Ministry of Health

National Family Planning Guidelines for Service Providers

(6th Edition)

Updated to reflect the 2015 Medical Eligibility Criteria of the World Health Organization

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Plan Your Family

The National Family Planning Guidelines for Service Providers 6th edition contain relevant information required by healthcare providers in the provision of family planning services as of the date of issue. All reasonable precautions have been taken by RMHSU to verify the information contained in this guideline document.

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FOREWORD

Kenya identifies family planning as a rights issue and underscores its role in both economic and social development. The Ministry of Health therefore continues to show commitment in improving the lives and health of women and families by investing in family planning (FP) as a key driver towards attaining Universal Health Coverage. Kenya has committed to national and global goals in FP to ensure that Kenyans access rights-based FP services through all healthcare levels.

The National Family Planning Program is mandated to provide policy direction and guidance on the implementation of FP services across the country. It is also mandated to ensure quality of FP services, capacity building and providing technical assistance to counties in the delivery of quality family planning services.

In line with this mandate, the RMHSU conducted a review of the National Family Planning Guidelines (5th Edition) in response to current global guidance on provision of FP services, addressing method mix and emerging issues such as re-categorization of FP methods in certain conditions.

Despite great strides by the National Family Planning Program, geographical and demographic disparities still persist in accessing quality FP services. It is therefore important to explore the opportunities both devolution and the country's agenda on Universal Health Coverage provide to cascade Family Planning services to the grass root level.

These national family planning guidelines are to be used by all health services providers offering family planning services within the country. They offer guidance in the provision of modern methods of family planning in response to local challenges, as well as highlighting opportunities for increasing uptake of family planning services.

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The review of the National Family Planning Guidelines for Service Providers has been a collaborative process between the Ministry of Health together with several stakeholders and partners. The review of the guidelines has been a consultative process with several review meetings and contributions from stakeholders. The current guidelines referenced heavily on the WHO Medical Eligibility Criteria of 2015 and the Family Planning Global Handbook for Providers (2018 update). The Reproductive and Maternal Health Services Unit (RHMSU) would like to thank all the individuals and organizations that contributed to the review process.

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LIST OF ABBREVIATIONS

ABC	Abacavir
ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral Drug
ASRH	Adolescent Sexual & Reproductive Health Policy
ATV	Atazanavir
AZT	Zidovudine
BBT	Basal Body Temperature
BMI	Body Mass Index
BP	Blood Pressure
BTL	Bilateral Tubal Ligation
CAL	Calendar (for Calendar-based methods)
CBD	Community Based Distributor
CBFP	Community Based Family Planning
CDRR	Contraceptives Consumption Data Report and Request
CHC	Combined Hormonal Contraceptives
CHEW	Community Health Extension Worker
CHSSP	County Health Sector Strategic & Investment Plan
CHV	Community Health Volunteer
CHW	Community Health Worker
CI	Contraceptive Implant
CIC	Combined Injectable Contraceptive

CIN	Cervical Intraepithelial Neoplasm
COC	Combined Oral Contraceptive
CPR	Contraceptive Prevalence Rate
CRPD	Convention on the Rights of Persons with Disabilities
CVA	Cerebral Vascular Accident
CVD	Cardiovascular Disease
CYP	Couple Years of Protection
DCDRR	District Contraceptives Consumption Data Report and Request
DDI	Didanosine
DHIS	District Health Information System 2
DMPA	Depot Medroxyprogesterone Acetate
DQA	Data Quality Assessment
DRV	Darunavir
DTG	Dolutegravir
DVT	Deep Vein Thrombosis
EC	Emergency Contraception
ECN	Enrolled Community Nurse
ECP	Emergency Contraception Pill
EFV	Efavirenz
ETR	Etravirine
FAM	Fertility Awareness-based Method
FCDRR	Facility Contraceptives Consumption Data Report and Request
FEFO	First Expiry First Out
FHI	Family Health International

FP	Family Planning
FSH	Follicle Stimulating Hormone
FTC	Emtricitabine
GA	General Anaesthesia
GRN	Goods Received Note
HBV	Hepatitis B Virus
HCG	Human Chorionic Gonadotrophin
HIV	Human Immunodeficiency Virus
HRIO	Health Records and Information Officer
HTSP	Healthy Timing and Spacing of Pregnancies
IDP	Internally Displaced Person
IHD	Ischaemic Heart Disease
IM	Intramuscular
IPC	Infection Prevention and Control
IUCD	Intrauterine Contraceptive Device
IUS	Intrauterine System
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package of Health
KQMH	Kenya Quality Model for Health
LAM	Lactational Amenorrhea Method
LH	Luteinizing Hormone
LMP	Last Menstrual Period
LNG-IUS	Levonorgestrel Intrauterine System
LPV	Lopinavir
MCH	Maternal & Child Health

MDG	Millennium Development Goal
MEC	Medical Eligibility Criteria
MOH	Ministry of Health
NET-EN	Norethisterone Enanthate
NFP	Natural Family Planning
NGO	Non-governmental Organization
NHIF	National Health Insurance Fund
NHSSIP	National Health Sector Strategic & Investment Plan
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NSAID	Non-steroidal Anti-inflammatory Drug
NVP	Nevirapine
OJT	On Job Training
OPD	Outpatient Department
PAC	Post Abortion Care
PE	Pulmonary Embolism
PID	Pelvic Inflammatory Disease
PHT	Public Health Technician
PLWHA	People Living with HIV/AIDS
PMTCT	Prevention of Mother-to-Child Transmission
POC	Progestin-only Contraceptive
POIC	Progestin-only Injectable Contraceptive
POP	Progestin-only Pill
PSA	Protein-specific Antigen
PV	Par Vagina
PVR	Progesterone-releasing Vaginal Ring
RAL	Raltegravir

RCO	Registered Clinical Officer
RH	Reproductive Health
RMHSU	Reproductive and Maternal Health Services Unit
RPV	Rilpivirine
SC	Subcutaenous
SDM	Standard Days Method
SDP	Service Delivery Point
SLE	Systemic Lupus Erythematosus
SMY	Symptoms (for Symptoms-based methods)
SRH	Sexual & Reproductive Health
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir
TDM	Two Day Method
TFR	Total Fertility Rate
UPA	Ulipristal Acetate
VIA	Visual Inspection with Acetic Acid
VILI	Visual Inspection with Lugol's Iodine
VSC	Voluntary Surgical Sterilization
WRA	Women of Reproductive Age

CHAPTER ONE:

1

INTRODUCTION TO THE 6TH EDITION

OVERVIEW OF FAMILY PLANNING IN KENYA

Family Planning (FP) has been identified as a crucial investment for Kenya's health and development. The large size of Kenya's young population and its rapid population growth are influenced by several factors that have serious consequences for the health and well-being of women and children as well as the Country's development. These include;

- Early marriage and early child bearing
- Unmet need for family planning
- High total fertility rate

To address this, the Ministry of Health, with support from local and international partners, aims to remove barriers that impede access to FP information and services. Major restrictive barriers in the provision of family planning services in Kenya include distance, cost, religion, culture, rumors and misconception, provider bias, and legal and medical regulations. These barriers disproportionately affect certain populations; particularly the youth, the unmarried, people with disabilities (PLwDs), the poor and hard-to-reach groups including pastoralists, refugees and mobile communities.

The fourth edition (2010) of the National Family Planning Guidelines for Service Providers was developed against the backdrop of improving reproductive health (RH) indicators including FP; as reported in KDHS 2009[1] .That KDHS showed that the contraceptive prevalence rate (CPR) had risen from 39% in 2003 to 46 % in 2009. It also showed a decline in total fertility rate (TFR) to 4.6 births per woman, with a further decline to 3.9 births per woman reported in the subsequent KDHS 2014. This indicates that Kenya's fertility could be returning to the declining trend that was observed from the mid-1970s to the late 1990s.

There has been a significant increase in contraceptive use, from 46% of married women in 2009 using any method to 58% % in 2014. Analysis of trends by method shows that the overall CPR is driven by the increased use of modern methods. Between 2009 and 2014, use of modern methods among married women increased from 39% to 53% while use of traditional methods over the same time period actually decreased from 6% to 4.8%. Despite

the overall increase in CPR, the level of unmet need for FP (≈18%) still remains high.

Current fertility rates [KDHS 2014] differ for urban and rural areas and across the regions in Kenya. The TFR in rural areas (4.5) is significantly higher than in urban areas (3.1). 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 particularly among rural adolescents and youths.

The 6th edition of the National Family Planning Guidelines for Service Providers therefore places more emphasis on improving access to quality FP services including expansion of method mix, ensuring there are no missed opportunities, reduction in unmet FP need and increasing the numbers of new users; thereby sustaining the gains made. It recognizes 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 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 Medical Eligibility Criteria (MEC), the guidelines address several other issues in the appropriate provision of contraceptive methods. These include task shifting, new strategies to increase access (e.g. Community Based Family Planning, postpartum FP packages and comprehensive Post Abortion Care (PAC) services which includes FP), services for persons with special needs (e.g. PLwD. mobile populations, adolescents and youth), integration of FP with other RH services (including HIV and AIDS and screening for cancers of reproductive organs), new contraceptive choices and male engagement.

These 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 case of method failure, the client should receive counselling and management or referral for appropriate care.

WHAT IS NEW IN THE 6TH EDITION OF THE FP GUIDELINES?

Most of the information in the 4th edition of the guidelines has been retained in this new edition. Changes have been made to incorporate emerging issues in line with the latest WHO MEC.

The Reproductive and Maternal Health Services Unit (RMHSU) 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 Division of Family Health website (*www.familyhealth.go.ke*) where interim updates will be posted.

The format and layout of the 6th edition of the FP guidelines

This has been altered in line with emerging need to put emphasis on specific areas of family planning.

- The chapter on the scope of Family Planning service delivery has been divided into 4 chapters (Chapter 1- Introduction to the 6th edition, Chapter 2 -Background and Context, Chapter 3 - Service Delivery Guidelines, Chapter 4 - Client Assessment).
- A new chapter on Monitoring and Logistics has been included to highlight the importance of FP data and FP commodity management
- Some appendices have been deleted (signs and symptoms of selected serious health conditions) while others have been added (Appendix 4 - how to be reasonably ensure a client in not pregnant, Appendix 5 - summary of FP options for postpartum clients).

WHO Medical Eligibility Criteria (MEC) 2015

The changes incorporated in these guidelines relate to the following conditions (see details under the relevant contraceptive methods):

- Recommendations have been made for new FP methods:-
  - Subcutaneously administered depot medroxyprogesterone acetate (DMPA-SC)
  - Ulipristal acetate (UPA) as a new method of emergency contraception
  - Progesterone-releasing vaginal ring
- Recommendations have been revised for the following conditions;
  - Use of Combined Hormonal Contraceptives (CHC) by age, breastfeeding, postpartum with or without risk factors for venous thromboembolism and, women with superficial venous disorders.
  - Progestogen-only contraceptive (POC) and Levonorgestrel-releasing intrauterine device (LNG-IUD) use among breastfeeding women.
  - Emergency contraceptive pills (ECPs) use – obesity added as a new condition for ECP use.
  - Intrauterine device (IUD) use for women with increased risk of sexually transmitted infections (STIs).
  - Use of hormonal contraception for women at high risk of HIV infection, women living with HIV, and women living with HIV using antiretroviral therapy (ART).

Specific highlights

1. Community Based Family Planning (CBFP)
   - The information on CBFP has been expanded to include; methods they are allowed to provide, sources of FP commodities, reporting and recording, referral of clients and supervision.

2. Male engagement
   - Male involvement has been replaced by the more inclusive male engagement in FP. Importance of male engagement and ways of engaging men in FP are discussed under this topic.
3. FP counselling:
   - The content has been reduced and tailored to focus on importance of FP counselling, informed choice and informed consent. For more details on the processes of counselling, refer to the FP training manuals.
4. Infection prevention and control (IPC):
   - The content has also been reduced to focus on the importance of infection and the universal precautions. For more details on the IPC processes, refer to FP training manuals.
5. Discontinuation of contraception:
   - This is a new topic added to give guidelines on discontinuation of contraception.
6. Under Medical eligibility criteria (MEC), the MEC for Fertility Awareness-based Methods (FAM) has been added.
7. Progesterone-releasing Vaginal Ring (PVR):
   This hormonal contraceptive has been discussed in these guidelines. Availability of this method increases the method mix for breastfeeding postnatal mothers.

CHAPTER TWO:

2

BACKGROUND

POLICY OVERVIEW AND FRAMEWORK

Since the launch of the 4th Edition of Family Planning Guidelines for Service Providers in 2010, several important developments have taken place in the reproductive health arena in Kenya. Key among these is the recognition of the central role of FP in the achievement of national and international goals, including the Sustainable Development Goals (SDGs)[3] which replaced the MDGs. The SDGs, of which Kenya is a signatory, reflect a renewed interest in FP both globally and nationally. This has been supported by new strategies; whose goal is persuading clients, providers, governments, and donors to recognize that FP is critical to the health and development of the people. To this end, efforts are ongoing to link FP to Population and Development with regards to harnessing the Demographic Dividend. The Demographic Dividend (DD) is a temporary opportunity for accelerated economic growth that is made possible by a sustained decline in birth and deaths rates, which leads to an increase in the ratio of working age population relative to young dependents. This age structure change can enhance economic productivity, as women are economically productive following reduction in childrearing roles due to low fertility. Further impetus for future economic growth is generated through increased household savings and investments, which result from reduced costs for basic needs of the fewer dependent children. In order to maximize, Kenya should concurrently make investments to a) accelerate rapid fertility decline; b) provide high-quality education and skills development; c) create employment opportunities for the resulting big working age population; d) sustain good health of the population; and e) ensure that there is accountability in use of public resources and delivery of public services. This dividend is not automatic or guaranteed – it is earned through economic reforms that create jobs, investments in human capital and efficient governance.

In Kenya, there has been a change in the governance structure as stipulated in the newly promulgated 2010 constitution which changed the way health services are delivered. In addition to the central government, there are 47 county governments to which health service delivery systems have been devolved. FP services are included in this devolved package of services by the counties.

The central government (MOH Headquarters) is mandated with the roles of policy making, developing standards, regulation and research.

Since the previous edition of the national FP guidelines, several policies and strategies have been developed with the goal of strengthening the demand for and supply of FP services. FP has been identified as a priority component in the Constitution of Kenya [2010], National Health Strategic & Investment Plan (NHSIP) 2013-17, Kenya Health Policy [2014-2030], Vision 2030, Minimum package for RH /HIV& AIDS integration services [2012] and the Population Policy for National Development (Sessional Paper 23 of 2012); that all individuals have the right to access FP, including all FP-pertinent data regarding benefits and scientific progress made in the area of contraception.

The NHSSP[5] recognizes RH (including FP) as an essential priority in the Kenya Essential Package for Health (KEPH). In addition, it has a Community Strategy to strengthen the interface between Tier 1 (the community) and Tier 2 (dispensaries and health centers) of the health care system. The goal of this strategy is to enhance the functional effectiveness of community health Volunteers (CHVs), 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. Each county have also developed their own CHSSP which contribute to the national one.

According to KDHS 2014[2], teenage pregnancy increased from 17% in 2008 to 18% in 2014 due to the unmet need of family planning services targeting this group. The 2015 National Adolescent Sexual and Reproductive Health Policy (ASRH) [7] , aims to enhance the SRH status of adolescents in Kenya through promoting provision of accurate information, services to prevent early pregnancies, unintended pregnancies among adolescents and complement existing service provision channels, to provide a wide range of contraceptive information and methods to capture diverse needs of adolescents.

GUIDING PRINCIPLES FOR THE FAMILY PLANNING PROGRAM

These include:

- Universal access to FP information and services without discrimination on the basis of religion, age, culture, social-economic status and disability
- Access to information on a wide variety of family planning methods, including the benefits and health risks of particular methods.
- Volunteerism and informed choice.
- Provision of high quality, safe FP services.
- Promoting male engagement as responsible partners in increasing access to and utilization of FP services.
- Provision of family planning services should take a multisectoral approach and is not limited to the Ministry of Health and its agencies, but includes other government ministries, NGOs, FBOs, for-profit private sector companies, community service organizations and the communities themselves.

PRIORITY AREAS

The Government of Kenya has prioritized the following areas towards universal access to family planning services in Kenya:

1. Advocacy for family planning services including post-pregnancy family planning.
2. FP Commodity security
3. Demand creation
4. Focus on adolescents, the youth and vulnerable populations
5. Integration of FP services into HIV and other programs
6. Capacity strengthening
7. Monitoring and evaluation for FP services

OBJECTIVES OF THE GUIDELINES

This document aims to:

- Provide health care providers, partners, County and National MOH health managers with evidence based information that will guide the effective provision of quality FP services.
- Provide updated information on the 2015 WHO Medical Eligibility Criteria (MEC) for contraceptive use as a way of eliminating barriers to contraceptive use.
- Provide up to date information on the types of FP services that can be provided by each cadre of the health care system.
- Provide information on the FP environment in Kenya, including challenges involved and possible solutions.

CHAPTER THREE:

3

SERVICE DELIVERY GUIDELINES

ESSENTIALS OF FP SERVICE DELIVERY

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, access to and utilization of quality FP services.

1. INCREASING DEMAND FOR AND UTILIZATION OF 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 the actual utilization of those services.

Facilities should develop and implement communication strategies that facilitate advocacy for the use of FP services among the communities they serve. These strategies include:

- Enhancing the image of FP Service Delivery Points within the target communities.
- Provision of information about specific methods and services—their health benefits, potential side effects, and where they can be obtained.
- Enhance community linkage and support systems.
- Link with other stakeholders to advocate for FP use.
- Dispelling myths and misconceptions related to specific family planning methods.

All health care workers including Community Health Volunteers (CHVs) also play a role in creating demand for family planning services. They should provide correct information on FP, facilitate client referrals for FP services and follow up clients at the community level where applicable.

2. ADEQUATE PROVIDER SKILLS

Contraceptives should be provided by adequately trained and competent providers in accordance with approved method-specific guidelines. The service providers should be able to provide clients with a wide range of methods (method mix) from which to choose.

Service providers should therefore continuously update themselves on new developments on FP methods, skills and services as well as transferring acquired skills to other service providers through mentorship and OJT.

In order to ensure the highest quality of FP capacity building, the Ministry of Health through the RMHSU is responsible for developing and updating training materials and methods for all cadres in the health system including nurses, doctors, pharmacists and CHVs.

3. ADEQUATE SUPPLIES, EQUIPMENT AND INFRASTRUCTURE

Certain supplies and equipment are required for successful FP service provision. In addition to contraceptive commodities, facilities should strive to have client examination couches, blood pressure machines, ward screens, weighing scales, trolleys, infection prevention supplies and data tools. The County Health team should ensure continuous availability of FP supplies and equipment for FP service provision.

Adequate infrastructure is also needed in order to avail private and confidential areas in which clients can receive quality FP services.

4. EFFICIENT 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 or experience adverse effects. Clients that require or choose a method that is not available at a facility must be advised where to obtain the method and referred accordingly. (Refer to the National Referral Guidelines for more information[8])

5. ADDRESSING FINANCIAL BARRIERS

The service provider must keep in mind that provision of FP services involves both financial and opportunity costs.

The costs to the client include:

- Time taken off work/ business to visit the health facility
- Transport costs
- Direct cost of services
- Cost of the contraceptive commodity

If the cost of a method will impose a major financial hardship on the client, then the provider should discuss an alternative contraceptive or a means of obtaining the desired contraceptive less expensively. The provider should also inform the client that FP methods are part of the health services covered by the existing national health insurance schemes, including NHIF.

6. HUMAN RESOURCE FOR FP SERVICES

Several cadres of healthcare providers can be involved in the provision of FP services after they have received the necessary training.

Similarly, FP services can be provided at various Tiers of the health care system and within facilities that are operated by various health care providers. These service providers must meet the MOH standards and guidelines for FP service provision to ensure delivery of quality services.

Table 3.1 **Provision of FP methods by different categories of service providers**[i]

Provider /method	Male condom	Female condom	LAM	Pills (COC, POP)	Injectable	IUCD	Implant	Standard Days Method (SDM)[ii]	Other FAMs (Two Days Method, Ovulation)	Female and male VSC
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.									Counsel refer
Clinical Officer	Adequately trained Registered Clinical Officers (RCOs)[iii] can provide full range of services related to the above									Counsel refer RH Trained RCOs can offer methods
CHEW[iv]	CHEWs provide an interface between CHVs and SDPs									
CHV[v]	Counsel Provide	Counsel Provide	Counsel Support Provide Refer	Counsel Provide* Refer	Counsel Provide* Refer	Counsel Refer	Counsel Refer	Counsel Provide Refer	Counsel Refer	Refer
Pharmacists and Pharmaceutical technologists	Counsel Provide	Counsel Provide	Counsel Refer	Counsel Provide	Counsel Dispense Provide*	Counsel Dispense Refer for insertion	Counsel Dispense Refer for insertion	Counsel Provide Refer	Counsel Refer	Refer

*Only if specifically trained to do so

Table 3.1 Provision of FP methods by different categories of service providers

i. All service providers are subject to appropriate training, skills and availability of specified requirements for the particular FP method.

ii. 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

iii. RCOs with post-basic training in reproductive health.

iv. CHEWs including appropriately trained Public Health Technicians (PHT), Enrolled Community Nurses (ECN), or Community Midwives.

v. CHVs trained to provide CBD.

7. COMMUNITY BASED DISTRIBUTION

Community Based Family Planning (CBFP) entails the process of providing family planning information and services to the communities where they live through the community health strategy. An objective of CBFP is to increase access to and choice of FP methods in underserved populations. In Kenya successful CBFP programmes have included community based distribution (CBD) of injectable contraceptives, condoms, and pills coupled with demand creation.

CBFP may be provided by various cadres of health workers as long as they have been trained and certified as competent by the Ministry of Health based on the community health training curriculum. Cadres eligible to provide CBFP include CHEWs, CHVs, and other cadres of service providers for organized community outreaches.

Methods to be provided by CBFP providers

CBFP providers should share information on all methods of FP. FP methods that can be provided directly by these CBFP providers include;

- Pills
- Condoms (Both Male and Female)
- Natural FP methods
- Cycle Beads
- Injectables (Only approved for underserved and hard-to-reach populations)

Commodities

Commodities required for CBFP are obtained from the linked facility. Commodities should be stored in a safe box that is lockable and not accessible to anyone other than the trained CBFP service provider.

Recording and Reporting

Providers are required to use existing service data collection and reporting tools. This information should be submitted to the linked facility for inclusion in the facility health information system.

Client Referral

Referrals should be done to the nearest, most appropriate health facility and will require use of the relevant referral tools as previously highlighted.

Supervision

There is a clear need for supervision to ensure that services are provided at the highest level of quality. Supervision of CBFP is led by CHEWs who ensure that the CHVs are routinely providing quality services, reviewing CHVs referrals and collating their data and uploading to DHIS2.

8. SELF-INJECTION

Injectables such as Sub Cutaneous Depot-medroxyprogesterone Acetate (DMPA-SC) have been approved for self-injection. This is dependent on training of healthcare workers to train clients for self injection. Close follow-up and monitoring mechanisms should be in place to ensure safety of self injecting clients and quality of family planning services.

9. INTEGRATION OF FP SERVICES

In many settings across Kenya, contraceptive services are provided in family planning clinics separate from clinics providing maternal and child health services, nutrition, antiretroviral therapy (ART) and related care for HIV-infected individuals, STI clinics, gynecology clinics and post rape care clinics. Within this fragmented set up, additional barriers to uptake of family planning methods including poor male involvement continue to abound. This often leads to missed opportunities for FP service provision for clients.

RH/FP, Immunization and HIV programs share a common target audience: mainly women and girls of reproductive age. By increasing entry points along the life cycle of women and girls, Kenya can increase access to FP, STI, HIV and RT cancer prevention, care, and treatment services. This can be done while helping to ensure the dignity and safety of all women.

Models for FP and integration

It is envisaged that the types of integration by level of care and context may vary. Three main approaches are suggested: on-site, off-site and mixed.

- ***On-Site:*** Could be where integrated FP services are offered by one service provider in one room during the same consultation while offering other health services e.g. FP services offered while woman is getting immunization services; or where integrated FP services are offered by more than one service provider within one facility. E.g. can get FP services in MCH, OPD or maternity.

- ***Off-Site:*** Integrated FP services are offered completely outside the facility through a facilitated referral.
- ***Mixed Approach*:** Integrated FP services are initiated in one facility but the rest of the services are received in another facility where all the skills, commodities or equipment are available.

For various levels of the health sector references should be made to the minimal package of integration for guidelines on integration of services.

The range of FP services that can be offered at various service areas in the health facility and community are shown in **Table 3.2**.

Table 3.2: **Integration of FP services into other health areas**

Area of FP Integration**	Benefits of integration	FP counseling	FP service provision	Referral information
ART Clinic	Among women infected with HIV who are sexually active but do not want to have children, contraception has the added benefit of reducing HIV positive births and by extension, the number of children needing HIV treatment, care and support.	Educate all clients about: • High-risk sexual behavior • The protective benefits of male and female condoms • Dual protection	Offer FP services on site. Encourage the use of barrier methods as a dual protection method. Refer to MEC for appropriate FP method for each client bearing in mind the drug interactions between ART and contraceptives	Clients should be referred to another FP clinic/Health facility if the desired method is not available at the clinic. Referral information should include the ART drugs the client is taking as this could influence the method used.
PMTCT	Family planning services that promote healthy timing and spacing of pregnancies are important in reducing the	Counseling mother on FP methods close to delivery and linking to service provision.	None offered	Link/refer counseled mother to health facility that offers FP services.

Area of FP Integration**	Benefits of integration	FP counseling	FP service provision	Referral information
	risk of adverse pregnancy outcomes such as low birth weight, preterm birth, and infant mortality.			
Mother and Child clinics	FP services should be integrated into the mother and child clinics which offer immunization services, growth monitoring and nutrition and child welfare clinic. This is a chance to address missed opportunities and follow up of FP clients after delivery. It is convenient and cost effective for mothers.	Counseling mother on methods (group and individual) and consenting for service provision.	Offer method of choice . Refer to MEC for appropriate FP method for each client. There are several methods that can be offered to lactating mother and non-lactating mothers.	Refer mother to FP clinic or health facility where FP services are offered.
Maternity (Delivery and postnatal)	Post parturm womenhave high unmet need for family planning. Some may not have attended antenatal clinic hence they may have missed out on family planning information. Offering PPFP	Counseling and consenting for service delivery.	Refer to MEC for appropriate FP method for each client Methods that can be provided immediately after delivery include IUCD, Implants, POPs and BTL	Refer to FP clinic/health facility if method is not initiated. In some facilities clients may need referral for BTL.

Area of FP Integration**	Benefits of integration	FP counseling	FP service provision	Referral information
	can increase uptake of FP.			
Post Abortion Care	Family Planning information and services is a component of the post-abortion care package. After an abortion, fertility resumes almost immediately (within 2 weeks). It is advisable that the client delays pregnancy for at least 6 months in order to reduce the risk of complications in subsequent pregnancy (maternal anemia, low birth weight, etc.)	Counseling and consenting for service provision	Refer to MEC for appropriate FP method for each client Provision of methods to the clients should be done on site. Invasive methods e. g. IUCD should be delayed in cases of sepsis and trauma.	If FP services are not offered on site the client should be referred to the nearest FP clinic/health facility.
ANC	Women counseled on FP services during ANC are more likely to take up FP services after delivery.	Counseling Antenatal mothers on FP methods and linking to service provision	None offered	Linking counseled mother to health facility that offers FP services.

Area of FP Integration**	Benefits of integration	FP counseling	FP service provision	Referral information
Reproductive Tract cancer screening	RT cancer screening should be linked to the FP service provision to ensure that clients receive appropriate services in one sitting.	Counsel clients on FP services.	Refer to MEC for appropriate FP method for each client Offer method of choice.	Refer to FP clinic/health facility if method is not initiated.
Community based distribution and integrated outreach programmes	Community based distribution for FP improves access to FP services at the community level. It is also cost effective and convenient to clients.	Counseling clients on methods and obtain consent.	Refer to MEC for appropriate FP method for each client Offer method of choice. Provide pills and condoms Continuation of provision of Injectable contraceptives (in hard to reach areas)	Refer client to the link facility for other methods and follow up. Refer clients for initiation of injectables at health facility
****All other service areas within the facility e.g. in-patient, OPD, pharmacy should offer FP counselling and referral services**				

10. POST PREGNANCY FAMILY PLANNING

Post pregnancy family planning (PPFP) defined as the use of any modern method of contraception in the prevention of unintended pregnancy and closely spaced pregnancies through the first 12 months following childbirth or loss of a pregnancy.

Note:

- Women are much more likely to take up postpartum FP if they have made a decision before going into labor.
- 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 post abortion care package and postnatal care package, along with other maternal and neonatal care services.

Post-partum women and their infants are recommended to receive at least five assessments by a skilled attendant within the first year of childbirth. (See **Table 3.3**) 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). Since not all clients come back to the health facility after delivery, service providers should ensure that clients have been offered the opportunity to receive immediate post-partum family planning before being discharged home.

Table 3.3 **FP counselling and services during the continuum of care from antenatal through postpartum periods**

Timing of visit or assessment	FP services for men and women
Antenatal	• Provide counselling on all FP methods available for men and women • Provide ANC profile to determine FP method eligibility • Document FP method of choice for intrapartum or postpartum provision
Intrapartum	• Assess client's pregnancy and labour for indication or contraindication of chosen postpartum contraceptive • Provide intrapartum BTL, if applicable • Perform IUCD insertion during caesarean section or following placental delivery.
Within 48 hours after birth	• Perform focused physical examination • Provide counselling on LAM where applicable • Provide postpartum BTL or IUCD or POP, Implants • Provide counselling on vasectomy where applicable
Within two weeks (preferably within one week) after birth	• Perform focused physical exam • Provide counselling on: LAM and HTSP, return to sexual activity, return to fertility and condoms, when to initiate FP methods based on breastfeeding status • Provide all methods except BTL , COCs and IUCD
Four weeks after birth	• Perform a focused physical exam • For LAM users: provide supportive counselling on transition to other FP methods, HTSP messages, return to fertility, and sexual activity • Provide counselling and provision of, or referral for, all other FP methods including ECs as appropriate (based on breastfeeding status, other eligibility criteria, and woman's choice) • Provide counselling on dual method use • BTL at 6 wks where applicable

Timing of visit or assessment	FP services for men and women
	• Offer information, screening and management of cervical cancer where the skills and infrastructure are available.
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 MEC
Post abortion	• Counsel and provide all FP methods except LAM according to MEC • Delay invasive methods (IUCD, BTL) in case of sepsis or genital trauma

11. FAMILY PLANNING SERVICES FOR SPECIAL GROUPS

FP service providers have a duty to ensure equitable access to services for all, including groups with special needs. Clients with special needs requiring extra attention from health care providers include: adolescents and youth, people living with disabilities, mobile populations, and persons living in informal settlements and humanitarian settings.

FP Services for Adolescents and Youth

Youths (persons aged 10 to 24 years)constitute 33.6% of Kenya's population. This includes adolescents (10-19 years) making up 24% of the total population. According to KDHS 2014[2], teenage pregnancy is at 18%. The teenage pregnancy rate has stagnated for over a decade due to the unmet need of family planning services targeting this group. The unmet need for the youth is 23% compared to 18% in the general population as per KDHS 2014.

Adolescents face greater adverse complications during pregnancy because they are not fully developed physiologically and biologically for pregnancy. These pregnancies, whether

intended or unintended, increase the risk of maternal morbidity and mortality.

Adolescents and youth including first time young mothers are a unique population and therefore special attention should be paid to when addressing their contraceptive needs.

The MOH has adopted five principles for service providers that should be emphasized to facilitate the provision of adolescent and youth-friendly services[9]: equitable, accessible, acceptable, appropriate, effective (see **Table 3.4**)

Table 3.4 **Principles for provision of adolescent and youth-friendly services**

Principle	Explanation
Equitable	• All adolescents and youth including those living with HIV, living with disabilities, those in emergency, resource constrained and humanitarian situations should receive the full range of SRH information and services they need. • Health care providers should provide this information and services to adolescents and youth regardless of age, sex, social status, cultural background, ethnic origin, disability or any other reason.
Accessible	• SRH services must be affordable and available to all adolescents and youth. • In order to be available, Information and services must be obtainable during convenient hours including after school or work and during weekends and holidays where applicable. • The (static, mobile, community) facility should be conveniently located such that it is easy to find and comfortable to enter. • The services, hours and location of these facilities must be clearly posted for adolescents and youth to be aware of their availability.
Acceptable	• Contraceptive information and services should be provided in a way that meets the expectations and needs of adolescents and youth. • Confidentiality should be maintained at all times including during registration, consultation, record-keeping, and disclosure. • The point of service delivery should be located in a place that affords auditory and visual privacy.

Principle	Explanation
	• Adolescents and youth should be able to consult with health-care providers at short notice, whether or not they have a formal appointment, and a referral appointment should be held promptly within a short timeframe. • Strategic communication should be adopted for information and demand creation for contraception. • Referral to be well defined to ensure continuity of AYFS
Appropriate	• The services should offer appropriate information that will be understood by the client depending on their age and other factors as indicated in the categories above. • The client should be enabled to make an informed decision on the full range of contraceptives available. • These must meet the widest possible range of individual adolescents and youth health needs.
Effective	• Services and accurate SRH information must be provided to make a positive contribution to the health of adolescents and youth. • This requires health care providers to have the knowledge and skills to provide contraceptive information and services in line with national policies, protocols and guidelines and the service delivery point to have the necessary contraceptive supplies, commodities and equipment. • Adolescents and youth should be given priority at all SDPs.

Adolescents and youth in need of contraceptive services can safely use any method, following the guidelines and MEC criteria accordingly.

- Permanent methods, such as tubal ligation and vasectomy should be discouraged for adolescents and youth without children
- Any adolescent and youth who requests emergency contraception should receive counseling on all methods of FP
- Adolescents may be less tolerant of side effects. It is important to explain the possible side effects during FP counseling in order to reduce the likelihood of discontinuation and seek alternative methods if the side effects persist

- Adolescents and youth should be strongly encouraged to use condoms for dual protection against pregnancy and STI/HIV
- Adolescents living with HIV and AIDS can safely use most of the currently available methods of contraception according to the 2015 WHO MEC recommendations

Persons Living with Disabilities (PLwDs)

In Kenya, about 5 % of the population live with some form of disability[10]. PLwDs encounter discriminatory practices and stigma within society as well as within health facilities. All discrimination constitutes a denial of human rights. According to United Nations Convention on the Rights of Persons with Disabilities (CRPD)[11], people with disabilities must have access, on an equal basis with others, to all forms of sexual and reproductive health care as part of the general right to marry, found a family and retain their fertility.

To effectively address the FP needs of PLwDs, service providers must:-

- Ensure women and men living with disabilities have access to counselling and education on sexuality and access to FP method choice.
- Be familiar with the special needs of PLwDs and be prepared to address them with a positive attitude without discrimination and stigma.
- Ensure that health facilities are disability friendly
- Take into account the individual's disability and specific needs as well as the method of choice.
    - Individuals who are mentally challenged or living with a psychiatric disorder may require specialized counselling or referral for treatment before making a decision on contraception.

Where the nature of the condition does not allow for informed choice (e.g., severe mental challenge), an FP method may be provided only after full discussion with guardians or care-givers.

- Individual reproductive rights must be protected and considered for all clients.

Mobile Populations

Mobile populations comprise of people who have moved out of their permanent residences for a variety of reasons including pastoralism, conflict, natural disasters (e.g. floods, earthquakes) or seeking a livelihood (jobs, natural resources). Migrants and mobile populations face many obstacles in accessing essential health care services. This is due to a number of factors such as irregular immigration status, language barriers, lack of migrant-inclusive health policies, and inaccessibility of services due to inopportune operation hours. Such disparities impact the well-being of mobile populations.

Mobile populations may comprise of women and girls whose RH needs include prevention of unintended pregnancies, reduction of STI transmission including HIV, the prevention and management of the consequences of sexual violence.

Health care providers' services to mobile populations should adhere to the following specific guidelines:

- Confidential counselling services to ensure privacy as much as possible.
- Counselling on dual protection is particularly important for persons living in IDP or refugee camps.
- Contraceptive methods should be provided according to MEC including emergency contraceptives.
- Some clients may be new users of FP while others may already be using a method and would require continuation services e.g. management of missed doses as described for individual methods in these guidelines.
- Survivors of sexual violence should receive prompt medical attention, which may include emergency contraception . The client should receive referrals for other methods, as necessary.

FP Services for People Living with HIV/AIDS

- Persons living with HIV and AIDS (PLWHA) have just as much need for FP services as non-infected persons.
- FP service providers must ensure that safe and effective contraception is accessible to HIV-positive women in order to help them not only plan their future childbearing, but also reduce the likelihood of HIV maternal to child transmission. FP is a core intervention 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.

12. MALE ENGAGEMENT IN FP

Evidence suggests that men's active participation in decisions about family planning and reproductive health promotes better health for families. Traditionally, efforts to improve information, counseling and access to family planning and reproductive health have been focused primarily on women. It is however, becoming evident that offering counseling and education to couples and to men in addition to women is more effective.

Importance of male engagement in FP

- Men are often the decision makers about sexual activity and the desired number of children. If they lack accurate information on FP they may not support their spouses to utilize FP services.
- Involving men can lead to better health outcomes including those specific to family planning knowledge and sustained contraceptive use.
- Engaging men can foster a positive environment for the couple's broader sexual and reproductive health.

Ways of engaging men in FP

- Empower men with FP information and clarify any myths and misconceptions.
- Enlighten them on male-specific FP methods such as male condoms and vasectomy.
- Utilize platforms like community meetings and church functions to share family planning information and create awareness.
- Utilize male peer educators and champions.
- Encourage men to accompany their spouses to the health facility and commend them when they come
- Address women's fears regarding male engagement in Family Planning
- Involve male political and opinion leaders to act as role models
- Utilize male health workers to reach other men as role models
- Introduce family clinics and organize FP outreaches that target males at appropriate places e.g. place of work.
- Add services that are beneficial to men (e.g. prostate cancer screening, male circumcision) to the FP package.

FAMILY PLANNING FOR WOMEN NEAR MENOPAUSE

A woman reaches menopause when her ovaries stop releasing eggs (ovulating). Because monthly menses become irregular as menopause approaches, a woman is no longer considered fertile once she has had 12 consecutive months of amenorrhea (absence of menses) or if her follicle stimulating hormone (FSH) level is more than 30mIU/ml. Menopause usually occurs between the ages of 45 and 55 years, with 50% of women reaching menopause by 50 years and by age 55 about 96% of women have reached menopause.

The term **perimenopause** describes the period around menopause, normally about three to five years before actual menopause sets in. Sexually active women in this age group continue to be at risk of unintended pregnancy unless they use effective methods of contraception until menopause. Perimenopausal women can use any FP method, subject to MEC guidelines.

Discontinuing Family Planning for Menopausal Women

In some clients, irregular menses around menopause may make it difficult for a woman whose bleeding seems to have stopped to know when to stop using contraception. Thus, it is recommended to continue using a family planning method for 12 months after the last menses.

Hormonal methods affect menses, making it difficult to know if a woman using them has reached menopause.

- After stopping a hormonal method, she should use a non-hormonal method.
- She will no longer need contraception once she has had no menses for 12 consecutive months.
- Copper-bearing IUDs can be left in place until after menopause. They should be removed within 12 months after a woman's last monthly period.
- Bilateral Tubal Ligation (BTL) and vasectomy may be a good choice for older women and their partners who know they may not want more children. Because of their age, older men and women are more likely to have conditions that require delay, referral, or caution for VSC (e.g. cardiac disease, complicated diabetes, hypertension)
- Male and female condoms are affordable and convenient for couples who may have occasional sex.
- Fertility awareness methods:-Lack of regular cycles before menopause makes it more difficult to use these methods reliably.

DISCONTINUATION OF CONTRACEPTION

According to KDHS 2014[2], 31% of family planning users discontinue use of a method within 12 months of starting its use, the main reason being side effects and health concerns (11%).

Whether a woman switches from one method to another or discontinues contraceptive use altogether depends on several factors:-

- They want to become pregnant.
- They can no longer become pregnant (menopausal, medical conditions, surgical procedures like hysterectomy)
- They are not sexually active at the moment.
- Discontinuation or switch due to side effects

Service providers have a duty to adequately counsel clients wishing to discontinue contraception about timely method-switching, as appropriate, in order to reduce the incidence of unplanned pregnancies. They should also clearly document the reasons for discontinuation.

Return to fertility after contraception

Most of the reversible methods of contraception available offer a prompt return of fertility after discontinuation though there may be slight delay with DMPA. After stopping a contraceptive, a woman may expect an average of 3 to 6 months delay in return to fertility for most methods and sometimes up to 12 months for DMPA.

In case of prolonged delay in return to fertility, underlying causes of female subfertility or infertility (e.g., tubal disease, ovulatory dysfunction, decreased ovarian reserve or uterine factors) may need to be considered.

QUALITY OF CARE IN FAMILY PLANNING SERVICE PROVISION

The Kenya Quality Model for Health (KQMH 2011)[12] recommends improved quality of health service provision for all Kenyans at all KEPH levels of care and application of this improvement model is a central component in the Kenya Health Sector Strategic and Investment Plan

Implementation of the KQMH demands the establishment of improvement teams at every level (leadership, facility and individual work units such as maternal and child health and family planning.) These teams should regularly analyze performance gaps, develop interventions to bridge the gaps, learn from interventions, scale up and institutionalize working ideas. This team-based approach inculcates a culture of continuous quality improvement, which is central to improving quality at points of service delivery.

Service sites that offer family planning services should have a system for conducting quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. The following dimensions of quality of care are key for family planning services:

- **Time & Timeliness:** Customer waiting time, completed on time
- **Completeness:** Customer gets all they asked for
- **Courtesy:** Handling of clients by employees
- **Consistency:** Same level of service for all customers
- **Accessibility & Convenience:** Ease of obtaining service
- **Accuracy:** Performed correctly every time
- **Responsiveness:** Reaction to the needs of clients

The "Clients' Rights and Staff's Needs" framework[13] is applicable to service delivery (see Table 3.5 for details of client rights and provider needs)

Table 3.5 **Client rights and provider needs**

Component	Explanation
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).
Access to Services	All clients have the right to FP services at all levels of care. The SDPs should be clean, well organized, and well stocked with quality contraceptives. Clients should not have long waiting times and should be able to obtain the contraceptive of their choice or referred to where they can be offered.
Informed Choice	Clients should be counseled 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 individualized and discrete. Clients should be provided with both auditory and visual privacy. Client records should be protected from anyone who is not directly involved in the clients 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 client has a right to follow up and provision of the selected service. To enable continuity of care the clients' records 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 emphasize mentoring and joint problem solving. The system should help staff provide the best possible FP services.

Component	Explanation
Information, Training, and Development	Staff should be knowledgeable and skilled in providing FP services, and have ongoing opportunities for training to update and maintain a high level of performance.
Supplies, Equipment, and Infrastructure	SDPs should have sufficient and appropriate supplies, instruments, and logistics infrastructure to ensure uninterrupted FP services and the safety of service providers.

FP COUNSELING AND INFORMED CHOICE

Family Planning Counselling

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

In addition to protecting a client's right to informed and voluntary decision-making, effective counselling is likely to:

- Increase acceptance of family planning services
- Promote effective use of family planning services
- Increase client's satisfaction with family planning methods and services
- Enhance continuation of family planning services
- Dispel rumors and misconceptions about contraceptive methods.

Quality counselling is the most important way that health workers support and safeguard the client's rights to informed and voluntary decision-making. This means, never pressuring a client to choose one family planning method over another, or otherwise limiting clients' choices for any reason other than medical eligibility.

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 time the woman has to seek and receive FP services, travel costs, personal preference and medical eligibility.
- The need for protection against STIs and HIV.

Informed Choice

Informed choice in FP is a voluntary, well-considered decision that an individual makes on the basis of options, information, and understanding of different FP methods. Enabling clients to make informed choices is a key to good-quality family planning services. To make informed choices, people need to know about family planning, to have access to a range of methods, and to have support for individual choice from social policies and community norms.

Benefits of Informed Choice

- People use family planning longer if they choose methods for themselves.
- Access to a range of methods makes it easier for people to choose a method they like and to switch methods when they want.
- People's ability to make informed choices invites a trusting partnership between clients and providers
- Encourages people to take more responsibility for their own health and meet their reproductive health goals.

Informed consent

Informed consent is the communication between client and provider that confirms that the client has made a voluntary choice to use or receive a medical method or procedure. Informed

consent can only be obtained after the client has been given information about the nature of the medical procedure, its associated risks and benefits and, other alternatives. Voluntary consent cannot be obtained by means of special inducement, force, fraud, deceit, duress, bias, or other forms of coercion or misrepresentation.

Most methods of FP require a verbal consent for services to be offered. For the surgical methods, a written consent is required (see **Appendix 3** for the recommended form)

Informed consent for PLwD

PLwD should also give informed consent for FP service provision. Where the nature of the condition does not allow for informed consent (e.g., severe mental challenge), then the service provider should consult with the guardian or care-giver. Longer acting FP methods are preferred to permanent methods in such clients.

Informed consent for adolescents and youth

According to the National Guidelines for Provision of Adolescent and Youth Friendly Services in Kenya 2016, adolescents and youth have access to FP information and services. The essential package for adolescent and youth friendly service provision includes contraception counselling and provision of full range of contraceptive methods, including long-acting reversible methods. All contraceptive are safe for young people. Age is not a medical reason for denying any method for adolescent, provided that they have attained both menarche and are sexually active.

Parental/Guardian consent is not a requirement for provision of FP counselling and services for adolescents and youths.

INFECTION PREVENTION AND CONTROL (IPC)

Infection prevention addresses the spread of infections within the health care setting; patient to patient, patient to staff, staff to patient or among staff.

The procedures done to prevent infection are simple, effective, and inexpensive. IPC should be observed in the provision of all FP

methods, according to *National Infection Prevention and Control Guidelines for Health Care Services in Kenya*.

Universal Precautions

These are a simple set of effective practices designed to protect health workers and patients from infection by a range of pathogens; helping to break the disease-transmission cycle at the mode of transmission step. These practices are used when caring for all patients regardless of diagnosis. Universal precautions include:

- Hand washing
- Wearing protective gears e.g. gloves
- Safe use and disposal of needles and sharps
- Decontamination of equipment and devices according to current IPC guidelines.
- Prompt clean-up of blood and body fluid spills.
- Use of safe disposal systems for waste collection and disposal.

CHAPTER FOUR:

4

CLIENT ASSESSMENT IN FAMILY PLANNING

CLIENT ASSESSMENT

THE PURPOSE OF CLIENT ASSESSMENT

The primary objectives of client assessment or screening, are to determine whether the family planning client:

- Is pregnant
- Has any conditions that affect the client's medical eligibility to start or continue using a particular family planning method
- Has any special problems that require further assessment, treatment or regular follow-up.

THE PROCESS OF CLIENT ASSESSMENT

History taking

Taking medical history is helpful in gathering basic information that will help the service provider and the client discuss family planning method options. This information can be gathered in a relaxed and friendly manner that puts the client at ease.

Information that can be gathered in a client history includes:

- Age of client (female)
- Number of living children
- Sex of living children
- Age of youngest child
- History of complications with pregnancy
- Current pregnancy status/date of last menstrual period
- Desire for more children
- Desired timing for birth of next child
- Breastfeeding status
- Regularity of menstrual cycle
- Number of current sexual partners
- Level of sexual activity (active, occasional, etc.)

- History of chronic illnesses (i.e. heart disease, diabetes mellitus, hypertension, liver/jaundice problem, kidney/renal disease, cervical/breast cancer)
- Smoking status.
- Explore client experience on current method in case of subsequent visit (include partner's view if possible).

Physical examination

Explain to the client that for most family planning methods there will be no need for a physical or pelvic exam. However, it is advisable for clients who are initiating FP (first time clients) to have a complete physical examination.

Physical and pelvic examinations may be necessary depending on answers given to the medical eligibility screening questions for specific methods, as indicated.

Before examination:

Explain the procedure and ensure client is comfortable, ensure privacy and gather all equipment to be used.

During physical examination:

- Observe client for gait, physical appearance and health status.
- Check vital signs as required.
- Conduct full examination (head to toe) especially for new Family Planning clients or as guided by client's history.
- Conduct pelvic and speculum examination where applicable (ensure sterility during procedure).

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 endeavor 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 the Medical Eligibility Criteria (MEC). Where

resources are limited, service providers should use the following classifications to prioritize examinations and tests[14]:

- **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 VSC).
- **Class B**: Examination or testing contributes substantially to the safe and effective use of the contraceptive method (e.g., checking a client's hemoglobin 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 initiating the contraceptive method.
- **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
- Hemoglobin test
- STI risk assessment: medical history and physical examination
- STI/HIV screening: laboratory tests
- Blood pressure screening

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 (refer to job aid in **Appendix 4**):

- She has had a baby less than six months ago, is exclusively breastfeeding, and has not resumed menses since then.
- She has had a baby in the last 21 days
- Has abstained from sex since the start of her last normal menstrual period
- Is within 5 days of the start of a normal period
- Is within 5 days post-abortion or post-miscarriage
- Has a negative pregnancy test and has not had unprotected sex in the last 3 weeks
- Has been consistently and correctly using a reliable method of contraception

A pelvic examination is seldom necessary, except to rule out pregnancy of more than 6 weeks – measured from the client's last menstrual period (LMP).

Pregnancy testing is not essential except in the following cases:

- The woman answered "no" to all questions on the pregnancy checklist. Pregnancy cannot completely be ruled out using the checklist (rule out pregnancy by other means)
- 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 assess the 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 occur or pregnancy is confirmed.

SCREENING FOR SEXUALLY TRANSMITTED INFECTIONS AND HIV/AIDS

Family Planning service providers have a responsibility to assess the risk of STIs and HIV/AIDS in all clients seeking FP services. 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 behaviors
- Be aware of the signs and symptoms of common STIs
- Be familiar with 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 including contact tracing (See Appendix 7).
- 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 condition, 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)?

SCREENING FOR CANCERS OF REPRODUCTIVE ORGANS

Cancers of the reproductive organs are among the major causes of morbidity and mortality among women and men. Cancers of the cervix and breast are the leading malignant diseases among women, while cancers of the prostate and testes are common in men. Both cervical and breast cancers present opportunities for their early detection since both develop in organs that are easily accessible by inspection or palpation. Similarly, prostate and testicular cancers can be detected early by careful clinical examination aided by biochemical markers.

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 counseling services, and arrangements should be made for referral of positive cases for appropriate management. FP service providers should ensure proper documentation into the first visit family planning card. **Table 4.1** shows the types of services that can be provided at the various levels of the health care system in Kenya.

Table 4.1 **Screening for reproductive organ cancers in clients seeking FP services**

Cancer type	Tiers of health care			
	Tier 2 *(Dispensary, Clinic)*	**Tier 3** *(Health centre, Nursing Home)*	**Tier 4** *(Sub County Hospital)*	**Tier 5** *(County Hospital and above)*
Cervix	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; mammogram; Refer if positive	History taking (family); breast palpation for lumps; mammogram; biopsy; Definitive treatment
Prostate	History of pattern of micturition; refer if not normal	History of pattern of micturition; rectal examination; refer if not normal	History of pattern of micturition; rectal examination and PSA refer if not normal	History of pattern of micturition; rectal examination and PSA definitive treatment

MEDICAL ELIGIBILITY CRITERIA

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 - The Medical Eligibility Criteria (MEC). Each condition is defined as representing either an individual's characteristics (e.g., age, history of pregnancy) or known pre-existing medical (diabetes, hypertension). The latest Edition (5th Edition) of the WHO MEC[15] was updated in 2015 and the new recommendations have been incorporated in the present guidelines. In addition to this, the updated 2018 Kenyan MEC wheel has been adapted from the WHO MEC and aligned with these guidelines.

THE PURPOSE OF MEC

- To base guidelines for family planning practices on the best available evidence
- To address misconceptions regarding who can and cannot safely use contraception
- To reduce medical barriers to access of FP services.
- To improve access and quality of care in family planning

The WHO groups medical conditions into these four categories:

- ***Category 1***: Conditions for which there is no restriction on the use of the contraceptive method.

  Recommendation: Use the method in any circumstance.
- ***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.
- ***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.

Table 4.2 shows the adaptation of the WHO MEC categories for use in the Kenyan setting.

Table 4.2 **Summary table for MEC in relation to clinical judgement**

WHO Category	Description	Recommendation	
		Where Clinical Judgement is possible	**Where Clinical Judgement is NOT possible (e.g Tier 1, CHV)**
1	A condition for which there is no restriction for the use of the method	Use method in any circumstance	Use the method in any circumstance
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks	Generally use the method with care—close follow-up might be required in some cases	Initiate the method and refer the client for evaluation as soon as possible
3	A condition where the theoretical or proven risks usually outweighs 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 the client or help her to choose another method
4	Conditions that present an unacceptable health risk if the contraceptive method is used	Do not use the method	Do not use the method. Refer as needed

MEC for Voluntary Surgical Contraception (Tubal Ligation and Vasectomy)

There is no medical condition that would absolutely restrict a person's eligibility for VSC, although some conditions and circumstances will require that certain precautions are taken, including those where the recommendation is C (Caution), D (Delay), or S (Special).

Table 4.3 shows the MEC criteria for VSC.

Table 4.3 **MEC Categories for surgical contraception methods**

WHO Category	Explanation
Accept (Category A)	There is 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. Underlying condition must be treated and resolved before the procedure can be performed. Provide an alternative temporary methods of contraception in the meantime
Special (Category S)	Special facilities and equipment are needed for surgical procedure, including an experienced surgeon and staff, general or regional (spinal) anesthesia and a specialist medical support. Otherwise refer. Provide alternative temporary methods in the meantime

MEC CRITERIA FOR FERTILITY AWARENESS-BASED METHODS (FAMS) OF FP

There are no medical conditions that become worse because of use of FAMs. In general, these methods can be provided without concern for health effects to people who choose them. However, there are a number of conditions that make their use more complex (see **Table 4.4**). The existence of these conditions suggests that:

- Use of FAMs should be delayed until the condition is corrected or resolved
- Use of FAMs will require special counselling for the client, and a more highly trained provider is generally necessary to ensure correct use

Table 4.4 **MEC categorizes for fertility awareness-based methods**

Category	Explanation
Accept (A)	There is no medical reason to deny the particular FAB method to a woman in this circumstance.
Caution (C)	The method is normally provided in a routine setting, but with extra preparation and precautions. For FAB methods, this usually means that special counselling may be needed to ensure correct use of the method by a woman in this circumstance.
Delay (D)	Use of this method should be delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be offered.

CHAPTER FIVE :

5

HORMONAL CONTRACEPTIVE METHODS

Hormonal contraceptives are among the most widely used FP methods worldwide. According to KDHS 2014 nearly 44% of women using modern contraceptives choose hormonal methods, with 26% choosing injectable contraceptives[2].

Hormonal contraceptives contain synthetic hormones (i.e., a combination of estrogen and progestin, or progestin alone), which work primarily by preventing ovulation and making the cervical mucus too thick for sperm movement. They can be taken in the form of oral pills, injectables (intramuscular or subcutaneous), implants, skin patches, hormone-releasing intrauterine systems or vaginal rings. Hormonal contraceptives are highly effective (if used correctly), safe, and convenient.

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 e.g. *Jadelle®*, *Implanon®*, *Zarin®* (Sino-implant)
- Hormone-releasing intrauterine systems (LNG-IUS)
- Dedicated products for emergency contraception

These methods are less commonly available in Kenya:

- Combined injectable contraceptives (see Injectable contraceptives below).
- Combined contraceptive skinpatch (*Evra®*)
- Vaginal contraceptive rings including combined hormonal e.g. *NuvaRing®* and progestin-only E.g. *Progering®*

COMBINED ORAL CONTRACEPTIVE PILLS

Combined oral contraceptives are pills that contain synthetic estrogen and progesterone (progestin), which are similar to the natural hormones produced in a woman's body. These are the contraceptives commonly referred to as *The Pill*.

Over the years, the amount of the estrogen 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 estrogen, and low dose pills contain 30-35 micrograms of estrogen. The ultra-low dose COCs contain 20 micrograms ethinyl estradiol. Low-dose pills are the most commonly available COCs in Kenya.

Key Messages

- *Take one pill everyday*
- *Take any missed pill as soon as possible*
- *Use of COCs helps protect from ovarian and endometrial cancers*

TYPES AVAILABLE

- 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. contain hormones). The remaining seven pills are inactive and usually contain iron.
- Types of COCs
  - Monophasic
  - Biphasic
  - Triphasic

MODE OF ACTION

- Works primarily by preventing the release of eggs from the ovaries (suppress ovulation)
- Thickens the cervical mucus thus interfering with sperm transport

EFFECTIVENESS

Effectiveness depends on the user: It is 99.7% effective in preventing pregnancy if used correctly and consistently. Risk of pregnancy is greatest when a woman starts a new pill pack 3 or more days late, or misses 3 or more pills near the beginning or the end of a pill pack.

Note: COCs do NOT disrupt an existing pregnancy

Advantages

Contraceptive Benefits

- Highly effective if used correctly and consistently
- Are effective immediately if given within the first 5 days of the cycle
- Easy to use
- Easy to obtain and can be provided by trained non-clinical service providers
- COCs are safe for the majority of women

Non-contraceptive Health Benefits

- Reduction of menstrual flow (lighter, shorter periods)
- Decrease in dysmenorrhea (painful periods)
- Reduction of symptoms of endometriosis and polycycstic ovarian syndrome (PCOS)
- Improvement and prevention of iron - deficiency anaemia
- Protection against ovarian and endometrial cancer
- Possible protection from symptomatic pelvic inflammatory disease
- Treatment for acne and hirsutism

Limitations of COCs

- COCs must be taken daily to be effective, preferably at the same time each day.
- Effectiveness may be lowered if client is on anti-TB drugs (Rifampicin or Rifabutin therapy), anti-epilepsy treatment and

some ARVs indicating a need for a backup method. Service providers should refer to MEC for possible interactions.
- Contraceptive effectiveness could also be lowered in the presence of gastroenteritis, severe vomiting, and diarrhea.
- COCs do not offer protection against STIs, including hepatitis B and HIV. Therefore, at-risk individuals should use condoms to ensure protection against STIs.
- Reduce milk production in breastfeeding women.

Side Effects of COCs

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

- 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
- Weight change
- Mood change
- Amenorrhea (some women see amenorrhea as an advantage)

Major side effects or complications are rare, but possible and include:

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

Eligibility criteria

Who Can Use COCs – (MEC Category 1)

- Age; from menarche to 40 years
- Women of any parity (Parous and nulliparous)
- Non-breastfeeding women more than 3 weeks postpartum.

If there is an additional risk that she might develop a blood clot in a deep vein (deep vein thrombosis, or VTE), then she should start at 6 weeks instead.

- Post abortion (first trimester, second trimester, immediate post septic abortion)
- Post ectopic pregnancy
- Previous pelvic surgery
- Minor surgery without prolonged immobilization
- Varicose veins
- Non-migraine headache (mild or severe), for **initiating clients**
- Epilepsy (refer to drug interaction if on treatment)
- Depressive orders (other medication may interact with the method)
- Vaginal bleeding patterns (irregular cycles, heavy or prolonged bleeding)
- Severe dysmenorrhea
- Endometriosis
- Benign ovarian tumours
- Gestational trophoblastic disease
- Endometrial and ovarian cancers
- Benign breast disease, or family history of breast cancer
- Uterine Fibroids (with or without distortion of the uterine cavity)
- Pelvic inflammatory disease (current or previous PID)
- Clients at high risk of STIs and those with active STIs including; chlamydia and gonorrhoea cervicitis, trichomonal vaginitis, bacterial vaginosis
- HIV
- Antiretroviral drugs
    - NRTIs: Abacavir (ABC), Tenofovir (TDF), Zidovudine (AZT), Lamivudine (3TC), Didanosine (DDI), Emtricitabine (FTC)
    - NNRTI: Etravirine (ETR), Rilpivirine (RPV)

- Integrase inhibitors: Raltegravir (RAL), Dolutegravir (DTG)

- TB (pulmonary or extra-pulmonary)
- Malaria
- Schistosomiasis
- History of gestational diabetes or Thyroid disease (simple goitre, hypothyroidism, hyperthyroidism)
- Mild liver cirrhosis (compensated)
- Iron deficiency anaemia and thalassaemias
- Antibiotics
- Antifungals
- Antiparasitics

MEC Category 2 – Use with Caution

The conditions in **table 5.1** are discussed in the scenarios of whether or not clinical judgment is possible.

Table 5.1 **Conditions that warrant extra precautions (MEC 2)**

Condition	Suggested Action	
	When clinical judgement is possible	**When clinical judgement is not possible or is limited (e.g. CHV with FP training, CBFP)**
Age; 40 years or more	Initiate method. Age by itself does not restrict use of any method.	Initiate and re-supply method.
Breastfeeding; 6 months or more after delivery (*baby has been weaned)*	Generally use the method and recommend follow up	Initiate the method and follow up. Resupply as needed
Non-breastfeeding women 21 days or more postpartum with no risk of venous thromboembolism	Generally use the method and recommend follow up	Initiate the method and follow up. Resupply as needed

Condition	Suggested Action	
	When clinical judgement is possible	**When clinical judgement is not possible or is limited (e.g. CHV with FP training, CBFP)**
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.
Antiretroviral therapy with the following NNRTIs: Efavirenz (EFV), Nevirapine(NVP), ritonavir or ritonavir-boosted PIs	Initiate method. Advise consistent condom use to prevent HIV and to compensate for any possible reduction in COC effectiveness.	Refer for review as soon as possible. Re-supply as needed
History of high blood pressure in pregnancy with normal current blood pressure	Generally use the method and recommend follow up	Initiate the method and follow up
Uncomplicated diabetes mellitus (no vascular disease or diabetes of less than 20 years duration)	Generally use the method and recommend follow-up.	Initiate method and refer as soon as possible
Women who suffer from obesity, i.e., weight equal to or greater than 30 kg/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 gallbladder disease who are currently asymptomatic or have been treated by cholecystectomy	Use the method, follow-up, and discontinue if symptoms develop. (Not: Women on medical treatment for this disease fall in category 3).	May initiate and re-supply as needed, especially where cholecystectomy has been performed.
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 in *Category 1;* women with breast cancer	Refer for evaluation **before** initiating method.

Condition	Suggested Action	
	When clinical judgement is possible	**When clinical judgement is not possible or is limited (e.g. CHV with FP training, CBFP)**
	fall into *Category 4* and COCs should be discontinued.	
Women with sickle cell disease	Initiate method and advice regular follow up.	Initiate method and refer for evaluation as soon as possible of symptoms start. Resupply 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.
	(Also note women over 35 years of age and smoke are in category 3 and 4)	May re-supply as needed
Women with superficial venous thrombosis	Initiate the method and arrange for investigations to rule out Deep Vein Thrombosis (DVT)	Initiate the method and refer for follow-up as soon as possible. Resupply 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.
Acute viral hepatitis for continuing clients	Use the method and follow-up	Refer for follow-up
Women who have migraines without aura and are less than 35 years of age (See Appendix 2)	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.

Condition	Suggested Action	
	When clinical judgement is possible	**When clinical judgement is not possible or is limited (e.g. CHV with FP training, CBFP)**
Women with liver tumor	If a woman is known to have focal nodular hyperplasia, initiate method.	Refer for evaluation **before** initiating method
	If the type of liver tumor isn't known, evaluate or refer for evaluation prior to initiation of method (Women with liver tumors other than focal nodular hyperplasia are classified as *Category 4*)	
Uncomplicated Valvular heart disease	Initiate method and arrange close follow-up	Refer for evaluation before initiating method
Cervical intraepithelial neoplasia or cervical cancer awaiting treatment	Initiate and follow up closely	Refer for review as soon as possible. Re-supply as needed

Women who should not use COCs (Includes MEC Category 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 judgment is possible, and careful follow-up can be assured (category 3).

Table 5.2 **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 who are less than 21 days postpartum and do not have other risk factors for venous thromboembolism (Category 3) or who have other risk factors for venous thromboembolism (Category 4); women who are more than 21 and less than 42 days postpartum with other risk factors for venous thromboembolism (Category 3)	3 / 4
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 cannot be measured), or moderate hypertension (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
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.	4
Women with current or previous history of DVT or pulmonary embolism (PE), acute DVT/PE, DVT/PE and on	4

Condition	MEC Category
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) liver cirrhosis	4
Women with hepatocellular adenoma or malignancy (hepatoma)	4
Women on certain anticonvulsants (Phenytoin, Carbamazepine, Barbiturates, Primidone, Topiramate, Oxycarbazepine or Lamotrigine)	3
Women on TB therapy who are on Rifampicin or Rifabutin	3

METHOD PRESCRIPTION AND USE

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.

For postpartum women

- Use of COCs is not usually recommended for women less than 6 months postpartum who are primarily breastfeeding.
- Non-Breastfeeding. If a woman is 21 or more days postpartum, amenorrhoeic and it is certain that she is not pregnant, she

can start COCs immediately; use of a backup method is required for the next 7 days. If her menstrual bleeding has returned, she can start COCs as for other women having menstrual bleeding.

- Post Abortion women can start COCs immediately

Switching of FP methods

- Switching from another hormonal method
  - Can start COCs immediately if she has been using her hormonal method consistently and correctly or if certain that she is not pregnant.
  - If her previous method was an injectable, start COCs when the next injection is due.
- Switching from a non-hormonal method (other than the IUCD)
  - Start immediately or at any other time, if certain that she is not pregnant.
  - Start within 5 days of menstrual bleeding.
- If it is more than 5 days after the start of her monthly bleeding, she can start COCs any time it is reasonably certain she is not pregnant. She will need a backup method* for the first 7 days of taking pills.
  * additional contraceptive method
- Switching from an IUCD (including a hormone-releasing IUCD)
  - Start at any time if certain that she is not pregnant.
  - Start within 5 days of menstrual bleeding and the IUCD can be removed at the same time.
  - After 5 days of menstrual bleeding start COC and remove the IUCD on the next menstrual bleeding.

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 onset of 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 to allow for client review and follow up.

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

MANAGEMENT OF 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 danger signs (ACHES):

- **A:** Abdominal pains
- **C:** Chest pain or shortness of breath
- **H:** Headaches
- **E:** Eye problems
- **S:** 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.

Table 5.3 describes how to manage some of the common side effects a client may encounter while using COCs.

Table 5.3 **Side effects and Management for COCs**

Side effect	Management
Nausea and dizziness	• Assess for pregnancy. • Reassure client that this is a common side effect in COC users and may diminish in a few months. • Advise client to take pills with meals or • at bedtime.
Amenorrhoea	• Assess for pregnancy. If client is not pregnant, explain that this is one of the possible side effects of COC use.
Spotting	• Assess for pregnancy. • Reassure client that irregular spotting is a harmless and common side effect in COC users, especially during the first three months. • Assess for other illnesses if appropriate • Encourage client to take pills at the same • time each day. • 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.

Community Based Distributers (CBDs) should be instructed to refer all clients with side effects to a health facility for further evaluation, advice, and management by a trained clinician.

MANAGEMENT OF MISSED PILLS

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 worsen side effects. Specific instructions for missed pill are provided in **Table 5.4**.

Table 5.4 **Actions to Take for Missed COC Pills**

Key Message	• **Take a missed hormonal pill as soon as possible.** • **Keep taking pills as usual, one each day. (She may take 2 pills at the same time or on the same day.)**
Missed 1 or 2 pills? Started new pack 1 or 2 days late?	• Take a hormonal pill as soon as possible. • Little or no risk of pregnancy
Missed pills 3 or more days in a row in the first or 2nd week? Started new pack 3 or more days late?	• Take a hormonal pill as soon as possible. • Use a backup method for the next 7 days. • Also, if she had sex in the past 5 days, she can consider EC.
Missed 3 or more pills in the 3rd week?	• Take a hormonal pill as soon as possible. • Finish all hormonal pills in the pack. Throw away the 7 nonhormonal pills in a 28-pill pack. • Start a new pack the next day. • Use a backup method for the next 7 days. • Also, if she had sex in the past 5 days, she can consider EC.
Missed any non-hormonal pills?(last 7 pills oin a 28-pill pack)	• Discard the missed non-hormonal pill(s). • Start the new pack as usual.
Severe vomiting or diarrhoea	• If she vomits within 2 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 2 days, follow instructions for 3 or more missed pills, above.

METHOD SUPPLY

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 3 cycles. 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.

PROGESTIN-ONLY PILLS (POPS)

The Progestin Only Pills (POPs), also called the "Mini Pill" are oral hormonal contraceptives that contain progesterone only in a smaller dose (typically 10 – 50%) less than that used in the combined pill. They do not contain Estrogen hence clients do not experience the side effects associated with estrogen.

Common brands available in the public sector and the local market contain Levonorgestrel 30mcg.

TYPES OF POPS

There are many brands of the Progestin Only Pills (POP) but they are all the same dose and contain the same active ingredient – norethindrone.

MODE OF ACTION

- Thicken cervical mucus thus interfering with sperm movement.
- Suppressing ovulation.

EFFECTIVENESS

POPs are 99.5 % effective if used correctly and consistently during exclusive breastfeeding. They are most effective when taken at the same time every day. For women who have monthly bleeding, risk of pregnancy is greatest if pills are taken late or missed completely.

ADVANTAGES OF POPS

Contraceptive benefits

- Effective and safe
- Does not affect breast milk production and can be used during breastfeeding starting 6 weeks after childbirth
- A pelvic exam is not required to initiate use.
- Suitable for women with risk factors such as heart attack, stroke and thrombosis.
- Return to fertility is immediate upon discontinuation

Non-contraceptive benefits

- Less side effects such as acne and weight gain
- Taking POPs does not increase risk of blood clotting.
- May prevent endometrial cancer
- May help to prevent anemia

LIMITATIONS AND SIDE EFFECTS OF POPS

Limitations

- 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.
- Effectiveness may decrease if clients are also taking some other medications (anti-TB drugs, anticonvulsants and antiretroviral) so a client should use a backup method
- Less effective in women who are not breastfeeding
- Effectiveness may also be lowered in the presence of diarrhea and vomiting

Side effects

- 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 CRITERIA

Who Can Use POPs – (MEC Category 1)

- It is suitable for all ages
- Women of any parity (Parous and nulliparous)
- Postpartum:
  - Non-breastfeeding mothers immediately postpartum and thereafter
  - Breastfeeding women at 6 weeks and thereafter
- Post abortion, miscarriage or ectopic pregnancy.
- Previous pelvic surgery
- Smoking
- Obesity
- Hypertension
  - Adequately controlled hypertension where BP can be evaluated
  - History of high blood pressure in pregnancy where current BP is normal
  - Elevated blood pressure (systolic 140–159 or diastolic 90–99 mm Hg)
- Deep Venous Thrombosis (DVT) /Pulmonary Edema (PE)
  - Family history of DVT/PE
  - Major or minor surgery without immobilization
- Varicose veins, superficial thrombophlebitis
- Valvular heart disease (complicated or uncomplicated)
- Headache
  - Non-migraine (mild or severe)

- Migraine headache without aura

- Depressive orders (other medication may interact with the method)
- Epilepsy (medications may interact with method)
- Endometriosis
- Cervical intraepithelial neoplasia or cervical cancer awaiting treatment
- Benign ovarian tumours (including cysts)
- Endometrial and ovarian cancers
- Severe dysmenorrhoea
- Gestational trophoblastic disease
- Uterine Fibroids (with or without distortion of the uterine cavity)
- Breast disease (benign breast disease, family history of breast cancer)
- Pelvic inflammatory disease (current and previous PID)
- STIs (chlamydia and gonorrhoea cervicitis, trichomonal vaginitis, bacterial vaginosis)
- HIV/AIDS (high risk of HIV, HIV infected, mild or advanced clinical HIV)
- TB (both pelvic and non-pelvic)
- Schistosomiasis
- Malaria
- Thyroid disease
- Viral hepatitis
- Mild liver cirrhosis (compensated)
- History of gestational diabetes
- Anaemia (iron deficiency, sickle cell disease, thalassemia)
- Antiretroviral drugs
- Broad-spectrum antibiotics
- Antifungals
- Antiparasitics

MEC Category 2 – Use with Caution

The conditions in **Table 5.5** are discussed in the scenarios of whether or not clinical judgment is possible.

Table 5.5 **Conditions that require extra caution 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.
Currently receiving ARV treatment	Method can be used unless ritonavir or ritonavir-boosted Pls 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. Client should be advised to use condoms in addition to POPs at least until a clinician confirms that she is not receiving ritonavir in any form. (Note: Generally, all women on ART, regardless of drug regiment, should be counselled to use condoms in addition to POPs to compensate for any possible reduction in effectiveness). Resupply as needed.
Breastfeeding below 4 weeks	Method can be used	Resupply when 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.
Women with diabetes (including those with vascular complications) and hypertension (BP higher than 160/100)	May initiate method use followed by careful evaluation in consultation with responsible clinician. Ensure regular follow-up at clinic.	Can initiate the method and send for evaluation. Resupply when needed.
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.

Client's Condition	Suggested Action	
	Where clinical judgement is possible	**Where clinical judgement is not possible or is limited (e.g. CBD)**
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.	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.
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.
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.

MEC Category 3 and 4 – Women who should not use POPs

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:

1. No other method is available or acceptable,
2. Clinical judgement is possible, and
3. Careful follow-up can be assured (category 3).

These circumstances include the following:

- 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:
  - 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

Clients should take one pill every day. POPs must be taken at the same time every day (+/- two hours) to avoid pregnancy and minimize side effects. When one pack is finished, client should begin the next pack immediately with no break in between packs. An estimated 48 hours of POP use is usually required to achieve the contraceptive effects on cervical mucus.

When to start

- Regular Menses
  - Start the first cycle within the first five days of menstrual period, preferably on the first day.

- If more than five days since menstrual bleeding started she will need to abstain from sex or use a backup method for the next 2 days.

- Postpartum
  - Breastfeeding: POPs can be started immediately after birth (MEC Category 2) or after 4 weeks, (MEC category 1). If a client with Lactational amenorrhea requests for the POPs after 4 weeks post-partum give the pill if confirmed not pregnant.
  - Non breastfeeding: the woman should start the POPs immediately or at any time within the first three weeks post-partum. After three weeks postpartum and she has not yet seen the first post-partum menses, pregnancy should be ruled out before starting the pill and she should use a backup method for 2 days
- Post abortion
  - Start POPs immediately

Switching of FP Methods

- Switching from another hormonal method
  - The client can start the pill immediately if she has been using other hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant.
  - If her previous method was an injectable contraceptive, she should start the pill when the repeat injection is due.
- Switching from a non-hormonal method (other than the IUCD)
  - The client can start the pill within 5 days of her menstrual bleeding.
  - After 5 days of her menstrual bleeding she can start immediately or at any time if pregnancy is ruled out; a backup method is needed for the next 2 days.
- Switching from an IUCD (including a hormone-releasing IUCD)
  - The client can start the pill within 5 days of menstrual bleeding and the IUCD can be removed at that time. She

can also start the pill at any time if it is confirmed that she is not pregnant.

- After 5 days since menstrual bleeding started, she will need to keep the IUCD and have it removed on her next menstrual period.

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

MANAGEMENT OF COMMON SIDE EFFECTS OF POPS

Community FP service providers such as CHVs should be instructed to refer all clients with side effects to a health facility for evaluation by a clinician. **Table 5.6** describes how service providers should manage typical side effects that clients might encounter.

Table 5.6 **Management of common side effects of POPs**

Side Effect	Management
Spotting	• Reassure client that this is common with POP use. Determine if client had vomiting or diarrhea 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
Heavy or prolonged bleeding	• Assess for underlying gynaecological problems and manage accordingly. • If there are no underlying gynaecological problems; - Give NSAIDs and COCs • If bleeding persists and becomes a threat to her life, remove the implants and help her choose another method.
Amenorrhea	• If client is breastfeeding, reassure her that it is normal not to have monthly bleeding while breastfeeding.

Side Effect	Management
	• If client is not breastfeeding, reassure her that some women stop having monthly bleeding while taking POPs. • 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.
Headache or dizziness	• Determine cause. If no cause is found, counsel client and recommend common pain relievers.. • If headaches worsen while using POPs (e.g., she develops migraines with aura), discontinue POPs and help client select alternative method. Refer if need be.
Abnormal suspicious vaginal bleeding	• Evaluate the client by history and pelvic examination (refer as necessary), including VIA/VILLI and Pap Smear. Treat or refer for treatment as necessary.
Breast fullness or tenderness	• Assess for pregnancy. - If pregnant, discontinue POPs - If not pregnant, reassure and give analgesics • If physical examination shows signs of sepsis, treat with antibiotics and analgesics • If she has breast lump or other suspicious lesions, refer for diagnosis and management.
Severe pain in the lower abdomen	• Rule out ectopic pregnancy directly or through immediate referral.
Mood changes or nervousness	• Counsel the clients • If the condition worsens, discontinues POPs and help her to select an alternative method

MANAGEMENT OF MISSED DOSES

If a woman is 3 or more hours late taking a pill or if she misses a pill completely, the primary advice is to take the missed pill as soon as possible and keep taking pills as usual, one each day. Specific instructions are provided in **table 5.7**.

Table 5.7 **Actions to Take for Missed POPs**

Key Message	• **Take a missed hormonal pill as soon as possible.** • **Keep taking pills as usual, one each day. (She may take 2 pills at the same time or on the same day)**
Do you have monthly bleeding regularly?	• If yes, she also should use a backup method for the next 2 days • Also, if she had sex in the past 5 days, she can consider EC
Severe vomiting or diarrhoea	• If she vomits within 2 hours after taking a pill, she should take another pill from her pack as soon as possible, then keep taking pills as usual

CHVs and CBDs should be instructed to refer clients that miss **3 or more** pills to a health facility for evaluation and advice by a clinician.

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.

METHOD SUPPLY

Non-clinical providers can:

- Initiate use of POPs and re-supply, using the approved MOH Checklist for MEC Category 1 conditions.
- Except where otherwise stated, trained CHVs and 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.

EMERGENCY HORMONAL CONTRACEPTIVE PILLS (EC)

Emergency contraception (EC) refers to the use of certain contraceptive methods by women to prevent pregnancy after unprotected sexual intercourse. EC provides emergency protection (prevents pregnancy) for about 75-95 % of those at risk. EC can reduce unwanted pregnancies that might lead to child neglect, abandonment, unsafe abortions, and maternal deaths. 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.

Depending on the regimen used and number of hours passed since unprotected intercourse, ECs seem to prevent between 75-95 % 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 %; after emergency oral contraception, it is 1-2 %[13].

Key Messages

The earlier the ECs are taken after unprotected sex, the more effective they are. ECs should not be used regularly as they are less effective than other methods

MODE OF ACTION

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

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

EFFECTIVENESS

- ECs are 98% effective if used correctly; i.e. taking the ECs within 120 hours The earlier the EC is used after unprotected sexual intercourse, the more effective they are.
- It should be emphasized that ECPs should not be used on a regular basis (from month to month) because it is less effective than other methods.

TYPES AVAILABLE AND DOSAGE

1. Progestin only pills

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% of expected pregnancies.

The standard dosage is as follows:

- One 750 µcg 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 µcg 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) Levonorgestrel 30mcg 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.

2. Combined oral contraceptives

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

- Low dose pill (30 mcg estrogen 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.
- High dose pill (50 mcg estrogen 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.

3. Ulipristal acetate dedicated product

Ulipristal Acetate (UPA) is a new oral emergency contraceptive that works by delaying ovulation. The dosage is 30 mg of Ulipristal acetate in a single dose within 120 hours after unprotected sex.

It is currently registered in 72 countries but not yet in Kenya.

NOTE: Copper IUCD is now recommended as a method for emergency contraception if it is inserted within five days of unprotected sex.

ADVANTAGES

- Safe, effective, and easy to use.
- Provides protection after unprotected sexual intercourse
- Can be used in emergency situations without having to see a clinician.
- Accessible and has less serious side effects.
- Can be used as a backup method.
- Can be used anytime in the menstrual cycle

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

LIMITATIONS AND SIDE EFFECTS OF ECS

- They are only effective if used within 120 hours of unprotected intercourse.
- They are not to be used as a regular method of contraception.
- Do not protect against STIs, HIV, or AIDS.
- EC pills do not continue to prevent pregnancy during the rest of the cycle.
- EC has the potential for misuse through self-prescription and sharing of pills.
- Efficacy depends on the client action.
- They can cause nausea (more common for the COC regimen).

ELIGIBILITY CRITERIA

Who Can Use ECPs – (MEC Category 1)

All women can use ECPs safely and effectively, including women who cannot use ongoing hormonal contraceptive methods. This includes:

- Breastfeeding women
- Post ectopic pregnancy
- Rape cases
- Obesity
- CYP3A4 (member of Cytochrome P450 enzymes) Inducers (e.g. Rifampicin, Rifabutin, Phenytoin, Phenobarbital, Carbamazepine, Efavirenz, Nevirapine)

MEC category 2 – Use with Caution

- Breastfeeding women who use UPA (it is secreted in breast milk)

- History of severe cardiovascular complications (ischaemic heart disease, cerebrovascular attack, or other thromboembolic conditions)
- Angina Pectoris
- Migraine
- Severe liver disease (including jaundice)

Table 5.8 **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. • Pregnancy poses much more risk for these women than ECPs does. • 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.
Woman with Angina Pectoris	
Women suffering from Migraine	
Women with severe liver disease (including jaundice)	
Women who are breastfeeding considering use of UPA for EC	

MEC category 3 and 4 – Women who should not use ECPs

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.

- ECs 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.

Indications for EC Use

- Following unprotected sexual intercourse when the client is not using contraceptives
- Following sexual assault
- In case of mistakes in contraceptive use e.g.
  - If a condom breaks during sexual intercourse, or there is spillage or incorrect use
  - Client misses oral Contraceptives consecutively for 3 days,
  - Expulsion of the IUCD
  - If the man delays withdrawal in case of coitus Interruptus
  - When a client is using the calendar method, and engages in sexual intercourse during the fertile period.

MANAGEMENT OF COMMON SIDE EFFECTS OF ECPS

The next table provides instructions for management of common side effects during ECP use.

Table 5.9 **Management of common side effects of ECPs**

Side effects	Management
Nausea & vomiting	• If mild reassure and advise to take milk or eat snack. • If vomiting is severe, put on antiemetic • If the woman vomits within 2 hours after taking ECPs, she should take another dose. (She can use anti-nausea medication with this repeat dose • If vomiting continues, she can take the repeat dose by placing the pills high in her vagina. • If vomiting occurs more than 2 hours after taking ECPs, she does not need to take any extra pills.
Breast tenderness	• If not pregnant, reassure

Side effects	Management
Irregular bleeding	• If not pregnant, reassure and help client to select a reliable method of contraception • If pregnant, counsel and refer for ANC
Fluid retention and headache	• If BP is normal, reassure and prescribe/give a mild analgesic • If BP is high, refer for further evaluation and management

STARTING FP METHODS AFTER EC

It should be emphasized that EC should not be used on a regular basis (from month to month) because it is less effective than other methods. All providers are supposed to counsel users on all FP methods available. **Table 5.10** describes contraceptive methods for use following EC.

Table 5.10 **Contraceptive methods and when to begin using them after EC use**

Method	When to start
Condoms	• Start immediately after EC; use also for dual protection
Oral contraceptive pills (COCs, POPs)	• Start the day after taking the ECPs. No need to wait for her next monthly bleeding
Progestin-Only Injectables	• Start on the same day as the ECPs, or if preferred, within 7 days after the start of her monthly bleeding. • She will need a backup method for the first 7 days after the injection
IUCDs	• A copper-bearing IUCD can be used for emergency contraception. This is a good option for a woman who wants an IUCD as her long-term method • If she decides to use an IUCD after taking ECPs, the IUCD can be inserted on the same day she takes the ECPs. No need for a backup method
Implants	• Start within the first seven days after the start of her next period

	• Give her a backup method or oral contraceptives to use until then, starting the day after she finishes taking the ECPs
Voluntary Surgical Contraception (VSC)	• Start within the first seven days after the start of her next period • Give her a backup method until then starting the day after she finishes taking the ECPs
Fertility-Awareness Methods (FAM)	• With the start of her next monthly bleeding. • Give her a backup method or oral contraceptives to use until she can begin the method of her choice.

COMMON QUESTIONS WOMEN HAVE ABOUT ECPS

Q1. 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.

Q2. 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.

Q3. 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. This is to be reasonably sure that conception did not take place.

Q4. 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.

Q5. 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 120 hours from the first sexual encounter. If a woman is already pregnant from an earlier act of unprotected sex, the ECPs will not have any effect.

Q6. Can I repeat use of ECP within same cycle

ECPs can be used more than once within the cycle. A woman does not need a repeat dose with the 120 hours. While repeated use is not harmful, the efficacy reduces with regular use of ECP. Such clients should be counselled about the use of more effective regular contraception.

INJECTABLE CONTRACEPTIVES

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 50% of all women in Kenya who use modern contraceptive methods choose injectable contraceptives.[2] The most widely used injectable methods contain only progestin (Progestin-only Injectable Contraceptives or POIs). Less common injectables are those that contain both progestin and estrogen (Combined Injectable Contraceptives or CIC).

PROGESTIN-ONLY INJECTABLE CONTRACEPTIVES (POIS)

The most widely available POICs are

- Depot-medroxyprogesterone acetate intramuscular injection (DMPA-IM) given at three monthly intervals (13 weeks).
- Norethisterone Enanthate (NET-EN) given at two monthly intervals administered as an intramuscular injection (IM).
- DMPA has also been formulated for sub-cutaneous injection (DMPA-SC) given at three-month intervals (13 weeks).

Table 5.11 **The dosages for the different progestin only injectables**

Type of injectable	Dosage
Depot-medroxyprogesterone acetate Intramuscular (DMPA IM) 150mg	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) 200mg	Given every two months, but it can be given as much as two weeks (14 days) earlier or two weeks (14 days) later
DMPA-SC containing 104 mg of DMPA instead of the 150 mg in the IM formulation.	Injected sub-cutaneously at three-month intervals (12-14 weeks).

MODE OF ACTION

POIs Progestin-only injectables prevent pregnancy by:

- Preventing the release of eggs from the ovaries (suppressing ovulation)

EFFECTIVENESS

Effectiveness depends on receiving injections on time: Risk of pregnancy is greatest when a woman is late for an injection or misses an injection.

- POIC is 99% effective if used correctly and consistently(as per recommendations) and 96% effective as commonly used.

ADVANTAGES OF POIS

Contraceptive Benefits

- They are highly effective and safe.
- A pelvic exam is not required to initiate use.
- They do not contain no estrogen; thus do not have the cardiac and blood-clotting side-effects associated with estrogen-containing pills and injectables.
- Convenient as it doesn't require daily action.
- Do not affect breast milk production hence can be used during breastfeeding

- Are private: No one else can tell that a woman is using the method

Non-contraceptive Health Benefits

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

LIMITATIONS AND SIDE EFFECTS OF POICS

Limitations include:

- Return of fertility may be delayed for 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.

Side effects include:

- Changes in menstrual bleeding patterns such as:
  - irregular bleeding
  - heavy and prolonged bleeding
  - light spotting or bleeding
  - amenorrhea, especially after one year of use
- Weight changes
- Headache
- Dizziness
- Mood swings
- Abdominal bloating
- Acne
- Breast tenderness

ELIGIBILITY CRITERIA

Who Can Use POIs – (MEC Category 1)

- Age between 18 and 45 years
- Women of any parity (Parous and nulliparous)
- Postpartum:
  - Non-breastfeeding mothers immediately postpartum and thereafter
  - Breastfeeding women from 6 weeks and thereafter
- Post abortion (first trimester, second trimester, immediate post septic abortion)
- Past ectopic pregnancy and previous pelvic surgery
- Smoking
- Obesity with BMI of 30 kg/m^2 or more
- History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)
- DVT/PE
  - Family history of DVT/PE
  - Major or minor surgery without immobilization
- Varicose veins, superficial thrombophlebitis
- Valvular heart disease (complicated or uncomplicated)
- Non migraine headaches (mild or severe)
- Epilepsy on certain anticonvulsants (phenytoin, carbamazepine, barbiturates)
- Depressive orders (other medication may interact with the method)
- Endometriosis
- Breast disease (benign breast disease, family history of cancer)
- Endometrial and Ovarian cancers
- Gestational trophoblastic disease
- Uterine Fibroids (with or without distortion of the uterine cavity)
- Pelvic inflammatory disease (current and previous PID)

- STIs (chlamydia and gonorrhoea cervicitis, trichomonal vaginitis, bacterial vaginosis)
- HIV/AIDS(high risk of HIV, HIV infected, mild or advanced clinical HIV)
- TB (both pelvic and non-pelvic)
- Schistosomiasis
- Malaria
- Thyroid disease
- History of Gestational diabetes mellitus
- Viral hepatitis
- Mild liver cirrhosis (compensated)
- Iron deficiency anaemia, sickle cell disease, thalassaemias
- Antiretroviral drugs
    - NRTIs: Abacavir (ABC), Tenofovir (TDF), Zidovudine (AZT), Lamivudine (3TC), Didanosine (DDI), Emtricitabine (FTC), Stavudine (D4T)
    - NNRTI: Etravirine (ETR), Rilpivirine (RPV)
    - Integrase inhibitors: Raltegravir (RAL), Dolutegravir (DTG)
- Antibiotics
- Antifungals
- Antiparasitics
- TB patients on Rifampicin or Rifabutin therapy (for DMPA)
- Anticonvulsant therapy (for DMPA)

MEC Category 2 – Use with Caution

- Age: Menarche to 18 years and after 45 years
- Obesity with BMI more than 30 kg/m^2 (in women <18 years of age and have attained menarche)
- Hypertension
    - History of hypertension, where blood pressure cannot be evaluated (including hypertension in pregnancy)
    - Adequately controlled hypertension, where blood pressure can be evaluated
    - Elevated BP (systolic 140–159 or diastolic 90–99 mm Hg)

- DVT/PE
  - History of DVT/PE
  - DVT/PE and established on anticoagulant therapy
  - Major surgery with prolonged immobilization
- Systemic lupus erythematous (associated with severe thrombocytopenia or are on Immunosuppressive treatment)
- Headaches
  - Migraine headaches without aura at any age
  - Migraine headache with aura for **initiating clients**
- Vaginal bleeding patterns (Irregular pattern without heavy bleeding, heavy bleeding or prolonged bleeding
- Cervical intraepithelial neoplasia or cervical cancer awaiting treatment
- Undiagnosed breast mass
- Uncomplicated Diabetes mellitus
- Gall bladder diseases (symptomatic or asymptomatic)
- Benign liver tumours (focal nodular hyperplasia)
- Antiretroviral therapy with the following
  - NNRTIs: Efavirenz (EFV), Nevirapine(NVP)
  - Protease inhibitors: Ritonavir-boosted Atazanavir (ATV/r), Ritonavir-boosted Lopinavir (LPV/r, Ritonavir-boosted Darunavir (DRV/r), Ritonavir (RTV)
- TB patients on Rifampicin or Rifabutin therapy for NET-EN
- Anticonvulsant therapy (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) for NET-EN

MEC Category 3 and 4 – Women Who Should not use Progestin-only Injectables

NOTE: For category 3 only in cases where clinical judgment 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 5.12 **Conditions that qualify as MEC categories 3 or 4 for POIs**

Condition	MEC category
Breastfeeding women less than six 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	3C
Women with multiple risk factors for arterial cardiovascular disease (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
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)

USE OF DMPA AND RISK OF HIV TRANSMISSION

According to the WHO 2017 guidance statement on hormonal contraceptive eligibility for women at high risk of HIV: -

DMPA is an effective contraceptive option for women using ART, including those on efavirenz or protease inhibitor-based regimens.

Women at high risk of acquiring HIV can generally use progestin only injectables (NET-EN and DMPA IM, SC) because the advantages of these methods generally outweigh the possible increased risk of HIV acquisition (MEC Category 2)

Women considering progestogen only injectables should, however, be advised about the possible risks i.e. the uncertainty over a causal relationship, and about how to minimize the risk of acquiring HIV.

EFFECT OF DMPA ON BONE DENSITY

During use , DMPA decreases bone mineral density slightly. This may increase the risk of developing osteoporosis and possibly having bone fractures later, after menopause. WHO has guided that this decrease in bone density does not place age limit or time limits on use of DMPA.

METHOD PRESCRIPTION AND USE

When to start

Regular Menses

- Give the initial injection within the first 7 days of the menstrual bleeding or at any time, if it is reasonably certain that she is not pregnant
- If after 7 days of menstrual bleeding she will need a backup method for the next 7 days.

Postpartum client

- Breastfeeding. Any time within 6 weeks postpartum and not amenorrhoeic treat as for regular menses. With lactation amenorrhea give between six weeks and six months postpartum, if you can establish that she is not pregnant.

- Non breastfeeding. Start immediately or at any time within the first 21 days postpartum. After 21 days postpartum and no menses, rule out pregnancy first and initiate but emphasize on the need of a backup method for the next 7 days.

Post abortion

- Immediately post abortion.

When to Repeat the Injection

The injection is administered regularly, 2-monthly for Norethisterone Enanthate(NET-EN) and 3-monthly for Depo, and the injection interval dates should be adhered to.

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.

Switching of FP methods

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

Table 5.13 **Switching from another method to injectables**

Method switching from	Instructions
Switching from another hormonal method	• Can initiate immediately if she has been using other hormonal method consistently and correctly, or if certain that she is not pregnant. There is no need to wait for next menstrual bleeding. • If previous method was another injectable, start the POI when the repeat injection is due.
Switching from a non-hormonal method (other than the IUCD)	• Can have the first injection immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period if she is within 7 days of her menstrual bleeding and • If after 7 days of menstrual bleeding she will need a backup method for the next 7 days.
Switching from an IUCD (including a hormone-releasing IUCD)	• Start the injection within 7 days of menstrual bleeding and the IUCD can be removed at that time. Start the injection at any time when pregnancy is ruled out. • After 7 days since menstrual bleeding started, keep the IUCD and have it removed on next menstrual period.
Switching between DMPA and NET-EN	• Using DMPA and NET-EN interchangeably is not recommended. • If it becomes necessary to switch from one to the other (e.g. because of stock outs), the switch should take place at the time the repeat injection would have been given.

MANAGEMENT OF SIDE EFFECTS IN POIS USE

The following table outlines the possible side effects associated with POI use and their management.

Table 5.14 **Side effects of POIs and their management**

Side Effect	Management
Irregular spotting or light bleeding between monthly periods	• Spotting or light bleeding is common during use of injectable contraceptives, particularly during the first 6-8 months of use. It is not harmful. Reassure the client • If the bleeding is persistent assess for gynecological problems and treat accordingly • If there is no gynecological problem treat with non-steroidal anti-inflammatory drugs (NSAIDs) e.g. Ibuprofen • If the treatment is not effective and she finds the bleeding unacceptable, discontinue injectable and help her choose another method.
Heavy or prolonged bleeding (lasting more than eight days or twice as long as her usual menstrual period)	• Assess for underlying gynecological problems and manage accordingly. • If there are no underlying gynecological problems give any of the following • Give NSAIDs (Ibuprofen 400-800 mg tds for 7-14 days) - COCs (one active pill daily up to 1-3 cycles) • 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. - If bleeding persists and becomes a threat to her life, discontinue injectable and help her choose another method.
Amenorrhea	• By the end of the first year on injectables, amenorrhea develops in the majority of clients. Normally amenorrhea does not require any medical treatment. Counselling and reassurance are sufficient. If in doubt, assess for pregnancy, and manage accordingly. • If client is bothered by lack of menses despite reassurance, discontinue injectable, and help her choose another method.
Headache or dizziness	• Assess for other causes including raised blood pressure. • Reassure client if symptoms are mild. • If severe, discontinue injectable and refer for evaluation. Help client choose another method.

Side Effect	Management
Breast fullness or tenderness	• Assess for pregnancy. • If pregnant, discontinue injectable • If not pregnant, reassure and give analgesics • If physical examination shows signs of sepsis, treat with antibiotics and analgesics • If she has breast lump or other suspicious lesions, refer for appropriate source for diagnosis.

MISSED APPOINTMENTS

The client should be counselled on the type of injectable she is using and frequency of repeat injections. The date of the next appointment should be communicated to her before she leaves the SDP and she should be encouraged to keep the appointments. If, however, she fails to keep the appointment date, she should be encouraged to come back to the clinic, regardless of how much time has passed since the missed appointment.

Table 5.16 **When client misses appointment for injection**

Timing	Suggested action
Comes earlier for her next injection	• The repeat injection for both DMPA (IM or SC) and NET- EN can be given up to 2 weeks early.
Comes up to 4 weeks late for DMPA and 2 weeks late for NET-EN	• The repeat injection for DMPA (IM or SC) can be given up to 4 weeks late, and for NET-EN, up to 2 weeks late without requiring additional contraceptive protection.
Comes more than four weeks for DMPA and more than two weeks for NET-EN	• 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 amenorrhea without pregnancy so pregnancy test or pelvic exam might be needed to rule out pregnancy). • 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. • She will need to abstain from sex or use additional contraceptive protection for the next 7 days after injection.

COMBINED INJECTABLE CONTRACEPTIVES (CICS)

The CICs consist of a natural estrogen plus a progestogen. There are two CIC formulations both given at four week (monthly) intervals on the market

Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg.

Norethisterone Enanthate 50mg plus estradiol valerate 5mg.

In both preparations, the natural estrogens might be less potent compared to the synthetic estrogens 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 estrogen-related side effects associated with CICs might differ from those experienced by COC users.

Table 5.17 **The dosages for the different combined injectables**

Type of injectable	Dosage
Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg	Given once every 30 days, but it could be given as much as three days earlier or later.
Norethisterone Enanthate 50mg plus estradiol valerate 5mg	Given once every 30 days, but it could be given as much as three days earlier or later

MODE OF ACTION

CICs prevent pregnancy mainly through the inhibition of ovulation

EFFECTIVENESS

- Effectiveness depends on receiving injections on time: Risk of pregnancy is greatest when a woman is late for an injection or misses an injection.
- CICs is 99% effective if used correctly and consistently (as per recommendations) and 97% effective as commonly used.
- Return of fertility after injections are stopped: An average of about 5 months.
- Can be administered up to 7 days before the scheduled date or 7 days late.

MANAGING LATE INJECTIONS

- A client who is more than 7 days late can receive her next injection if:
  - She has not had sex since 7 days after the scheduled date of her injection, or
  - She has used a backup method or has taken emergency contraceptive pills (ECPs) after any unprotected sex since 7 days after the scheduled date of her injection.
  - She will need a backup method for the first 7 days after the injection.
  - If the client is more than 7 days late and does not meet these criteria, additional steps can be taken to be reasonably certain she is not pregnant.

CONTRACEPTIVE IMPLANTS

Contraceptive implants (also called sub-dermal implants) are small hormone (progesterone) bearing capsules or rods which when inserted under the skin of a woman's upper arm, release the hormone slowly over a period of time to prevent pregnancy. Implants do not contain oestrogen; therefore, they are free from the side effects associated with that hormone.

Key Messages

- *Implants provide long-term pregnancy protection. Very effective for 3 to 5 years, depending on the type of implant. Immediately reversible.*
- *Bleeding changes are common but not harmful.*
- *Some ARVs e.g. EFV reduce the effectiveness of implants particularly after the first year or second year.*

MODE OF ACTION

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

EFFECTIVENESS OF IMPLANTS

Implants provide 99.9% effective protection against pregnancy.

They are effective 24 hours post insertion.

TYPES OF CONTRACEPTIVE IMPLANTS

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

Table 5.18 **Descriptions of contraceptive implants**

Product	Design	Active ingredients	Duration of effectiveness
Jadelle	2 rods	Levonorgestrel 75 mg/rod	5 years
Implanon & Implanon NXT	1 rod	Etonogestrel 68 mg/rod	3 years
Sino-implant [Zarin]	2 rods	Levonorgestrel 75mg/rod	4 years
Indoplant	2 rods	Levonorgestrel 75mg/rod	4 years

NOTE: Levoplant/ sino-implant despite its 4-year duration of effectiveness, it is currently registered for 3 years.

ADVANTAGES OF IMPLANTS

Contraceptive Benefits

- Highly effective and offers long term protection against pregnancy
- Does not interfere with act of sexual intercourse
- Effective within 24 hours after insertion
- No frequent clinic visits required
- Fertility returns almost immediately after implants are removed

Non-contraceptive Health Benefits

- Implants do not affect breastfeeding and can be used by breastfeeding mothers starting immediately post-partum

- May reduce menstrual flow (thinning of the endometrium)
- They help prevent ectopic pregnancy (but do not eliminate the risk altogether)
- They protect against iron-deficiency anemia
- They help protect from symptomatic PID
- May protect against endometrial cancer

LIMITATIONS AND SIDE EFFECTS OF CONTRACEPTIVE IMPLANTS

Some of the limitations include:

- The client cannot initiate or discontinue the method on her own as it requires a trained provider to insert and remove the implant.
- Insertion and removal requires minor surgical procedures and may be uncomfortable.
- Do not protect against STIs, including hepatitis B and HIV. Individuals at risk should use condoms in addition to the implants.
- There may be slight delay in resumption of fertility (about 1 year)

Common side effects of using implants include:

- Change in menstrual pattern including; amenorrhea, spotting, intermenstrual bleeding or prolonged bleeding
- Headache
- Dizziness
- Nausea
- Breast tenderness
- Mood changes
- Weight changes
- Mild abdominal pain

ELIGIBILITY CRITERIA

Who Can Use Implants – (MEC Category 1)

- Women of any age
- Women of any parity (Parous and nulliparous)
- Postpartum:
  - Non-breastfeeding mothers immediately postpartum and thereafter
- Post abortion (first trimester, second trimester, immediate post septic abortion)
- Past ectopic pregnancy and previous pelvic surgery
- Smoking
- Obesity with BMI 30 kg/m^2 or more
- Hypertension
- History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)
- Adequately controlled hypertension, where blood pressure can be evaluated
- Elevated blood pressure levels (systolic 140–159 or diastolic 90–99MmHg)
- DVT/PE
  - Family history of DVT/PE
  - Major or minor surgery without immobilization
- Varicose veins, superficial thrombophlebitis
- Valvular heart disease (complicated or uncomplicated)
- Non migraine headaches (mild or severe)
- Epilepsy on certain anticonvulsants (phenytoin, carbamazepine, barbiturates)
- Depressive orders (other medication may interact with the method)
- Endometriosis
- Breast disease (benign breast disease, family history of cancer)
- Endometrial and Ovarian cancers

- Gestational trophoblastic disease Uterine Fibroids (with or without distortion of the uterine cavity)
- Pelvic inflammatory disease (current and previous PID)
- STIs (chlamydia and gonorrhoea cervicitis, trichomonal vaginitis, bacterial vaginosis)
- HIV/AIDS (high risk of HIV, HIV infected, mild or advanced clinical HIV)
- TB (both pelvic and non-pelvic)
- Schistosomiasis
- Malaria
- Thyroid disease
- Cholecystitis (pregnancy related)
- Cirrhosis (mild)
- Anaemia
- History of Gestational diabetes mellitus
- Viral hepatitis
- Mild liver cirrhosis (compensated)
- Iron deficiency anaemia, sickle cell disease, thalassaemias
- Antiretroviral drugs
  - NRTIs: Abacavir (ABC), Tenofovir (TDF), Zidovudine (AZT), Lamivudine (3TC), Didanosine (DDI), Emtricitabine (FTC)
  - NNRTI: Etravirine (ETR), Rilpivirine (RPV)
  - Integrase inhibitors: Raltegravir (RAL), Dolutegravir (DTG)
- Antibiotics
- Antifungals
- Antiparasitics

MEC Category 2 – Use with Caution

- Breastfeeding – from immediately postpartum to less than 6 weeks postpartum
- Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, diabetes, hypertension and known dyslipidaemias)
- Hypertension

  - Elevated blood pressure(systolic 160mm Hg or more or diastolic 100 mm Hg or more)
  - Associated with vascular disease
- DVT/PE
  - History of DVT/PE
  - DVT/PE and established on anticoagulant therapy
  - Major surgery with prolonged immobilization
- Current and history of ischaemic heart disease for **initiating clients**
- Stroke (history of cerebrovascular accident) for **initiating clients**
- Systemic lupus erythematous (associated with severe thrombocytopenia or are on Immunosuppressive treatment)
- Headaches
  - Migraine headaches without aura at any age
  - Migraine headache at any age with aura for **initiating clients**
- Vaginal bleeding patterns (Irregular pattern without heavy bleeding, heavy bleeding or prolonged bleeding
- Cervical intraepithelial neoplasia or cervical cancer awaiting treatment
- Undiagnosed breast mass
- Uncomplicated Diabetes mellitus
- Gall bladder diseases (symptomatic or asymptomatic)
- Benign liver tumours (focal nodular hyperplasia)
- Benign liver tumours
- Antiretroviral therapy with the following
  - NNRTIs: Efavirenz (EFV), Nevirapine(NVP)
  - Protease inhibitors: Ritonavir-boosted Atazanavir (ATV/r), Ritonavir-boosted Lopinavir (LPV/r, Ritonavir-boosted Darunavir (DRV/r), Ritonavir (RTV)
- TB patients on Rifampicin or Rifabutin therapy
- Anticonvulsant therapy (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)

MEC CATEGORY 3 & 4 – WOMEN WHO SHOULD NOT USE CONTRACEPTIVE IMPLANTS

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 5.19 **Conditions that represent MEC Categories 3 and 4 for implants**

Condition	MEC category
Women who have severe cirrhosis or liver tumors (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 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)

METHOD PRESCRIPTION AND USE

When to start

Clients with Regular Menses

- Insert the sub-dermal implant within the first 7 days of the menstrual bleeding.
- Can also be inserted at any time, if certain that she is not pregnant.

- After 7 days of menstrual bleeding there is a need for a backup method for the next 7 days.
- Postpartum and breastfeeding
- Can be inserted immediately postpartum. If amenorrhoeic she can have the implant inserted at any time. If she has resumed menses, implant can be inserted as for other women with regular menstrual cycle.
- Non Breastfeeding
    - Insert immediately or at any time within the first 21 days postpartum.
    - After 21 days postpartum and she has not yet had the first postpartum menses, rule out pregnancy before insertion.
- Post abortion
    - Can be inserted immediately.

Switching of FP methods

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

Table 5.20 **Switching from another FP method to implants**

Method switching from	Instructions
Switching from another hormonal method	‣ Can be inserted immediately if she has been using another hormonal method consistently and correctly, or if certain that she is not pregnant. There is no need to wait for next menstrual bleeding. ‣ If previous method was an injectable, implant should be inserted when the next injection is due.
Switching from a non-hormonal method (other than the IUCD)	‣ Can be inserted immediately if certain that she is not pregnant. There is no need to wait for her next menstrual period if she is within 7 days of her menstrual bleeding. If after 7 days of menstrual bleeding, she will need a backup method for the next 7 days.
Switching from an IUCD (including a hormone-releasing IUCD)	‣ Insert within 7 days of menstrual bleeding and remove the IUCD can be at the same time. ‣ After 7 days of menstrual bleeding insert implant and keep the IUCD until the next menstrual period before removal.

INSTRUCTIONS TO WOMEN AFTER INSERTION OR REMOVAL OF IMPLANTS

After Insertion

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

- Keep insertion area dry for five days.
- Remove the gauze bandage after one day, but leave the adhesive plaster in place for an additional five days(come back to the health facility for removal)
- Return to the clinic if the rod(s) 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 emphasize that implants must be removed by the due date. The provider should give the following information in writing:

- The type of implant that was inserted
- The date of insertion
- The month and year when the implant will need to be removed.

Instructions for Clients Following Removal of Implants

Implants should only be removed by trained healthcare providers in the removal procedure. If the provider is not trained he/she must not attempt the removal and should instead refer the client.

Before removal of the implant, the service provider should counsel the client for subsequent contraceptive options depending on the reason for removal.

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 (to be removed by trained service provider in the clinic)
- Return to the clinic if swelling and pain develop

Management of Side Effects of Contraceptive Implants

Prior to insertion, the provider should discuss the potential side effects. **Table 5.21** 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 5.21 **Side effects of implants and their management**

Side Effect	Management
Irregular spotting or light bleeding	• Reassure client that light bleeding/spotting is common in women using this method especially in the first year. It is not serious and usually does not require treatment. • If the bleeding is persistent assess for gynecological problems and treat accordingly - If there is no gynecological problem treat with non-steroidal anti-inflammatory drugs (NSAIDs) e.g. Ibuprofen or give a cycle of Combined Oral Contraceptives (COCs) - If the treatment is not effective and she finds the bleeding unacceptable, remove the implants and help her choose another method.
Heavy or prolonged bleeding (more than eight days or twice as much as her usual menstrual period)	• Assess for underlying gynecological problems and manage accordingly. • If there are no underlying gynecological problems give NSAIDs, COCs or haemostatics - NSAIDs regimes; Ibuprofen: 800 mg three times a day for five days or Mefenamic acid: 500 mg twice a day for five days - COCs regimes; Low-dose COCs: 30 µg ethinylestradiol 150 µg Levonorgestrel a day for 21 days or COCs: 50 µg ethinylestradiol 250 µg Levonorgestrel a day for 21 days - Heamostatics; Transnexamic acid 500mg three times a day for five days or Ethamsylate 500mg three times a day for five days • If bleeding persists and becomes a threat to her life, remove the implants and help her choose another method.
Amenorrhea	• Reassure her that this is a common occurrence while using implants, and it is not harmful. • Amenorrhea does not require any medical treatment. Counselling is sufficient. • If suspicious, assess for pregnancy. - If she is pregnant, remove the implants. - If she is not pregnant, reassure her and continue method.
Headache	• Assess for other causes including raised blood pressure. Reassure client if symptoms are mild. • If she has migraine headaches without aura, she can continue to use implants if she wishes.

Side Effect	Management
	• If she has migraine headache with aura (MEC category 3), remove the implants and help her choose a method without hormones.
Breast fullness or tenderness	• Assess for pregnancy. - If pregnant, remove Implant manage as above (see amenorrhea) - If not pregnant, reassure and give analgesics • If physical examination shows signs of sepsis, treat with antibiotics and analgesics • If she has breast lump or other suspicious lesions, refer to appropriate source for diagnosis.
Implant expulsion	• 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.
Suspected pregnancy	• Assess for pregnancy, including ectopic pregnancy. • Remove the implants or refer for removal • There are no known risks to a fetus conceived while a woman has implants in place

PROGESTERONE-RELEASING VAGINAL RING (PVR)

The progesterone-releasing vaginal ring (PVR) consists of a flexible ring that releases progesterone. During use, average plasma concentrations of 20 nmol/L are achieved, which are similar to those detected in the average luteal phase in normal fertile women. The progesterone-releasing vaginal ring (PVR) is a contraceptive method for women who must be actively breastfeeding (i.e. at least 4 breastfeeding episodes per day) during PVR use to maintain efficacy.

Key Messages

- *Suitable for breastfeeding women who are actively breastfeeding, at least 4 times per day.*
- *A woman places a flexible ring in her vagina, leaving it in place at all times for 90 days.*
- *Start each new ring immediately after removal of the previous ring for greatest effectiveness.*

MODE OF ADMINISTRATION

- The PVR is inserted higher up into the vagina. It is worn continuously for three-month periods (approximately 90 days).
- After insertion, the ring releases progesterone which is absorbed through the wall of the vagina into the bloodstream (approximately 10 μg/day).
- The used ring must be replaced with a new ring at three-months interval (± two weeks)
- A woman may use rings successively for up to one year after she gives birth if she continues breastfeeding (i.e. at least 4 breastfeeding episodes per day).

MODE OF ACTION

- The hormone makes the cervical mucus thicker, thus interfering with sperm penetration.
- Inhibits ovulation by suppression of follicle growth
- May thin the endometrium
- Prolongs lactational amenorrhea

EFFECTIVENESS OF PVR

- PVR is safe and highly effective (over 98.5 %) if used consistently and correctly in breastfeeding women
- Pregnancy rate in the first year of use (if used consistently and correctly) is 1 to 2 pregnancies per 100 women (1 to 2%). (One –year pregnancy rate 1.5 per cent)[16]

ADVANTAGES

- User-controlled. Can be inserted and be removed by the user without the help of a health provider. After an initial examination and orientation to the method by a healthcare provider, the woman can insert and remove the ring herself in private, reducing the need for frequent visits to the provider.
- Does not require refrigeration. It should be stored at room temperature

- Does not affect breast milk production
- Uses natural progesterone hormone (which has fewer side effects than synthetic progestin that are used in pills, implants, and injections). The vaginal route allows for the use of lower dose of the hormone.
- Increases the range of available contraception methods for breastfeeding women in the PP period.
- Sexual partners have limited exposure to the progesterone in the ring and hence are not affected by it. If inserted correctly, the ring does not interfere with sex.
- Women using PVR experience a longer a lactational amenorrhea and hence extends the contraceptive effectiveness of Lactational Amenorrhea Method (LAM)
- Fertility returns immediately after removal

LIMITATIONS AND SIDE EFFECTS OF PVR:

Limitations

Women with the following conditions are not eligible to use PVR:

- Women who are not actively breastfeeding (at least 4 episodes in a day) cannot use this method
- Hypersensitive to contraceptive hormonal preparations or silicone rubber
- Presence of genital or urinary tract infection, endometritis and has a history of pelvic inflammatory disease (PID) or salpingitis since delivery
- Has a medical history of thrombophlebitis or thromboembolism
- PVR does not protect against sexually transmitted infections (STIs), including HIV. If there is a risk of STI/HIV, the correct and consistent use of condoms is recommended.

Side Effects

Side effects are generally minor and are similar to those experienced with other progesterone-based contraceptives and their management is similar. They include:

- Vaginal discharge
- Irregular bleeding patterns
- Breast discomfort
- Lower abdominal pains
- Urinary discomfort (rarely)

Eligibility for Using PVR

- Women who are breastfeeding and are 4 weeks or more postpartum can use the progesterone-releasing vaginal ring without restrictions (MEC Category 1).
- A woman who uses the PVR must be actively breastfeeding (e.g. at least four breastfeeding episodes per day) to maintain the efficacy of the method.

Clients are advised to return to the health facility any time they may be pregnant or if:

- They have any questions
- Develop any health problems.
- They plan to receive the next ring or the alternative contraceptive method

CORRECTING MYTHS ABOUT HORMONAL CONTRACEPTIVES

Myth: hormonal contraceptives cause abortion

Fact: Hormonal contraceptives do not disrupt an existing pregnancy therefore cannot cause abortion. They should not be used to try to cause an abortion.

Myth: Do hormonal contraceptives cause birth defects?

Fact: Hormonal contraception will not cause birth defects. The fetus will not be harmed if the client becomes pregnant while using hormonal methods of contraception.

Myth: The injectable and implants make a woman infertile

Fact: There may be a delay in regaining fertility after stopping the injectable, but in time, the client is able to become pregnant as before. Delay can be up to 12 months.

Myth: Can stop monthly bleeding and accumulation of blood inside the woman.

Fact: The progesterone only contraceptives may cause amenorrhea but this is not harmful. It is due to thinning of endometrial lining hence no accumulation of blood in the body.

Myth: Implants may move to other parts of the body.

Fact: implants do not move around the body. They remain where they are inserted until they are removed. Rarely, a rod may start to come out and is due to poor technique of insertion or infection.

Myth: Hormonal contraceptives reduce sexual drive (libido)

Fact: A few women using hormonal contraception have reported reduced libido. It is hard to pinpoint hormonal contraceptives as the only cause. Many other things affect a woman's sex drive, including her health, age, feelings about her relationship, use of alcohol and whether she's under a lot of stress.

CHAPTER SIX:

6

INTRAUTERINE CONTRACEPTIVE DEVICES (IUCD)

Intra uterine device is a small flexible plastic device that is inserted into the uterine cavity to prevent pregnancy. It provides long term protection against pregnancy.

Key Messages

- *Long-term pregnancy protection. Very effective for up to 12 years for copper based and up to 5 years for levonorgestrel based devices.*
- *Immediately reversible.*
- *Bleeding changes are common but not harmful*
- *Copper based IUCD can be used as a form of emergency contraception.*

TYPES OF IUCD

- Copper based devices
- 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 sperms 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 fertilized eggs were found in IUCD users[17]. This is an indication that prevention of fertilization is highly effective in women using copper IUCDs than other possible mechanisms, such as prevention of implantation.

In Kenya, the most widely used copper-bearing IUCD is Copper T380A.

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 (LNG), during a period of five years. Mirena®, the LNG-20 IUS, is the most widely used hormone-releasing intrauterine system in use in Kenya. Lingus® is generic version of Mirena that is available in the Kenya market.

Mode of action

- Prevent fertilization by interfering with sperms mobility
- Copper IUCD – Copper ions decrease sperm motility and function by altering the uterine and tubal fluid environment

- Hormonal IUCD – the progesterone released thickens cervical mucus, suppress ovulation in some cycles and thins the endometrial lining

Brands available

- Copper T: it is made of the plastic with copper sleeves. Example CuT-380A
- Hormone releasing IUCD: contains Levonorgestrel which is released during a period of five years. Examples are Mirena®, Lingus® and Liletta®.

Effectiveness

- IUCD is 99% effective if used correctly and consistently.
- Copper IUCD: Less than 1 pregnancy per 100 women using an IUD over the first year (6 to 8 per 1,000 women).
- Hormone releasing IUCD: Less than 1 pregnancy per 100 women using an LNG-IUD over the first year (2 per 1,000 women).

The table below lists the various types of IUCDs and their duration of effectiveness.

Table 6.1 **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® (LNG-IUS)**	5 years
• **Liletta® (LNG-IUS)**	3 years

Advantages of IUCDs

Contraceptive Benefits

- High effectiveness and safety
- Provides immediate protection after insertion
- Long-acting protection (copper based - 12 years, hormone releasing - 5 years)
- Does not require client action for efficacy
- Can be used immediately after delivery (copper based)
- Client has no further cost following insertion
- Immediate return to fertility upon removal of device
- Copper IUCD is effective as an emergency contraceptive if inserted within 5 days of unprotected sexual intercourse.
- Do not interfere with breastfeeding hence can be used by women who are breastfeeding

Non-contraceptive benefits

- IUCDs do not interfere with intercourse.
- IUCDs help prevent ectopic pregnancies.
- IUCDs, including the Cu-IUCDS, might help protect from endometrial cancer.
- LNG-IUS minimizes bleeding and is suitable for women with menorrhagia, it has been found to be beneficial in women who experience cramps
- LNG-IUS provides benefits in the reduction of symptoms of endometriosis

Limitations and side effects

Limitations

- Do not offer protection against STI/HIV transmission.
- Require a trained service provider for insertion and removal
- Appropriate infection prevention practices must be observed during insertion and removal
- May be expelled or translocated if not properly inserted
- Perforation of the uterus may occur, but is rare

Side effects

- Cu-IUCDs might increase menstrual bleeding and cause cramping, more commonly during the first few months of use (LNG-IUS does not increase menstrual bleeding and is associated with less cramping).
- LNG-IUS has similar side effects to progestin only contraceptives.

Eligibility criteria

Who can use (MEC Category 1) – No Restrictions

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

The table below lists conditions for which there is no restriction to provision of IUCD.

Table 6.2 **MEC category 1 conditions for IUCD**

Conditions that apply to both Cu- IUCD and LNG-IUS	Conditions that apply to Cu-IUCD only	Conditions that apply to LNG-IUS only
• **Women who want long-term, highly effective protection against pregnancy** • **Breastfeeding or non-breastfeeding, four weeks postpartum** • **After first trimester abortion or ectopic pregnancy** • **Smoking at any age** • **Blood pressure between 140/90 to 159/99** • **Family history of DVT or PE** • **Major surgery without prolonged immobilization** • **Superficial venous disorders including**	• Breastfeeding or non-breastfeeding women if insertion occurs less than 48 hours from delivery of placenta • Blood pressure of 160/100 or higher • History or acute DVT/PE, IHD or stroke, including those on anticoagulant therapy • Major surgery with prolonged immobilization • SLE without severe thrombocytopenia • Positive or unknown antiphospholipid antibodies (initiation and continuation)	• Non-breastfeeding women if insertion occurs less than 48 hours from delivery of placenta • Heavy or prolonged menstrual bleeding (regular or irregular patterns): initiation only (see continuation under Category 2) • Endometriosis or sever dysmenorrhea (LNG-20 IUS may have beneficial effect) • Anemias, such as iron deficiency anemia, sickle cell disease, thalassaemia (LNG-

Conditions that apply to both Cu- IUCD and LNG-IUS	Conditions that apply to Cu-IUCD only	Conditions that apply to LNG-IUS only
varicose veins and veinous thrombosis • **Uncomplicated valvular heart disease** • **Non-migrainous headaches** • **Irregular menstrual bleeding patterns without heavy bleeding** • **Benign ovarian tumors or benign breast disease** • **Family history of breast cancer** • **Non-pelvic TB** • **Viral hepatitis (acute or flare, carrier or chronic) or mild (compensated) cirrhosis of the liver** • **Anticonvulsants and antimicrobials including TB therapy** • **Thyroid disorders** • **Cervical ectropion (erosion) or uterine fibroids without distortion of uterine cavity** • **History of PID in women who have subsequently conceived** • **Obesity (BMI greater than 30 kg/m2)**	• Known dyslipidaemias without other known cardiovascular risk factors • Immunosuppressive treatment (continuation only) • Severe(decompensated) cirrhosis of the liver • Any type of liver tumors (benight or malignant) • Multiple risk factors for CVD • Hypertension of 160/100 or higher, including with vascular complications • Uncomplicated or complicated diabetes • Migraines with or without aura at any age • Gall bladder disease • Undiagnosed breast tumour or breast cancer	20 IUS users are more likely to experience light bleeding or even amenorrhea , which is beneficial for women with anemia 38

MEC Category 2 – Use with Caution

Women who have any of the conditions listed in Table 6.3 below, should proceed with caution if they choose to use the

IUCD. Careful counselling is required, and follow up may be necessary. The next table highlights the conditions which fall under category 2 of Medical Eligibility.

Table 6.3 **Category 2 conditions for IUCD**

Condition	Cu-IUCD	LNG-IUS
Menarche, younger than 18 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 behavior in younger age groups. Ensure follow up	Proceed as for Cu-IUCD.
For LNG-IUS only: less than 48 hours Postpartum if breastfeeding	No action (Category 1 if Cu-IUCD)	Proceed as for Cu-IUCD (if not breastfeeding).
Following second-trimester abortion (where there is no sepsis)	Generally, follow-up is needed because of higher chance of expulsion compared with after first-trimester abortion.	Proceed as for Cu-IUCD.
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 ¾ 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
STIs including current purulent cervicitis or	A current IUD user who becomes infected with	Proceed as for Cu-IUCD

Condition	Cu-IUCD	LNG-IUS
chlamydial infection or gonorrhea; other STIs (excluding HIV and hepatitis); vaginitis	gonorrhea or chlamydia or develops PID can safely continue using an IUCD during and after treatment	
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, e.g. 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)
Women with endometriosis or severe dysmenorrhea	Use of Cu-IUCD could intensify dysmenorrhea including that associated with endometriosis. Generally, provide method and follow-up carefully. Provide analgesics if necessary.	No restrictions (see Category 1 above)
Anemias: iron deficiency anemia, sickle cell disease, thalassemia	There is concern about an increased risk of blood loss with Cu-IUCD. Generally, provide method and follow up carefully. Advise on use of hematinics	No restrictions (see Category 1 above)
Women with valvular heart disease (complicated by pulmonary hypertension,	Generally, provide method, but give prophylactic antibiotics to prevent endocarditis during insertion. Needs careful	Proceed as for Cu-IUCD.

Condition	Cu-IUCD	LNG-IUS
risk of atrial fibrillation and those with history of SBE)	counselling follow-up and referral.	
Women with 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, follow up might be warranted. Women who develop severe thrombocytopenia while using IUCD can generally continue, but cannot initiate use.	Generally, can initiate and continue use of LNG-IUS regardless of the presence of 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).	Generally initiate, but follow-up might be warranted. Discontinue if migraines become worse while using LNG-IUS (see category 3).

Category 3 and 4 – Women Who Should Not use IUCD (Cu-IUCD and LNG-IUS)

Table 6.4 lists conditions where risk outweighs benefits.

Table 6.4 **Category 3 and 4 conditions for IUCD**

Conditions that apply to both Cu-IUCD and LNG-IUS	Conditions that apply to LNG-IUS only
• **Postpartum women after 48 hours and before the end of 4 weeks.**	• Women with acute DVT or PE[2]
• **Women with puerperal sepsis or immediately post-septic abortion**	• Women with severe (decompensated) cirrhosis or liver tumors (hepatocellular adenoma or hepatoma).
• **Women living with HIV who have AIDS are category 3 for initiating method[1]**	• Women with SLE with positive or unknown antiphospholipid antibodies.
• **Women with unexplained vaginal bleeding before evaluation. Method should not be initiated before evaluation (category 4)[1], but a woman who already is using IUCD can continue with it pending findings of the evaluation (category 2).**	• Women with migraine headaches with aura that worsened while using LNG-IUS (continuation only)
• **Women with gestational trophoblastic disease: with decreasing or undetectable ß-hCG levels (Category 3) or persistently elevated ß-hCG levels or malignant disease (Category 4)**	• Women with current diagnosis or a history of IHD (continuation only)
• **Women with fibroids distorting the uterine cavity.**	• Current breast cancer (copper IUCD can be used)
• **Women with anatomical abnormalities of the uterus and cervix that interfere with insertion and retention of IUCD, including uterus size less than 6cm**	

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

METHOD PRESCRIPTION AND USE

When to Start

The IUCD insertion is categorized as postpartum, post-abotal, and interval.

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.

Postpartum insertion

Both Cu-IUCDS and LNG-IUS can be inserted;

- 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.

NOTE: Post pregnancy IUCD is contraindicated in situations that increase the risk of infections. These situations include:

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

Post abortion

Following first or second trimester abortion

- Insert the IUCD immediately or within 12 days where there are no complications. 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).

1. Danger signs and symptoms following PP IUCD insertion
2. Perforation
3. Pain,
4. Vaginal bleeding
5. Hypovolemic shock
6. Sepsis
7. Foul smelling discharge
8. Fever
9. Rigors
10. Endotoxic shock

Switching FP methods

Instructions for switching between IUCD and other methods of FP are given in **table 6.5**.

Table 6.5 **Switching between IUCD and other FP methods**

Switching from	When to start
Other FP method to IUCD	• Insert immediately if pregnancy is ruled out. No need to wait for the next menstrual period.
IUCD to Hormonal method	• If within 7 days from the start of menstrual bleeding (5 days for COCs and POPs), start the hormonal method and remove the IUD. No need for back up method. • If more than 7 days from the start of menstrual bleeding (5 days for COCs and POPs) and the client has been sexually active since her last menstrual cycle, start the hormonal method but do not remove the IUD until the start of the next menstrual cycle. • If more than 7 days from the start of menstrual bleeding (5 days for COCs and POPs) and the client has not been sexually active since her last menstrual cycle, start the hormonal method and the IUD may remain in place until the next menstrual cycle or it may be removed at the same time provided the client use a backup contraceptive for the next 7 days (2 days for POPs).
IUCD to non-hormonal method (e.g. condoms, Fertility awareness methods)	• Immediately the next time the client is sexually active after the removal of the IUD.
IUCD to BTL	• If within 7 days from the start of menstrual bleeding, remove the IUD and perform the BTL procedure. No need for a backup method. • If more than 7 days from the start of menstrual bleeding, perform the BTL procedure; the IUD may remain in place until the client's follow-up visit or next menstrual cycle. If a follow-up visit is not possible, the IUD may be removed at the time of BTL. No need for a backup method.
IUCD to vasectomy	• Any time. The client should continue to use the IUD for 3 months after her partner's vasectomy for contraception until the vasectomy is fully effective.

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.

Reasons for client to return to facility following IUCD insertion

Counsel the client to return to health facility if she:

- Has symptoms of PID which include fever, chills, nausea/vomiting, increasing or severe lower abdominal pain, pain during sex, unusual vaginal discharge especially in the first 20 days of insertion
- Missed periods
- Expelled IUCD

MANAGEMENT OF COMMON PROBLEMS ASSOCIATED WITH IUCD USE

The table below shows the common side effects and problems with IUCD use and their management.

Table 6.6 **Side Effects and Problems Associated with IUCD and Their Management**

Side effect	Management
Abnormal bleeding patterns (spotting, intermenstrual bleeding, prolonged or heavy bleeding)	• Reassure her that this problem usually decreases over time. • If she requires treatment give a short course of Non-Steroidal Anti Inflammatory drugs e.g. Ibuprofen • If persistent spotting or heavy or prolonged bleeding, exclude gynecological problem. - If a gynecological problem is identified, treat the condition or refer for care. - If no gynecological problems are found, and she finds the bleeding unacceptable, especially if there are clinical signs of anemia, remove the IUCD and help her choose another method.
Abdominal cramping and pain	• Inform client that some abdominal cramping may occur in the first 24-48 hours

Side effect	Management
	• If cramping continues give analgesics • If pain and cramping is severe evaluate for underlying conditions including signs of partial IUCD expulsion, PID or ectopic pregnancy and treat accordingly. • If pain and cramping persists and no cause is found, remove IUCD, counsel client to select another method.
Partner complains about pricking during coitus	• This may happen when the threads are cut too short or the IUCD is partially expelled - Examine and insert another IUCD
Partial or complete expulsion	• Conduct appropriate assessment including pelvic examination to rule out other conditions e.g. infection or pregnancy • If complete expulsion is confirmed (seen by woman, confirmed by X-ray or ultra sound) insert IUCD if pregnancy is ruled out or give any other FP method of choice • If partial expulsion is confirmed, remove IUCD and insert another IUCD if desired and appropriate or counsel client for any other FP method of choice • If IUCD is embedded in cervical canal and cannot be easily removed by standard technique refer appropriately
Woman develops PID	• Treat with appropriate antibiotics. • There is no need for removal of IUCD if she wishes to continue its use • If symptoms do not improve after a few days of antibiotics, IUD removal may be considered and antibiotic treatment continued. • In all cases woman should be closely monitored until PID is fully resolved
Pregnancy with IUCD	• Exclude ectopic pregnancy (ultrasound scan where available; otherwise careful clinical monitoring). • If woman wants IUCD to be removed and the IUCD strings are visible or can be retrieved safely from the cervical canal (in the first 3 months) - Remove IUCD by pulling on the strings gently.

Side effect	Management
	- Explain that she should return promptly if she experiences heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever. • If the IUCD strings are not visible, determine if IUCD is still in the uterus by Ultra sound. - If the IUCD is not located, this may suggest that an expulsion of the IUCD has occurred. - If the IUCD is located inside the uterus, she can continue with the pregnancy and seek care promptly if she experiences heavy bleeding, cramping, pain, abnormal vaginal discharge, fever.

Management of common problems associated with PP IUCD

The table below shows the problems that may be encountered during post partum IUCD insertion and how to manage them.

Table 6.7 **Management of problems at the time of insertion of PPIUCD**

Problem	Management
Client discomfort or pain	• Reassure client and continue communicating during procedure • Perform procedure as gently and quickly as possible
Displacement of IUCD	• Using sterile forceps, remove IUCD and reinsert. If contaminated, discard and use a new IUCD
Cervical lacerations	• If lacerations are seen repair depending on size and amount of bleeding
Uterine perforation	• If suspected during insertion, stop procedure immediately and remove IUCD and instruments • Keep client at rest, start IV drip, monitor vital signs and abdominal tenderness, guarding or rigidity • In case of severe abdominal pain, any change in vital signs or peritoneal signs appear refer for emergency surgical intervention accordingly • Prophylactic antibiotics should be given

OBTAINING THIS METHOD

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

All health facilities with trained clinicians can provide IUCDs including during outreaches.

CORRECTING MYTHS ABOUT IUCD

Myth: IUCD causes abortion

Fact: IUCD works by prevents the sperm from meeting the egg hence. It does 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.

Myth: IUCD is not safe for those who have never given birth

Fact: IUCDs are very safe, including for adolescents and youth

Myth: IUCD causes PID

Fact: IUCD does not cause PID in low-risk couples. Risk of infection is very low when the IUCD is inserted using the "non-touch" technique in women who have no cervical infection. But if the client already has gonorrhea 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 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.

Myth: IUCD causes cancer

Fact: IUCD does not cause cancer. In fact, research has shown that the IUCD may protect against some cancers, such as endometrial cancer.

Myth: IUCD may travel from the uterus to other parts of the body such as the heart or brain

Fact: The IUCD does not travel to any part of the body outside the uterus. It normally stays within the uterus like a seed within a shell until the time of removal. It may be expelled through the vagina partially or completely especially if it was not well inserted.

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

CHAPTER SEVEN:

7

VOLUNTARY SURGICAL CONTRACEPTION

Voluntary Surgical Contraception (VSC) includes surgical procedures that are intended to provide permanent contraception. These include: Bilateral Tubal Ligation (female) and vasectomy (male). As such, special care must be taken to ensure 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 illness including depressive disorders.

Key Messages

- *Permanent & irreversible method-very effective protection against pregnancy.*
- *Has no effect on sex drive.*
- *After vasectomy, the couple must use a backup method for at least 3 months.*

RECOMMENDATIONS FOR MEC FOR VSC METHODS

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

WHO MEC FOR VSC

The following table shows categories used for recommending VSC.

Table 7.1 **WHO MEC categories for VSC**

Category	Explanation
Accept (Category A)	There is no medical reason to deny VSC 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/or corrected. 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 anesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate procedure and anesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.

NOTE:

- No incentives should be given to clients, to accept any form of contraception or to providers to recruit clients and perform the surgical procedure. Alternative FP methods should be easily accessible to client.
- The client is free to change his or her mind any time prior to the procedure. Multiple caesarean sections and grand multiparity are not absolute indications for BTL.
- 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 4**).
- Health care providers should ensure counselling is provided both before and after the procedure.

FEMALE VOLUNTARY SURGICAL CONTRACEPTION

Female voluntary surgical contraception is also referred to as Bilateral Tubal Ligation (BTL). It is a minor surgical operation that involves cutting and tying the fallopian tubes in order to prevent the sperm from fertilizing the ovum that was released from the ovary, and reaching the uterine cavity. In Kenya, only 3.2% users of modern methods of contraception rely on BTL[2]. It is a highly effective method of contraception, with a pregnancy rate of less than 1% of women in the first year after surgery. BTL can be performed on a conscious client using local anesthesia, and it is generally a safe procedure when performed by a trained service provider. Few women experience side effects or complications. Overall rates of complications are in the range of 0.4 to 2.0 %.

BTL is a permanent contraception method for women not wanting any more children. 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 from the parent or guardian (see **Appendix 4**).

EFFECTIVENESS

BTL is 99.9% effective in preventing pregnancy (Less than 1 pregnancy per 100 women over the first year after having the sterilization procedure).

WAYS OF PERFORMING BTL

There are several ways to perform TL;

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

ADVANTAGES OF BTL

Contraceptive Benefits

- Highly effective and safe
- Efficacy does not depend on the client's action.
- It is permanent.
- Has no effect on breast-feeding
- TL does not affect a woman's sexual desire, ability and performance
- It is cost effective after the initial procedure
- No significant long term side effects.

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 BTL

Limitations include the following:

- Does not protect against STIs and HIV.
- Generally irreversible—the success of reversal surgery cannot be guaranteed
- Procedure needs specially equipped facilities and trained personnel.
- Failure of procedure pre-disposes to ectopic pregnancy.
- Subjects client to pain and leaves permanent scar.
- The client needs to sign a consent
- Only adequately trained service providers can offer the method
- There may be side effects associated with the surgical procedure

Side effects include:

- Minimal risks and side effects of anesthesia
- Risks associated with surgical procedures
- Post procedural pain may be experienced.

- In rare cases when pregnancy occurs, it is more likely to be ectopic (although overall, BTL greatly reduces the risk for ectopic pregnancy compared to women who use no contraception).

ELIGIBILITY CRITERIA FOR BTL

Women Who Can Use BTL (MEC Category A: There is no medical reason to deny sterilization to a person with this condition)

- Women of any parity
- Breastfeeding
- Postpartum less than 7 days and after 42 days
- Mild preeclampsia and previous history of pre eclampsia
- Post abortion without sepsis or complications like uterine perforation
- Past ectopic pregnancy
- Smoking
- History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)
- History of DVT/PE or family history of DVT/PE
- Major surgery without prolonged immobilization and Minor surgery without immobilization
- Superficial venous thrombosis (Varicose veins) and superficial thrombophlebitis
- Migraine and non-migraine headaches
- Vaginal bleeding patterns; irregular or heavy or prolonged
- Benign ovarian tumors
- Severe dysmenorrhea
- Gestational trophoblastic disease with decreasing levels of beta HCG
- Cervical intraepithelial neoplasia (CIN)
- Breast disease
  - Undiagnosed breast mass
  - Benign breast disease
  - Past breast cancer and no evidence of current disease for 5 years
  - Family history of breast cancer

- Previous PID with subsequent pregnancy
- Vaginitis (e.g. trichomoniasis, bacterial vaginitis)
- Increased risk of STIs
- HIV
  - High risk of HIV
  - Asymptomatic or mild HIV clinical disease (WHO stage 1 or 2)
- Uncomplicated schistosomiasis (without liver cirrhosis)
- Malaria
- Non-pelvic TB
- Simple goiter
- Symptomatic gall bladder disease treated by cholecystectomy or medically treated
- Mild liver cirrhosis (compensated)
- Benign focal nodular hyperplasia of the liver
- Sterilization concurrent with caesarean section

Table 7.2 **Conditions that require Caution, Delay or Special requirements for BTL**

(C) CAUTION	(D) DELAY	(S) SPECIAL
Procedure can be conducted in a routine setting, but with extra preparation and precautions.	**Delay procedure until condition is evaluated and corrected. Provide alternative temporary contraception.**	**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** • **Hypothyroidism** • **Mild cirrhosis** • **Liver tumors (benign and malignant)** • **Anemias** • **Previous abdominal or pelvic surgery, diaphragmatic hernia** • **Kidney disease** • **SLE without complications** • **Severe nutritional deficiencies** • **Previous history of PID without subsequent pregnancy**	• 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: • Prolonged rupture of membranes • Puerperal sepsis or post-abortal sepsis or pyrexia • Severe APH, PPH or post-abortal hemorrhage • Severe trauma to genital tract, including uterine perforation. • Severe pre-eclampsia or eclampsia • Peritonitis • Delay interval procedure to ensure careful evaluation and	• 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 • Complicated valvular heart disease • Diabetes with vascular complications • Hyperthyroidism • Endometriosis • Severe cirrhosis • Coagulation disorders • DVT/PE if established on anticoagulant therapy • SLE with positive (or unknown) antiphospholipid antibodies, severe thrombocytopenia, and those on immunosuppressive treatment

(C) CAUTION	(D) DELAY	(S) SPECIAL
Procedure can be conducted in a routine setting, but with extra preparation and precautions.	**Delay procedure until condition is evaluated and corrected. Provide alternative temporary contraception.**	**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.**
	treatment in women with the following conditions (and arrange follow-up): • Current DVT or major surgery with prolonged immobilization or PE • Current ischaemic heart disease • Unexplained vaginal bleeding before diagnosis • Procedure should be delayed to ensure investigations and definitive management are undertaken. • 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 anemia (Hb <7gm) • Sickle cell disease • Local infection (abdominal skin) • Acute respiratory disease • Systemic infection or gastroenteritis	• Chronic respiratory disease • AIDS (Note: The presence of an acute AIDS-related illness could require delay of the procedure). • Reported allergy to local anesthetics

Women Who Should Not Use BTL

Providers should not perform BTL on certain women:

- Young women and women with no children - who are uncertain of their desire for future fertility.
- Women or girls who do not give voluntary informed consent; in situations where the client is mentally challenged, consent may be given by parent or guardian.

METHOD USE

Timing of BTL

- Immediately postpartum (within 7 days)
- Interval
- Post abortion
- Intra operative abdominal surgeries, e.g. caesarian section, ectopic pregnancy

Switching from other FP methods

- Switching from a hormonal method
  - If she is switching from oral contraceptives, she can have the BTL immediately and then continue taking the pills until she has finished the pill pack to maintain her regular cycle
  - If she has been on injectable she can have the BTL any time before the return date for the next injection
- Switching from an IUCD
  - If during the first 7 days of monthly bleeding, remove the IUCD and perform the BTL procedure. No need for a backup method.
  - If after the first 7 days of monthly bleeding, perform the BTL procedure. The IUD can be kept in place until her next monthly bleeding before removal

MANAGEMENT OF COMMON COMPLICATIONS

Complications may occur during the procedure or after.

Table 7.3 highlights these complications and how they should be managed.

Table 7.3 **Management of common complications**

Complication	Management
Wound infection	• Treat with antibiotics • If abscess is present, drain and continue with antibiotics
Anxiety	• Counsel and follow up client
Haematoma	• This usually will resolve overtime but may require drainage if extensive.
Pain at incision site	• Assess for infection and manage accordingly
More serious injuries e.g., bladder or bowel injury	• Give appropriate management or refer for competent care in a hospital.

Obtaining This Method

BTL can be performed in all health facilities including the community during outreaches and mobile facilities as long as they meet the following criteria:

- Have a minor theatre
- Have appropriate equipment
- Have the ability to observe infection-prevention measures
- Have 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 managed

Tubal ligations can be performed by doctors or RCOs with post-basic training in RH.

One surgeon should perform not more than 15 procedures in a day, and not more than 30 procedures should be performed in one operating room per day.

MALE VOLUNTARY SURGICAL CONTRACEPTION (VASECTOMY)

Vasectomy is the surgical process of cutting and tying the vas deferens in order to prevent spermatozoa from mixing with seminal fluid. Consequently, when ejaculation occurs, the seminal fluid will not have any sperm. The operation is performed under local anesthesia. According to KDHS 2014 less than 1% of men had vasectomy[2].

TYPES OF VASECTOMY

There are scalpel and non-scalpel vasectomy techniques

MODE OF ACTION

- It prevents sperm movement from the testes to the seminal vesicle and urethra thus preventing fertilization.

EFFECTIVENESS

Vasectomy is 99.8% effective.

ADVANTAGES

- Highly effective and safe
- It is considered permanent providing a lifelong protection.
- Does not interfere with the act of sexual intercourse.
- It is not associated with long-term health risks.
- Less expensive; easy to perform
- Has fewer side effects and complications than many methods for women
- The man takes responsibility for contraception

LIMITATIONS AND RISKS

The procedure is virtually irreversible (i.e., success of reversal surgery cannot be guaranteed).
Only a trained and skilled health provider can offer vasectomy.

- There is a delay in effectiveness after the procedure has been performed (3 months) hence the need for a backup method
- Does not protect against STIs and HIV.
- There are minimal risks and side effects of local anesthesia and surgical procedure.

ELIGIBILITY CRITERIA FOR VASECTOMY

Accept (A): There is no medical reason to deny vasectomy to a person with this condition

Vasectomy is 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 at high risk of HIV and those with asymptomatic or mild HIV clinical disease (WHO stage 1 or 2)
- Sickle-cell disease

Classification of Medical Conditions According to Precautionary Measures Needed for vasectomy

Table 7.4 **Conditions that require caution, delay, or special requirements for vasectomies**

(C) CAUTION	(D) DELAY	(S) SPECIAL
Procedure can be conducted in a routine setting, but with extra preparation and precautions	**Delay procedure until condition is evaluated and corrected if necessary. Provide alternative temporary contraception**	**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**
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	Local skin infection: treat prior to procedure	Coagulation disorders present increased risk of bleeding and postoperative hematoma: might need additional medical support

(C) CAUTION	(D) DELAY	(S) SPECIAL
Procedure can be conducted in a routine setting, but with extra preparation and precautions	**Delay procedure until condition is evaluated and corrected if necessary. Provide alternative temporary contraception**	**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**
Depressive disorders (include job aid to rule out DD)	Any local infection, including active STI, balanitis, epididymitis, or orchitis: treat prior to procedure	Severe or advanced HIV clinical disease (WHO stage 3 or 4) might require special care depending on the man's health status.
Diabetics could have increased risk of post-operative wound infection. Follow-up and treat with antibiotics in any signs of infection are present.	Systemic infection or gastroenteritis: treat prior to procedure	Previous scrotal injury, large varicocele, large hydrocele: might require an extensive surgery to locate the vas
Previous scrotal injury	Filariasis, elephantiasis: if condition involves the scrotum, it may be difficult to palpate the spermatic cord. Delay until treated and corrected.	Cryptoorchidism (undescended testicle): might require an extensive surgery to locate the vas
Large varicocele and Large hydrocele (might have difficulty palpating the spermatic cord.		Inguinal hernia: vasectomy can be performed at the time of hernia repair. Intra-scrotal mass: might be difficult to palpate the spermatic cord. Rule out underlying disease; delay procedure until treated and corrected.

Men Who Should Not Have Vasectomy

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

- Clients who are uncertain of their desire for future fertility
- Clients who cannot withstand surgery e.g bleeding disorders

CLIENTS WHO DO NOT OR CANNOT GIVE VOLUNTARY INFORMED CONSENT

Method use

When to start

Vasectomy can be offered anytime. It is considered effective 3 months after the procedure as the seminal fluid may continue to contain sperm for some time. A backup method must be used to ensure efficacy of method.

Management of Common complications

Complications may occur after vasectomy. **Table 7.5** lists some of the potential complications and their management.

Table 7.5 **Complications of vasectomy and their management**

Side effect	Management
Bleeding at the incision site or inside the incision	• Confirm cause then control
Pain and swelling	• Determine presence of haematoma, infection or abscess, then - If there is infection treat with antibiotics and analgesics - If there is haematoma or abscess, drain and continue antibiotics
Chronic pain after vasectomy	• Recommend taking an anti-inflammatory medication such as ibuprofen

Side effect	Management
	• Wearing a supporter and sitting in a warm tub to increase blood flow is enough to treat the problem. Eventually the pain goes away
Failed vasectomy	• Serial semen analysis
Regret	• Counselling and referral

Obtaining This Method

Vasectomy should be provided by trained health providers only.

Vasectomy can be performed at any health facility with a minor operating theatre, the appropriate equipment, the ability to observe infection-prevention measures, and the drugs and equipment to handle emergencies, including an efficient and effective referral system.

Vasectomy can also be performed during outreach and through mobile facilities as long as the above conditions are met. Outreach services must be linked to health facilities where complications can be properly managed.

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.

Correcting myths about VSC

- Vasectomy is not synonymous with castration, and it does not affect a man's sexual desire, ability or performance.
- Vasectomy does not become effective immediately until after 3 months. The client should be instructed to use condoms or another FP method for three months after the operation.
- Reversal surgery for both BTL and vasectomy 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.
- BTL has no effect on monthly period and does not cause bleeding.
- BTL has no effect on sexual desire.
- VSC does not make you gain weight

CHAPTER EIGHT:

BARRIER METHODS OF CONTRACEPTION

Barrier methods prevent the sperm from gaining access to the upper reproductive tract and making contact with the ova. These methods include male and female condoms. Whereas condoms, diaphragms, and cervical caps are mechanical barriers, spermicides are chemicals that interfere with the movement of the sperm and its ability to fertilize the ova. 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 STIs including HIV. As a result, the main focus in this edition of the *FP Guidelines* is on male and female condoms.

Key Messages

- *Condom use-requires correct and consistent use with every act of sexual intercourse for effectiveness.*
- *Condoms should not be used with petroleum products and oils, which lead to rapid degeneration and could reduce their effectiveness.*
- *Condoms are used for dual purposes (For prevention of pregnancy and STIs*

MODE OF ACTION OF CONDOMS

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 and prevents any disease organisms in the vagina from entering the penis.

MALE CONDOM

The male condom is a thin, latex rubber sheath made to fit a man's erect penis. Some are coated with a lubricant or spermicide. Condoms come in different sizes, colors, and textures. Condom types in the market include plain, flavored, colored, and spermicide-added condoms.

EFFECTIVENESS

For contraception, male condoms are only moderately effective in typical use (85%), but much more effective when used consistently and correctly (98%).

ADVANTAGES OF CONDOMS

- Easily accessible and affordable
- Offer contraception only if used appropriately
- With consistent and proper use, they are highly effective for prevention against STIs, including HIV/AIDS.
- Reduce the risk of cervical cancer.
- May help to 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

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

NOTE:

ELIGIBILITY CRITERIA

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

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

Allergy to latex male condoms

METHOD USE AND DISPOSAL

When to Start

Any time client is ready to use

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.

MANAGEMENT OF POSSIBLE SIDE EFFECTS

In **table 8.1** are some side effects of using condoms and how to manage them.

Table 8.1 **Management of possible side effects of using condoms**

Side effect	Management
Irritation	May result from allergy to latex though this is very rare • Advice the couple to use a non-latex brand of condoms • Screen for presence of infection and treat, if present
Spillage or breakage of condom	Offer emergency contraception and counsel on HIV and STIs.

FEMALE CONDOM

The female condom is a sheath made of thin transparent, polyurethane pre-lubricated with a silicone-based substance (dimethicone). It has a flexible ring at the ends; the ring at the closed end helps to insert the condom and the ring at the open end holds the condom outside the vagina.

EFFECTIVENESS

The effectiveness of the female condom is slightly less than the male condom. The failure rate is about 5 % in perfect use, and 21% in typical use.

ADVANTAGES AND BENEFITS

- Almost every woman is eligible to use this method.
- They are effective if used consistently and correctly.
- They offer contraception only when needed.
- Condoms can be used without seeing a health care provider.
- With consistent and proper use, condoms are highly effective for prevention against STIs, including HIV/AIDS.
- They protect against PID.
- The woman can control 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

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

ELIGIBILITY CRITERIA

Women Who Can Use the Female Condom

- All women of reproductive age of any parity, including nulliparous women
- 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

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-dependent, methods of contraception.

METHOD USE AND DISPOSAL

When to Start

- Any time client is ready to use

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.

Note: Demonstration of condom Use by the provider is critical for consistent and proper use.

CORRECTING MYTHS AND MISCONCEPTIONS ABOUT BARRIER METHODS

- Condoms often break or slip off during sex
- On average, about 2% of condoms break or slip off completely during sex, primarily because they are used incorrectly. When properly use, condoms rarely break or slip off.
- The female condom makes a lot of noise during sex
- The female health companies acknowledges this concern and states that their new and improved female condom does not make much noise during sex.
- The female condom is difficult to use

- It requires some practice before one can use it with ease. It is recommended to try inserting it several times before utilizing it in a sexual situation.
- The inner ring causes pain to both male and female
- It should not cause any discomfort if inserted properly.
- Usage of both male and female condoms at the same time or wearing 2 male condoms for effectiveness
- Using both condoms simultaneously may cause friction due to inadequate lubrication resulting in either or both condoms slipping or tearing. Or the outer ring of the female condom being pushed further inside the vagina.

CHAPTER NINE:

9

LACTATIONAL AMENORRHOEA METHOD (LAM)

The Lactational Amenorrhea Method (LAM), a sub-set of Natural Family Planning (NFP), is a temporary, postpartum method of FP based on the natural effect of breastfeeding on fertility. 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 2 per 100 women in the first 6 months. With perfect use, the pregnancy rate is less than 1 per 100 women (see **Appendix 1**).

Key Messages

- *Exclusively breastfeeding means the baby receives no other liquid or food, not even water in addition to breast milk.*

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 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.

MODE OF ACTION

Prolactin released during continuous breastfeeding suppress ovulation which makes pregnancy unlikely.

EFFECTIVENESS

LAM is up to 98% effective, if practiced during exclusive breastfeeding period. Effectiveness is reduced in the absence of exclusive breastfeeding.

ADVANTAGES AND BENEFITS OF LAM

Contraceptive benefits

- Effective protection against pregnancy as long as all the three LAM criteria are met.

- Return to fertility is immediate once you stop exclusive breastfeeding.

Non contraceptive benefits

- Breastfeeding provides passive immunity for the child.
- Counselling for LAM encourages women to start a follow-on method at the appropriate time.
- LAM does not interfere with sexual activity.
- It has no known health risks.
- LAM is affordable FP—it has no direct costs.
- Women living with HIV/AIDS can use LAM.

Key Messages

- *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

- The method is effective only as long as all three LAM criteria are met.
- Breastfeeding can transmit HIV from a mother to her baby.
- A woman may not breastfeed because she is taking certain drugs (e.g., mood altering drugs, reserpine, ergotamine, antimetabolites, cyclosporine, cortisone, bromocriptine, radioactive drugs, lithium, or certain anticoagulants).
- Exclusive breastfeeding may be inconvenient or difficult for some women, especially working mothers.
- LAM does not protect a woman against STIs, including hepatitis B, HIV, and AIDS.
- Fertility may resume before resumption of menses.

ELIGIBILITY CRITERIA

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 Who Should Not Rely on LAM

- Those who are not exclusively breastfeeding
- Those who have resumed menses
- The baby is more than six months of age
- may not be appropriate for Women with conditions that make pregnancy an unacceptable risk because of its relatively higher typical-use failure rates.
- The newborn has a condition that makes it difficult to breastfeed (e.g. prematurity, deformities of the mouth, jaw, or palate)

METHOD USE

When to start

- Start breastfeeding immediately (within one hour) or as soon as possible after delivery of the baby.

Helping clients Switch to a continuing Method

- A woman can switch to another method any time she wants while using LAM.
- It is reasonably certain a woman is not pregnant If she still meets all 3 LAM criteria,. She can start a new method with no need for a pregnancy test.
- To continue preventing pregnancy, a woman must switch to another method as soon as any one of the 3 LAM criteria no longer applies. Managing any limitation LAM cIf the client reports any challenges, listen to her concerns, give her advice, and treat appropriately.
- If the challenges cannot be overcome or the client wishes to switch to another method, help her to make an informed choice.

CHAPTER TEN:

10

FERTILITY AWARENESS-BASED METHODS (FAMS)

Fertility awareness-based methods (FAMs), also referred to as natural family planning (NFP) methods, require abstaining from intercourse or use of a barrier method during the fertile time of a woman's menstrual cycle, thereby avoiding conception.

EFFECTIVENESS

Pregnancy rates range from 1-14 % with correct and typical use in the first year. Effectiveness of FAMs is enhanced by use of multiple techniques to identify the fertile time.

To achieve this, the woman must be able to recognize 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

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..

SDM is more than 95-% effective with correct use, and more than 88-% effective with typical use among women with regular cycles of 26-32 days.

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.

Image Source: Institute for Reproductive Health Georgetown University – http://irh.org

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, the SDM may 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. It is also based on changes in the amounts and characteristics of the cervical mucus and body temperature, or a combination of the latter two, or use of specific ovulation detection kits.

TWO DAY METHOD (TDM)

The Two Day 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 notice secretions today?"* and (2*) "Did I notice 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-% effective in preventing pregnancy when used correctly, and 86 % 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 specific time every day. 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.

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.

- Recognize evidence of ovulation (peak day), when the mucus is very clear, stretchy (Spinnberkeit'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.

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 0.2^0C - 0.5^0C, 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 devices provide a more precise way to detect ovulation:

- Advanced thermometers for detection of BBT thermal shift
- Hand-held electronic devices that record multiple signs to predict ovulation
- Ovulation-detection kits that measure levels of luteinizing hormone (LH) in urine
- Mobile phone App of the SDM that enables the women to track their Cycle days

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 be aware of her body's changes or keep track of her days, according to the rules of the specific method.

ADVANTAGES OF FAMS

Contraceptive benefits

- They do not require contraceptive commodities and supplies.
- Less expensive.
- There are no side effects or health risks.
- Return to fertility is immediate.

Non-contraceptive benefits

- Improve knowledge of the reproductive system and understanding of menstrual cycle.
- Shared responsibility by couples.
- Limited need for professional consultation.
- Enhances Male engagement and spousal communication /Cooperation
- They can be used by both literate and illiterate women.
- They allow adherence to religious and cultural norms.
- 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 FAMS

- Clients require intensive education and instruction before being confident to use method.
- Does not protect against sexually transmitted infections including HIV
- These are user-dependent methods hence need cooperation and commitment by both partners.
- May not be easy to use if menstrual cycle is irregular.
- Require accurate daily record keeping.
- Unreliable if client is breastfeeding and has amenorrhea.
- Has a high failure rate if client is not well trained
- These methods require varying periods of sexual abstinence during fertile phase.

ELIGIBILITY CRITERIA

WHO MEC categorizes fertility awareness based methods as follows;

- **Accept (A):** There is no medical reason to deny the particular FAM method to a woman in this circumstance.
- **Caution (C):** The method is normally provided in a routine setting, but with extra preparation and precautions. For FAM methods, this usually means that special counselling may be

needed to ensure correct use of the method by a woman in this circumstance.

- **Delay (D):** Use of this method should be delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be offered.

Women Who Can Use FAMs - Accept (A)

All women of reproductive age with established menstrual cycles 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 couples who are willing to abstain from intercourse during the fertile time.

The **table 10.1** summarizes specific conditions under the MEC categories for FAM.

Table 10.1 **WHO MEC criteria for FAMs for specific conditions**

Condition	Symptoms-based methods (SMY)	Calendar-based methods (CAL)	Comments
Post- menarche	Caution (C)	Caution (C)	Menstrual irregularities are common in post-menarche and perimenopause
Peri-menopause	Caution (C)	Caution (C)	
Breastfeeding less than 6 weeks postpartum	Delay (D)	Delay (D)	Women who are exclusively breastfeeding and are amenorrhoeic are unlikely to have sufficient ovarian function to produce detectable fertility signs
Breastfeeding more than 6 weeks postpartum	Caution (C)	Delay (D)	
Breastfeeding after menses begin	Caution (C)	Caution (C)	First postpartum menstrual cycles in breastfeeding women vary significantly in length
Non-breastfeeding women less than 4 weeks postpartum	Delay (D)	Delay (D)	Delay till resumption of regular menses
Non-breastfeeding women more than 4 weeks postpartum	Accept (A)	Delay (D)	Delay till resumption of regular menses for CAL methods

Condition	Symptoms-based methods (SMY)	Calendar-based methods (CAL)	Comments
Post abortion	Caution (C)	Delay (D)	Delay till resumption of regular menses for CAL method
Irregular vaginal bleeding	Delay (D)	Delay (D)	Delay until evaluation and treatment
Vaginal discharge	Delay (D)	Accept (A)	Delay until after treatment for SYM methods
Chronic diseases that elevate body temperature	Caution (C)	Accept (A)	May affect temperature monitoring in SYM methods
Acute diseases that elevate body temperature	Delay (D)	Accept (A)	Delay for symptom based methods until after treatment
Use of drugs that affect cycle regularity and fertility signs e.g. mood-altering drugs, antidepressants, some long-term antibiotics, or long-term NSAIDs	C/D	C/D	

Women Who Should Not Use FAMs

This method would not be appropriate for the following:

- Women who dislike touching their genitals (symptom methods)
- Women whose partners will not cooperate
- Couples who require highly effective protection against pregnancy (e.g., the woman has conditions that can be made worse by pregnancy)

METHOD USE

Table 10.2 **When to start FAMs**

When to Start	Symptoms Based Methods	Calendar Method
Regular menstrual cycles	Any time of the month. No need to wait until the start of next monthly bleeding	Any time of the month No need to wait until the start of next monthly bleeding.
Amenorrhoeic	Delay until monthly bleeding returns	Delay until monthly bleeding returns
After childbirth (whether or not breastfeeding)	She can start once normal secretions have returned. Normal secretions will return later in breastfeeding women than in women who are not breastfeeding	Delay the method until she has had 3 menstrual cycles and the last one was 26–32 days long. Regular cycles will return later in breastfeeding women than in women who are not breastfeeding
After miscarriage or abortion	She can start immediately with special counseling and support, if she has no infection-related secretions or bleeding due to injury to the genital tract	Delay until the start of her next monthly bleeding, when she can start if she has no bleeding due to injury to the genital tract

WITHDRAWAL METHOD (COITUS INTERRUPTUS)

Coitus Interruptus is one of the traditional methods of preventing pregnancy. It is a method in which the man completely removes the penis from the vagina, and away from the external genitalia of the female partner, before he ejaculates 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

Key Messages

All men can use withdrawal. No medical conditions prevent its use. Withdrawal may be especially appropriate for couples who:

- *have no other method available at the time*
- *are waiting to start another method*
- *have objections to using other methods*
- *Have infrequent intercourse*

have entered into a sexual act without any other method and need contraception immediately.

EFFECTIVENESS

Effectiveness of this method depends on the user: Risk of pregnancy is greatest when the man does not withdraw his penis from the vagina before he ejaculates with every act of sex. Its important to note that:

- Its one of the least effective methods, as commonly used.
- As commonly used, about 20 pregnancies per 100 women whose partners use withdrawal over the first year. This means that 80 of every 100 women whose partners use withdrawal will not become pregnant.
- When used correctly with every act of sex, about 4 pregnancies per 100 women whose partners use withdrawal over the first year.
- There is no delay in return of fertility after use of withdrawal is stopped.
- It does not protect against sexually transmitted infections.

ADVANTAGES OF COITUS INTERUPTUS

- Promotes male engagement and couple communication
- Does not affect breastfeeding.
- Has no economic cost
- Does not involve use of devices or chemicals.
- Has no health risks associated directly with it
- Always available as a back-up method and no need for professional supervision.

LIMITATIONS

- It demands consistent self-control by couples .
- It is possible for pre-ejaculatory fluid containing sperm to flow out during the excitement phase, before the penis is withdrawn.

- 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;
- However, couples who have intercourse infrequently should not solely 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.

WHO SHOULD NOT USE:

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

CHAPTER ELEVEN:

11

MONITORING, EVALUATION AND FP COMMODITY MANAGEMENT

Good-quality reproductive health care requires a continuous supply of contraceptives and other commodities. Family planning providers are the most important link in the contraceptive supply chain that moves commodities from the manufacturer to the client. Accurate and timely reports and orders from providers help supply chain managers determine what products are needed, how much to buy, and where to distribute them. Health facility staff members do their part when they properly manage contraceptive inventory, accurately record and report what is provided to clients, and promptly order new supplies.

The aim of this chapter is to provide guidance on documentation and reporting of FP data with regards to;

- Understanding the principles of data quality
- Outlining roles and reporting requirements for commodities and services data at various service delivery points and levels
- Describing the data collection and reporting tools available
- Highlighting the role of data in decision making

FP DATA MANAGEMENT

ENSURING QUALITY OF FP COMMODITIES AND SERVICES DATA

It is important that data errors are minimized at all levels. Dimensions of data quality need to be met in order to avoid erosion of trust in the data generated within the Health information system. The table shows the various dimensions of data quality.

Table 11.1 **Dimensions of data quality**

Dimension	How to ensure quality
Timeliness	Reports are submitted within stipulated time
Accuracy	Data that has been reported matches the primary source documents at the point of collection.
Reliability	Data collection is consistently aligned with protocols and procedures that do not change depending on the data collector ,when or how often the data is used
Precision	Data contains sufficient detail as per the specific data element.
Integrity	The data collection system is protected from bias or manipulation for reasons other than medical care
Confidentiality	Personal client data are not inappropriately disclosed or left unsecured.

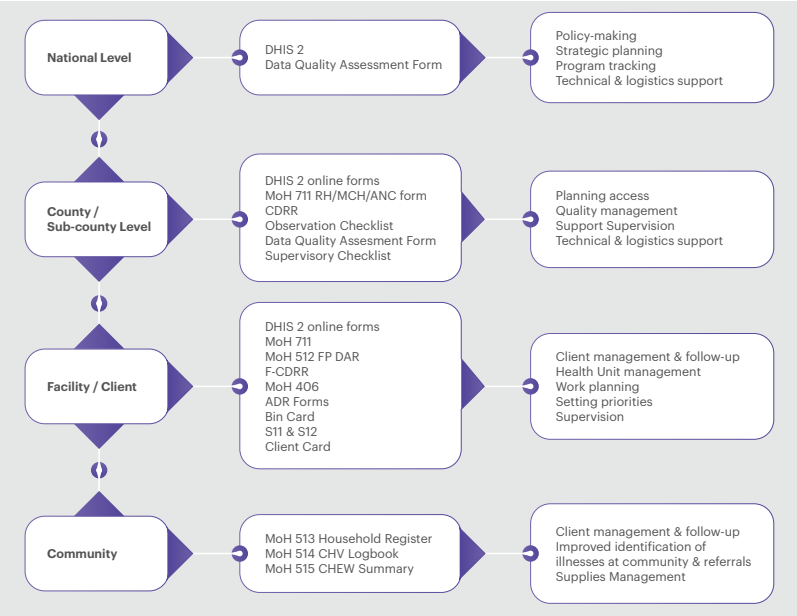
DATA FLOW AND USE AT VARIOUS LEVELS OF THE HEALTH CARE SYSTEM

Decision makers and stakeholders explicitly consider information in one or more steps in the process of service provision, policymaking, program planning and management,. Decision making should be based on evidence.

Every level of family planning service provision needs to secure the technical and human capacity to satisfy the demand for data, as well as manage, analyze, and disseminate data to users.

- Service providers for FP should not only accurately document and report to the next level but also routinely use these data for decision making and performance review, as outlined in below.

Figure 11.1 **Data Flow and use at various levels**



ROLES AND REPORTING REQUIREMENTS BY SERVICE DELIVERY LEVELS

Each Service Delivery Point requires an Master Facility List codes (MFL) to enable them report. Family planning providers at all levels are required to report on services provided and commodity movement, using the appropriate reporting tools and submit within the stipulated timelines.

All FP providers should maintain proper records on each client served and the specific contraceptive methods provided.

Service providers from Non-governmental organizations (NGOs) and the private sector should also follow the Ministry of Health's service provision and reporting guidelines.

Health care providers will collect the various data according to the Service Delivery Point.

- Facility details (includes county, sub-county, facility name, type and reporting period)
- Services offered
- Commodity requisition and use

Family Planning Services and Commodities Reporting Tools

The Ministry of Health has a series of tools for reporting on family planning services and commodities at various levels of service provision, most culminating into the DHIS 2. **Table 11.1** below.

Table 11.1 **Summary of Family Planning Data tools by service delivery level**

Data Tools	Data points	Frequency	Who Fills
Community Level			
MOH513 Household register	data indicates the family planning method used modern, traditional or no FP	6 monthly	CHVs
MOH514 Service Delivery Logbook	Women 15-49 provided with FP commodities (not specific)	Monthly	CHVs
MOH515 CHEW Summary	Summary of MOH514 logbook	Monthly	CHEW
MOH516 Community Health Chalkboard	Information on the health action days held	Monthly	CHEW
MOH100 Client Referral Form	Information on reasons for referral	As need arises	CHVs
Facility: Dispensary, Health Centers and hospitals, Nursing Homes			
MOH512 Daily Family Planning Activity Register	New clients Revisits Method dispensed Method Switch	Daily	Health Service Provider
MOH711 RH/MCH Form	New clients Revisit Method dispensed	Monthly	Health Service Provider

Data Tools	Data points	Frequency	Who Fills
	Method Switch		
MOH406 Post Natal Register	Women attending post natal care clinics provided with a modern FP method	Daily	Health Service Provider
New Client cards	Information on the clinical evaluation and method provided	Every visit	Health Service Provider
FP Client follow up card	Revisits client Any side effects Methods dispensed	Every visit	Health service provider
Pharmaco-vigilance forms PV-1,2,3	Adverse events/Side effects	As needs arises	Health Service Provider
Client Referral Form	Clients being referred	As needs arises	Referring staff
DHIS 2	It is a platform for data reporting collate and analysis Summary on MOH 711 delivery	Done by 15th of every month	The HRIO/ sub county HRIO

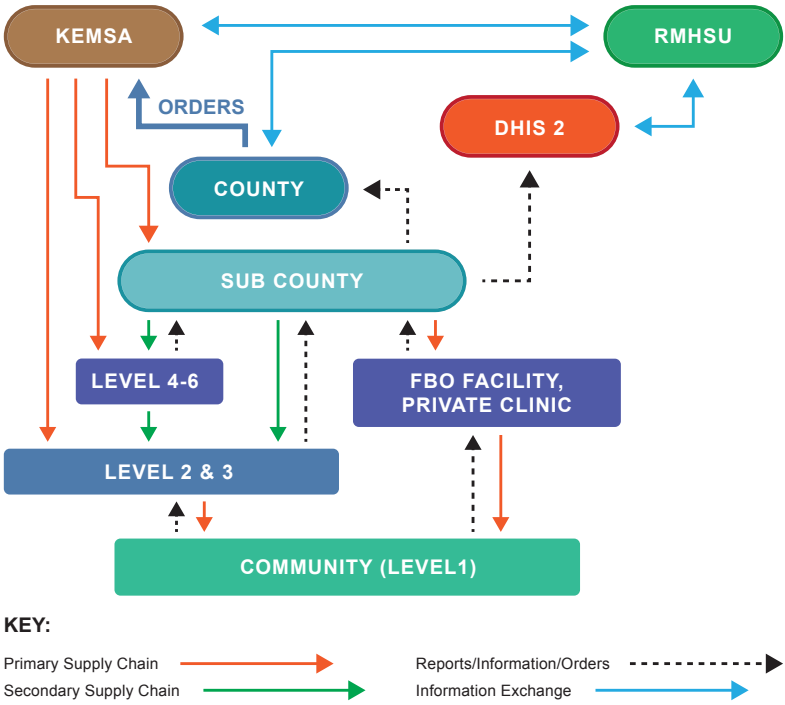
Data Quality Management

Increasing access and use of quality data is nested on the development and operationalization of an efficient Data Quality Assessment (DQA) system which will harness evidence based decision making. The service provider should incorporate strategies for data quality assessments. Deliberate efforts should be put in place to ensure the reported data are verified on a regular basis. These strategies include supportive supervisions, data review meetings and Routine Data Quality Assessment.

COMMODITIES AND LOGISTICS MANAGEMENT

In order to ensure uninterrupted supply of contraceptives for FP programs, an efficient commodity logistics and management systems is required. The **Figure 11.2** summarizes FP commodity and information flow at the various levels.

Figure 11.2 **FP Commodity and Information Flow**



Receiving commodities

- All FP commodities should be received at the facility store by an authorized person.
- The commodities received (e.g. from KEMSA) should be verified against the quantities on the **delivery note**. Important information enclosed is the destination of the commodities, expiry date, actual quantities and the condition of the products.

- A **Goods Received Note (GRN**) should be prepared and signed, after properly making adjustments for any products that are returned(expirely damaged or not usable).
- The received commodities should then be entered into the **Bin Card (S5)** and balances adjusted accordingly.
- The **S11** (Counter Requisition and Issue voucher) should be used for issuing
- Use the First Expiry First Out System (FEFO) and/or First In First Out (FIFO) in issuing FP commodities to minimize expiries.
- Proper records on **charting drug expiry dates; temperature logs**; and other **storage check lists** should be accurately maintained.

Storage of commodities

- The FP store should be organized, clean and well ventilated with temperature maintained in accordance with product specifications.
- Drugs should be kept off the floor to avoid contact with moisture.
- All the documents used in commodities management should be signed, verified by an authorized person, stamped and copies filed.
- The store should be secured safely and access limited only to authorized personnel.

Issuing commodities

- At the service delivery point, all the service providers should on a daily basis correctly document in the **Daily Activity Register** (MOH 512)the type and quantity of the FP commodity issued to the FP clients.
- FP service providers should maintain proper records on each client and the distribution of contraceptives both at facility and community level.

Reporting

- At the end of every month, the FP service provider should summarize and prepare the **SDP Facility Commodity Consumption Report and Request (FCDRR),** correctly document the commodities consumed in the month including any commodity adjustments.
- The health facility should calculate the **Quantity Requested (ordered)** for each contraceptive in line with the National FP program guidelines in the glossary of the FCDRR report (general guide is to multiply the average monthly consumption by six then subtract the month's closing balance to determine the quantity to order).
- The FCDRR report should be filled completely, dated, and signed by the person preparing it and verified by the Facility in-charge. The original copy should be forwarded to the Sub-County pharmacist for updating in the DHIS2; the duplicate to the Sub-County; and the triplicate retained and properly filed at the health facility.

Tools used in Commodities reporting

The table 11.2 shows the different tools used in reporting of commodities at facility level.

Table 11.2 **Commodity reporting tools at facility level**

Tool	Use	Who fills
FCDRR – Facility Commodities Report	Facility FP commodities consumption data (Closing balances, receipts , issues, adjustments and losses)	Facility staff providing FP service
DCDRR	Aggregation of FCDRR. Available at www.hiskenya.org	HRIO for hospitals Sub-county pharmacist
Bin cards	Closing balances, receipts and issues	Store-in-charge,
S11 (Counter Requisition and Issue Voucher)	Used for intra-facility Issuing	Person issuing

Checklist for data collection

- Use standard MOH coded data collection tools
- Refer to the guidelines provided in the data collection tools (cover page of registers)
- Fill in the data collection tool/register as the clients are being seen – ***do not fill the tools later or after service delivery***
- When starting a new month , start in a new page.
- Do monthly and daily summary
- Complete all rows and columns appropriately
- All summary tools must have the supervisor's signature, facility name, date and stamp
- All summary tools should reach the next level by 5th of the following month and aggregated to DHIS 2 by 15th of the following month.

Reporting Adverse Drug Reaction (ADR) and Poor Quality Medicines

The safety of modern family planning methods on the health of the women of reproductive age is an essential component in determining choice and continued use of the method. Modern FP methods can have varying side effects (adverse events) most of which are underreported or not reported at all. Family planning service providers need to routinely document adverse events through collecting, monitoring, assessing and evaluating information on adverse reactions.

An Adverse Drug Reaction (ADR) is defined by WHO as *"A response to a drug which is noxious and unintended, and which occurs at doses normally used or tested in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function"*

Any suspected ADR should be reported through the Pharmaco-vigilance forms. These forms are:

- Yellow form (PV 1)
- White form (PV 4)
- Pink form (PV 6)

When completing the ADR forms, the health care provider should provide the following information

- **Patient** identification
- Clear description of the **event**
- Information on the **product** (generic name, brand name, strength, dosage, and batch number)
- **Details of the service provider** reporting (name, address, contact information)

The ADRs can be reported by the health care workers; the CHVs and relatives. Filled forms should be sent immediately through appointed courier; direct post; Fax/Telephone/Email or through the MoH system in existence to the sub-county pharmacist, Pharmacy and Poisons Board or any other designated official/organization.

Table 11.3 **Pharmaco-vigilance Tools**

Tool	Use	Who Fills
Yellow form (PV 1)	To report suspected adverse drug reactions	Pharmacist
White card (PV 4)	An Alert card issued to patients with an adverse event	FP service provider-Pharmacist
Pink form (PV 6)	For reporting poor quality medicinal products	Pharmacist

For more information on ADRs and reporting refer to the "Guideline for The National Pharmaco-vigilance System in Kenya". Online link: http://www.pv.pharmacyboardkenya.org/

Indicators for FP commodity management and services

Table 11.4 **FP Service Indicators**

Indicator	Indicator definition
Uptake of FP modern methods	Number of new acceptors to modern contraception
Couple Years of Protection (CYP)	Multiplying the quantity of each method distributed to clients by a conversion factor, to yield an estimate of the duration of contraceptive protection provided per unit of that method
Contraceptive Prevalence Rate (CPR)	% of WRA who are currently using at least one method of contraception regardless of the method used. **Numerator:** Total number of WRA using any method of contraception **Denominator:** Total WRA
Modern Contraceptive Prevalence Rate (mCPR)	% of WRA who are currently using any modern method of contraception **Numerator:** Total number of WRA using any modern method of contraception. **Denominator**: Total WRA.
Total Fertility Rate (TFR)	Number of children that would be born to a woman if she were to live to the end of her childbearing years and bear children in accordance with current age-specific fertility rates
Discontinuation rate (per method)	% of WRA who stop using contraceptive method(s) within the first year
Unmet need for FP	% of women currently married or in union who are fecund and who desire to either terminate or postpone childbearing, but who are not currently using a contraceptive method
Total Demand for FP	% of (married) women using FP + %age (married) women with unmet need for FP
Met need for FP	% of (married) women using FP / %age (married) women with demand for FP
Unintended Birth Rate	% of births that resulted from pregnancies that were reported to be either unwanted or mistimed **Numerator:** # of births reported as unintended **Denominator:** total # of births reported

Table 11.5 **FP Commodity Management Indicators**

Indicator	Indicator definition
Reporting (Rate)	% of facilities submitting (timely, complete, accurate) commodity consumption reports to the central level for priority program
Stock Status	% of facilities with current stocks within the Min (1 MOS) -Max (4MOS) level (not overstocked, under-stocked; or stocked out)- in the last 3 months
Stock Outs	% of facilities providing the service that did not experience a stock out of a tracer health commodity (DMPA) in the last 3 months
Expiries	% of facilities having expiries of at least one commodity from the tracer commodities list (DMPA)
Verification of the services offered	% of facilities whose service statistics and consumption data have a variance of ≤10% for a given commodity and service
Forecasting Performance	% difference between consumption forecast and actual consumption
Ensuring FP commodity security/coordination	Existence of an active County coordination committee that works on contraceptive or RH commodity security

FREQUENTLY ASKED QUESTIONS ON REPORTING ON FP

1. What is the difference between and importance of Facility CDRR vs District CDRR
   - The Facility Consumption Data report and request form (F-CDRR) is a reporting tool used by the facility to report on the use of contraceptive commodities. This form is currently entered into the DHIS-2 directly.
   - The District Consumption Data Report and Request form used to aggregate facility CDRR but with the use of the DHIS2, the District CDRR is used to report on the district store contraceptive commodities.

The CDRR at all levels are used to;

- Forecast for facility and district requirements respectively.
- Plan for distribution of contraceptives
- Request for contraceptive commodities
- Ensure inventory management practices are observed
- Identify facilities that will require support supervision to support the inventory management

2. What are the timelines for reporting?
   - The FCDRR and DCDRR should be submitted to the sub county Health Records Officer at the sub county level by 5th of each month. The sub county health record officer will subsequently enter this to the DHIS-2 by the 15th of each month.
3. When to re-order?
   - The ordering cycle is dependent on the county supply plans. Contraceptives are currently distributed by KEMSA together with other essential commodities and should therefore be ordered from KEMSA at the same time with other essential commodities that the county is procuring.
4. How much of each commodity to order
   - The facility and Sub-County should order their monthly supply requirements multiplied by the number of months in between the supply periods plus the buffer if the buffer is below what is expected. Therefore if the County is procuring contraceptives every quarter the order should be for 3 months (calculated based on the average monthly consumption) plus buffer.
   - Monthly Consumption = Opening balance + stocks received - closing balance - losses + adjustments.
   - The buffer stock is usually 1 month stock at facility level and 3 month stock at Sub-County level. The buffer stock can be adjusted taking the particular challenges and situations the facility and store face.

5. How do we report and dispose of expired commodities?
    - The Facility CDRR and the District CDRR have the losses column through which reporting on expired drugs is done. This column should be used to report on expired, damaged, and defective contraceptives.
    - Please refer to the national guidelines on the safe disposal of drugs at the county level.
6. How to synchronize consumption vs service data?
    - Service data refer to the reports on services offered at the facility. This data is reported in the FP register (MoH 512) and summarized through the MOH 731 form. Consumption data refers to contraceptive commodity data. This data is reported through the FCDRR. Synchronizing of these two data reports is useful in ensuring that services and commodities tally. This can be done by comparing monthly commodity data and monthly reservices data. Services and commodities should match taking into account the number of commodities provided to a client for each service.
    - This can be done monthly by using the DHIS2 Pivot table function to compare the 2 data points together.

APPENDICES:

APPENDIX 1: EFFECTIVENESS OF FP METHODS

Pregnancy Rates per 100 Women during First Year of Use

(Number of pregnancies per year among 100 women using the method)

Method	Pregnancy Rate as commonly used	Pregnancy Rate used correctly and consistently
Contraceptive Implants	0.05	0.05
Male sterilization-Vasectomy	0.15	0.1
LNG-IUS (Mirena)	0.2	0.2
Female sterilization-Tubal Occlusion	0.5	0.5
Copper IUCD (380A IUD)	0.8	0.6
Lactational Amenorrhea Method- LAM (for 6 months only)	2	0.5
Progestin-only Injectable Contraceptives (DMPA, NET-EN)	3	0.3
Combined Oral Contraceptive Pill	8	0.3
Progestogen-only Contraceptive Pill	8	0.3
Combined contraceptive skin patch (Evra)	8	0.3
Combined vaginal contraceptive ring (NuvaRing)	8	0.3
Progesterone vaginal ring		1.5
Male condoms	15	2
Ovulation method (BBT/cervical mucus)	25	3
TwoDay method		4
Standard Days Method (SDM)	25	5
Female condoms	21	5
Withdrawal (Coitus Interruptus)	27	4
NO METHOD OF CONTRACEPTION	85	85

APPENDIX 2: HOW TO IDENTIFY MIGRAINE HEADACHES AND AURAS

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.	1.	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 3: INFORMED AND VOLUNTARY CONSENT FORM FOR SURGICAL CONTRACEPTION

Ministry of Health

Consent Form for Surgical Contraception

I, ……., the undersigned, wish to be sterilized by the following procedure:

……..……

I understand the following:

1. There are temporary methods of contraception that I can use instead of sterilization for family planning.
2. Sterilization is a surgical procedure, the details of which my doctor, nurse, or midwife has explained to me.
3. The sterilization operation carries certain risks, complications, and side effects, which my doctor, nurse, or midwife has explained to me.
4. The sterilization procedure will permanently prevent future pregnancies.
5. The sterilization 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)	Client's signature
……	……..	……
Date	Spousal name (when applicable)	Spousal signature (when applicable)
……	……	…… ..
Date	Surgeon's signature	Witness (can be another service provider)

APPENDIX 4: HOW TO BE REASONABLY SURE A CLIENT IS NOT PREGNANT

Checklist

Ask the client questions 1–6. As soon as the client answers "yes" to *any question*, stop and follow the instructions below.

NO		YES
	1 Did your last monthly bleeding start within the past 7 days?*	
	2 Have you abstained from sexual intercourse since your last monthly bleeding, delivery, abortion, or miscarriage?	
	3 Have you been using a reliable contraceptive method consistently and correctly since your last monthly bleeding, delivery, abortion, or miscarriage?	
	4 Have you had a baby in the last 4 weeks?	
	5 Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no monthly bleeding since then?	
	6 Have you had a miscarriage or abortion in the past 7 days?*	

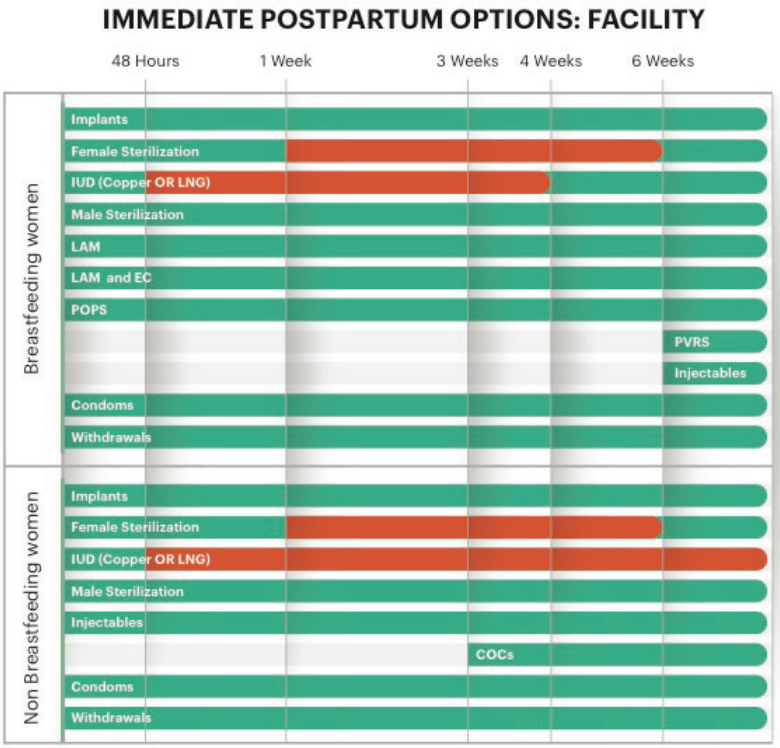
* If the client is planning to use a copper-bearing IUD, the 7-day window is expanded to 12 days.

If the client answered NO to *all of the questions*, pregnancy cannot be ruled out using the checklist.

Rule out pregnancy by other means.

If the client answered YES to *at least one of the questions*, you can be reasonably sure she is not pregnant.

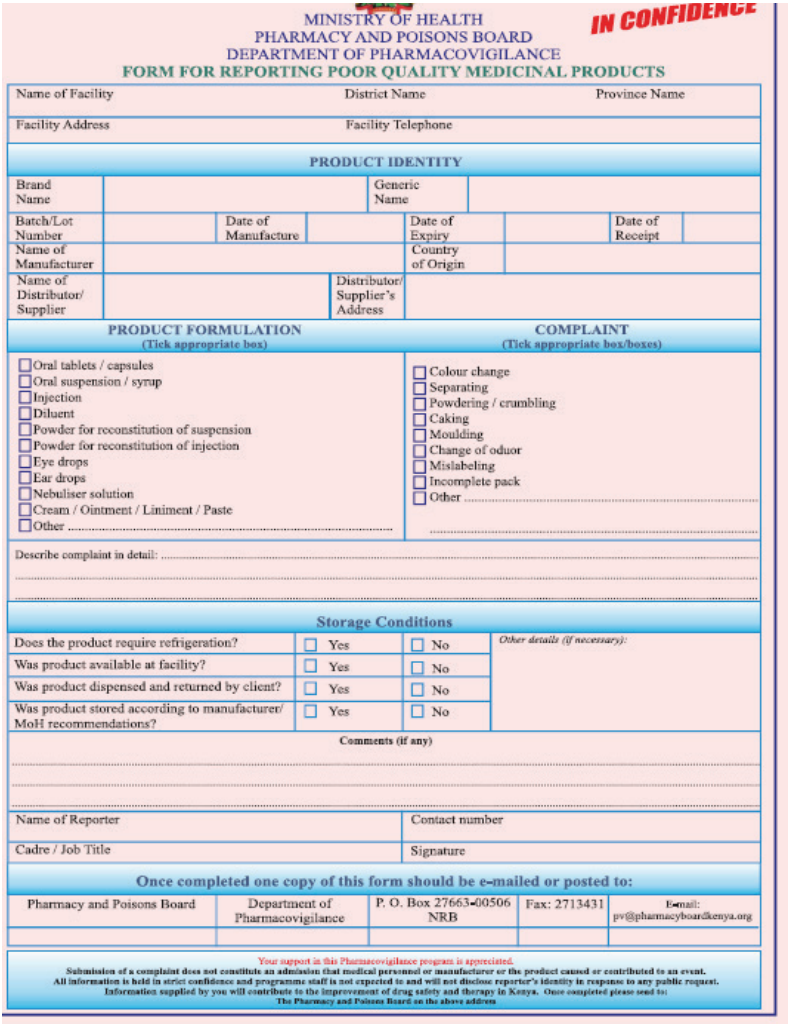
APPENDIX 5: SUMMARY OF FP OPTIONS FOR POSTPARTUM CLIENTS



COCs should not be initiated by breastfeeding women until atleast 6 months postpartum. In addition fertility awareness methods such as standard day methods (cycle beads) require women to chart 4 regular menstrual cycles before beginning this method so timing varies from one woman to the next.

APPENDIX 6: PHARMACOVIGILANCE FORMS

Can be accessed at : http://www.pv.pharmacyboardkenya.org/



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
DEPARTMENT OF PHARMACOVIGILANCE

IN CONFIDENCE

FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS

Name of Facility	District Name	Province Name
Facility Address	Facility Telephone	

PRODUCT IDENTITY

Brand Name		Generic Name					
Batch/Lot Number		Date of Manufacture		Date of Expiry		Date of Receipt	
Name of Manufacturer				Country of Origin			
Name of Distributor/ Supplier		Distributor/ Supplier's Address					

PRODUCT FORMULATION (Tick appropriate box)

- ☐ Oral tablets / capsules
- ☐ Oral suspension / syrup
- ☐ Injection
- ☐ Diluent
- ☐ Powder for reconstitution of suspension
- ☐ Powder for reconstitution of injection
- ☐ Eye drops
- ☐ Ear drops
- ☐ Nebuliser solution
- ☐ Cream / Ointment / Liniment / Paste
- ☐ Other .....

COMPLAINT (Tick appropriate box/boxes)

- ☐ Colour change
- ☐ Separating
- ☐ Powdering / crumbling
- ☐ Caking
- ☐ Moulding
- ☐ Change of oduor
- ☐ Mislabeling
- ☐ Incomplete pack
- ☐ Other .....

Describe complaint in detail: .....

Storage Conditions

Does the product require refrigeration?	☐ Yes	☐ No	*Other details (if necessary):*
Was product available at facility?	☐ Yes	☐ No	
Was product dispensed and returned by client?	☐ Yes	☐ No	
Was product stored according to manufacturer/ MoH recommendations?	☐ Yes	☐ No	

Comments (if any)

Name of Reporter	Contact number
Cadre / Job Title	Signature

Once completed one copy of this form should be e-mailed or posted to:

Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB	Fax: 2713431	E-mail: pv@pharmacyboardkenya.org

Your support in this Pharmacovigilance program is appreciated.
Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event.
All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

PV 1

MINISTRY OF HEALTH
THE PHARMACY AND POISONS BOARD
P. O. Box 27663-00506 NAIROBI
Tel: (020)-2716905 / 6 Ext 114 Fax: (020) 2713431/2713409.
Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

☐ Initial Report
☐ Follow-up Report

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

NAME OF INSTITUTION: ..... **INSTITUTION CODE:** .....

ADDRESS: ..... **CONTACT:** .....

PATIENT'S NAME/ INITIALS: ..... **IP/OP. NO.:** ..... **D.O.B:** .....

PATIENT'S ADDRESS: ..... **WARD/CLINIC:** ..... **GENDER:** ☐ Male ☐ Female
(Name/Number)

ANY KNOWN ALLERGY: ☐ No ☐ Yes (specify) .....

PREGNANCY STATUS: ☐ Not Pregnant ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester

WEIGHT (kg): .....

HEIGHT (cm): .....

DIAGNOSIS: (What was the patient treated for) .....

BRIEF DESCRIPTION OF REACTION: .....

LIST OF *ALL* DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)(use rear side of this form for additional drugs)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (√) SUSPECTED DRUG(S)
1						
2						
3						
4						
5						

SEVERITY OF THE REACTION: (Refer to scale overleaf)
☐ Mild
☐ Moderate
☐ Severe
☐ Fatal
☐ Unknown

ACTION TAKEN:
☐ Drug withdrawn
☐ Dose increased
☐ Dose reduced
☐ Dose not changed
☐ Unknown

OUTCOME:
☐ Recovering / resolving
☐ Recovered / resolved
☐ Requires or prolongs hospitalization
☐ Causes a congenital anomaly
☐ Requires intervention to prevent permanent damage
☐ Unknown

CAUSALITY OF REACTION: (Refer to scale overleaf)
☐ Certain
☐ Probable / Likely
☐ Possible
☐ Unlikely
☐ Conditional / Unclassified
☐ Unassessable / Unclassifiable

ANY OTHER COMMENT: .....

NAME OF PERSON REPORTING: ..... **DATE:** .....

E-MAIL ADDRESS: ..... **PHONE NO.** .....

DESIGNATION: ..... **SIGNATURE:** .....

You need not be certain ... just be suspicious !

Your support in this Pharmacovigilance program is appreciated.
Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

EXPLANATORY NOTES

CONFIDENTIALITY
All information collected in this form, identities of the reporter and patient, will remain confidential

WHAT TO REPORT
An Adverse Drug Reaction (ADR) is defined as a reaction that is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or treatment of a disease, or for modification of physiological function.

Report all suspected adverse experiences with medications,
especially those where the patient outcome is:

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You are not certain if the drug caused the reaction
- You do not have all the details

WHO CAN REPORT
All healthcare professionals (clinicians, dentists, nurses, pharmacists, physiotherapists, community health workers etc) are encouraged to report. Patients (or their next of kin) may also report.

WHAT HAPPENS TO THE SUBMITTED INFORMATION
All information submitted is handled in strict confidence. The Pharmacy and Poisons Board will assess causality and statistical analysis on each form. Data will periodically be used for review and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uppsala Monitoring Centre - the WHO Collaborating Center for International Drug Monitoring in Sweden.

SUBMISSION OF INITIAL OR FOLLOW-UP REPORTS
It is important to tick the appropriate box on the top-right corner of the front page to indicate whether the report is an initial (original) report or is a follow-up (subsequent) report.
It is very important that follow-up reports are identified and linked to the original report.

WHERE TO REPORT
After completing this form, please forward the same to your Pharmacy Department for onward submission, or mail directly, to:

THE PHARMACY AND POISONS BOARD
Lenana Road.
P. O. Box 27663-00506 NAIROBI
Tel: (020)-2716905 / 6 Ext 114 Fax: (020)-2713431/2713409
E-mail: pv@pharmacyboardkenya.org

Please use the space provided below for any further information. You may attach more pages to this form if required.

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (√) SUSPECTED DRUG(S)
6						
7						
8						
9						
10						

Criteria for Assessment of Severity of an ADR

Mild	• The ADR requires no change in treatment with the suspected drug • The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required • No increase in length of stay.
Moderate	• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required. • Increases length of stay by at least one day • The ADR is the reason for admission.
Severe	• The ADR requires intensive medical care • The ADR causes permanent harm to the patient
Fatal	• The ADR either directly or indirectly leads to the death of the patient

WHO-UMC Causality Assessment Scale

Causality Term	Assessment
Certain	• Event of laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically *(i.e an objective and specific medical disorder or a recognized pharmacological phenomenon)* • Rechallenge satisfactory , if necessary.
Probable / Likely	• Event or laboratory tests abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory tests abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drugs withdrawal lacking or unclear
Unlikely	• Event or laboratory tests abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper, assessment needed or • Additional data under examination
Unassessable/ unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because of insufficient or contradictory information • Data cannot be supplemented or verified.

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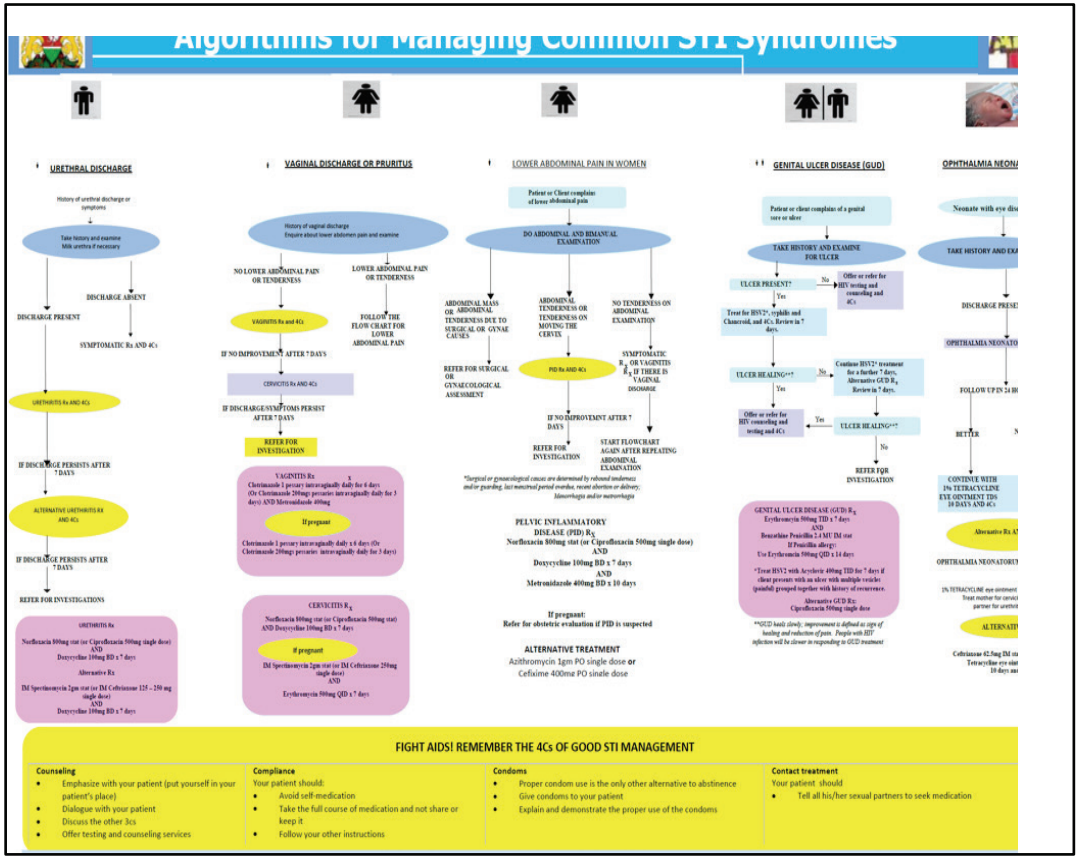
Once completed please send to: The Pharmacy and Poisons Board on the above address

APPENDIX 7: ALGORITHM FOR THE MANAGEMENT OF STI



APPENDIX 8: RECOMMENDED JOB AIDS

- Client learning sessions manual
- Charts (male and female reproductive system, menstrual cycle, symptothermal charts)
- Mambo Matatu unayostahili kujua: Three things to know about ECPs
- *Counselling Protocol for Standard Days Method and CycleBeads (Institute of Reproductive Health/Georgetown University)*
- Audio-visual aids
- CycleBeads®
- BBT GRAPH
- Clinical thermometer

REFERENCES

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11. United Nations Convention on the Rights of Persons with Disabilities. Resolution adopted by the United Nations General Assembly. United Nations; 2006 (article 23 and 25)
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14. Family Planning – A Global Handbook for Providers. 2011 Update
15. WHO Medical Eligibility Criteria (MEC) for contraceptive use, Fifth edition, 2015
16. Sivin, Irving, Soledad Díaz, Horacio B. Croxatto, et al.. "Contraceptives for lactating women: A comparative trial of a progesterone-releasing vaginal ring and the Copper T 380A IUD" Contraception 55: 225–232. 1997
17. Irving Sivin - IUDs are Contraceptives, Not Abortifacients: A Comment on Research and Belief

For more information or additional copies, contact:

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Old Mbagathi Road
P.O. Box 43319
Nairobi, Kenya
Alternatively, visit: **www.familyhealth.go.ke**