:

- Clients who are uncertain of their desire for future fertility
- Clients who cannot withstand surgery
- Clients who do not or cannot give voluntary informed consent

Management of Common Side Effects

Table 4.4

Management of side effects of vasectomy

Side effects	Management
Pain	Check for blood clots in the scrotum. Small, uninfected blood clots require rest and pain-relief medication.
Pain lasting for months (uncommon)	Suggest elevating scrotum with snug underwear or an athletic supporter. Suggest soaking in warm water. Recommend painkillers, such as Ibuprofen 200-400 mg three times a day. If pain continues or cannot be tolerated, surgery or injection of the anaesthetic into the spermatic cord may be considered.
Bleeding	Control bleeding
Blood clots or haematoma	Small, uninfected blood clots require rest and pain-relief medication. Large blood clots or hematoma might need to be surgically drained. Infected blood clots require antibiotics and, possibly, hospitalization.

Table 4.4
Management of side effects of vasectomy (cont.)

Side effects	Management
Infection	Treat with antibiotics for 7-10 days, may require hospitalisation
Abscess	Incise and drain the abscess following infection-prevention procedures. Ensure proper wound care. Treat with antibiotics for 7-10 days. Occasionally, hospitalisation might be required for more aggressive treatment (IV antibiotics).

Obtaining This Method

Vasectomies should be provided by trained providers only.

Vasectomies can be performed at any health facility with a minor theatre, the appropriate equipment and ability to observe infection-prevention measures, and with the drugs and equipment to handle emergencies, including an efficient and effective referral system. These facilities would probably include the following:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 1 (outreach services)

NOTE:

In outreach programmes, all appropriate infection-prevention practices, counselling, and follow-up should be arranged as per procedures in static sites. Outreach services must be linked to health facilities where complications can be referred.

No more than 30 procedures should be performed in one operating theatre or by one surgeon in one day.

Chapter Five

BARRIER METHODS OF CONTRACEPTION

Chapter 5

BARRIER METHODS OF CONTRACEPTION

Introduction

Barrier methods prevent the sperm from gaining access to the upper reproductive tract and making contact with the egg. These methods include male and female condoms, spermicides, diaphragms, and cervical caps. Whereas condoms, diaphragms, and cervical caps are mechanical barriers, spermicides are chemicals that interfere with the movement of the sperm and its ability to fertilise the egg. Currently in Kenya, the use of diaphragms, cervical caps, and spermicides is negligible. In addition, scientific evidence has shown that repeated and high-dose use of the spermicide nonoxynol-9 might cause vaginal and cervical irritation or abrasions, which could increase the risk of infection with HIV. As a result, the main focus in this edition of the *FP Guidelines* is on male and female condoms.

The effectiveness of barrier methods is largely dependent on the way in which they are used. For example, condoms are only moderately effective in typical use (15 percent pregnancy rate), but much more effective when used consistently and correctly (2 percent pregnancy rate; See **Appendix 1**).

Male and female condoms help prevent both pregnancy and most STIs (including HIV), because when used correctly, the condoms

keep sperm and any disease organisms in semen out of the vagina; also, they prevent any disease organisms in the vagina from entering the penis. Another advantage of barrier methods is that, with the exception of the male condom, all the barrier methods are controlled by women, and almost every woman can use them. Barrier methods can be used without restriction (i.e., they are included in MEC category 1).

Male Condom

The male condom is a thin, latex rubber sheath or covering, made to fit a man's erect penis. Some are coated with a lubricant or spermicide. Condoms come in different sizes, colours, and textures. As stated above, condoms help prevent both pregnancy and some STIs, including HIV/AIDS. Condom types in the market include plain, flavoured, coloured, and spermicide-added condoms.

Advantages of Condoms

Condoms are effective contraception if used properly, and they offer the following benefits as a contraceptive:

- Condoms offer contraception only when needed.
- Condoms are easy to obtain and can be used without seeing a health care provider.

Other benefits of using condoms include the following:

- With consistent and proper use, they are highly effective protection against STIs, including HIV/AIDS.
- Condoms reduce the risk of cervical cancer.
- Condoms prevent premature ejaculation.

- Almost every man is eligible to use a condom.
- Condoms are easy to use with a little practice.
- There is no health risk associated with this method.
- Condoms do not interfere with the act of intercourse, as do the foaming tablets.

Limitations of Condoms

Some limitations of condoms are the following:

- A new condom must be worn for each act of sexual intercourse.
- Condoms have a higher failure rate if used inconsistently or incorrectly.
- Condoms might reduce sensitivity.
- Condoms might cause itching for a few people who are allergic to latex.
- Condoms are user-dependent.
- Condoms cannot be used with oil-based lubricants.
- Condoms are affected by heat, light, and humidity.

NOTE:

Male condoms should not be used with petroleum products and oils, which lead to rapid degeneration and could reduce their effectiveness in preventing pregnancy and protection against STI, including HIV/AIDS.

Men Who Should Use Male Condoms

Condoms are a good contraceptive choice for men and couples in a variety of circumstances:

- Men who wish to participate actively in FP
- Couples who need a back-up method (e.g., for missed pills)
- Couples who have sex infrequently and who do not need continual protection
- Couples who need temporary methods while awaiting another method
- Couples who want protection from STI/HIV
 - Those who are not using another method, or
 - Those who are using another method for pregnancy prevention, and are at a risk of acquiring an STI or HIV/AIDS (dual method use)
- Postpartum clients or post-abortion clients before initiating more appropriate methods, or any client who needs more time to make a decision about a contraceptive method
- Couples living with HIV/AIDS—whether discordant or concordant

Men Who Should Not Use Male Condoms

Men or couples who want a more effective protection against pregnancy (e.g., when the woman has a condition that makes pregnancy dangerous, and therefore need to consider a more reliable method) should not use male condoms (see Appendix 2). If the woman is at risk of STI, her partner should use a condom in addition to the more reliable and effective contraceptive method.

Management of Possible Side Effects

Table 5.1

Management of possible side effects of using condoms

Side effects	Management
Allergy or irritation (very rare)	<p>In case of a latex allergy, advise couple to use another method. Rule out infection.</p> <p>If the lubricant is a cause of irritation, suggest using water as a lubricant.</p> <p>Note: Clients at risk of STI and HIV/AIDS should be counselled to continue to use condoms despite discomfort as long as they are at risk. If irritation is unacceptable to the client, assist in choosing another method, including the female condom, which is made of polyurethane. Rule out infection.</p>
In case of spillage or breakage	Offer ECP and counsel on HIV and STIs.

Obtaining This Method

All levels of service providers, including trained CHWs or CBDs, pharmacists, and retail shopkeepers can provide male condoms. Condoms should be available at all SDPs, including households, pharmacies, dispensaries, HTC centres, private clinics, and retail outlets.

Disposal of Male Condoms

Clients should be advised on proper ways of using condoms (male and female) as well as disposing of the used ones.

In the case of the male condom:

- After ejaculation and before completely losing his erection, the man should hold the rim of the condom to the base of the penis so it will not slip off when he is pulling his penis out of the woman's vagina.
- He should take the condom off his penis without spilling the semen on the vaginal opening.
- The used condom can be thrown into a pit latrine, burned, or buried. It should be kept away from children. Condoms must not be reused.

Female Condom

The female condom is made of thin, transparent soft plastic (polyurethane).

Advantages and Benefits

Contraceptive Benefits

Female condoms provide the following contraceptive benefits:

- They are effective if used consistently and correctly. The effectiveness of the female condom is slightly less than the male condom. The failure rate is about 5 percent in perfect use, and 21 percent in typical use.
- They offer contraception only when needed.
- Condoms can be used without seeing a health care provider.

Other Benefits

Other benefits to using condoms include the following:

- With consistent and proper use, condoms are highly effective protection against STIs, including HIV/AIDS.
- They protect against PID.
- The woman can control this method.
- Almost every woman is eligible to use this method.
- It can be inserted eight hours before an anticipated sexual act.
- There is no need to see a health care provider before use.
- Condoms are easy to use with a little practice.
- No health risk is associated with the method.
- Unlike latex rubber, there is no known allergy to polyurethane, the material from which female condoms are made.

Limitations of Female Condoms

Female condoms have the following limitations:

- Condom must be inserted before sexual intercourse (although they can be inserted in advance—as much as eight hours).
- Female condoms are expensive.
- A condom can be used only once—it cannot be reused.

Women Who Can Use the Female Condom

All women of reproductive age of any parity, including nulliparous women, can use a female condom. The female condom is appropriate in many circumstances:

- Women who need to rule out possible pregnancy before proceeding with another method.
- Women who need a back-up method.
- Women who need temporary methods of contraception.
- Post-abortion clients before initiating other methods.
- Women who need dual protection if they are using another method for pregnancy prevention, but are at a risk of acquiring an STI or HIV/AIDS (e.g., a woman who has more than one partner, or a woman whose partner has more than one partner).

Women Who Should Not Use a Condom

A woman who has one or more conditions that make pregnancy dangerous and needs a more effective method of protection against pregnancy may want to consider other, less client-dependant, methods of contraception (see **Appendix 2**).

Disposal of Used Female Condoms

The female condom should be carefully removed and appropriately disposed of:

- At the end of intercourse, the woman should hold the outside rim of the female condom, twist it to seal in the fluids, and carefully pull out the device without spilling semen.
- The used condom can be thrown into a pit latrine, burned, or buried. It should be kept away from children.
- Condoms must not be reused.

Obtaining This Method

All service providers can provide female condoms, including the following:

- Doctors
- Nurses and midwives
- Clinical officers
- Trained community health workers or CBDs
- Pharmacists or pharmaceutical technologist
- Shopkeepers

Female condoms can be obtained at all SDPs:

- Level 4 and above (hospitals)
- Level 3 (health centres, nursing or maternity homes)
- Level 2 (dispensaries, HTC centres, private clinics)
- Level 1 (outreach, mobile services, home-based care, pharmacies)

Chapter Six

LACTATIONAL AMENORRHOEA METHOD (LAM)

Chapter 6

LACTATIONAL AMENORRHOEA METHOD (LAM)

Introduction

The Lactational Amenorrhoea Method (LAM), a sub-set of Natural Family Planning (NFP), is a temporary method of FP based on the lack of ovulation that results from exclusive breastfeeding. LAM works primarily by preventing ovulation—but for this to occur, exclusive breastfeeding is mandatory. Therefore, effectiveness depends on the user. As commonly used, the pregnancy rate is about two per 100 women in the first six months. With perfect use, the pregnancy rate is less than one per 100 women (see **Appendix 1**).

For this method to be effective, **all three** of the following criteria must be met:

- The woman’s menstrual periods have not resumed.
- The baby is exclusively or nearly exclusively breastfed.
- The baby is less than six months old.

When any of these three criteria is no longer met, another FP method must be introduced in a timely manner to ensure healthy birth spacing.

Advantages and Benefits of LAM

LAM provides effective protection against pregnancy as long as all three LAM criteria are met. Its other contraceptive benefits include the following:

- LAM does not interfere with sexual activity.
- It has no known health risks.
- Return to fertility is immediate.

LAM offers other benefits, as well:

- Optimal breastfeeding provides health benefits for both the mother and the baby.
- Breastfeeding provides passive immunity for the child.
- Counselling for LAM encourages women to start a follow-on method at the appropriate time.
- LAM is affordable FP—it has no direct costs.
- Women living with HIV/AIDS can use LAM.

NOTE:

The risk of transmitting HIV to the infant is reduced by exclusive breastfeeding compared to mixed feeding, but it is still greater than with exclusive alternative feeding.

Limitations of LAM

This method is effective only as long as all three LAM criteria are met. However, there are a number of reasons that discourage a woman from breastfeeding:

- Breastfeeding can transmit HIV from a mother to her baby.
- A woman might not breastfeed because she is taking certain drugs (e.g., mood altering drugs, reserpine, ergotamine, antimetabolites, cyclosporine, cortisone, bromocryptine, radioactive drugs, lithium, or certain anticoagulants).
- Exclusive breastfeeding might be inconvenient or difficult for some women, especially working mothers.
- LAM does not protect a woman against STIs, including hepatitis B, HIV, and AIDS.

Women Who Can Use LAM without Restrictions

Women whose babies are less than six-months old, who are exclusively breastfeeding, and are amenorrhoeic can use this method as contraception.

Women should be counselled in advance about future FP options and the need to initiate another method as soon as any of the following occurs:

- Supplementary feeding begins, or baby starts to skip regular meals (e.g., sleeps through the night).
- Menstruation begins.
- The baby is about to turn six-months old.

Women Who Can Use LAM, with Precautions (Includes MEC Category 2)

Women living with HIV/AIDS should proceed with caution and receive counselling when they choose this method.

Women Who Should Not Rely on LAM

In the following circumstances, a woman should not rely on this method:

- The woman is not exclusively breastfeeding.
- The woman's menses has resumed.
- The baby is more than six months of age.
- Couples need highly effective protection against pregnancy (e.g., the woman has conditions that make pregnancy dangerous—see **Appendix 2**).

Obtaining Assistance with This Method

All trained providers, including CHWs, can assist with this method. A woman can visit any appropriate site with qualified providers for counselling.

Chapter Seven

FERTILITY AWARENESS-BASED METHODS (FAMs)

Chapter 7

FERTILITY AWARENESS-BASED METHODS (FAMs)

Introduction

Fertility awareness-based methods (FAMs), also referred to as natural family planning (NFP) methods, require abstinence from intercourse during the fertile time of a woman’s menstrual cycle, thereby avoiding conception. To achieve this, the woman must be able to recognise her fertile time. This is managed through several approaches, either singly or in combination, which include calendar-based methods and symptoms-based methods. These are detailed below.

Success in the practice of FAMs is largely dependent on the motivation of the learner and, for some methods (e.g., Cervical Mucus, Ovulation, BBT, and Symptothermal), the competence of the teacher. Newer FAM options, such as the Standard Days Method® (SDM) and TwoDay Method® (TDM), require less reliance on the provider, as they are offered and learned in one client-provider contact. For other FAMs, couples must abstain from sex during the learning phase. Once trained, the couple can begin using FAMs at the start of a new cycle. Pregnancy rates range from 1-14 percent with correct and typical use in the first year. Effectiveness of FAMs is enhanced by use of multiple techniques to identify the fertile time.

Calendar-Based Methods

In the calendar-based methods, the couple keeps track of the days in the menstrual cycle to identify the start and end of the fertile time.

Standard Days Method® (SDM)

The SDM is based on the fact that there is a fertile window during the woman's menstrual cycle when she can become pregnant. Typically, this window occurs several days before ovulation and a few hours after. To prevent pregnancy, couples avoid unprotected sex or abstain between days 8-19 of the menstrual cycle. This formula is based on computer analysis of some 7,500 menstrual cycles. An efficacy trial⁴⁴ found that the SDM was more than 95-percent effective with correct use, and more than 88-percent effective with typical use among women who reported regular recent cycles of 26-32 days. Most women who get their periods about once a month fall within this range. The SDM efficacy is similar to most other user-dependent methods (see **Appendix 1**).

The SDM is appropriate for women who can avoid unprotected sex on fertile days and usually have cycles between 26-32 days long (approximately 80 percent of cycles are in this range). The SDM makes use of CycleBeads, a color-coded string of beads used with the SDM that represent the days of a woman's fertility cycle. CycleBeads help the woman track her cycle days, know on which days she is fertile, and monitor her cycle length. The woman and her partner must avoid unprotected intercourse or abstain on the 12 fertile days identified by the white colour beads.

Arévalo M, Jennings V, Sinai I. Efficacy of a New Method of Family Planning: the Standard Days Method, *Contraception*, 2002, 65:333-338.

CycleBeads serve as a visual tool to help women use the SDM correctly. On the day she starts her period, the woman moves the ring to the red bead to begin a new cycle and marks that day on her calendar. To keep track of her cycle days and know whether she is on a fertile day, the woman moves a rubber ring one bead every day. To monitor her cycle length, the woman knows that if her period starts before she moves the ring to the darker brown bead, her cycle is shorter than 26 days. If she doesn't start her period by the day after she moves the ring to the last brown bead, her cycle is longer than 32 days. If she has a cycle shorter than 26 days or longer than 32 days more than once in a year, the SDM will not be effective for her.

Symptoms-Based Methods

Symptoms-based methods depend on observation of signs of fertility, such as the presence or absence of cervical mucus, changes in the amounts and characteristics of the cervical mucus, changes in body temperature, a combination of the latter two, or use of specific ovulation detection kits.

TwoDay Method® (TDM)

The TwoDay method® (TDM) is a simple, symptom-based method by which women check for the presence or absence of cervical secretions as the sign of fertility. The TDM does not require interpretation of the quality or quantity of secretions. A woman who uses the TDM asks herself two questions: (1) "Did I note secretions today?" and (2) "Did I note secretions yesterday?" She should consider herself fertile today if she notices cervical secretions of any type today, or if she noticed them yesterday. Women who use the TDM are instructed to avoid unprotected intercourse on these days to prevent pregnancy. Most users are able to learn the method

in one short counselling session. The TDM is 96-percent effective in preventing pregnancy when used correctly, and 86 percent effective with typical use.

Women can start using the TDM at any time in their cycles. To use the method, a woman pays attention to her secretions every day starting at a particular time. Women can check for secretions by seeing them or touching them in their underwear or on toilet paper. She may also touch her genitals. Later, as women become more familiar with their body, they identify secretions simply by sensation.

In TDM counselling, women purposely are not taught to distinguish normal cervical secretions from infectious or other abnormal vaginal discharge. However, the users are taught that if they notice secretions for more than 14 consecutive days, they should consult with their health care provider for diagnosis, treatment, and referral, if necessary. Clients might consider using another method until their situation is resolved.

Cervical Mucus, or Billings Ovulation Method

In this method, the days of infertility, possible fertility, and maximum fertility of the menstrual cycle are defined by observation of changes in the cervical mucus. The woman identifies the fertile time by observing the characteristics of the cervical mucus.

To use this method correctly, the woman should:

- Avoid sex on days of monthly bleeding. In cases when ovulation occurs early in the cycle, bleeding could make it hard to observe cervical mucus signs (this can happen to women with short cycles and heavy menses).

- Avoid sex as soon as she notices any secretions. The fertile phase of the menstrual cycle begins with the appearance of a mucus secretion, which changes as the days go by, becoming more stretchy and slippery.
- Recognise evidence of ovulation (peak day), when the mucus is very clear, stretchy (Spinnbarkeit's sign), and slippery.
- Continue to avoid sex for three more days after peak day, even if secretions completely disappear before three days have expired.

The couple can resume sex on the fourth day after the peak day and until her next monthly bleeding. The client should be taught to apply the method rules appropriately.

A major advantage of this method is that it can be used by women wanting to achieve a pregnancy by identifying her fertile days.

Basal Body Temperature (BBT)

With this method, the woman is instructed to take her body temperature either orally, rectally, or vaginally at the same time each morning before getting out of bed and before eating anything. The routine for taking the temperature must be the same for the entire cycle.

The temperature readings are recorded on a special graph paper, which makes it easy to identify small changes in temperature readings. The woman's temperature rises by 0.20C - 0.50 C, around the time of ovulation (about midway through the menstrual cycle for many women). The couple avoids sex from the first day of monthly bleeding until three days after the woman's temperature has risen above her regular temperature.

The couple should be taught to apply method rules appropriately.

Sympto-thermal Method (Cervical Mucus + BBT)

In this method, the pre-ovulatory and post-ovulatory infertile phases of the menstrual cycle are identified by a combination of the above two techniques (the cervical mucus and BBT shift), as well as other signs and symptoms around ovulation.

The signs and symptoms used in the sympto-thermal method include:

- Thermal shift (BBT)
- Cervical mucus changes (BILLINGS)
- Cervical changes (consistency, position, openness, or closure)
- Other appropriate signs and symptoms, such as sharp lower abdominal pain (mittelschmerz), breast tenderness, increased libido, or intermenstrual bleeding

Couples are taught to apply the combined rules of the above methods to identify the fertile time.

New Approaches

To enhance the efficacy of FAMs and make the methods easier for couples to use, several new technologies for identifying fertility signs have been developed. These items provide a more precise way to detect ovulation:

- Advanced thermometers for detection of BBT shift
- Hand-held electronic devices that record multiple signs to predict ovulation
- Ovulation-detection kits that measure levels of luteinizing hormone (LH) in urine

- CycleBeads® that help women keep track of their cycle days when using the SDM

Key Points about FAMs for Providers and Clients

Fertility- awareness-based methods require partners' cooperation. Couples must be committed to abstaining from unprotected vaginal intercourse on fertile days. The woman must stay aware of her body's changes or keep track of her days, according to the rules of the specific method.

Advantages of These Methods

When used correctly and consistently, FAMs can be reasonably effective and have several other contraceptive benefits:

- They do not require contraceptive commodities and supplies.
- There are no side effects or health risks.
- Some couples like the active involvement of the male partner.

These methods offer other benefits, as well:

- They result in an improved knowledge of the reproductive system and possible closer relationship between couples (strengthen male involvement).
- They can be used by both literate and illiterate women.
- They allow adherence to religious and cultural norms.
- HIV-positive women can use them.
- Women who want to become pregnant can use them to identify fertile days.
- They can be used where other methods are contra-indicated.

Limitations of These Methods

- These are user-dependent methods, so their effectiveness relies greatly on correct and consistent use.
- Some FAM methods require daily record keeping and monitoring of menstrual cycles.
- Ovulation, Basal-body Temperature, and Sympto-thermal methods require individualised training before use of the methods and more intensive counselling.
- These methods require varying periods of sexual abstinence during fertile phase⁴⁵.
- Both partners must actively cooperate.
- These methods offer no protection against STIs, including HIV/AIDS and HBV.
- Breastfeeding women and current or recent users of injectable contraceptives need to wait until their menstrual cycles resume their regular pattern before they can use the SDM.
- The SDM requires more extensive counselling following recent childbirth, in recent menarche, during perimenopause, and following recent discontinuation of injectable contraceptive methods.

Women Who Can Use FAMs

All women of reproductive age with established menstrual cycles, including women with disabilities and migrant populations, can use FAM methods if they can learn to identify their fertile days. These methods are good FP options for couples that cannot use modern methods on religious, cultural, or medical grounds; and

⁴⁵ Studies have shown that many couples use FAM methods to identify the fertile phase of the menstrual cycle, but use condoms or withdrawal to obviate the need for prolonged abstinence.

couples who are willing to abstain from intercourse during the fertile time.

Women Who Can Use This Method, with Extra Care (Includes MEC Category 2)

The following women should proceed with caution when they choose to use this method:

- Women with chronic conditions that raise body temperature
- Women who take drugs that could delay ovulation (e.g., mood-altering drugs, antidepressants, some long-term antibiotics, or long-term NSAIDs)
- Women with irregular or not well established cycles, as in the following situations:
 - Recent menarche
 - Recent childbirth
 - Recent abortion or miscarriage
 - Recent discontinuation of injectable contraceptive methods
 - Perimenopause
 - Medical conditions that affect ovarian function (e.g., liver tumors, liver cirrhosis, and stroke)

Women Who Should Delay Starting This Method

Women with the following conditions should delay starting this method until the condition has been resolved:

- Infections or diseases that may alter cervical mucus
- Irregular vaginal bleeding
- Abnormal vaginal discharge
- Habit of taking mood-altering drugs

Women Who Should Not Use This Method

This method would not be appropriate for the following:

- Women who dislike touching their genitals
- Women whose partners will not cooperate
- Couples who want highly effective protection against pregnancy (e.g., the woman has conditions that can be made worse by pregnancy—see **Appendix 2**)

Obtaining These Methods

Health professionals and lay persons who have received training in FAMs and NFP methods can counsel women on these methods. Women and couples can obtain assistance at any appropriate site with a qualified service provider.

Recommended Job Aids

- Client learning sessions manual
- Charts (male and female reproductive system, menstrual cycle, symptothermal charts)
- *Counselling Protocol for Standard Days Method and CycleBeads (Institute of Reproductive Health/Georgetown University)*
- Audio-visual aids
- CycleBeads®
- BBT GRAPH
- Clinical thermometer

Withdrawal (Coitus Interruptus) Method

Coitus interruptus (CI) is one of the traditional methods of birth control. A couple that is using this method may have intercourse in any way acceptable to them until ejaculation is about to occur. Before ejaculation, the male withdraws his penis from the vagina and external genitalia of the female in order to prevent sperm from entering the female's reproductive tract, thereby preventing contact between the spermatozoa and the ovum. This method might be appropriate for couples who need a temporary method while they await the start of another method, or for those who have entered into a sexual act without any other method and need contraception immediately.

The method has one strong disadvantage: it demands consistent self-control on the part of the male partner, which could be difficult at times. In addition, it is possible for pre-ejaculatory fluid containing sperm to flow out during the excitement phase, before the penis is withdrawn. The failure rate of the withdrawal method ranges from 4-10 pregnancies per 100 women per year when it is used consistently, to 14-23 pregnancies per 100 woman per year among actual users (i.e., when it is not used consistently).

Advantages of CI

Coitus interruptus can be an effective method if it is used correctly, and it is always available for use as a primary or back-up method. This method offers several other benefits:

- CI does not affect breastfeeding.
- CI involves no economic cost.
- CI involves no use of devices or chemicals.
- CI has no health risks associated directly with it.

Limitations

The withdrawal method has two major limitations: (1) it does not protect from STIs, including HIV/AIDS and HBV—couples at high risk of infection should use a condom with each act of intercourse; and (2) effectiveness depends on the willingness and ability of the male partner to use withdrawal with every act of intercourse.

NOTE:

Couples who have intercourse infrequently should not rely on the withdrawal method because it requires a lot of practice. Service providers should counsel couples who want to rely on the withdrawal method to use another method while the man is learning to withdraw on time.

Lack of ejaculatory control (or premature ejaculation) is a contraindication to the use of the withdrawal method of birth control.

APPENDICES

APPENDIX 1

Contraceptive Effectiveness ⁴⁶

Rates of Unintended Pregnancies per 100 Women

Family Planning Method	First-Year Pregnancy Rates ^a		12-month Pregnancy Rates ^b
	Consistent and correct use	As commonly used	As commonly used
Implants	0.05	0.05	
Vasectomy	0.1	0.15	
Levonorgestrel IUCD	0.2	0.2	
Female sterilisation	0.5	0.5	
Copper-bearing IUCD	0.6	0.8	2
LAM (for six months)	0.9 ^c	2 ^c	
Monthly injectables	0.05	3	
Progestin-only injectables	0.3	3	2
Combined oral contraceptives	0.3	8	7
Progestin-only oral pills	0.3	8	
Combined patch	0.3	8	
Combined vaginal ring	0.3	8	
Male condoms	2	15	10
Ovulation method	3		
Two-day method	4		
Standard-days method	5		
Female condoms	5	21	
Other fertility awareness methods		25	24
Withdrawal	4	27	21
No method	85	85	85

^a Rates largely from the United States. Source: Trussell J. Contraceptive efficacy. In: Hatcher R et al., editors. Contraceptive technology. 19th revised ed. 2007 (in press). Rates for monthly injectables and cervical cap are from Trussell J. Contraceptive failure in the United States. Contraception. 2004;70(2): 89-96.

^b Rates from developing countries. Source: Cleland J and Ali MM. Reproductive consequences of contraceptive failure in 19 developing countries. Obstetrics and Gynecology. 2004;104(2): 314-320.

⁴⁶ Adapted from *FP Global Handbook*.

APPENDIX 2

Medical Conditions That Make Pregnancy Especially Risky⁴⁷

Some common medical conditions make pregnancy riskier to a woman's health. The effectiveness of her contraceptive method therefore has special importance. For a comparison of the effectiveness of FP methods, see Appendix 1. Some methods depend more on their users for effectiveness than do others. Mostly, the methods that require correct use with every act of sex or abstaining during fertile days are the less effective methods, as commonly used. These methods include withdrawal, fertility awareness methods, female condoms, and male condoms.

Women with any of the conditions listed below should be informed that pregnancy could be especially risky to their health and, in some cases, to the health of her baby. During counselling, special focus should be on the effectiveness of methods. Clients who are considering a method that requires correct use with every act of sex should think carefully about whether they can use it effectively or not.

- Reproductive Tract Infections and Disorders
 - Breast cancer
 - Endometrial cancer
 - Ovarian cancer

⁴⁷ Adapted from *FP Global Handbook*.

- Some sexually transmitted infections (gonorrhea, chlamydia)
- Some vaginal infections (bacterial vaginosis)
- Cardiovascular Disease
 - High blood pressure (systolic blood pressure higher than 160 mm Hg or diastolic blood pressure higher than 100 mm Hg)
 - Complicated valvular heart disease
 - Ischemic heart disease (heart disease due to narrowed arteries)
 - Stroke
- Other Infections
 - HIV/AIDS
 - Tuberculosis
 - Schistosomiasis with fibrosis of the liver
- Endocrine Conditions
- Diabetes if insulin dependent, with damage to arteries, kidneys, eyes, or nervous system (nephropathy, retinopathy, neuropathy); or of more than 20 years' duration
- Anemias
- Sickle cell disease
- Gastrointestinal Conditions
 - Severe (decompensated) cirrhosis of the liver
 - Malignant (cancerous) liver tumors (hepatoma)

APPENDIX 3

How to Identify Migraine Headaches and Auras⁴⁸

For women who want a hormonal method, or are using one, identifying whether or not they suffer from migraine headaches, with or without auras, is important because **migraines, and aura in particular, are linked to higher risk of stroke**. Some hormonal contraceptives can increase that risk further.

Identifying Migraine Headaches

For women who report having very bad headaches, ask these questions to tell the difference between a migraine headache and an ordinary headache. If she answers “yes” to any two of these questions, she probably suffers from migraine headaches.

1. Do your headaches make you feel sick to your stomach?
2. When you have a headache, do light and noise bother you a lot more than when you do not have a headache?
3. Do you have headaches that stop you from working or carrying out your usual activities for one day or more?

Identifying Migraine Auras

Ask this question to identify the most common migraine aura. If a woman answers “yes,” she probably suffers from migraine auras.

⁴⁸ Adapted from *FP Global Handbook*.

- Have you ever had a bright light in your eyes lasting 5-60 minutes, loss of clear vision usually to one side, and then a headache? (Women with such aura often bring one hand up beside their heads when describing the vision change. In some cases the bright light is not followed by a headache.)

If her headaches are not migraines and she does not have aura, she can start or continue hormonal methods if she is otherwise medically eligible. Any later changes in her headaches should be evaluated.

APPENDIX 4

Signs and Symptoms of Selected Serious Health Conditions⁴⁹

The table below lists signs and symptoms of some serious health conditions, which are mentioned within these FP Guidelines. Even though these conditions occur only rarely among users of FP methods, it is important to recognise early the symptoms and signs of the conditions, and to take action or refer for care clients that report them. In some cases, clients who develop one of these conditions might need to choose another contraceptive method.

Appendix Table 4.1

Conditions and their symptoms that require attention when using FP methods

Condition	Description	Signs and symptoms
Deep vein thrombosis	A blood clot develops in the deep veins of the body, generally in the legs.	Persistent, severe pain in one leg, sometimes with swelling or red skin is a symptom.
Ectopic pregnancy	The fertilised egg implants in tissue outside the uterus, most commonly in a fallopian tube, but sometimes in the cervix or abdominal cavity.	In the early stages of ectopic pregnancy, symptoms could be absent or mild, but eventually they become severe. A combination of the following signs and symptoms should increase suspicion of ectopic pregnancy: unusual abdominal pain or tenderness; abnormal vaginal bleeding or no monthly bleeding, especially if this is a change from her usual bleeding pattern; light-headedness or dizziness; fainting.

⁴⁹Adapted from *FP Global Handbook*.

Appendix Table 4.1

Conditions and their symptoms that require attention when using FP methods (cont.)

Condition	Description	Signs and symptoms
Gall bladder disease	Gallbladder disease results from inflammation of the gallbladder and the bile duct, and it is usually associated with stones. The condition could be acute (Acute Cholecystitis) or chronic (Gallbladder or Bile duct stones).	Signs of gallbladder disease are intermittent pain (biliary colic) in the middle or right portion of the upper abdomen, which could be associated with fever, chills, nausea or vomiting. Large or fatty meals can trigger the pain, but it usually occurs several hours after eating and often awakens the patient during the night.
Heart attack	The blood supply to the heart is blocked, usually due to a build-up of cholesterol and other substances in the coronary arteries.	Heart attack symptoms include: chest discomfort or uncomfortable pressure; fullness, squeezing, or pain in the centre of the chest that lasts longer than a few minutes or that comes and goes; spreading pain or numbness in one or both arms, back, jaw, or stomach; shortness of breath; cold sweats; and nausea.
Migraine headaches	A migraine headache is a throbbing or pulsating headache that often is one sided (unilateral) and associated with nausea; vomiting; sensitivity to light, sound, and smells; sleep disruption; and depression. Migraines are classified according to the symptoms they produce. The two most common types are migraine without aura and migraine with aura. Migraines and aura in particular, are linked to higher risk of stroke.	Migraine without aura is the most prevalent type and may occur on one or both sides (bilateral) of the head. Tiredness or mood changes might be experienced the day before the headache. Nausea, vomiting, and sensitivity to light (photophobia) often accompany migraine without aura. Migraine with aura is experienced 10 to 30 minutes before the headache. Most auras are visual and are described as bright, shimmering lights around objects, or hallucinations. Others experience temporary vision loss. Nonvisual auras include motor weakness, speech or language abnormalities, dizziness, vertigo, and tingling or numbness (parasthesia) of the face, tongue, or extremities.

Appendix Table 4.1

Conditions and their symptoms that require attention when using FP methods (cont.)

Condition	Description	Signs and symptoms
Liver disorders	Infection with hepatitis inflames the liver; cirrhosis scars tissue, which blocks blood flow through the liver.	Yellow eyes or skin (jaundice) and abdominal swelling, tenderness, or pain, especially in the upper abdomen, are signs of liver disorders.
Pelvic inflammatory disease (PID)	PID is an infection of the upper genital tract that can be caused by various types of bacteria.	Symptoms include lower abdominal pain; pain during sex, pelvic examination, or urination; abnormal vaginal bleeding or discharge; and fever. In a pelvic examination, signs of PID include: tenderness in the ovaries or fallopian tubes; yellowish, cervical discharge that contains mucus and pus; and tenderness or pain when moving the cervix and uterus during pelvic examination.
Pulmonary embolism	A blood clot travels through the bloodstream to the lungs.	Sudden shortness of breath that might worsen with a deep breath, a cough that might bring up blood, a fast heart rate, and a light-headed feeling could indicate this condition.
Ruptured ectopic pregnancy	A fallopian tube breaks as a result of an ectopic pregnancy.	Symptoms are a sudden sharp or stabbing pain in lower abdomen, sometimes on one side, and sometimes accompanied by right shoulder pain. Usually, within hours the abdomen becomes rigid and the woman goes into shock.

Appendix Table 4.1

Conditions and their symptoms that require attention when using FP methods (cont.)

Condition	Description	Signs and symptoms
Severe allergic reaction to latex	A person's body has a strong reaction to contact with latex.	A rash over much of the body, dizziness brought on by a sudden drop in blood pressure, difficulty breathing, and loss of consciousness (anaphylactic shock) are symptoms of a severe allergic reaction.
Stroke	The arteries to the brain become blocked or burst, preventing normal blood flow and leading to the death of brain tissue.	Signs and symptoms of stroke develop suddenly and include numbness or weakness of the face, arm, or leg, especially on one side of the body; confusion or trouble speaking or understanding; trouble seeing in one or both eyes; trouble walking, dizziness, loss of balance or coordination; and severe headache with no other known cause.
Systemic lupus erythematosus (SLE)	A chronic autoimmune disease, SLE can affect any part of the body. It occurs nine times more often in women than in men, especially between the ages of 15 and 50. Most often it harms the heart, joints, skin, lungs, blood vessels, liver, kidneys, and nervous system.	SLE symptoms and signs vary widely depending on the body parts affected, and they come and go unpredictably. The most common are skin and musculoskeletal manifestations: malar rash; alopecia; ulcers in mouth, nose, and vagina; joint pain, especially in small joints of the hand and wrist. These may be associated with fever, malaise, myalgias, fatigue, and temporary loss of cognitive abilities. Other symptoms and signs are due to haematological, cardiac, pulmonary, renal, and neuropsychiatric manifestations of the disease.

APPENDIX 5

Informed and Voluntary Consent Form for Surgical Contraception

I,, the undersigned, wish to be sterilised by the following procedure:

.....

I understand the following:

1. There are temporary methods of contraception that I can use instead of sterilisation for family planning.
2. Sterilisation is a surgical procedure, the details of which my doctor, nurse, or midwife has explained to me.
3. The sterilisation operation carries certain risks, complications, and side effects, which my doctor, nurse, or midwife has explained to me.
4. The sterilisation procedure will permanently prevent future pregnancies.
5. The sterilisation procedure is considered permanent and probably cannot be reversed.
6. I know that I can change my mind and decide against the procedure at any time before the procedure is done, and I will continue to be provided with medical services from my doctor, nurse, or midwife.

..... Date:
Client's name (print)

..... Date:
Client's signature

..... Date:
Spousal name, when applicable (print)

..... Date:
Spousal signature, when applicable]

..... Date:
Surgeon's signature

..... Date:
Witness (can be another service provider)

APPENDIX 6

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