REPUBLIC OF KENYA
MINISTRY OF HEALTH

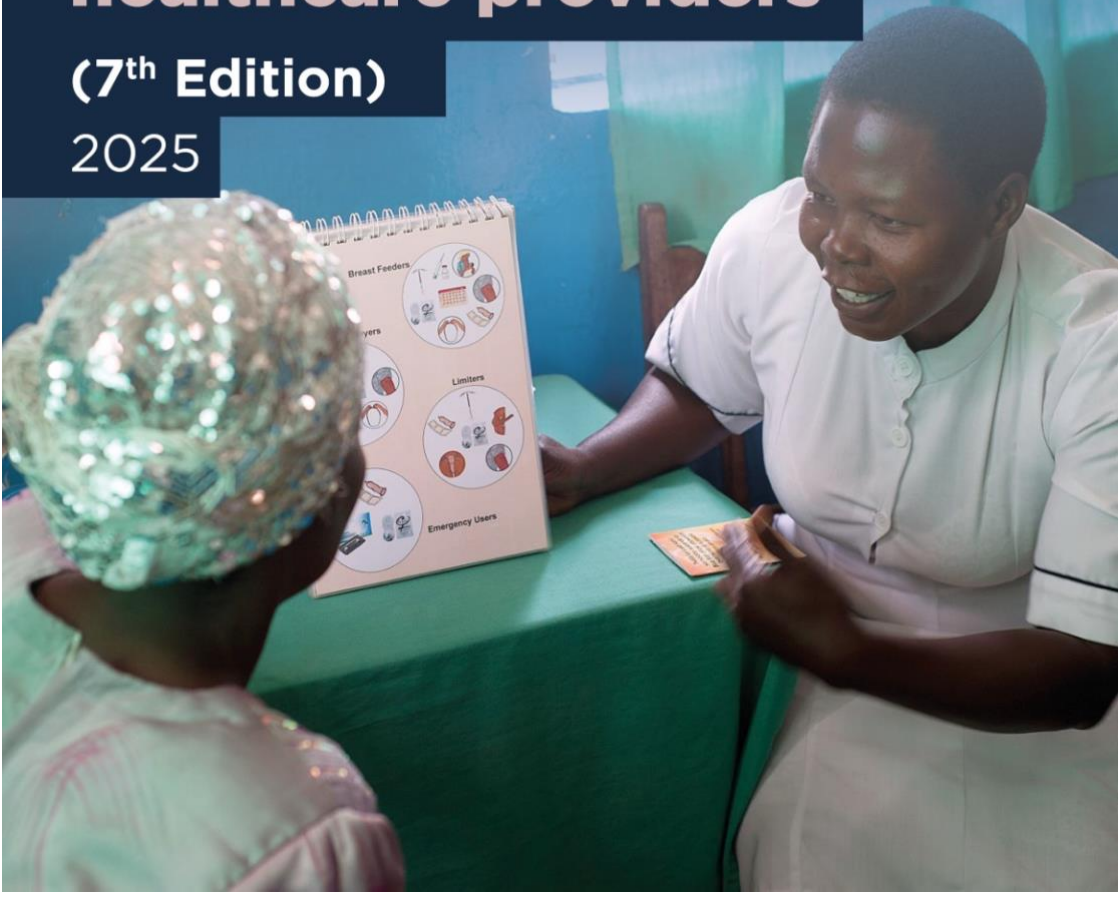
Division of Reproductive, Maternal, Newborn, Child and Adolescent Health
Every Life counts

Updated to include Counselling for Continuation, Infertility Diagnosis and Management, Operational Research in Family Planning, FP Integrated Logistics Management Information System, and Self-Care Interventions in FP

National Family Planning Guideline for healthcare providers

(7th Edition)

2025



The National Family Planning Guideline for Service Providers 7th Edition contains 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 the DRMNCAH to verify the information contained in this guideline document.

For clarifications contact the Head, Division of Reproductive Maternal, Newborn, Child and Adolescent Health, Ministry of Health, P. O. Box 43319 - 00100, Nairobi Kenya, Email: headrmncah.moh@gmail.com

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FOREWORD

The Ministry of Health is committed to providing quality and integrated family planning services to all Kenyans. This is in line with the provisions enshrined in the Bill of Rights of the Constitution of Kenya (2010), Article 43 (a), which provides that every person has a right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

Family planning has been recognized as a crucial investment for Kenya's health and development. The country has made progress in increasing access to and utilization of quality family planning information and services over time, as reported in the Kenya Demographic and Health Survey (KDHS) 2022. The modern contraceptive prevalence rate increased from 53% in 2014 to 57% in 2022, accompanied by a notable decline in the total fertility rate (TFR) from 3.9 to 3.4 births per woman. The same period also saw the unmet need for family planning dropping from 18% to 14%, and teenage pregnancy declining from 18% to 15%, according to KDHS data.

In its Family Planning 2030 commitments, Kenya has committed to achieving a modern contraceptive prevalence rate (mCPR) of 64% and reducing teenage pregnancy to less than 10%. In line with its mandate, the Division of Reproductive Maternal, Newborn, Child and Adolescent Health (DRMNCAH) has conducted a review of the national family planning guideline (6th edition, 2018) in response to emerging issues and current innovations and technologies to guide delivery and reporting of family planning services in Kenya.

This 7th Edition of the National Family Planning Guideline incorporates emerging innovations and technologies in the family planning space to support healthcare providers in the delivery of equitable, accessible, affordable and quality family planning information and services to achieve Universal Health Coverage (UHC), Sustainable Development Goals (SDGs) and the Family Planning 2030 (FP2030) commitments. The National Reproductive Health policy 2022–2032 outlines the commitment by the government to meet the needs of all citizens who seek reproductive health

services in the context of UHC.

This guideline is to be used by all healthcare providers offering family planning services within the country. They offer guidance for the provision of comprehensive, safe and quality family planning information and services in response to local challenges and highlight opportunities for increasing the uptake of family planning services.

Dr Patrick Amoth, EBS
Director General, Ministry of Health

TECHNICAL NOTE ON THE 7TH EDITION

The Ministry of Health is pleased to present the ***National Family Planning Guideline for Healthcare Providers (7th Edition)***, a crucial milestone in our ongoing commitment to delivering quality, accessible, and client-centered family planning (FP) services in Kenya. This edition introduces new and comprehensive guidance aimed at enhancing the quality and reach of FP services across the country.

The key feature of this edition is the introduction of digital health solutions, including Digital Counselling (DC) and Direct-to-Consumer (DTC) services, which revolutionize access to quality family planning (FP) information, counselling, and products. Central to this initiative is the Counselling for Continuation (C4C) framework, a transformative approach that prioritizes client-centered care at every interaction. By addressing individual concerns, delivering tailored information, and empowering clients in their FP decisions, C4C aims to enhance adherence and reduce discontinuation rates. Effective counselling is the cornerstone of FP services, fostering trust, promoting consistent use, and ultimately improving health outcomes. The Ministry of Health recognizes counselling not just as a service, but as a critical tool to uphold client autonomy, satisfaction, and overall well-being.

A holistic approach to FP care is further exemplified by the inclusion of *diagnosis and management of infertility* in this edition. Infertility affects numerous couples, and its recognition within our FP guideline signifies a comprehensive commitment to address all aspects of family planning. Through this inclusion, the Ministry underscores the right of every person to access a full spectrum of reproductive health services, fostering dignity and comprehensive care.

Supply chain efficiency has been strengthened through the *Integrated Logistics Management Information System (iLMIS)*. The guidance provided in this edition will ensure that FP commodities are available down to the last mile, reaching every client in need. This system supports a sustainable FP supply chain, aiming for uninterrupted access to commodities nationwide. Self-care interventions represent another important focus in this edition. Recognizing the need for flexibility, convenience, and autonomy, self-care interventions empower clients with options to manage their FP needs directly.

Self-injection of contraceptives, for instance, is not only a method of choice but a step towards reinforcing client agency, enhancing privacy, and respecting individual preferences in FP.

With these advancements, the Ministry remains steadfast in its mission to uphold the highest standards of service delivery, ensuring that every person in Kenya has access to safe, effective, and client-centered family planning options. We urge all healthcare providers to embrace this guideline and continue to support individuals in making informed and empowered reproductive health choices.

Dr. Issak Bashir
Ag. Head, Directorate of Family Health, Ministry of Health

ACKNOWLEDGEMENTS

The development of this 7th edition of the National Family Planning Guideline has been made possible by the concerted efforts of various individuals and organizations. The review and finalization of the guideline was through a highly consultative process involving a range of stakeholders drawn from national and county governments, the private sector, and implementing and development partners.

A literature review to identify emerging evidence-based best practices was conducted to generate updated content that aligns with current developments, innovations and technologies. Key informant interviews (KIIs) were also undertaken to collate experiences of the 6th edition by users and policymakers, both at the ministry and programme implementation levels, which provided invaluable inputs in developing this edition. Finally, the document was validated and finalized for use by healthcare providers in a consultative stakeholders' forum.

The Ministry of Health extends its gratitude to the following for steering the consultations at the national level to develop this document: Dr. Albert Ndwiga, Dr. Jeanne Patrick, Hambulle Mohammed, Talaso Wario, Dr. Estella Waiguru, Scolastica Wabwire, Hellen Mutsi, Mary Gathitu, Martin Mburu, and Alice N. Mwangangi of family planning programme at the DRMNCAH.

We thank the team that provided their technical contributions and who greatly participated in this process (see list of contributors in appendix 14.9).

We also acknowledge West Pokot, Nyeri and Nyandarua county teams and other implementing partners at AMREF Health Africa, Kenya Medical Training College, Nairobi, Population Services Kenya, Midwives Association Kenya, Marie Stopes Kenya, KNH-CCC, and for sharing their experiences and insights during the KIIs, which enriched this document.

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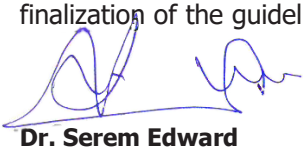

Dr. Serem Edward
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Ministry of Health

LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARVs	Antiretrovirals
ASRH	Adolescent Sexual & Reproductive Health
BBT	Basal Body Temperature
BMI	Body Mass Index
BP	Blood Pressure
BTL	Bilateral Tubal Ligation
CBD	Community-Based Distributors
CBFP	Community-Based Family Planning
CDRR	Consumption Data Report and Request
CHC	Combined Hormonal Contraceptive
CHA	Community Health Assistant
CHP	Community Health Promoter
CIN	Cervical Intraepithelial Neoplasm
COC	Combined Oral Contraceptive
CPR	Contraceptive Prevalence Rate
CVA	Cerebral Vascular Accident
CVD	Cardiovascular Disease
CYP	Couple Years of Protection
DFH	Directorate of Family Health
DHIS	District Health Information System
DMPA	Depot Medroxyprogesterone Acetate
DMPA-SC	Depot Medroxyprogesterone Acetate-Subcutaneous
DQA	Data Quality Assessment
DRMNCAH	Division of Reproductive, Maternal, Newborn, Child and Adolescent Health
DTG	Dolutegravir

DVT	Deep Vein Thrombosis
EC	Emergency Contraception
ECN	Enrolled Community Nurse
ECP	Emergency Contraceptive Pill
FAM	Fertility Awareness-Based Method
FCDRR	Facility Consumption Data Report and Request
FEFO	First Expiry First Out
FP	Family Planning
FP2030	Family Planning 2030
FSH	Follicle Stimulating Hormone
FTC	Emtricitabine
HBV	Hepatitis B Virus
HCG	Human Chorionic Gonadotropin
HIPs	High-Impact Practices
HIV	Human Immunodeficiency Virus
H-IUD	Hormonal Intrauterine Device
HRIO	Health Records and Information Officer
HPTs	Health Products and Technologies
IHD	Ischemic Heart Disease
IM	Intramuscular
IPC	Infection Prevention and Control
IUCD	Intrauterine Contraceptive Device
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Authority
KHIS	Kenya Health Information System
KIIs	Key Informant Interviews
LAM	Lactational Amenorrhoea Method
LH	Luteinizing Hormone
LNG-IUD	Levonorgestrel Intrauterine Device
iLMIS	integrated Logistics Management Information System
LMP	Last Menstrual Period
LNG-IUS	Levonorgestrel Intrauterine System
LPV	Lopinavir

MCH	Maternal and Child Health
mCPR	Modern Contraceptive Prevalence Rate
MEC	Medical Eligibility Criteria
MER	Monitoring, Evaluation and Research
MoH	Ministry of Health
NET-EN	Norethisterone Enanthate
NGO	Non-Governmental Organization
NHIF	National Health Insurance Fund
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NOMT	National Order Management Team
NVP	Nevirapine
OPD	Outpatient Department
PAC	Post-Abortion Care
PCN	Primary Care Networks
PE	Pulmonary Embolism
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	Prostate-Specific Antigen
PVR	Progesterone-Releasing Vaginal Ring
RCO	Registered Clinical Officer
RH	Reproductive Health
SC	Subcutaneous
SDGs	Sustainable Development Goals
SDM	Standard Days Method
SDP	Service Delivery Point
SLE	Systemic Lupus Erythematosus
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir

TDM	Two-Day Method
TFR	Total Fertility Rate
UHC	Universal Health Coverage
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 1: INTRODUCTION TO THE 7th EDITION

OVERVIEW OF FAMILY PLANNING IN KENYA

Family Planning (FP) has been recognized as a necessary 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 could have profound socioeconomic implications, in addition to the adverse effects on the health and well-being of families, women and children. These factors include:

- Unmet need for family planning
- Intimate Partner Violence and Gender-Based Violence
- High maternal and neonatal morbidity and mortality

To address this, the Ministry of Health (MoH), with support from partners, aims to eliminate barriers that impede access to and utilization of quality FP information and services. Major obstacles in providing FP services in Kenya include distance to health facilities, cost, religion, culture, myths and misconceptions, provider bias, and legal and medical regulations. These barriers disproportionately affect particular sections of the population, including the youth, unmarried, persons with disabilities, and hard-to-reach groups such as pastoralists, refugees and mobile populations.

The 7th edition of the national FP guideline for healthcare providers was developed against the backdrop of improving reproductive health (RH) indicators. The recent Kenya Demographic and Health Survey (KDHS) indicated an increase in the mCPR among married women from 53% in 2014 to 57% in 2022[(1)] and a decline in the total fertility rate (TFR) from 3.9 births to 3.4 births per woman in the same period [(2)]. The country has also seen a significant decrease in teenage pregnancy, from 18% in 2014 to 15% in 2022. Further success is indicated by a drop in unmet need for family planning, from 18% to 14%, though this remains still high.

Viewed over a longer period, the TFR has declined markedly in Kenya. Between 1989 and 2022, the TFR declined by 3.3 children (from 6.7 to 3.4). Over the same period, the TFR among women in rural areas reduced from 7.1 births to 3.4 births per woman. Among urban women, the TFR declined from 4.5 births to 2.8 births per woman, according to the KDHS 2022.

The 7th edition of the national FP guideline for healthcare providers places emphasis on improving access to quality FP services and expanding the method mix available with FP innovations and health products and

technologies, including the introduction and roll-out of the Hormonal Intra-Uterine Device (H-IUD) and subcutaneous depot-medroxyprogesterone Acetate (DMPA-SC). It seeks to ensure a reduction in missed opportunities, a reduction in unmet need for FP, and increase the number of new FP users to sustain the gains made. It recognizes that sexual and reproductive 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. Emphasizing self-care interventions and approaches to FP, the guideline recognize that all citizens have a right to access, with voluntariness of choice, and the right to utilize available FP methods in line with the Medical Eligibility Criteria (MEC).

A rights-based approach to the provision of contraceptives assumes a holistic view of the client, which includes taking clients' sexual and reproductive health care needs into account and considering all appropriate MEC for FP use in helping clients choose and safely use an FP method. The guideline also provide a guide on adopting other strategies, such as task shifting to increase access to FP services (e.g., Community-Based Family Planning: community pharmacy channel, post-pregnancy FP packages, both postpartum and post-abortion care services integrating FP), services for special population groups (e.g., persons with disabilities, mobile populations, adolescents and youth), integration of FP with other Reproductive Health (RH) services (including HIV and AIDS and screening for cancers of the reproductive organs), new contraceptive methods and male engagement.

All clients seeking FP services should receive comprehensive counselling and management, including information on correct and consistent use, expected side effects, and method failure rate, and receive appropriate referral where necessary.

WHAT IS NEW IN THE 7TH EDITION OF THE FP GUIDELINE?

This edition emphasizes accelerating high-impact practices (HIPs) in FP. Based on the commitments in the FP2030,[3] the programme interventions focus on increasing the mCPR, reducing unmet need for FP and ensuring sustained availability of FP commodities to the last mile. They also seek to enhance the capacity of Human Resources for Health (HRH) to provide FP information and services while paying special attention to under-served, vulnerable and hard-to-reach populations, including those in humanitarian/emergency settings. Reducing pregnancy among adolescent girls, transforming social and gender norms to improve male engagement, improving the availability and utilization of quality FP data for decision-making, and increasing domestic financing for FP commodities to cover 100% of the requirements by 2026 have been highlighted among the key priority areas of the programme.

The DRMNCAH routinely formulates and reviews the guideline when the lapse of an existing document occurs, when emerging issues and innovations become formulated, or when gaps become identified. Government directives or a change in the government mandate can also lead to a review of the guidelines or other policy documents. However, these are not limited reasons leading to the review of guideline or policy. Printed copies of the guideline will be provided by the DRMNCAH or can be accessed through the Department of Family Health website (*www.familyhealth.go.ke*).

FORMAT AND LAYOUT OF THE 7TH EDITION OF THE FP GUIDELINE

The outline of this edition has changed to adopt and incorporate new areas of evidence, such as HIPs in FP. Changes include the following:

- The chapter on the scope of FP service delivery has been divided into 2 chapters (Ch 1: Introduction to the 7th edition; Ch 2: Background and context; Ch 3: Service delivery guideline now contains client assessment in family planning).
- The chapter on Monitoring & Evaluation (M&E) and FP commodity management is now subdivided into two chapters: FP commodity management, and M&E and research.
- The appendices section has been updated in line with the current practices, e.g., with the algorithms for post-pregnancy FP and

balanced counselling strategy plus (BCS+), and Counselling for Continuation (C4C).

WHO MEDICAL ELIGIBILITY CRITERIA (MEC) 2015

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

- Medical Eligibility Criteria for new methods:
    - Subcutaneously administered depot medroxyprogesterone acetate (DMPA-SC)
    - Ulipristal acetate (UPA) as a new method of emergency contraception
    - Progesterone-releasing vaginal ring
- MEC screening has 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.
    - Progestin-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

The following high-impact intervention and innovations have been discussed in this edition of the guideline:

- iLMIS (integrated Logistics Management Information System)
- Self-care in FP
- New products and technologies (hormonal intrauterine device (H-IUD) and DMPA-SC)
- Community family planning through community-based distribution (CBD) and community pharmacy channel
- Social Behaviour Change and Communication (SBCC)
- FP in humanitarian settings
- Last Mile Assurance (LMA)

CHAPTER 2: BACKGROUND

GOAL OF THE GUIDELINE

The overall goal of the guideline is to provide the standards that will guide all healthcare providers delivering comprehensive and quality FP services, aligned with programme priorities to accelerate access in tandem with national commitments.

OBJECTIVES

This guideline aims to:

- Provide health care providers, implementing partners, and county and national MoH health managers with evidence-based information to guide the provision of comprehensive and quality FP services
- Provide up-to-date information on the role description of various cadres in the healthcare system for service provision
- Provide practical guideline to be followed for each FP method service provision

POLICY OVERVIEW AND FRAMEWORK

Several policies and strategies have been developed to support improved demand for and supply of FP information and services, including the Constitution of Kenya (2010), Kenya Health Sector Strategic and Investment Plan (KHSSIP) 2013-17, Kenya Health Policy (2014-2030), Vision 2030, Minimum package for Reproductive Health (RH) / Human Immunodeficiency Virus (HIV) & Acquired Immune Deficiency Syndrome (AIDS) integration services (2012), the National Reproductive Health Policy 2022-2032,[4] and the Sessional Paper 1 of 2023 on the Kenya National Population Policy for Sustainable Development. These legal and policy frameworks advocate for the rights of all individuals to access quality FP information and services.

The KHSSIP recognizes RH (including FP) as an essential priority in the Kenya Essential Package for Health (KEPH). In addition, the community health strategy has been developed and implemented to strengthen the interface between level 1 (the community) and other higher levels of the health care system. The goal of this strategy is to enhance the effectiveness of community health promoters (CHPs), including community-based

distributors (CBDs) under the supervision of community health assistants (CHAs). The Division RMNCAH has developed a training package for utilizing trained pharmacy and pharmaceutical technologists to offer FP services in the private sector. These strategies have provided opportunities to increase access to FP information and services at the community level.

Since the launch of the 6th Edition of Family Planning Guidelines for Service Providers in 2018[5], several important developments have taken place in the reproductive health space in Kenya. Key among these is recognition of the central role of FP in the attainment of national and international goals and commitments, including the Sustainable Development Goals (SDGs) and the FP2030 commitments, and the development of new evidence-based practices. Kenya is a signatory to the SDGs and the eight FP2030[3] commitments that reflect a renewed interest in FP globally and nationally.

FP is linked to a healthy population and development, and to harnessing the demographic dividend (DD). The DD is a temporary opportunity for accelerated economic growth, made possible by a sustained decline in birth and death rates, which leads to an increase in the ratio of the working-age population relative to young dependents. This age structure change can enhance economic productivity, as lower fertility reduces childbearing roles, allowing women to be more economically active. Further impetus for future economic growth is generated through increased household savings and investments, which result from reduced costs for the basic needs of the few. In addition, Kenya is also a signatory of other global and regional agreements and the International Conference on Population and Development (ICPD 25).

GUIDING PRINCIPLES FOR THE FAMILY PLANNING PROGRAMME

FP programmes aim to support individuals to freely decide the number and spacing of their children. These are guided by various principles:

- **Universal access** to FP information and services without discrimination on the basis of religion, age, culture, socioeconomic status and disability
- **Access to quality FP information and services** on a wide variety of FP methods, including the benefits and health risks
- **Rights-based approach and informed choice:**
    - **Promoting male engagement** as responsible partners in increasing access to and utilization of FP services
    - **Multisectoral approach** in the provision of FP services with other state and non-state actors, including within the community
    - **Inclusivity and equitable access** to quality FP information and services

PRIORITY AREAS OF THE FAMILY PLANNING PROGRAMME

The Ministry of Health through DRMNCAH has prioritized the following areas towards universal access to FP services in Kenya:

- Advocacy for FP programming and services
- FP Commodity security that aims to reduce commodity stock-outs (sustainable financing, functional national and regional FP commodity management systems)
- Demand creation through social behaviour change and communication (SBCC) interventions
- Focus on adolescents, youth and vulnerable populations
- Integration of FP services into HIV and other services
- Capacity strengthening for provision of quality FP information and services
- Data management, monitoring & evaluation, and reporting

in FP

- Increased choice by providing expanded FP options including H-IUD and DMPA-SC for self-administration
- Strengthening of the total market approach (TMA) to maximize and expanded access for all clients in need of FP information and services, including those requiring free services and those willing to pay
- Strengthening of community FP strategies, such as community-based distribution through trained CBDs, pharmacists and pharmaceutical technologists
- Participation and input in the pre-service training curriculum of all training institutions (Kenya medical training colleges (KMTCs), medical schools and other private medical training institutions)

CHAPTER 3: SERVICE DELIVERY AND CLIENT ASSESSMENT IN FAMILY PLANNING

ESSENTIALS OF FP SERVICE DELIVERY

Successful delivery of FP services requires effective 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.

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 shall embrace and implement communication strategies that support advocacy for the use of FP services among the communities they serve. These strategies include:

- Enhancing the image of FP service delivery points (SDPs) within the target communities
- Provision of information about specific methods and services—their health benefits, potential side effects and where they can be obtained
- Enhancing community linkage and support systems
- Dispelling myths and misconceptions related to specific FP methods

All healthcare providers, including CHPs, play a role in creating demand for FP services. Providers at all levels shall provide correct information on FP, facilitate client referrals for FP services and follow up clients at the community level where applicable.

ADEQUATE PROVIDER SKILLS

Contraceptives shall be provided by adequately trained and competent providers in accordance with approved method-specific guidelines. Healthcare providers shall provide clients with a wide range of methods (method mix) from which to choose and shall continuously update themselves on new developments on FP methods, skills and services as

well as transferring acquired skills to other healthcare providers through mentorship and on-job training.

In order to ensure the highest quality of FP capacity building, the MoH through DRMNCAH shall be responsible for developing and updating training materials and methods for all cadres in the health system, including nurses, doctors, pharmacists and CHPs.

ADEQUATE FP HEALTH PRODUCTS AND TECHNOLOGIES

Family planning health products and technologies (FPHPTs) are essential for quality FP service provision, as per the National FP Standards for Healthcare Facilities, Kenya, 2021.[6] The health departments shall ensure efficient institution and management of the integrated Logistics Management Information System (iLMIS) for FPHPTs to promote quality FP service provision, be gender sensitive and disability friendly.[7]

EFFECTIVE LINKAGES, FOLLOW-UP AND REFERRAL

All clients who choose an FP method shall be informed of the appropriate follow-up requirements and encouraged to return to the healthcare provider if they have any concerns or experience adverse effects. (Refer to the National Referral Guidelines for more information[8].)

ADDRESSING FINANCIAL BARRIERS

Healthcare providers shall consider cost implications to the client during provision of FP services. The costs to the client include transport costs, direct cost of services and cost of the contraceptive commodity.

HUMAN RESOURCES FOR FP SERVICES

Family planning services at all levels shall be provided by trained health care providers. FP service provision by cadre is detailed in **Table 3.1** below.

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

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	Registered Medical Doctors can provide a full range of services related to the above									
Nurse Midwife	Registered Nurse/Midwife can provide a full range of services related to the above									Counsel Refer
Clinical Officer	Registered Clinical Officers can provide a full range of services related to the above									Counsel clients & refer. RH Trained RCOs can offer methods
CBDs	Counsel Provide*	Counsel Provide *	Counsel Support Provide Refer*	Counsel Provide Refer*	Counsel Provide Refer*	Counsel Refer	Counsel Refer	Counsel Provide Refer	Counsel Refer	Refer
CHAs	CHAs provide an interface between CHPs and SDPs									
Pharmacists and Pharmaceutical technologists	Counsel Provide*	Counsel Provide *	Counsel*	Counsel Provide*	Counsel Dispense Provide*	Counsel Refer	Counsel Refer	Refer	Counsel Refer	Counsel Refer

*Only if specifically trained to do so

COMMUNITY-BASED Family planning

Community-based FP (CBFP) entails the process of providing FP 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. Currently in Kenya, DRMNCAH at the MoH has approved administration of injectable contraceptives by CBDs in 14 counties namely: Baringo, Garissa, Mandera, Marsabit, Narok, Samburu, Tana River, Turkana, Wajir, West Pokot, Kajiado, Kilifi, Isiolo, and Tharaka Nithi.

CBFP may be provided by trained healthcare providers including pharmacists and pharmaceutical technologists and CHPs as long as they have been trained and certified as competent by the MoH based on the community health training curriculum (refer to Table 3.1 above on Provision of FP methods by different categories of service providers).

INTEGRATION OF FP SERVICES

Healthcare facilities shall put measures in place to ensure the integration of FP with other services, including in maternal child health clinics, nutrition, comprehensive care clinics (CCC), STI clinics, youth-friendly clinics, gynecology clinics and post-rape care clinics.

The RH/FP, immunization and HIV programmes are potential spaces and common places for reaching 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 reproductive tract cancer prevention, care, and treatment services. This can be done while helping to ensure the dignity and safety of all women.

Family Planning Integration Models

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:*** Integrated FP services are offered by one healthcare provider alongside other health services in the same room (e.g., FP services offered while the woman receives immunization services); or integrated FP services are offered by more than one service provider within one facility (e.g., FP services in MCH, OPD or maternity).
- ***Off-Site:*** Integrated FP services are offered outside the facility through a facilitated referral.
- ***Mixed Approach:*** Integrated FP services are initiated in one facility but the rest of the services are provided in another facility where all the skills, commodities or equipment are available.

For various levels of the health sector, references shall 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** below.

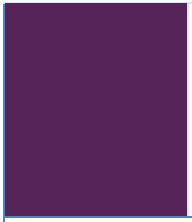
Table 3.2 **Integration of FP services into other health areas**

Area of FP Integration**	Benefits of integration	FP counselling	FP service provision	Referral information
Comprehensive care clinics (CCC)	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 behaviour • Protective benefits of male and female condoms • Dual protection	Offer FP services on site. Encourage the use of barrier methods, such 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	FP services that promote healthy timing and spacing of pregnancies are important in reducing the risk of adverse pregnancy outcomes, such as low birth weight, preterm birth and infant mortality.	Counselling mother on FP methods close to delivery and linking to service provision.	None offered.	Link/refer the counselled mother to health facility that offers FP services.

Area of FP Integration**	Benefits of integration	FP counselling	FP service provision	Referral information
Mother and Child clinics	FP services should be integrated into mother and child clinics that offer immunization services, growth monitoring and nutrition and child welfare. This provides the opportunity to address missed opportunities and follow up of FP clients after delivery. It is convenient and cost effective for mothers.	Counselling 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)	Postpartum women have a high unmet need for FP. Some may not have attended an antenatal clinic hence they may have missed out on FP information. Offering postpartum FP (PPFP) can increase uptake of FP.	Counselling 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, Progestin-Only Pills (POPs), and Bilateral Tubal Ligation (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 counselling	FP service provision	Referral information
Post-Abortion Care	FP 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 anaemia, low birth weight, etc.).	Counselling 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 counselled on FP services during antenatal care (ANC) are more likely to take up FP services after delivery.	Counselling antenatal mothers on FP methods and linking to service provision.	None offered.	Linking counselled mother to health facility that offers FP services.

Area of FP Integration**	Benefits of integration	FP counselling	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.
Theatre (Major/Mino r)	Postpartum women have high unmet need for family planning. Some may not have attended an antenatal clinic hence they may have missed out on FP information. Offer PPFP. Vasectomy takes care of missed opportunities in men.	Counselling 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 and BTL. Vasectomy and BTL can be provided anytime as per the MEC wheel.	Refer to FP clinic / health facility if method is not initiated
Community based distribution and integrated outreach programmes	Community-based distribution for FP increases access to FP services at the community level. It is also cost effective and convenient to clients.	Counselling 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-	Refer client to the link facility for other methods and follow up. Refer clients for initiation of injectables at health facility.

			to-reach areas)	
****All other service areas within the facility, e.g., in-patient, OPD, pharmacy, should offer FP counselling and referral services.**				

FAMILY PLANNING SERVICES FOR SPECIAL GROUPS

Family planning healthcare 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 healthcare providers include adolescents and youth, persons with disabilities, mobile populations and persons living in informal settlements and humanitarian settings.

FP Services for Adolescents and Youth

Adolescents (persons aged 10 to 19 years) constitute 24.5% of Kenya's population according to the population census of 2019.[9] According to KDHS 2022[1], teenage pregnancy currently stands at 15%. Youth (18–34 years) constitutes 29% of Kenya's population.

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.

Special attention shall be paid to adolescents and youth, including first time young mothers, as when addressing their contraceptive needs. The MoH through DRMNCAH recommends universal access to age-appropriate information and services for all adolescents and young people.

Healthcare providers, as guided by the existing legal frameworks,[10] shall provide adolescent and youth-friendly services that are equitable, accessible, acceptable, appropriate and effective, as detailed in **Table 3.3**.

Table 3.3 **Principles for the provision of adolescent and youth-responsive services**

Principle	Explanation
Equitable	All adolescents and youth, including those living with HIV or disabilities, or in emergency, resource constrained and humanitarian situations, should receive the full range of SRH information and services they need.
	Healthcare providers should provide 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 shall be made obtainable during convenient hours, including after school or work and during weekends and holidays, where applicable.
	• The (static, mobile, community) facility shall be conveniently located such that it is easy to find and comfortable to access.
	• 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.
	Adolescents and youth should be able to consult with healthcare 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.
	• The contraceptives shall meet the widest possible range of individual adolescent and youth health needs.

Effective	• 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 adolescent and youth health needs.

Adolescents and youth in need of contraceptive services can safely use any method that follows the guideline and MEC criteria.

- Permanent methods, such as tubal ligation and vasectomy shall be discouraged for adolescents and youth without children.
- Any adolescent and youth who requests emergency contraception shall receive counselling on all methods of FP.
- Adolescents may be less tolerant of side effects. Healthcare providers shall explain the possible side effects during counselling in order to reduce the risk of discontinuation and seek alternative methods if the side effects persist.
- Adolescents and youth shall be sensitized on the use of 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.
- Adolescents below 18 years shall provide assent and their guardian shall provide consent for FP services.

Persons with disabilities

In Kenya, 2.5% of women and 1.9% of men (2019 census) in the population live with some form of disability. Persons with disabilities encounter discriminatory practices and stigma within society as well as within health facilities. All discrimination constitutes a denial of human rights. According to the United Nations Convention on the Rights of Persons with Disabilities,[(11)] persons with disabilities need to have access, on an equal basis with others, to all forms of sexual and reproductive health care.

To effectively address the FP needs of persons with disabilities, healthcare providers shall:

- Ensure women and men living with disabilities have access to

counselling and education on sexuality and access to FP methods of choice

- Be familiar with the special needs of persons with disabilities 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 the guardian or caregivers.

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

Persons with disabilities shall provide 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 healthcare provider shall consult with the guardian or caregiver. Longer acting FP methods are preferred to permanent methods for such clients.

Mobile Populations

Mobile populations comprise people who have moved out of their permanent residences for a variety of reasons, including conflict and natural disasters (floods, earthquakes) or for reasons of livelihood (e.g., pastoralists or to seek natural resources). Migrants and mobile populations face many obstacles in accessing essential healthcare 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 operating hours. Such disparities impact the well-being of mobile populations.

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

Healthcare providers delivering services to mobile populations shall adhere to the following specific guidelines:

- Provide confidential counselling services that ensure auditory and visual privacy
- Offer counselling on dual protection, particularly important for persons living in IDP or refugee camps
- Provide contraceptive methods according to the MEC
- Recognize that some clients may be new users of FP while others may require a continuation of services (e.g., management of missed doses
- Ensure survivors of sexual violence receive prompt medical attention, which may include emergency contraception and post-exposure prophylaxis. The client should receive referrals for other methods as necessary.

FP Services for People Living with HIV/AIDS

People living with HIV and AIDS (PLWHA) have just as much need for FP services as non-infected persons.

FP healthcare providers shall ensure that safe and effective contraception is accessible to HIV-positive persons in order to help PLWHAs not only plan their future childbearing but also reduce the likelihood of HIV maternal to child transmission. FP is a core intervention for the prevention of mother-to-child transmission (PMTCT).

Healthcare providers shall refer to the particular sections in this FP guideline for eligibility criteria for use of different methods by persons living with HIV and AIDS.

MALE ENGAGEMENT IN FP

Evidence suggests that men's active participation in decisions about FP and reproductive health promotes better health for families. Traditionally, efforts to improve information, counselling and access to FP and reproductive health have been focused primarily on women. It is, however, becoming evident that offering counselling 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, the desired number of children and spacing of births. If they lack accurate information on FP, they may not utilize FP services or support their spouses in doing so. This may lead to reproductive coercion (RC) or intimate partner violence (IPV).
- Involving men can lead to better health outcomes, including those specific to family planning knowledge, sustained contraceptive use and elimination of RC/IPV.
- 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:

- Demystify myths and misconceptions
- Enlighten men on male-specific FP methods such as male condoms and vasectomy
- Address women's fear regarding male engagement in FP
- Utilize platforms like community-based forums, social forums and digital space to share FP 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
- Involve male political and opinion leaders to act as role models
- Utilize male health workers to reach other men as role models
- Scale up family clinics and organize FP outreaches that target males at appropriate places e.g., places of work
- Strengthen the integration of services that are beneficial to men in the FP package (e.g., prostate cancer screening, male circumcision)

FAMILY PLANNING FOR PERIMENOPAUSAL WOMEN

Women reach menopause when the ovaries stop releasing eggs (ovulating). A woman is no longer considered fertile once she has had 12 consecutive months of amenorrhoea (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 age 50 and around 96% by age 55.

The term **perimenopause** describes the period around menopause, normally about three to five years before actual menopause sets in. Even though menses may become irregular in some women, 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 FP for Menopausal Women

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 that these women shall continue using an FP method for 12 months after the last menses.

Hormonal methods affect menses, making it difficult to know if women using hormonal contraception have reached menopause.

- After stopping a hormonal method, a woman shall use non-hormonal contraceptives for some time.
- There will be no need to use contraception once there have been no menses for 12 consecutive months.
- Copper-bearing IUDs can be left in place until after menopause and shall be removed 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. Due to advanced age, older men and women are more likely to have conditions that require delay, referral or caution for voluntary surgical sterilization (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 may not be ideal for this group of women due to lack of irregular cycles just before menopause.

DISCONTINUATION OF CONTRACEPTION

According to KDHS 2014,[2] 31% of women-FP 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:

- The wish to become pregnant
- Can no longer become pregnant (menopausal, medical conditions, surgical procedures like hysterectomy)
- Not currently sexually active
- Discontinuation or switch due to side effects

Healthcare 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 unintended pregnancies. They should also document the reasons for discontinuation.

RETURN TO FERTILITY AFTER CONTRACEPTION

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

In cases of prolonged delay in the return to fertility, underlying causes of female sub-fertility or infertility may need to be considered, such as tubal disease, ovulatory dysfunction, decreased ovarian reserve or uterine factors.

QUALITY OF CARE IN FAMILY PLANNING SERVICE PROVISION

The Kenya Quality Model for Health (KQMH, 2018)[12] recommends improved quality of health service provision for all Kenyans at all levels of care in the Kenya Essential Package for Health (KEPH). 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 family planning SDPs). These teams should regularly analyze performance gaps, develop interventions to bridge the gaps, learn

from interventions, and 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 FP services shall have systems of conducting quality improvement, designed to review and strengthen the quality of services on an ongoing basis. The following dimensions/aspects of quality of care are key for family planning services: (Refer to the National FP Standards for Healthcare Facilities in Kenya, 2021[6]

- **Timeliness**: Client appointments completed on time
- **Completeness**: Client needs are met
- **Courtesy**: Appropriate handling of clients by all staff
- **Consistency**: Same level of service for all customers
- **Accessibility & Convenience**: Ease of obtaining service
- **Accuracy:** Performed correctly every time
- **Responsiveness**: Sensitive response to needs of clients

The "Clients' Rights and Staff's Needs" framework is applicable to service delivery. **Table 3.4** summarizes details of client rights and provider needs.

Table 3.4 **Client rights and provider needs**

Component	Explanation
Client's rights	
Information	Healthcare providers shall 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 shall be clean, well-organized and well stocked with quality contraceptives. Clients shall not have long waiting times and shall be able to obtain the contraceptive of their choice or be referred to where they can be offered.
Informed Choice	Clients shall be counselled on the range of contraceptive options and methods that are available at all levels of care, and shall be provided with accurate and complete information to enable them to make an informed decision.
Safety of Services	Healthcare providers shall adhere to infection-prevention practices and client instructions for effective use of the contraceptive method.
Privacy and Confidentiality	Care shall be individualized and discrete. Clients shall be provided with both auditory and visual privacy. Client records shall be protected from anyone who is not directly involved in the client's care.
Dignity, Comfort, Expression of Opinion	Clients shall be treated with dignity and friendliness. Precautions shall be taken to ensure minimal discomfort. Clients' opinions shall 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. For continuity of care, the client's 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 mentorship and joint problem-solving. The system

	shall assist staff to provide the best possible FP services.
Information, Training and Development	Staff shall be competent when providing FP services, and have ongoing opportunities for training to update and maintain a high level of performance.
Supplies, Equipment and Infrastructure	SDPs shall have sufficient and appropriate supplies, instruments, and logistics infrastructure to ensure sustained FP services and the safety of healthcare providers.

FP COUNSELLING AND INFORMED CHOICE

Family Planning Counselling

Counselling is a vital part of FP service provision and should be a part of every interaction with the client. When discussing contraceptive options with clients, healthcare providers shall briefly review all available methods of FP. The role of FP counselling is to help clients choose the FP method that best suits them and to support clients in solving any problems that could arise during the selection, use or discontinuation of the chosen method.
Kenya has adopted the Balanced Counselling Strategy Plus (BCS+), as one of the practical, interactive and client-friendly counselling approach that uses job aids to facilitate FP consultation. BCS+ has 4 key stages: pre-choice, method choice, post-choice and systematic screening for other services. The BCS plus is a toolkit that provides information and materials that healthcare providers need to offer complete, high-quality family planning counselling to clients (refer to **appendix 14.7**).

Counseling For Continuation (c4c)

Counseling for Continuation (C4C) is an evidence-based, client centered approach to contraceptive counseling, that supports clients to decide which method is right for them. By addressing many of the root causes of unmet need for contraception and discontinuation, C4C aims to improve how providers and clients interact during a counseling session. The approach comprises the use of the *Choice Book for Providers*, which is a job aid and visual tool for health care providers (refer to the choice book for providers flip chart).

Features of Counseling for Continuation

C4C places the client at the center: C4C recognizes that clients are the experts on their own lives and experiences, and their needs and preferences should guide family planning decisions. This approach fosters respect, improves the quality of care, and strengthens multiple indicators of person-centered outcomes.

C4C is rooted in informed choice: Informed choice is essential in family planning, and information must be communicated in a way that resonates with clients. The C4C approach empowers clients with relevant information, addresses their concerns, and enhances their confidence in making decisions.

C4C facilitates collaborative dialogue between client and provider: C4C employs the concept of shared decision-making in its counselling approach. The C4C approach helps providers to solicit important input from the client on information that they are uniquely placed to provide: their past experiences with FP, information about their lifestyles, and which contraceptive's benefits are most attractive to them.

C4C aims to enable clients to find a method that satisfies them, allowing them to continue using their method of choice: C4C improves the counselling experience and supports clients to choose the method that is right for them. When clients are in control of their contraceptive decisions, they can choose methods that suit their lifestyle, leaving them satisfied with their choice to continue using their method of choice.

Steps in Counselling for Continuation

Greet	Establish warm cordial relationship: Hi, my name is__, what's your name? Everything you tell me is confidential.

Ask	How can I help you with today? Tell me about your past experience with contraception. **(Say less and listen more by starting the conversation with the client, not with the methods)** Tell me about your concerns **(Ask questions about preferences and needs using the matrix page, to begin to understand the benefits of the method that are perhaps most important to the client).** What do you like about this method? (If s/he has a method in mind)
Tell	Period changes are NORMAL. **(Use the messages in the NORMAL tool and the bleeding profile page to inform the client of the changes in bleeding caused by hormonal contraceptives).** Tell the client which 2-3 methods meet the most of his/her stated need or confirm the method in mind meets his/her needs**. (After listening to the client's preferences and needs, reduce information overload by narrowing down to 2 or 3 contraceptive options using the Counselling Matrix. Use the method-specific pages in the *Choice Book for Providers* to examine each potential choice in depth using the medical eligibility criteria).**
Help	Help compare the differences between the top 2-3 methods, if applicable. Refer to the medical eligibility criteria for chosen method. Let the client decide which method is right for him/her.
Explain	Explain the 3 Ws of his/her chosen method and have him/her repeat them (Ask clients to repeat the most important information (**3Ws i.e. What to do to use the method correctly, What to expect with their method and When to come back to the clinic)** to promote information retention. To reduce information overload, use the pages in the **C*hoice Book for Providers*** (See annex XX) devoted to specific methods). Make a plan together on how to use and what to do if side effects occur. **(Prepare a plan for side effects management and when to return, so that the client is fully informed of his/her choice and prepared to use the chosen method effectively).**

Return	Come back anytime if you have questions.

The Counseling Matrix

- The matrix gives an overview of the detailed comparison pages.
- Based on the client's needs, use it to narrow down to methods the client is eligible for.
- Compares methods based on benefits.
- Should be used to narrow methods based on desired benefits to focus on the details of 2-3 contraceptive options.

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 satisfaction with family planning methods and services
- Enhance continuation of family planning services
- Dispel rumors and misconceptions about contraceptive methods
- Screen for and address IPV/RC

Healthcare providers shall be aware of a number of factors about each client that could be important when selecting a method. The 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 based on options, information and understanding of different FP methods. Quality counselling is a crucial way healthcare providers support and safeguard the client's rights to informed and voluntary decision-making. That is, not pressuring clients to choose one FP method over the other or limiting clients' choices for reasons other than medical eligibility.

Enabling clients to make informed choices is key to good quality FP services. To make informed choices, clients need to know about FP, have access to a range of methods, and 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 voluntarily.
- 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.

- People are encouraged 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 an assent for services to be offered. For surgical methods, written consent is required (refer to Appendix 14.3**: Informed and voluntary consent for surgical contraception**).

INFECTION PREVENTION AND CONTROL (IPC)

Infection prevention addresses the spread of infections within the health care setting: client to client, client to staff, staff to client, and among staff.

Procedures to prevent infection are simple, effective and inexpensive. IPC should be observed before, during and after every procedure in the provision of all FP services according to National Infection Prevention and Control Guidelines for Health Care Services in Kenya.[13]

Universal Precautions

These are a simple set of effective practices designed to protect healthcare providers/workers and patients from infection by a range of pathogens. This helps break the disease-transmission cycle at the mode of transmission step. The practices are used when caring for all clients regardless of diagnosis. These include:

- Hand washing
- Wearing protective gear (e.g., gloves)
- Safe use and disposal of needles and sharps
- Instrument/equipment and devices processing according to current IPC guidelines

- Housekeeping
- Prompt clean-up of blood and body fluid spills
- Waste management

CLIENT ASSESSMENT IN FAMILY PLANNING

THE PURPOSE OF CLIENT ASSESSMENT

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

- Any conditions that affect their eligibility to start or continue using a particular family planning method
- Any special problems that require further assessment, treatment or regular follow-up

This serves as a baseline for subsequent client-provider interactions.

PROCESS OF CLIENT ASSESSMENT

History taking

Taking a medical history is important for gathering basic information that will help the healthcare provider, and the client discuss family planning method options. This can be done in a relaxed and friendly manner that puts the client at ease. Relevant information includes:

- Age of client, lifestyle
- 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
- Sexual History (the '5 Ps': Partners, Practices, Protection, Past History of STIs, Pregnancy Intention).
- History of chronic illnesses (such as heart disease, diabetes mellitus, hypertension, liver/jaundice problem, kidney/renal disease, cervical/breast cancer)
- Smoking status
- Client experience of current FP method (in case of subsequent visit—include partner's view if possible)
- Last pregnancy
- Partner support and male involvement in FP

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 the client is comfortable; ensure auditory and visual privacy and gather all equipment to be used. Request client consent before the procedure.

During physical examination:

- Observe the client for gait, physical appearance and health status
- Check vital signs as required
- Conduct full examination (head to toe), especially for new FP clients or as guided by the client's history
- Perform a breast examination; teach client self-breast examination (SBE)
- 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. FP healthcare providers shall therefore endeavour to offer women as many services as possible through the FP clinics, including counselling, health screening examinations or tests, and referrals as appropriate. Persons with known medical conditions, or persons in whom medical conditions are detected, shall be handled as per the Medical Eligibility Criteria (MEC).

Where resources are limited, healthcare providers shall use the following classifications to prioritize examinations and tests:

- **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. 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.

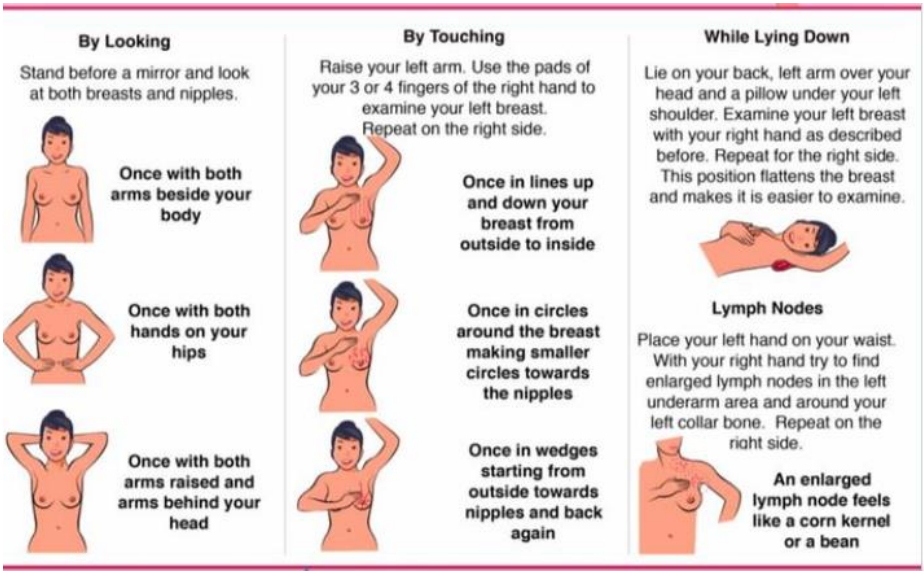
Specific Examinations or Tests

Specific examinations and tests that the provider shall 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

Figure 3.1 **Self-Breast Examination**



Lower Abdominal Examination

- Perform abdominal examination to rule out any abnormalities e.g., abdominal masses.
- **Inspect the abdomen for abnormal colouring, scars, stretch marks** or rashes.
- Palpate all areas of the abdomen using light pressure and then palpate the abdomen using deeper pressure to rule out splenomegaly and hepatomegaly
- Identify any tender areas and check for rebound tenderness.

Examine the lower limbs to rule out:

- Varicosity
- Tenderness of calf muscles
- Oedema
- Other abnormalities

Give the client feedback on the findings and inform them of the next steps.

Provide the client with the method of choice.

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 14.4**):

- Had a baby less than six months ago, is exclusively breastfeeding, and has not resumed menses since then.
- 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 of 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

FP healthcare 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 behaviours
- 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,[16] including contact tracing.
- Know where to refer clients who require a higher level of care
- Ensure clients are counselled on dual protection

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 THE REPRODUCTIVE SYSTEM

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. FP services offer an opportunity to screen clients for early detection of both cervical and breast cancers, as these 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 cancers 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 into the counselling 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 3.5** shows the types of services that can be provided at the various levels of the health care system in Kenya.

Table 3.5 **Screening for reproductive organ cancers in clients seeking FP services**

Cancer type	Health Facility Levels			
	Level 2 (Dispensary, Clinic)	**Level 3** (Health Centre, Nursing Home)	**Level 4** (Sub County Hospital)	**Level 5** (County Hospital and above)
Cervix	VIA/VILI; Refer if positive	VIA/VILI; Refer if positive	VIA/VILI; Pap smear; RNA/DNA HPV testing; biopsy; Treat/Refer if positive	VIA/VILI; RNA/DNA HPV testing, 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 conditions (diabetes, hypertension). The latest Edition (5th Edition) of the WHO MEC[14] was updated in 2015 and the new recommendations have been adopted and incorporated in the present guideline. Kenya adapted and localized the MEC in 2016 and incorporated the standards of FP service provision in line with WHO 2015 MEC.

Objective of the 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 accessing 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 judgment is adequate, use the method with care - close follow-up might be required in some cases; but where clinical judgment 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 judgment is adequate, help the client choose an alternative method OR use the method with extreme care (ensure access to continuous clinical services). Where clinical judgment 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 3.6 shows the adaptation of the WHO MEC categories for use in the Kenyan setting.

Table 3.6 **Summary table for MEC in relation to clinical judgment**

Recommendation			
WHO Category	**Description**	**Where clinical Judgment is possible**	**Where clinical judgment is NOT possible (e.g., Tier 1, CHP)**
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 outweigh the advantages of using the method	Generally, advise suitable alternative. Method may be used only if no others are available or acceptable to the client and careful follow-up can be assured.	Do not use the method. Refer 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 (VSC) (Bilateral Tubal Ligation (BTL) and Vasectomy)

There is no medical condition that is contraindicated for 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 3.7 shows the MEC criteria for VSC.

Table 3.7 **MEC Categories for surgical contraception methods**

WHO Category	Explanation
Accept (Category A)	No medical reason prevents performing the procedure in a routine setting
Caution (Category C)	The procedure can be performed in a routine setting, but with extra preparation and precautions
Delay (Category D)	Delay the procedure. Underlying condition must be treated and resolved before the procedure can be performed. Provide an alternative temporary method 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) anaesthesia and specialist medical support. Otherwise refer. Provide alternative temporary methods in the meantime.

MEC CRITERIA FOR FERTILITY AWARENESS-BASED METHODS (FAM)

There are no known medical contraindications indicated for FAMs. In general, these methods can be provided without concern for health effects to clients who choose to use FAM. However, there are a number of conditions that make use of these methods more complex (see **Table 3.8**).

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 3.8 **MEC categories for fertility awareness-based methods**

Category	Explanation
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.

CHAPTER 4: HORMONAL CONTRACEPTIVE METHODS

HORMONAL CONTRACEPTIVE METHODS

Hormonal contraceptives are among the most widely used FP methods worldwide. According to the KDHS 2022, 47% of married and 35% of unmarried women using modern contraceptives choose hormonal methods, with 20% of married and 16% of unmarried women choosing injectable contraceptives.[15],[1]

Hormonal contraceptives contain synthetic hormones (i.e., a combination of oestrogen and progestin, or progestin alone), which work primarily by preventing ovulation and thickening the cervical mucus, making sperm movement difficult. Hormonal contraceptives can be administered as oral pills, injectables (intramuscular or subcutaneous), implants, skin patches, hormone-releasing intrauterine systems or vaginal rings. Hormonal contraceptives are highly effective if used correctly, and are safe and convenient. The use of hormonal contraceptives is known to cause bleeding changes that are known to often contribute to discontinuation or non-use of contraception. The Normal Counselling Tool for Menstrual Bleeding Changes was developed to guide healthcare providers to counsel FP clients on bleeding changes[16].

The following hormonal methods are commonly available in Kenya:

- Combined oral contraceptives (COCs)
- Progestin-only contraceptive pills (POPs)
- Progestin-only injectable contraceptives (DMPA IM, DMPA-SC)
- Progestin-only contraceptive implants
- Hormone-releasing intrauterine systems (LNG-IUD)[17]
- Dedicated products for emergency contraception

Other hormonal contraceptives less commonly available in Kenya:

- Combined injectable contraceptives (see injectable contraceptives below)
- Combined contraceptive skin patch
- Vaginal contraceptive rings, including combined hormonal rings

COMBINED ORAL CONTRACEPTIVE (COCs) PILLS

Combined Oral Contraceptives (COCs) are pills that contain synthetic oestrogen 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 oestrogen hormone in COCs has decreased to lower and safer levels, which has decreased the occurrence of side effects. High-dose COCs are now defined as those containing 50 micrograms or more of oestrogen, while low dose pills contain 30-35 micrograms of oestrogen. The ultra-low dose COCs contain 20 micrograms of ethinyl estradiol. Low-dose pills are the most commonly available COCs in Kenya.

Key messages

- *Take one pill daily at the same time*
- *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.

MODE OF ACTION

- Works primarily by preventing the release of ovum from the ovaries (suppresses ovulation)
- Thickens the cervical mucus thus interfering with sperm movement

EFFECTIVENESS

Effectiveness depends on the use. COCs are 99.7% effective in preventing pregnancy if used correctly and consistently. The 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. In addition, COCs do **NOT** disrupt an existing pregnancy.

COCs 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
- Safe for the majority of women

Non-contraceptive health benefits

- Reduction of menstrual flow (lighter, shorter periods)
- Decrease in dysmenorrhoea (painful periods)
- Reduction of symptoms of endometriosis and polycystic 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

COCs LIMITATIONS

- COCs must be taken daily to be effective, preferably at the same time each day.
- Effectiveness may be lowered if the 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 diarrhoea.
- COCs do not offer protection against STIs, including hepatitis B and HIV. Therefore, at-risk individuals should use condoms to ensure protection against STIs.
- COCs 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
- Amenorrhoea (some women see amenorrhoea 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

MEC Category 1 – Able to use COCs

- 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 dysmenorrhoea
- 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, trichomonas vaginitis, bacterial vaginosis
- HIV
- Antiretroviral drugs
    - NRTIs: Abacavir (ABC), Tenofovir (TDF), Zidovudine (AZT), Lamivudine (3TC), 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 thalassemia
- Antibiotics
- Antifungals
- Antiparasitic

MEC Category 2 – Use with caution

The conditions and circumstances in **Table 4.1** are discussed according to scenarios of whether or not clinical judgment is possible.

Table 4.1 **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., CHP with CBD training)
Age 40 years or more initiate method	Age by itself does not restrict use of any method	Initiate and resupply 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.
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. Resupply as needed.
History of high blood pressure in pregnancy with	Generally, use the method and recommend follow-up	Initiate the method and follow up

normal current blood pressure		
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/m2 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. Resupply 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 for women on medical treatment for this disease, who fall under Category 3).	May initiate and resupply 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 under Category 1; women with breast cancer fall under Category 4 and discontinue.	Refer for evaluation before initiating method
Women with sickle cell disease	Initiate method and advise regular follow-up	Initiate method and refer for evaluation as soon as possible. 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). (Also note women over 35 years of age and who smoke are under Category 3 and 4)	Initiate method and refer for evaluation as soon as possible. May resupply 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. Resupply 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. Resupply 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.

Women with liver tumour	If a woman is known to have focal nodular hyperplasia, initiate method. If the type of liver tumour is not known, evaluate or refer for evaluation prior to initiation of method. (Women with liver tumours other than focal nodular hyperplasia are classified as Category 4.)	Refer for evaluation before initiating method
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. Resupply as needed.

MEC Category 3 and 4 - Women who should not use COCs

This section outlines circumstances that would entirely 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 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 4.2 **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 ischemic 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 to 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, but 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 current or history of breast cancer	4
Women with symptomatic gallbladder disease, including those on medical treatment (who have not undergone cholecystectomy)	3
Women with current or history of DVT or pulmonary embolism (PE), acute DVT/PE, DVT/PE and on anticoagulant therapy or known thrombogenic mutations	4
Women who have had major surgery with prolonged immobilization	4
Women with SLE and positive (or unknown status) 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, Oxcarbazepine 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 backup 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. The use of a backup method is required for the first 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 previous method was 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 more than 5 days after the start of her monthly bleeding, she can start COCs any time if it is reasonably certain she is not pregnant. She will need a backup (additional) contraceptive method for the first 7 days of taking pills.

- Switching from an IUCD (including a hormone-releasing IUCD)
    - Start at any time if certain she is not pregnant
    - Start within 5 days of menstrual bleeding and remove the IUCD at the same
    - If starting COC after 5 days of menstrual bleeding, remove the IUCD at 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

Healthcare providers shall 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 4.3 describes how to manage some of the common side effects a client may encounter while using COCs.

Table 4.3 **Side effects and management of 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 Distributors (CBDs) should be instructed to refer all clients with side effects to a health facility for further evaluation, advice and management by a trained healthcare provider.

What to do in case of missed doses

For greatest effectiveness, a woman must take one pill daily preferably at the same time 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 pills are provided in **Table 4.4.**

Table 4.4 **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 second 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 non-hormonal 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 in 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 diarrhoea 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 resupply 3 cycles. Counselling by the non-clinical provider should be given to the client to ensure that all drugs are kept in safe custody and that all unused pills are to be returned to the provider if she changes to another method. All clients should be encouraged to attend a clinic for any problems or concerns.

Providers should ensure that any unused pills returned by clients are disposed of correctly to avoid reissue to other clients.

PROGESTIN-ONLY PILLS (POPS)

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 oestrogen; hence clients do not experience the side effects associated with oestrogen.

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

TYPES OF POPS

There are several brands of POPs available in Kenya. All contain the same dose of the active ingredient Levonorgestrel.

MODE OF ACTION

- Thickens cervical mucus, thus interfering with sperm movement
- Suppresses 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

- Fewer side effects such as acne and weight changes
- Taking POPs does not increase risk of blood clotting
- May prevent endometrial cancer
- May help to prevent anaemia

LIMITATIONS AND SIDE EFFECTS OF POPS

Limitations

- POPs provide a slightly lower level of contraceptive protection than COCs
- Requires strict daily pill-taking, preferably at the same time each day
- Do not protect against STIs, including hepatitis B and HIV/ AIDS. At-risk individuals should therefore use a barrier method to ensure protection against STIs and HIV/AIDS.
- Effectiveness may decrease if clients are also taking other medications (anti-TB drugs, anticonvulsants and antiretroviral), so a backup method should also be used
- POPs are less effective in women who are not breastfeeding

Side effects

- Irregular spotting or bleeding, frequent or infrequent bleeding, prolonged bleeding, amenorrhoea (less common). Bleeding changes are common, but not harmful.
- Headaches, dizziness, nausea
- Mood changes
- Breast tenderness (although less common than with COCs)

ELIGIBILITY CRITERIA

MEC Category 1 – Able to use POPs

- Women of any parity (parous and nulliparous)
- Women of any age
- Postpartum:
    - Breastfeeding women 6 weeks after childbirth and up to 6 months
- Previous pelvic surgery
- Post-abortion, miscarriage or ectopic pregnancy
- 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 Vein Thrombosis (DVT) / Pulmonary Edema (PE)
    - Family history of DVT/PE
    - Major or minor surgery without immobilization
- Varicose veins, superficial venous thrombosis (SVT)
- Valvular heart disease (complicated or uncomplicated)
- Headache
    - Non-migraine (mild or severe)
    - Migraine headache without aura

- Depressive disorders (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, trichomonas 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
- Antiparasitic

MEC Category 2 – Use with caution

The conditions and circumstances in **Table 4.5** are discussed according to scenarios of whether or not clinical judgment is possible.

Table 4.5 **Conditions and circumstances that require extra caution when taking POPS**

Client's Condition / Circumstance	Suggested Action	
	Where clinical judgement is possible	Where clinical judgement is not possible or is limited (e.g., CHP with CBD training)
History of ectopic pregnancy	Method can be used, but advise clients to report to the clinic without delay if developing any symptoms suggestive of ectopic pregnancy	Can initiate and resupply method but refer for evaluation any client with abdominal pain
Currently receiving ARV treatment	Method can be used unless ritonavir or ritonavir-boosted Protease Inhibitors (PIs) are used. For all other regimens, advise condom use, which prevents HIV transmission and compensates for any possible reduction in effectiveness.	Initiate and refer for review as soon as possible. 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 regimen, 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. Resupply as needed.
History of DVT and pulmonary embolism, or prolonged post-op immobilization	Method can be initiated. Ensure regular follow-up at clinic.	CBD should initiate method, but refer for evaluation from time to time. Resupply 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. Resupply as needed.
At risk for cardiovascular disease: current or history of ischemic 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). Resupply 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 under Category 1; women with breast cancer fall under	Refer for evaluation before initiating method.

	Category 4 and POPs should be discontinued.	
Diagnosis of SLE with or without severe thrombocytopenia or receiving immunosuppressive therapy	Method can be used (unless client has 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 entirely prohibit a woman from using POPs (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, the 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, client 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 amenorrohea requests 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 if 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, the client 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 healthcare providers. **Table 4.6** describes how service providers should manage typical side effects that clients might encounter.

Table 4.6 **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 diarrhoea recently or is taking any drugs that might interact with POPs. • If bleeding starts after several months of normal or no monthly bleeding, or there are other reasons to suspect pregnancy (e.g., client has missed pills), assess for pregnancy or other underlying conditions. Manage condition or refer client to appropriate level.

Heavy or prolonged bleeding	• Assess for underlying gynaecological problems and manage accordingly • If there are no underlying gynaecological diagnosis; - Give NSAIDs and COCs • If bleeding persists and becomes a threat to her life, discontinue the POP and help her choose another method
Amenorrhoea	• If client is breastfeeding, reassure her that it is normal not to have monthly bleeding while breastfeeding. • 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. o If client is pregnant, advise her to stop using POPs and refer for antenatal care (ANC). o 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 as necessary.
Abnormal or 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 client • If the condition worsens, discontinue POPs and help her to select an alternative method

What to do in case 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 4.7.**

Table 4.7 **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. (Client may take 2 pills at the same time or on the same day)**
Does the client 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 client 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

CHPs and CBDs should be instructed to refer clients who miss **3 or more** pills to a health facility for evaluation and advice by healthcare providers.

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.

METHOD SUPPLY

Non-clinical providers:

- Can initiate and re-supply POPs, using the approved MoH Checklist for MEC Category 1 conditions
- Shall not initiate clients with conditions falling in category 3 or 4
- Can supply up to (but not more than) three cycles to women with category 2 conditions before evaluation by a healthcare provider. After evaluation, non-clinical providers may resupply up to three cycles per visit.

Healthcare 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 disposed off correctly to avoid re-issue to other clients.

EMERGENCY CONTRACEPTION (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. EC is an important element in post-rape care and in the PMTCT, and it is an essential component of quality FP service provision. Other situations where EC is recommended include incorrect use of contraceptives and when there are concerns about possible contraceptive failure.

ECs seem to prevent 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%.

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 ovum 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 it is.
- It should be emphasized that ECs 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 EC pills (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 µg 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 µg 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 is 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 oestrogen and progestin, and they prevent about 75% of expected pregnancies. Two standard dosage options are available:

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

3. Ulipristal Acetate Pills

Ulipristal acetate (UPA) is a synthetic hormone used as an emergency contraceptive pill (ECP) to prevent pregnancy after unprotected sex. It can be taken up to 120 hours (5 days) after unprotected sex, however it's most effective when taken as soon as possible after unprotected sex. It is taken as a single 30-mg dose.

NOTE: Copper IUCD is now recommended as a method for emergency contraception if inserted within five (5) days of unprotected sex.

ECs 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

- ECs are available in government, private and NGO health facilities, and also over the counter at pharmacies

ECs LIMITATIONS AND SIDE EFFECTS

- Only effective if used within 120 hours of unprotected intercourse
- Not to be used as a regular method of contraception
- Does not protect against STIs, HIV or AIDS
- Does not continue to prevent pregnancy during rest of cycle
- Can be misused through self-prescription and sharing of pills
- Efficacy depends on client action
- Can cause nausea (more common for the COC regimen)

ELIGIBILITY CRITERIA

MEC Category 1 – Able to use ECs

Most women can use ECs safely and effectively, including those who cannot use ongoing hormonal contraceptive methods. This includes:

- Breastfeeding women
- Post-ectopic pregnancy
- Rape cases
- Obese
- Those on 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 (UPA is secreted in breast milk)
- History of severe cardiovascular complications (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions)
- Angina Pectoris
- Migraine
- Severe liver disease (including jaundice)

Table 4.8 **Conditions that warrant caution when using ECPs**

Condition	Suggested Action
Women with a history of 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 no longer effective • Pregnancy poses much more risk for these women than risks associated with ECPs • 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 ECs

Emergency contraception is not to be used as a regular method. Recurrent demand for ECs 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 under the "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 ECs 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

Emergency contraception 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 ECs

Table 4.9 provides instructions for the management of common side effects during EC use.

Table 4.9 **Management of common side effects of ECs**

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 EC, she should take another dose. (She can use antinausea 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 EC, she does not need to take any extra pills
Breast tenderness	• If not pregnant, reassure
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 4.10** describes contraceptive methods for use following EC.

Table 4.10 **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 ECs

Q1. What are the effects of ECs on my periods?

ECs 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 ECs protect me for the rest of the cycle?

They will not, and any further unprotected acts will 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 a method, such as pills or condoms, immediately. She has to wait until her next period to begin using injections, Hormonal IUCDs and implants. This is to be reasonably sure that conception did not take place.

Q4. Can I use ECs every time I have sex?

Women and girls should not use ECs as a regular method. ECs should be used only in emergency situations. ECs are less effective than many regular FP methods.

Q5. What if I had sex multiple times before taking ECs?

A woman can still use EC 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 ECs will not have any effect.

Q6. Can I repeat use of ECs within same cycle

ECs 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 EC. 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. In Kenya, about 20% of married women and 16% of unmarried women who use modern contraceptive methods choose injectable contraceptives.[15]

The most widely used injectable methods contain only progestin (Progestin-only Injectable Contraceptives, or POICs). Less common injectables are those that contain both progestin and oestrogen (Combined Injectable Contraceptives or CICs).

PROGESTIN-ONLY INJECTABLE CONTRACEPTIVES (POICs)

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 formulated for subcutaneous injection (DMPA-SC), given at three-month intervals (13 weeks)

Table 4.11 **Dosages for 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	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.

MODE OF ACTION

Progestin-only injectables prevent pregnancy by:

- Thickening cervical mucus
- Suppressing ovulation

EFFECTIVENESS

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

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

ADVANTAGES OF POICs

Contraceptive benefits

- They are highly effective and safe.
- A pelvic exam is not required to initiate use
- They do not contain oestrogen; thus, do not have the cardiac and blood-clotting side effects associated with oestrogen-containing pills and injectables
- Convenient, as it does not require daily action
- Do not affect breast milk production, hence can be used during breastfeeding
- Discrete: No one else can tell that a woman is using the method

Non-contraceptive health benefits

- Amenorrhoea, which might be beneficial for women with (or at risk of) iron-deficiency anaemia
- Reduction of symptoms of endometriosis
- Reduces risk of endometrial cancer
- Reduces risk of 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 except DMPA-SC

Side effects include:

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

ELIGIBILITY CRITERIA

MEC Category 1 – Able to use POICs

- 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 venous thrombosis
- 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, trichomonas 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, thalassemia
- Antiretroviral drugs
    - NRTIs: Abacavir (ABC), Tenofovir (TDF), Zidovudine (AZT), Lamivudine (3TC), Emtricitabine (FTC)
    - 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 who 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 erythematosus (SLE) (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
- Gallbladder 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, 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 4.12 **Conditions that qualify as MEC Categories 3 or 4 for POICs**

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. Caution; If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation	3
Women with multiple risk factors for arterial cardiovascular disease (combinations of older age, smoking, diabetes and hypertension)	3
Women with a current case 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, 2022, all FP methods are safe for all people at high risk for HIV, including both hormonal (either combined or progestin-only) and non-hormonal methods.

In high HIV burden settings, adolescents and women should be offered or referred for an HIV test as a routine part of family planning services.

Pre-exposure prophylaxis (PrEP) can be used safely with all family planning methods and while breastfeeding.

Male and female condoms are the only methods that can prevent both HIV and other sexually transmitted infections (STIs), as well as unintended pregnancy, when used consistently and correctly.

Depot medroxyprogesterone acetate (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 progestin-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 after 6 weeks postpartum, and if not amenorrhoeic, treat as for regular menses. Method is safe to by breastfeeding women 6 weeks postpartum up to 6 months postpartum
- Non breastfeeding. Start immediately or at any time within the first 21 days postpartum. After 21 days postpartum, and with 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 within seven days, or anytime if reasonably sure the client is not pregnant
- If more than seven days post-abortion, they may start the method but will need a backup for the next seven days after the injection

When to Repeat the Injection

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

Administering the Injection

Provider administered

Providers should follow these guidelines for giving injectable contraceptives:

- Perform hand hygiene
- Obtain 1 dose of injectable contraception (DMPA : 150 mg or NET-EN: 200 mg)
- Use disposable syringes and needles
- Do not reuse disposable syringes and needles
- Observe proper handling and disposal of needles and syringes (refer to the section on infection prevention and control in Chapter 3)
- 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 FP method to injectables.

Table 4.13 **Switching from another method to injectables**

Method switching from	Instructions
Switching from another hormonal method	• Can initiate 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 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. • 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 once pregnancy is ruled out. • If 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 POICs USE

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

Table 4.14 **Side effects of POICs 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 gynaecological problems and treat accordingly • If there is no gynaecological 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 gynaecological problems and manage accordingly
	• If there are no underlying gynaecological problems give any of the following:
	  ○ 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 amenorrhoea, which would stop the bleeding.
	  ○ If bleeding persists and becomes a threat to her life, discontinue injectable and help her choose another method.

Amenorrhoea	• By the end of the first year on injectables, amenorrhoea develops in the majority of clients. Normally amenorrhoea does not require any medical treatment. Counselling and reassurance are sufficient. If in doubt, assess for pregnancy and manage 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.
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

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 clinic (or other 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 4.15 **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 late for DMPA and more than two weeks late 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 amenorrhoea without pregnancy so a 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 oestrogen plus a progestogen.

There are two CIC formulations on the market, both given at four-week (monthly) intervals:

- Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg
- Norethisterone Enanthate 50mg plus estradiol valerate 5mg

In both preparations, the natural oestrogen might be less potent compared to the synthetic oestrogen of COCs. In addition, the intramuscular administration of CICs eliminates the first-pass effect of the hormones on the liver. As a result, the type and magnitude of oestrogen-related side effects associated with CICs might differ from those experienced by COC users.

Table 4.16 **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 seven days earlier or later
Norethisterone Enanthate 50mg plus estradiol valerate 5mg	Given once every 30 days, but it could be given as much a seven 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 or misses an injection
- CIC 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

Clients who are more than 7 days late can receive the next injection if:

- They have not had sexual intercourse after 7 days beyond the scheduled date of injection; or
- They have used a backup method or taken emergency contraceptive pills (ECPs) after any unprotected sex occurring 7 days after the scheduled date of her injection
- They 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 should 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 or second year.*

MODE OF ACTION

Contraceptive implants prevent pregnancy primarily by making cervical mucus 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 4.17 **Descriptions of contraceptive implants**

Product	Design	Active ingredients	Effectiveness
Jadelle	2 rods	Levonorgestrel 75 mg/rod	5 years
Implanon and Implanon NXT	1 rod	Etonogestrel 68 mg/rod	3 years
Levoplant	2 rods	Levonorgestrel 75mg/rod	3 years

ADVANTAGES OF IMPLANTS

Contraceptive benefits

- Highly effective and offers long-term protection
- Does not interfere with act of sexual intercourse
- Effective 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 postpartum.
- May reduce menstrual flow (thinning of the endometrium)
- They help prevent ectopic pregnancy (but do not eliminate the risk altogether)
- They may reduce risk of iron-deficiency anaemia
- They help protect from symptomatic PID
- May protect against endometrial cancer

LIMITATIONS AND SIDE EFFECTS OF CONTRACEPTIVE IMPLANTS

Limitations of contraceptive implants include:

- The client cannot initiate or discontinue the method on her own as it requires a trained healthcare provider to insert and remove the implant
- Insertion and removal require 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 the resumption of fertility (up to 1 year)

Common side effects of implant contraceptives include:

- Change in menstrual pattern including; amenorrhoea, spotting, intermenstrual bleeding or prolonged bleeding.
- Headache
- Dizziness
- Nausea

- Breast tenderness
- Mood changes
- Weight changes
- Mild abdominal pain

ELIGIBILITY CRITERIA

MEC Category 1 – Able to use implants

- Women of reproductive 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 90–99 mm Hg)
- 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 disorders (other medication may interfere 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, trichomonas 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, thalassemia
- 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 – immediately postpartum to less than 6 weeks postpartum
- Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, diabetes, hypertension and known dyslipidemia's)
- 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 ischemic heart disease for **initiating clients**
- Stroke (history of cerebrovascular accident) for **initiating clients**
- Systemic lupus erythematosus (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
- Gallbladder diseases (symptomatic or asymptomatic)
- Benign liver tumours (focal nodular hyperplasia)
- Antiretroviral therapy with the following
    - NNRTI : Efavirenz (EFV), Névirapine (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 4.18 **Conditions that represent MEC Categories 3 and 4 for implants**

Condition	MEC category
Women who have severe cirrhosis or liver tumours (hepatocellular adenoma or hepatoma)	3
Women who have unexplained vaginal bleeding (suspicious for serious condition) before evaluation. Caution; If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation	3
Women who have breast cancer or a history of breast cancer	4
Women who currently have DVT, or who developed ischemic heart disease or stroke while using implants	3 (Note: DVT is Category 3 for both initiation and continuation; ischemic 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 4.19 **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 nonhormonal 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 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 anaesthetic wears off. This is common and does not require treatment. She should be counselled and given these instructions:

- Keep the 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 experiencing pain, heat, pus or redness at the insertion site, or if a rod comes out.

The healthcare provider should emphasize that implants can be removed anytime the client desires or on the maturity of the implant. The client is given a return date as indicated on the follow up card, but may also return any other time she has a concern. The follow-up card should detail the following:

- The type of implant inserted;
- Date of insertion; and
- Date of removal.

Following removal of implants

Implants should only be removed by healthcare providers trained 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 a 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 4.20** 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 4.20 **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 gynaecological problems and treat accordingly
	  ○ If there is no gynaecological 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
	  o NSAIDs regimes: Ibuprofen: 800 mg three times a day for five days or Mefenamic acid: 500 mg twice a day for five days
	  o COCs regimes: Low-dose COCs: 30 µg ethinylestradiol 150 µg Levonorgestrel a day for 21 days or higher-dose COCs: 50 µg ethinylestradiol 250 µg Levonorgestrel a day for 21 days
	  o Haemostatics: Tranexamic 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

Amenorrhoea	• Reassure her that this is a common occurrence while using implants, and it is not harmful
	• Amenorrhoea does not require any medical treatment. Counselling is sufficient.
	• If suspicious, assess for pregnancy
	  o If she is pregnant, remove the implants
	  o 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. 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 and manage as above (see amenorrhoea)
	  ○ 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

COMBINED CONTRACEPTIVE PATCH

What is the Combined Patch?

- A small, thin, square of flexible plastic worn on the body
- Continuously releases 2 hormones—progestin and oestrogen, like the natural hormones progesterone and oestrogen in a woman's body—directly through the skin into the bloodstream
- The woman puts on a new patch every week for 3 weeks, then no patch for the fourth week. During this fourth week the woman will have monthly bleeding

Mode of action: Works primarily by preventing ovulation

How effective?

- Effectiveness depends on the user
- Risk of pregnancy is greatest when a woman is late to change the patch. As commonly used, about 7 pregnancies per 100 women result using the combined patch over the first year. This means that 93 of every 100 women using the combined patch will not become pregnant. When no mistakes are made with use, less than 1 pregnancy per 100 women results using a patch over the first year (3 per 1,000 women).

Key points for providers and clients

- A woman wears a small adhesive patch on her body at all times, day and night
- A new patch is put on each week for 3 weeks, and then no patch for the fourth week
- Replace each patch on time for greatest effectiveness
- Bleeding changes are common but not harmful
- Typically, irregular bleeding occurs for the first few months and then lighter and more regular bleeding. Pregnancy rates may be slightly higher among women weighing 90 kg or more.
- No delay in return to fertility after patch use is stopped
- Does not protect against HIV and sexually transmitted infections

Side effects

Some users report the following **side effects**:

- Skin irritation or rash where the patch is applied
- Changes in bleeding patterns: Lighter or fewer days of bleeding, irregular, prolonged or no monthly bleeding
- Headaches
- Nausea / Vomiting
- Breast tenderness and pain
- Abdominal pain
- Flu symptoms / upper respiratory infection
- Irritation, redness or inflammation of the vagina (vaginitis)

Known health benefits and risks: Long-term studies of the patch are limited, but researchers expect that its health benefits and risks are similar to those of combined oral contraceptives.

Medical eligibility criteria guidelines: user criteria for starting and continuing with the combined patch are the same as for combined oral contraceptives and the combined vaginal ring

How to use:

- Apply the patch on the upper outer arm, back, stomach, abdomen, or buttocks, when clean and dry, but not on the breasts.
- Press the sticky, medicated part against her skin for 10 seconds. She should run her finger along the edge to make sure it sticks.
- The patch will stay on during work, exercise, swimming, and bathing.
- Apply each new patch on the same day of each week for 3 weeks in a row; for example, if she puts on her first patch on a Sunday, all of her patches should be applied on a Sunday.
- The patch should not be worn on the 4th week. During the 4th week she should have monthly bleeding.
- To avoid irritation, she should not apply the new patch to the same area of skin as the previous patch.
- After the patch-free week, she should never go without wearing a patch for more than 7 days. Doing so risks pregnancy.

Table 4.21 **Instructions for late replacement or removal, or if the patch comes off**

Forgot to apply a new patch after the 7-day patch free interval	• Apply a new patch as soon as possible • Keep the same patch-change day • If late by only 1 or 2 days (48 hours or less), there is no need for a backup method • If more than 2 days late (more than 48 hours), that is, no patch was worn for 10 days or more in a row, use a backup method for the first 7 days of patch use • If more than 2 days late and unprotected sex has occurred in the past 5 days, consider taking emergency contraceptive pills (ECPs)

Late changing the patch at the end of week 1 or 2	• If late by only 1 or 2 days (48 hours or less), apply a new patch as soon as possible. Keep the same patch-change day. No need for a backup method. • If more than 2 days late (more than 48 hours), apply a new patch as soon as possible. This patch will begin a new 4-week patch cycle, and this day of the week will become the new patch-change day. Also use a backup method for the next 7 days. • If more than 2 days late and unprotected sex has occurred in the past 5 days, consider taking ECPs
Late taking off the patch at the end of week 3	• Remove the patch • Start the next cycle on the usual patch-change day • No need for a backup method
The patch came off and was off for less than 2 days (48 hours or less)	• Apply a new patch as soon as possible. (The same patch can be re-used if it was off less than 24 hours.) • No need for a backup method • Keep the same patch change day

The patch came off and was off for more than 2 days (more than 48 hours)	• Apply a new patch as soon as possible • Use a backup method for the next 7 days • Keep the same patch-change day • If during week 3, skip the patch-free week and start a new patch immediately after week 3 • If a new patch cannot be started immediately, use a backup method and keep using it through the first 7 days of patch use • If during week one, and unprotected sex has occurred in the past 5 days, consider taking ECPs

COMBINED CONTRACEPTIVE VAGINAL RING

What is the Combined Vaginal Ring?

- A flexible ring that a woman places in her vagina
- Continuously releases 2 hormones—progestin and oestrogen, like the natural hormones progesterone and oestrogen in a woman's body—from inside the ring. Hormones are absorbed through the wall of the vagina directly into the bloodstream.
- She leaves the ring in place for 3 weeks, then removes it for the fourth week. During this fourth week the woman will have monthly bleeding.

Mode of action

- Works primarily by preventing the release of eggs from the ovaries (ovulation).

Effectiveness

- Effectiveness depends on the user: Risk of pregnancy is greatest when a woman is late in starting a new ring
- As commonly used, about 7 pregnancies per 100 women result using the combined vaginal ring over the first year. This means that 93 of every 100 women using the combined vaginal ring will not become pregnant.
- No delay in return to fertility after ring use is stopped
- Does not protect against HIV and sexually transmitted infections

Side effects

Some users report the following:

- Changes in bleeding patterns, including lighter bleeding and fewer days of bleeding, irregular, infrequent or prolonged bleeding, or no monthly bleeding
- Headaches
- Irritation, redness, or inflammation of the vagina (vaginitis)
- White vaginal discharge

Known health benefits and health risks

Long-term studies of the vaginal ring are limited, but researchers expect that its health benefits and risks are like those of combined oral contraceptives.

Medical eligibility criteria: guidelines for starting and continuing the use of the combined ring are the same as for combined oral contraceptives and the combined patch.

How to Use

- The user can choose the position most comfortable for her—for example, standing with one leg up, squatting or lying down
- She should press opposite sides of the ring together and gently push the folded ring entirely inside the vagina
- The exact position is not important, but inserting it deeply helps it to stay in place, and she is less likely to feel it. The muscles of the vagina naturally keep the ring in place.
- She should leave the ring in place at all times, every day and night for 3 weeks
- She can take the ring out at the end of the third week and dispose of it in a waste receptacle
- To remove the ring, she can hook her index finger inside it, or squeeze the ring between her index and middle fingers, and pull it out
- She will probably have monthly bleeding this week
- If she forgets and leaves the ring in for as long as a fourth week, no special action is needed
- The ring can be removed for sex, cleaning or other reasons, although

removing it is not necessary and is not recommended because some women forget to put it back within 48 hours.

- If the ring slips out, she should rinse it in clean water and immediately reinsert it

Table 4.22 **Instructions for late replacement or removal of ring**

Left ring out for 48 hours or less during weeks 1 through 3	• Put the ring back in as soon as possible • No need for a backup method
Left ring out for more than 48 hours during weeks 1 or 2	• Put the ring back in as soon as possible • Use a backup method* for the next 7 days • If the ring was left out for more than 48 hours in the first week and unprotected sex occurred in the previous 5 days, consider taking emergency contraceptive pills (ECPs)
Left ring out for more than 48 hours during week 3	• Put the ring back in as soon as possible • Use a backup method for the next 7 days • Start a new ring at the end of the third week and skip the ring-free week. If unable to start the new ring at the end of the third week, use a backup method and keep using it through the first 7 days after starting a new ring.

Forgot to insert a new ring at the beginning of the cycle	• Insert a new ring as soon as possible. If late by only 1 or 2 days (48 hours or less)—that is, the ring is left out no longer than 9 days in a row—no need for a backup method. • Keep the same ring removal day • If the new ring is inserted more than 2 days (more than 48 hours) late—that is, the ring is left out 10 days or more in a row—use a backup method for the first 7 days of ring use. • Also, if unprotected sex has occurred in the past 5 days, consider taking ECPs
Kept ring in longer than 3 weeks	• If the same ring is used for up to 28 days (4 weeks), no backup method is needed. She can take a ring-free week or start a new ring immediately. • If the same ring is used for 28 to 35 days (more than 4 weeks but less than 5 weeks), insert a new ring and skip the ring-free week. No backup method is needed.

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 typical fertile women. The PVR is a contraceptive method for women who must be actively breastfeeding (at least 4 breastfeeding episodes per day) during PVR use to maintain efficacy.[7]

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

- PVR is inserted higher up into the vagina. It is worn continuously for a three-month period (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-month intervals (± two weeks)
- A woman may use rings successively for up to one year after she gives birth if she continues breastfeeding (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 amenorrhoea

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%, average 1.5%).

ADVANTAGES

- User-controlled. Can be inserted and 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 healthcare facility.
- 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 a lower dose of the hormone.
- Increases the range of available contraception methods for breastfeeding women in the postpartum 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 longer lactational amenorrhoea and hence extend the contraceptive effectiveness of Lactational Amenorrhoea Method (LAM)
- Fertility returns immediately after removal

LIMITATIONS AND SIDE EFFECTS OF PVR:

Limitations

Women **not** eligible to use PVR:

- Women who are not actively breastfeeding (at least 4 episodes in a day)
- 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. Side effects 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 (at least four breastfeeding episodes per day) to maintain the efficacy of the method

Clients are advised to return to the health facility if they suspect pregnancy or if:

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

CHAPTER 5 : INTRAUTERINE (CONTRACEPTIVE) DEVICES (IU(C)D)

INTRAUTERINE (CONTRACEPTIVE) DEVICE (IU(C)D)

The Intrauterine (Contraceptive) Device (IU(C)D) is a small flexible plastic device that is inserted into the uterine cavity to prevent pregnancy. It provides long-term protection against pregnancy as a long acting and reversible contraceptive (LARC).

Key Messages

- *Offers protection for up to 10-12 years for copper-based and 5 years for levonorgestrel-based devices.*
- *Return to fertility is immediate*
- *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

The device has a thin copper wire wrapped around the stem of the "T" that ends in a smooth ball to avoid injury to the cervix. 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.[18]

In studies in which the uterine cavity and fallopian tubes were flushed after exposure to semen, no fertilized eggs were found in IU(C)D users. This is an indication that copper IU(C)Ds are highly effective in preventing fertilization, rather than relying on other possible mechanisms, such as preventing implantation. In Kenya, the most widely used copper-bearing IU(C)D is Copper T380A. The use of copper intrauterine devices is known to cause bleeding changes that are known to often contribute to discontinuation or non-use of contraception. The Normal Counselling Tool for Menstrual Bleeding Changes was developed to guide healthcare providers to counsel FP clients on bleeding changes[16].

Hormone-releasing IUCDs

The hormone-releasing IUDs are widely available in Kenya. They are devices made of plastic whose top part of the "T" one that work by releasing the synthetic progesterone an example is Levonorgestrel (LNG), released during a period of five years. Mirena®, the LNG-20 IUD, is the most widely used hormone-releasing intrauterine system used in Kenya. Lingus® is a generic version of Mirena that is available in the Kenya market.

Mode of action

- Prevent fertilization by interfering with sperm mobility
- Copper IUD—Copper ions decrease sperm motility and function by altering the uterine and tubal fluid environment
- Hormonal IUD—the progesterone released thickens cervical mucus, suppress ovulation in some cycles and thins the endometrial lining

Brands available

- Copper T: made of plastic with copper sleeves. Example CuT-380A.
- Hormone-releasing IUD: contains Levonorgestrel which is released over a period of five years. Examples are Mirena®, LNG-IUD® and Avibela.

Effectiveness

- IU(C)D are 99% effective if used correctly and consistently
- Copper IU(C)D: Less than 1 pregnancy per 100 women using an IUD over the first year (6 to 8 per 1,000 women)
- Hormone-releasing IU(C)D: 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 IU(C)Ds and their duration of effectiveness.

Table 5.1 **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 T2OO**	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-20 IUD)**	5 years
· **Lingus® (LNG-IUD)**	5 years
· **Liletta® (LNG-IUD)**	3 years

ADVANTAGES OF IU(C)DS

Contraceptive Benefits

- Highly effective and safe
- 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 IU(C)D is effective as an emergency contraceptive if inserted within 5 days of unprotected sexual intercourse
- Does not interfere with breastfeeding, hence can be used by women who are breastfeeding

Non-contraceptive benefits

- IU(C)Ds do not interfere with intercourse
- Help prevent ectopic pregnancies
- IU(C)Ds, including the Cu- IU(C)Ds, might help protect from endometrial cancer
- LNG-IUD minimizes bleeding and is suitable for women with menorrhagia; it has been found to be beneficial in women who experience cramps
- LNG-IUD provides benefits in the reduction of symptoms of endometriosis

LIMITATIONS AND SIDE EFFECTS

Limitations

- Does not offer protection against STI/HIV transmission
- Requires a trained healthcare 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-IU(C)Ds might increase menstrual bleeding and cause cramping, more commonly during the first few months of use. (LNG-IUD does not increase menstrual bleeding and is associated with less cramping.)
- LNG-IUD has similar side effects to progestin-only contraceptives

Eligibility criteria

MEC Category 1 - Able to use the IU(C)D

NOTE: MEC for LNG-IUD 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 the provision of IU(C)D.

Table 5.2 **MEC category 1 contexts and conditions for IU(C)D**

Conditions that apply to both Cu-IU(C)D and LNG-IUD	Conditions that apply to Cu-IU(C)D only	Conditions that apply to LNG-IUD 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 varicose veins and venous thrombosis • Uncomplicated valvular heart disease • Non-migraine headaches • Irregular menstrual bleeding patterns without heavy bleeding	• Breastfeeding or non-breastfeeding women if insertion occurs less than 48 hours from delivery of placenta • Blood pressure of 160/100 or higher • History of 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) • Known dyslipidemias without other known cardiovascular risk factors • Immunosuppressive treatment (continuation only) • Severe (decompensated) cirrhosis of the liver	• 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 severe dysmenorrhoea (LNG-20 IUD may have beneficial effect) • Anaemia, such as iron deficiency anaemia, sickle cell disease, thalassemia (LNG-20 IUD users are more likely to experience light bleeding or even amenorrhoea, which is beneficial for women with anaemia)

• Benign ovarian tumours 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)	• Any type of liver tumours (benign 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	

MEC Category 2 – Use with caution

Women who are in the circumstances or have any of the conditions listed in Table 5.3 should proceed with caution if they choose to use the IU(C)D. Careful counselling is required, and follow-up may be necessary.

Table 5.3 **Category 2 conditions and circumstances for IU(C)D**

Condition / Circumstance	Cu-IU(C)D	LNG-IUD
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 **IU(C)D** expulsion because of nulliparity and the risk of STIs because of sexual behaviour in younger age groups. Ensure follow-up.	Proceed as for Cu-**IU(C)D**
For LNG-IUD only: less than 48 hours postpartum if breastfeeding	No action (Category 1 if Cu-**IU(C)D**)	Proceed as for Cu-**IU(C)D** (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-**IU(C)D.**

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-**IU(C)D**
Increased risk of STIs including HIV (see category3 and 4 if woman has very high likelihood of exposure to STIs)	Generally, provide, but counsel client that IUCDs do not protect against STIs, including HIV. Advise use of dual protection (i.e., condom).	Proceed as for Cu-**IU(C)D**
STIs including current purulent cervicitis or chlamydial infection or gonorrhoea; other STIs (excluding HIV and hepatitis); vaginitis	A current IUD user who becomes infected with gonorrhoea or chlamydia or develops PID can safely continue using an IUCD during and after treatment	Proceed as for Cu-**IU(C)D**
HIV-infected, as well as those with AIDS who are clinically well on ARVT	Generally initiate use or continue use. Careful follow-up is needed. There is no known interaction between ARVT and IUD use.	Proceed as for Cu-**IU(C)D**

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., IU(C)D may be inserted but some follow-up may be required. Counsel the woman that her bleeding may become even heavier after Cu- IU(C)D 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 IUD (Category 2 for continuation)
Women with endometriosis or severe dysmenorrhoea	Use of Cu-IU(C)D could intensify dysmenorrhoea, including that associated with endometriosis. Generally, provide method and follow up carefully. Provide analgesics if necessary.	No restrictions (see Category 1 above)
Anaemia: iron deficiency anaemia, sickle cell disease, thalassemia	There is concern about an increased risk of blood loss with Cu-**IU(C)D**. 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, risk of atrial fibrillation and those with history of SBE)	Generally, provide method, but give prophylactic antibiotics to prevent endocarditis during insertion. Needs careful counselling follow-up and referral.	Proceed as for Cu-**IU(C)D**

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-IUD 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 IU(C)D can generally continue, but cannot initiate use.	Generally, can initiate and continue use of LNG-IUD 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-IUD (see Category 3).

MEC Category 3 and 4 - Women who should not use IU(C)D (Cu-IU(C)D and LNG-IUD)

Table 5.4 lists conditions where the risks of using an IU(C)D outweigh the benefits.

Table 5.4 **Category 3 and 4 conditions for IU(C)D**

Conditions that apply to both Cu-IUCD and LNG-IUD	Conditions that apply to LNG-IUD 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 tumours (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 is already using IU(C)D can continue with it pending findings of the evaluation (Category 2).	• Women with migraine headaches with aura that worsened while using LNG-IUD (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 IU(C)D can be used)
• Women with anatomical abnormalities of the uterus and cervix that interfere with insertion and retention of IU(C)D,	

including uterus size less than 6cm • Women with current PID or current purulent cervicitis. After treatment (syndromic approach and refer), she can have an IU(C)D inserted (Category 2). Women who develop PID while using an IU(C)D can be treated with IU(C)D 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 gonorrhoea 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 IU(C)D insertion is categorized as interval, postpartum and post-abortion.

Interval

Insert IU(C)D within the first 12 days after the start of menstrual bleeding or any other time of the woman's menstrual cycle if provider is reasonably sure she is not pregnant.

Postpartum insertion

Both Cu-IU(C)D and LNG-IUD can be inserted:

- Trans-caesarean (i.e., following a caesarean delivery): The IU(C)D can be inserted before the uterus is sutured
- Post-placental: The IU(C)D can be inserted within 10 minutes after expulsion of the placenta following a vaginal delivery
- Immediate postpartum: The IU(C)D can be inserted after the post-placental window, but within 48 hours of birth
    - If IU(C)D is not inserted within 48 hours, wait until four weeks after childbirth.

NOTE: Post-pregnancy IU(C)D is contraindicated in situations that increase the risk of infections. These include:

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

Post-abortion

Following first or second-trimester abortion

- Insert the IU(C)D immediately or within 12 days where there are no complications. Insertion of the IU(C)D 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, IU(C)D insertion should be delayed until after appropriate treatment (see interval insertion).
- Danger signs and symptoms following PP IU(C)D insertion:
    a) Perforation
    b) Pain
    c) Vaginal bleeding
    d) Hypovolemic shock
    e) Sepsis
    f) Foul-smelling discharge
    g) Fever
    h) Rigors
    i) Endotoxic shock

Switching FP methods

Instructions for switching between IU(C)D and other methods of FP are given in **Table 5.5**.

Table 5.5 **Switching between IU(C)D and other FP methods**

Switching from	When to start
Other FP method to IU(C)D	• Insert immediately if pregnancy is ruled out. No need to wait for the next menstrual period.
IU(C)D 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 backup 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 uses a backup contraceptive for the next 7 days (2 days for POPs).
IU(C)D 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

IU(C)D 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.
IU(C)D 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 IU(C)D strings cannot be felt on bimanual examination, refer the client for ultrasound scan or X-Ray to confirm whether the device is still in situ. Advise the woman to use a backup contraceptive method in the meantime.

Reasons for client to return to facility following IU(C)D insertion

Counsel the client to return to the healthcare facility if she:

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

MANAGEMENT OF COMMON PROBLEMS ASSOCIATED WITH IU(C)D USE

The table below shows the common side effects and problems with IU(C)D use and their management.

Table 5.6 **Side Effects and problems associated with IU(C)D, 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 gynaecological problem
	  ○ If a gynaecological problem is identified, treat the condition or refer for care
	  ○ If no gynaecological problems are found, and she finds the bleeding unacceptable, especially if there are clinical signs of anaemia, remove the IU(C)D and help her choose another method.

Abdominal cramping and pain	• Inform client that some abdominal cramping may occur in the first 24–48 hours • If cramping continues, give analgesics • If pain and cramping is severe, evaluate for underlying conditions, including signs of partial IU(C)D expulsion, PID or ectopic pregnancy, and treat accordingly • If pain and cramping persist and no cause is found, remove IU(C)D and counsel client to select another method

Partner complains about pricking during coitus	• This may happen when the threads are cut too short or the IU(C)D is partially expelled. Examine and insert another IU(C)D.
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, or confirmed by X-ray or ultrasound), insert IU(C)D if pregnancy is ruled out or give any other FP method of choice • If partial expulsion is confirmed, remove IU(C)D. Insert another IU(C)D if desired and appropriate, or counsel the client for any other FP method of choice. • If IU(C)D is embedded in the 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 IU(C)D if she wishes to continue its use • If symptoms do not improve after a few days of antibiotics, IU(C)D removal may be considered and antibiotic treatment continued • In all cases, the woman should be closely monitored until PID is fully resolved

Pregnancy with IU(C)D	• Exclude ectopic pregnancy (ultrasound scan where available; otherwise, careful clinical monitoring)
	• If client wants IU(C)D to be removed and the IUCD strings are visible or can be retrieved safely from the cervical canal (in the first 3 months)
	  ○ Remove IU(C)D by pulling on the strings gently
	  ○ Explain that she should return promptly if she experiences heavy bleeding, cramping, pain, abnormal vaginal discharge or fever
	• If the IU(C)D strings are not visible, determine if IU(C)D is still in the uterus by ultrasound
	  ○ If the IU(C)D is not located, this may suggest that an expulsion of the IU(C)D has occurred
	  ○ If the IU(C)D 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 or fever

Management of common problems associated with PP IU(C)D

The table below shows the problems that may be encountered during postpartum IU(C)D insertion and how to manage them.

Table 5.7 **Management of problems at the time of insertion of PP IU(C)D**

Problem	Management
Client discomfort or pain	• Reassure client and continue communicating during procedure • Perform procedure as gently and quickly as possible
Displacement of IU(C)D	• Using sterile forceps, remove IU(C)D and reinsert. If contaminated, discard and use a new IU(C)D
Cervical lacerations	• If lacerations are seen, repair depending on size and amount of bleeding
Uterine perforation	• If suspected during insertion, stop IU(C)D procedure immediately and remove IU(C)D 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 if peritoneal signs appear, refer for emergency surgical intervention accordingly • Prophylactic antibiotics should be given

OBTAINING THIS METHOD

IU(C)D should be provided within healthcare facilities that follow appropriate infection prevention practices. All healthcare facilities with trained clinicians can provide IU(C)Ds, including during outreaches.

RECOMMENDED JOB AIDS

- Checklist for Screening Clients Who Want to Initiate Use of the Copper IU(C)D (MoH)
- How to Be Reasonably Sure a client is Not Pregnant (MoH)
- Quick Reference Chart for the WHO Medical Eligibility Criteria for Contraceptive Use
- Sample of IU(C)D

CHAPTER 6: VOLUNTARY SURGICAL CONTRACEPTION

Voluntary Surgical Contraception (VSC) includes surgical procedures intended to provide permanent contraception.

Procedures 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 should be taken when the following individuals choose permanent methods:

- Nulliparous women
- Youth
- Men who have not fathered a child
- 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 completely disqualifies a person from 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, backup medical support, and the necessary equipment that might be needed to manage complications that might arise during the VSC procedure.

WHO MEC CATEGORIES FOR VSC

The following table shows medical eligibility criteria for VSC.

Table 6.1 **WHO MEC categories for VSC**

Category	Explanation
Accept (Category A)	There is no medical reason to deny VSC to a person with Category A conditions
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 anaesthesia, and other backup medical support. For these conditions, the capacity to decide on the most appropriate procedure and anaesthesia 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 clients.
- The client is free to change his or her mind at 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 3).

- Healthcare 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 to prevent sperm from fertilizing the ovum, thus preventing it from reaching the uterine cavity. In Kenya, only 3.2% of users of modern methods of contraception rely on BTL.[15] 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 anaesthesia, 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 written consent from the parent or guardian (see **Appendix 14.3**).

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 BTL;

- (Mini)laparotomy (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
- 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 undergone BTL have a decreased risk of 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
- Failure of procedure pre-disposes to ectopic pregnancy
- Subjects the client to pain and leaves permanent scar
- The client needs to give signed consent
- Only adequately trained service providers can offer the method
- There may be side effects associated with the surgical procedure

Side effects include:

- Anaesthesia reaction
- Risk of heavy bleeding from surgical procedures
- Possible post-procedural pain
- 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

MEC Category A – Women who can use BTL

There is no medical reason to deny sterilization to a person with the following conditions, circumstances or history:

- 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 tumours
- Severe dysmenorrhoea
- 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 goitre
- Symptomatic gallbladder disease treated by cholecystectomy or medically treated
- Mild liver cirrhosis (compensated)
- Benign focal nodular hyperplasia of the liver
- Sterilization concurrent with caesarean section

Table 6.2 **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 ischemic heart disease • History of stroke • Uncomplicated valvular heart disease • Current breast cancer • Epilepsy or depressive disorders • Uterine fibroids • Uncomplicated diabetes • Hypothyroidism • Mild cirrhosis • Liver tumours (benign and malignant) • Anaemia • Previous abdominal or pelvic surgery, diaphragmatic hernia • Kidney disease • SLE without complications • Severe nutritional deficiencies • Previous history of	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 assure 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-abortion sepsis or pyrexia • Severe APH, PPH or post-abortion hemorrhage • Severe trauma to genital tract, including uterine perforation. • Severe pre-eclampsia or eclampsia	• 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

(C) CAUTION	(D) DELAY	(S) SPECIAL
PID without subsequent pregnancy	• Peritonitis Delay interval procedure to ensure careful evaluation and treatment in women with the following conditions (and arrange follow-up): • Current DVT or major surgery with prolonged immobilization or PE • Current ischemic 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 gallbladder disease • Active viral hepatitis • Severe anaemia (Hb<7gm) • Sickle cell disease • Local infection (abdominal skin) • Acute respiratory disease • Systemic infection or gastroenteritis	those on immunosuppressive treatment • 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 switching from oral contraceptives, client can have the BTL immediately and then continue taking the pills until she has finished the pill pack to maintain her regular cycle
    - If client has been on injectable, BTL can be performed at any time before the return date for the next injection
- Switching from an IU(C)D
    - If during the first 7 days of monthly bleeding, remove the IU(C)D 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 IU(C)D 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 6.3 Highlights these complications and how they should be managed.

Table 6.3 **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
Hematoma	This usually will resolve over time 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 community outreach in mobile facilities as long as providers 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 reproductive health. One surgeon shall perform not more than 15 procedures in a day, and not more than 30 procedures 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 anaesthesia. According to KDHS 2022, less than 1% of men have had vasectomy.[1]

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 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 anaesthesia

and surgical procedure

ELIGIBILITY CRITERIA FOR VASECTOMY

MEC Category A – No medical reason to deny vasectomy

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 6.4 **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 an 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 an 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 if 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.	Cryptorchidism (undescended testicle): might require 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:

- 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 protection in the meantime.

Management of common complications

Complications may occur after vasectomy. **Table 6.5** lists some of the potential complications and their management.

Table 6.5 **Complications of vasectomy and their management**

Complication	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 • 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 community 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.

CHAPTER 7: BARRIER METHODS OF CONTRACEPTION

Barrier methods prevent the sperm from gaining access to the upper reproductive tract and making contact with the ova.

Barrier methods include condoms (male and female), diaphragms and cervical caps. Their action can be augmented by use of spermicidal chemicals, e.g., nonoxynol-9 (N-9). 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.[7] As a result, the main focus in this edition of the FP Guideline 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 prevent any disease organisms in the vaginal fluids from coming into contact with the penile urethral mucosa. Therefore, condoms offer dual protection against unintended pregnancies and sexually transmitted infections (STIs), including HIV.

MALE CONDOM

The male condom is a thin sheath made to fit a man's erect penis. Most are made of thin latex rubber. Male condoms also are made from other materials, including polyurethane, polyisoprene, lambskin and nitrile. Some are coated with a lubricant or spermicide. Condoms come in different sizes, colours, and textures. Condom types in the market include plain, flavoured, coloured, and spermicide-added condoms.

EFFECTIVENESS

For contraception, male condoms are 87% effective in typical use and much more effective, at 98%, when used correctly and consistently.

ADVANTAGES OF CONDOMS

- Easily accessible, affordable and easy to use
- Have no hormonal side effects
- Can be used as a regular, temporary or backup method
- Offer contraception if used appropriately
- Male condoms prevent 80% to 95% of HIV transmission that would have occurred without condom use
- Reduce the risks of PID-related infertility
- Reduce the risk of cervical cancer
- May help to manage premature ejaculation
- Have no associated health risks

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
- Cannot be used with oil-based lubricants
- Condoms are affected by heat, light and humidity
- Women may have difficulty in requesting their partners to use male condoms
- Can cause an environmental hazard if not properly disposed of

ELIGIBILITY CRITERIA

Men who can use male condoms: Condoms are a good contraceptive choice for men and couples in a variety of circumstances:

- Those that wish to participate actively in FP
- Couples who need a backup 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 using another method for pregnancy prevention and are at 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

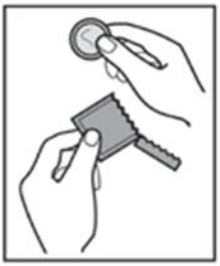
Men who should not use male condoms

Those allergic to latex.

CONDOM USE AND DISPOSAL

When to Start: Any time the client is ready to use.

Table 7.1 **Instructions for condom use**

Basic steps	Important details	Illustration
Use a new condom for each act of sex	• Check the condom package. Do not use it if it is torn, damaged or past the expiration date. • Tear to open the package carefully as per the instructions	
Unroll the condom all the way to the base of the erect penis	• The condom should unroll easily. Forcing it on could cause it to break during use • Use a new condom if the condom doesn't unroll easily • If the condom is on backwards and another one is not available, turn it over and unroll it onto the penis	

Immediately after ejaculation, hold the rim of the condom in place and withdraw the penis while it is still erect	• Withdraw the penis • Slide the condom off, avoiding spilling semen • If having sex again or switching from one sex act to another, use a new condom	
Proper disposal of used condoms	• Wrap the condom in its package and dispose of it in the waste bin or pit latrine. Do not dispose of the condom in a flush toilet.	

NOTE: In case of semen spillage or breakage of condom during use, the healthcare provider should offer emergency contraception and counsel on HIV and STIs.[7]

What condom users should not do

Certain practices can increase the risk of condom breakage. Do not:

- Unroll the condom first, then try to put it on the penis
- Use lubricants with an oil base
- Use a condom if the colour is uneven or changed
- Use a condom that feels brittle, dried out, or very sticky
- Reuse condoms
- Have dry sex
- Use more than one condom at the same time
- Use a male and female condom at the same time

Disposal 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 disposed of into a pit latrine, burned, or buried and should be kept away from children.
- Condoms should not be reused.

MANAGEMENT OF POSSIBLE SIDE EFFECTS

Table 7.2 shows some side effects of using condoms and how to manage them.

Table 7.2 **Management of possible side effects of using condoms**

Side Effect	Management
Irritation may result from allergy to latex, though this is very rare	• Advise the couple to use a non-latex brand of condom • Screen for presence of infection and treat, if present
Female partner is using vaginal pessaries, e.g., miconazole or econazole (for treatment of vaginal infections)	• These can damage latex; hence one should use plastic condoms, female condoms or other methods during this period of treatment
Lubrication enhances condom use and prevents condom breakage	• There are 3 ways to provide lubrication—natural vaginal secretions, adding a lubricant safe for use with condoms, or using condoms packaged with lubricant on them • Water-based, silicone and glycol lubricants are safe • Unsafe lubricants that damage latex include: oil-based, cooking oils, petroleum jelly, margarine
Lambskin (natural) condoms are not effective in protection against HIV and other STIs	• Condoms made of other materials should be used when there is risk of HIV / STI transmission

FEMALE CONDOM

The female condom is a thin, transparent sheath made of polyurethane and pre-lubricated with a silicone-based substance (dimethicone). Others are made of latex or nitrile. It has flexible rings on both 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, with a failure rate of about 5% in perfect use, and 21% in typical use. Effectiveness ranges from 79% to 95%.

BENEFITS OF FEMALE CONDOMS

- Condoms can be used without seeing a healthcare provider
- With consistent and proper use, condoms are highly effective for prevention against STIs, including HIV/AIDS
- Protect against PID
- The woman can control this method
- It can be inserted eight hours before an anticipated sexual act
- Condoms are easy to use
- No health risk is associated with the method
- Unlike latex rubber, there is no known allergy to polyurethane, the material from which most female condoms are made
- Does not interfere with fertility

LIMITATIONS OF FEMALE CONDOMS

- Condoms must be inserted before sexual intercourse (they can be inserted in advance—as much as eight hours prior)
- Female condoms are expensive
- 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 backup 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 risk of acquiring an STI or HIV/AIDS

Women who should not use a condom

Women with one or more conditions that make pregnancy dangerous and who need a more effective method of protection against pregnancy may want to consider other, less client-dependent, methods of contraception.

Women with latex allergy should use female condoms made of other non-latex materials e.g., polyurethane (these are the most readily available).

METHOD USE AND DISPOSAL

When to start: Any time the 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.
- Thrown in a pit latrine, burned, or buried. It should be kept away from children.
- Condoms should not be reused.

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

Table 7.3 **Instructions on female condom use**

Basic Steps	Important Details
1. Use a new female condom for each act of sex	• Check the condom package. Do not use it if torn or damaged. Avoid using a condom past its expiration date. Do so only if newer condoms are not available. • If possible, wash your hands with mild soap and clean water before inserting the condom.
2. Insert condom	• For the most protection, insert the condom before the penis comes in contact with the vagina. Can be inserted up to 8 hours before sex. • Choose a position that is comfortable for insertion—squat, raise one leg, sit, or lie down • Rub the sides of the female condom together to spread the lubricant evenly • Grasp the ring at the closed end and squeeze it so it becomes long and narrow • With the other hand, separate the outer lips (labia) and locate the opening of the vagina Gently push the inner ring into the vagina as far up as it will go. Insert a finger into the condom to push it into place. About 2 to 3 centimeters of the condom and the outer ring remain outside the vagina.

Basic Steps	Important Details
3. Ensure that the penis enters the condom and stays inside the condom	• The man or woman should carefully guide the tip of his penis inside the condom—not between the condom and the wall of the vagina. If his penis goes outside the condom, withdraw and try again. • If the condom is accidentally pulled out of the vagina or the outer ring is pushed into it during sex, put the condom back in place
4. After the man withdraws his penis, hold the outer ring of the condom, twist to seal in fluids, and gently pull it out of the vagina	• The female condom does not need to be removed immediately after sex • Remove the condom before standing up, to avoid spilling semen • If the couple has sex again, they should use a new condom • Reuse of female condoms is not recommended
5. Dispose of the used condom safely	Wrap the condom in its package and put it in the rubbish bin or pit latrine. Do not put the condom into a flush toilet, as it can cause problems with plumbing.

SPERMICIDES AND DIAPHRAGMS

Spermicides

Spermicides are sperm-killing substances inserted deep in the vagina, near the cervix, before sex.

- Nonoxynol-9 is most widely used
- Others include benzalkonium chloride, chlorhexidine, menfegol, octoxynol-9 and sodium docusate
- Spermicides are available in foaming tablets, melting or foaming suppositories, cans of pressurized foam, melting film, jelly and cream
- Jellies, creams and foam from cans can be used alone, with a diaphragm or with condoms
- Films, suppositories, foaming tablets or foaming suppositories can be used alone or with condoms

Effectiveness

Effectiveness is 79% (21 pregnancies per 100 women)

Mode of Action

Works by causing the membrane of sperm cells to break, killing them or slowing their movement. This keeps sperm from meeting the egg.

Side Effects

- Irritation in and around the vagina/penis
- Vaginal lesions

Key points

- Spermicides are placed deep in the vagina shortly before sex
- Require correct use with every act of sex for optimum effectiveness
- It is one of the least effective contraceptive methods which can be used as a primary method or as a backup method

- Does not interfere with fertility
- All women can safely use spermicides except those who:
    - Are at high risk for HIV infection
    - Have HIV infection

Women who are at high risk for HIV infection or who have HIV should use an alternative FP method.

Diaphragms

Diaphragms are soft latex cups that cover the cervix. Plastic and silicone diaphragms may also be available. The rim contains a firm, flexible spring that keeps the diaphragm in place.

- Used with spermicidal cream, jelly or foam to improve effectiveness
- Most diaphragms come in different sizes

Mode of Action

- Works by blocking sperm from entering the cervix; spermicide kills or disables sperm. Both keep sperm from meeting an egg.

Key notes

- The diaphragm is placed deep in the vagina before sex. It covers the cervix. Spermicide provides additional contraceptive protection.
- A pelvic examination may be needed before starting use. The provider must select a diaphragm that fits properly.
- Requires correct use with every act of sex for greatest effectiveness
- Nearly all women can use the diaphragm safely and effectively

Tips for users of spermicides or the diaphragm with spermicide

- Spermicides should be stored in a cool, dry place, if possible, out of the sun. Suppositories may melt in hot weather. If kept dry, foaming tablets are not as likely to melt in hot weather.
- The diaphragm should be stored in a cool, dry place, if possible
- A woman will require a new diaphragm fitted if she has had a baby or a second-trimester miscarriage or abortion

CHAPTER 8: LACTATIONAL AMENORRHOEA METHOD (LAM)

The Lactational Amenorrhoea 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.

Key Messages

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

As commonly used, the pregnancy rate is about 2 per 100 women in the first 6 months. With perfect use, the pregnancy rate occurs in less than 1 per 100 women (see **Appendix 1**).

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

- The woman's menstrual periods have not resumed
- The baby is exclusively breastfed
- The baby is less than six months old

NOTE: 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 suppresses ovulation which makes pregnancy unlikely.

EFFECTIVENESS

LAM is up to 98% effective if practiced during an 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 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

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

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

METHOD USE

When to start

- Start breastfeeding immediately (within one hour) or as soon as possible after delivery of the baby
- Breastfeed often
- The ideal pattern is feeding on demand (that is, whenever the baby wants to be fed) and at least 10 to 12 times a day in the first few weeks after childbirth, and after those, 8 to 10 times a day, including at least once at night in the first months
- Daytime feeding is recommended to be not more than 4 hours apart, and nighttime feedings should be no more than 6 hours apart
- Some babies may not want to breastfeed 8 to 10 times a day and may want to sleep through the night. These babies may need gentle encouragement to breastfeed more often.

Follow up visits

Plan for the next visit while the LAM criteria still apply, so that she can choose another method and continue to be protected from pregnancy.

Helping clients switch to another 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.

Addressing client's concerns on LAM

- If 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.
- Use condoms consistently in addition to LAM if there is a risk of STI/HIV transmission.

CHAPTER 9: 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. The effectiveness of FAMs is enhanced by use of multiple techniques to identify the fertile time.[7]

Women can identify their fertile time by using several approaches, either singly or in combination, which include calendar-based methods and symptoms-based methods. These details are provided in this chapter.

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 colour-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.

Figure 9.1 **CycleBeads® for SDM**

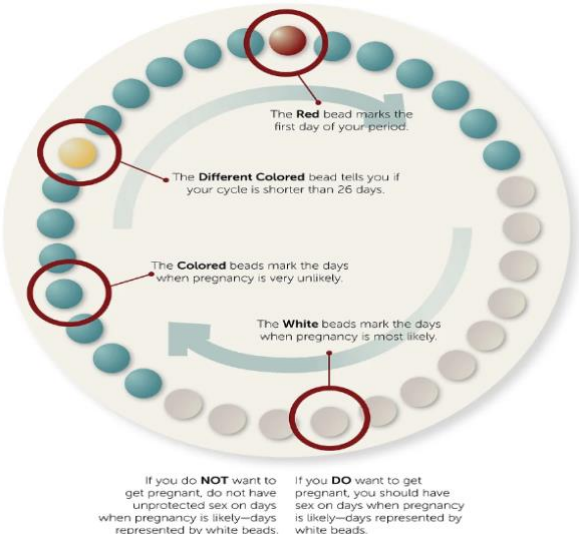


Image Source: Institute for Reproductive Health Georgetown University http://irh.org

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 the 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 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 can 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. 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 (Spinnbarkeit's sign) and slippery
- Continue to avoid sex for three more days after peak day, even if secretions completely disappear before three days have expired
- The couple can resume sex on the fourth day after the peak day and until her next monthly bleeding. The client should be taught to apply the method rules appropriately.

BASAL BODY TEMPERATURE (BBT)

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

The temperature readings are recorded on a special graph paper, which makes it easy to identify small changes in temperature readings. The woman's temperature rises by 0.20C–0.50C 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 or increased libido.

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 women to track their Cycle days

KEY POINTS ABOUT FAMS FOR PROVIDERS AND CLIENTS

FAMs require the partner's cooperation and couples must be committed to abstaining from unprotected vaginal intercourse on fertile days. The woman should 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 the 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 contraindicated

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 the client is breastfeeding and has amenorrhoea
- Has a high failure rate if client is not well-trained
- The methods require varying periods of sexual abstinence during the 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 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 who cannot use modern methods on religious, cultural or medical grounds and couples who are willing to abstain from intercourse during the fertile time.[14]
Table 9.1 summarizes specific conditions under the MEC categories for FAM.

Table 9.1 **WHO MEC criteria for FAMs for specific conditions**

Condition	Symptoms-based methods (SYM)	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
Breastfeeding more than 6 weeks postpartum	Caution (C)	Delay (D)	

Condition	Symptoms-based methods (SYM)	Calendar-based methods (CAL)	Comments
			detectable fertility signs
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 until resumption of regular menses
Non-breastfeeding women more than 4 weeks postpartum	Accept (A)	Delay (D)	Delay until resumption of regular menses for CAL methods
Post-abortion	Caution (C)	Delay (D)	Delay until resumption of regular menses for CAL methods
Irregular vaginal bleeding	Delay (D)	Delay (D)	Delay until evaluation and treatment
Vaginal discharge	Delay (D)	Accept (A)	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	C/D	C/D	

Condition	Symptoms-based methods (SYM)	Calendar-based methods (CAL)	Comments
antibiotics or long-term NSAIDs			

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 9.2 **When to start FAMs**

Symptoms	When to start	
	Symptoms 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 counselling and support if she has no infection-related secretions or bleeding due	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

	to injury in the genital tract	

WITHDRAWAL METHOD (COITUS INTERRUPTUS)

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, or have infrequent intercourse.*

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

EFFECTIVENESS

The 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. It's important to note that:

- It's one of the least effective methods, as commonly used
- As commonly used, about 20 out of 100 women whose partners use withdrawal will become pregnant in 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 out of 100 women whose partners use withdrawal will become pregnant in the first year
- There is no delay in return of fertility after withdrawal use has stopped
- It does not protect against sexually transmitted infections

ADVANTAGES OF COITUS INTERRUPTUS

- 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 backup 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
- 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.

Emergency Contraception should be used in case a man ejaculates before withdrawing.

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 10: FAMILY PLANNING HEALTH PRODUCTS AND TECHNOLOGIES MANAGEMENT

Good-quality reproductive healthcare requires a continuous supply of Reproductive Health Products and Technologies (RHPT). Family planning service providers are the most important link in the contraceptive supply chain that move family planning health products and technologies (FPHPTs) from the manufacturer to the end user. Accurate and timely reports and orders from service providers help supply chain managers determine what products are needed, how much to procure, 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 the documentation and reporting of FP data by

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

FP DATA MANAGEMENT

ENSURING QUALITY OF FPHPTs AND SERVICE 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. **Table 10.1** below shows the various dimensions of data quality.

Table 10.1 **Dimensions of data quality**

Dimension	How to ensure quality
Accuracy	Data that have been reported matches the primary source documents at the service delivery point
Timeliness	Reports are submitted within the stipulated timelines
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 are used
Precision	Data contain 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
Completeness	Dataset contains all the expected and required information without any omissions
Consistency	Data remain the same across all systems

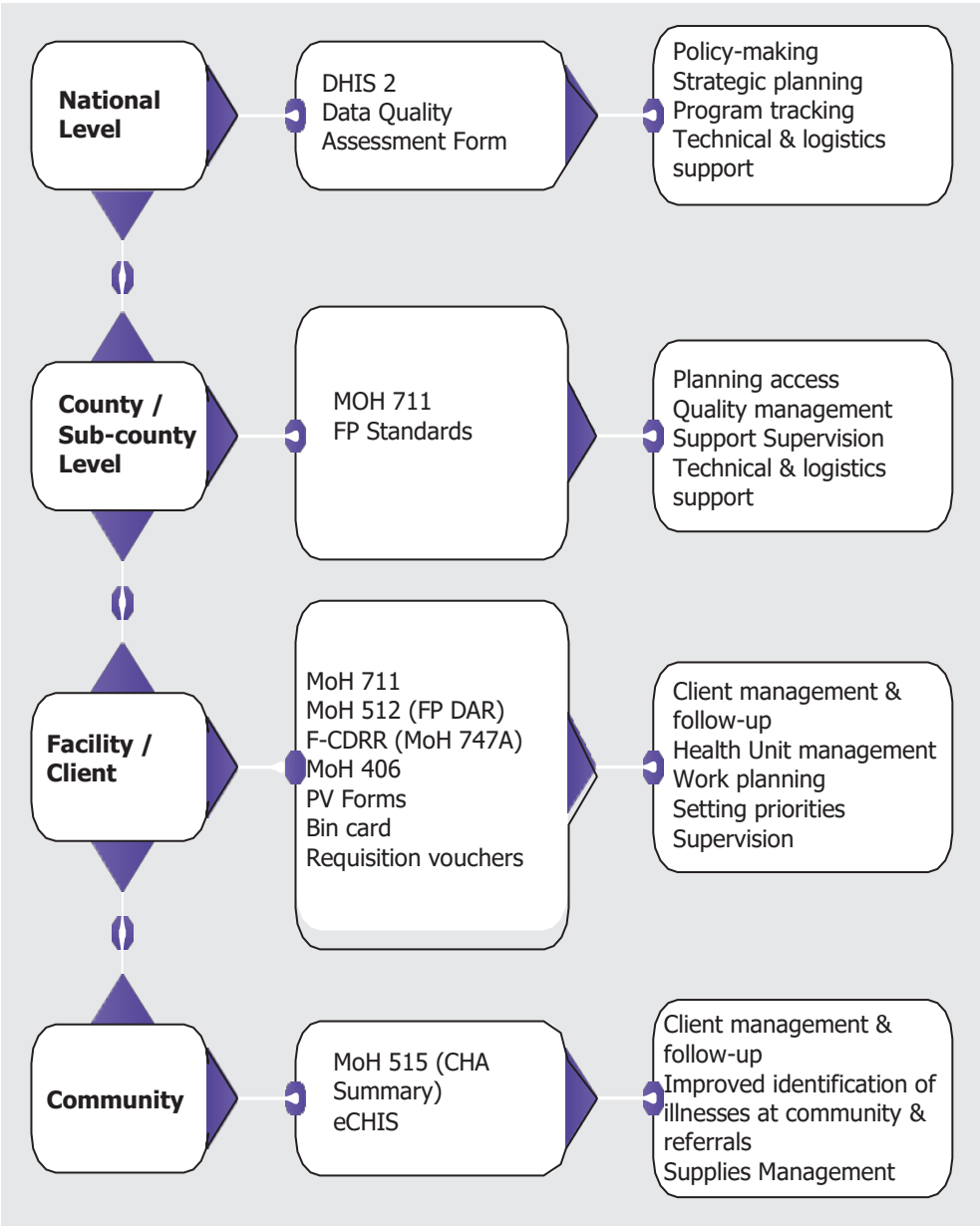
DATA FLOW AND USE AT VARIOUS LEVELS OF THE HEALTHCARE SYSTEM

Decision makers and stakeholders consider and incorporate data at various stages of service provision, program planning, management and policy-making. Decision-making should be informed by 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.

Healthcare providers for FP should not only accurately document and report to the next level but also routinely use this data for decision-making and performance review, as outlined in **Figure 10.1** below.

Figure 10.1 **Data flow and use at various levels**



ROLES AND REPORTING REQUIREMENTS BY SERVICE DELIVERY LEVELS

Each Service Delivery Point requires a Master Facility List (MFL) code to enable them to 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.

Healthcare providers from non-governmental organizations (NGOs) and the private sector should also follow the MoH service provision and reporting guidelines.

Healthcare providers will collect various data according to the Service Delivery Point as per the existing MoH data management tools. This cover:

- Facility details (includes county, sub-county, facility name, type, MFL Code and reporting period)
- Services offered
- HPTs receipt, use and requisition

Family Planning Services and RHPT Reporting Tools

The MoH has a series of tools for reporting on family planning services and RHPT at various levels of service provision. Most reports ultimately feed into the KHIS, as illustrated in **Table 10.2** below.

Table 10.2 **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	CHPs
MOH514 Service Delivery Logbook	Diary that is used to collect information from the household during the period of offering a health service (e.g., referral)	Monthly	CHPs
MOH515 CHEW Summary	Summary of MOH 514	Monthly	CHEW/CHA
MOH516 Community Health Chalkboard	Used by the community unit as reference for their performance. Chalk board for presenting analyzed information to the community	Monthly	CHEW/CHA
MOH100 Client Referral Form	Information on reasons for referral	As need arises	CHPs
Facility: Dispensary, Health Centres and Hospitals, Nursing Homes			
MOH 512 Daily Family Planning Activity Register	New clients Revisits Method dispensed Method Switch	Daily	Health Service Provider
MOH 711 RH/MCH Form	New clients Revisit Method dispensed Method Switch	Monthly	Health Service Provider
MOH 406 Postnatal Register	Women attending postnatal 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	Revisit dates Any side effects Methods dispensed	Every visit	Health Service Provider
Pharmaco-vigilance forms	Adverse events / Side effects	As needs arise	Health Service Provider
Client Referral Form	Clients being referred	As needs arise	Referring staff
DHIS 2	A platform for reporting, collating and analyzing health data Summarized on MOH 711	Done by 15th of every month	The HRIO / sub-county HRIO

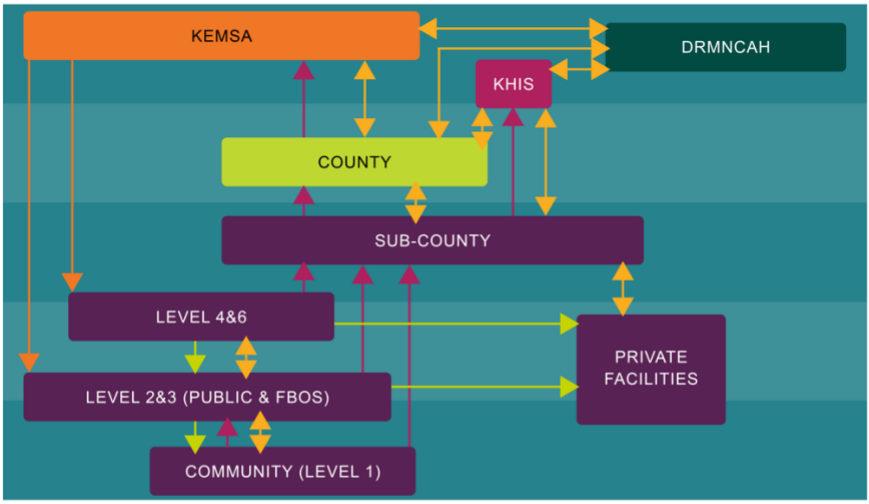
DATA QUALITY MANAGEMENT

Increasing access to and use of quality data is dependent on the development and operationalization of an efficient Data Quality Assessment (DQA) system which harnesses evidence-based decision-making. Deliberate efforts shall be put in place to ensure the reported data is verified on a regular basis. The healthcare provider shall incorporate strategies to enhance data quality, which include supportive supervision, data review meetings, routine data quality assessments (rDQA) and periodic data quality audits.

FP HPTs AND LOGISTICS MANAGEMENT

With the advancement in technology and expanding innovations, FPHPT management on an integrated logistics management information system (iLMIS) is implemented from the national central stores at the Kenya Medical Supplies Authority (KEMSA) to the county, sub-county and facility levels. The system promotes commodity security, protecting facilities and counties from commodity stock-outs. The iLMIS also houses an alert system that enhances end-to-end visibility of health commodities by highlighting commodity scenarios at each level (national, county, sub-county, and facility). It promotes redistribution if counties or facilities are overstocked and alerts when commodities are nearing stock-out, overall ensuring commodity security to promote access for end users (women, girls and all population). **Figure 10.2** summarizes FP commodity and information flow at the various levels.

Figure 10.2 **FP Commodity and information flow**



Note: The primary supply chain, reports and orders are facilitated through the i-LMIS platform. Primary Supply Chain moves FPHPTs from KEMSA to health facilities. The secondary supply chain involves re-distribution of FPHPTs amongst health facilities.

Receiving FP Health Products and Technologies (HPTs) at health facility level

- All HPTs shall be received at the facility store by an authorized person.
- The FP HPTs received (e.g., from KEMSA) shall be verified against the quantities on the delivery note. Important information indicated in the delivery note includes the destination of the commodities, expiry date, batch number, actual quantities and the condition of the FPHPTs.
- The delivery note shall be signed by the receiving officer and stamped using the official health facility stamp after properly making adjustments for any products that are returned (expired, damaged or not usable). The signed and stamped delivery notes shall then be scanned and uploaded onto the

electronic proof of delivery (EPOD) system.

- The received commodities shall then be entered into the Bin Card (S5) and balances adjusted accordingly.
- The Counter Requisition and Issue voucher (S11) shall be used for issuing commodities.
- Use the First Expiry, First Out (FEFO) system 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 checklists shall be accurately maintained.

Storage of FP HPTs

Health facilities shall adhere to SOPs for the storage of RHPTs:

- FPHPT stores shall be organized, clean and well-ventilated with temperature maintained in accordance with product specifications.
- FPHPTs shall be kept off the floor and away from walls to avoid contact with moisture, destruction by pests and to protect them from temperature fluctuations.
- All documents used in FPHPT management shall be signed, verified by an authorized person, stamped and copies filed.
- The FPHPT store shall be safely secured and access limited only to authorized personnel.

Issuing FP HPTs

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

Reporting

Tools used in Family Planning HPT Reporting

Table 10.3 shows the different tools used in the reporting of reproductive health products and technologies at the facility level.

Table 10.3 RHPT **reporting tools at facility level**

Tool	Use	Who fills
FCDRR – Facility Consumption Data and Requisition Report MOH 747A	Facility FP Commodities	Facility staff providing FP service
	Consumption data	
	Opening balances, receipts, issues, adjustments	
	Available at www.hiskenya.org	Sub-county pharmacist
Bin cards	Closing balances, receipts and issues	Store-in-charge
S11 (Counter Requisition and Issue Voucher)	Used for intra-facility issuing	Facility Staff Issuing

The MOH 747A Facility Consumption Data Report and Request form (F-CDRR) is a reporting tool used by the facility to report on the use of FP HPTs. It is also an important tool that is used to:

- Forecast facility RHPT requirements
- Plan for distribution of RHPTs
- Request RHPTs
- Ensure RHPT inventory management practices are observed
- Identify health facilities that will require support supervision and capacity building to support their inventory management practices
- Document the FP products and technologies consumed in the month, including receipts, expiries and any adjustments

At the end of every month, the FP healthcare provider shall summarize and prepare the **MOH 747A F-CDRR reporting tool correctly.**

The health facility shall calculate the **quantity requested for resupply (reorder quantities)** for each FP HPT in line with the National FP Program guideline and indicate these quantities in the provisional resupply quantities column of the F-CDRR report. (A general guide is to multiply the average monthly consumption by four then subtract the month's closing balance to determine the reorder quantity).

The F-CDRR report shall be filled in triplicate, dated and signed by the preparing officer and verified by the facility in-charge. The original copy (white) shall be forwarded to the Sub-County Pharmacist for updating in the DHIS2; the duplicate (pink) to the Sub-County; and the triplicate retained and properly filed at the health facility.

Ordering

Family planning HPTs are currently distributed by KEMSA to health facilities in line with the ordering cycle for FP HPTs, which happens quarterly. FP HPT managers at the health facility level submit their orders to the sub-county pharmacist, who uploads them to LMIS. The county pharmacist approves the orders and forwards them to the

National Order Management Team (NOMT). Health facilities are therefore required to submit their FP HPT orders to the sub-county pharmacist every quarter.

The health facilities shall calculate their monthly supply requirements by multiplying the number of months in between the supply periods (3 months) by their Average Monthly Consumption (AMC) and subtracting the Stock at Hand at the time of ordering. The health facility shall always include a one-month buffer stock in their re-order quantity that can be adjusted depending on particular challenges and situations the facility faces (e.g., unforeseen delays in the supply of commodities). This is calculated automatically by iLMIS and included in the re-order quantity for each FP HPT.

EXPIRED COMMODITIES

Expired stock is a major health and environmental hazard and must be disposed off in accordance with government procedures. The FCDRR has a losses column in which expired FP HPTs are reported. This column shall also be used to report the quantities of damaged or defective and missing FP HPTs. Once FP HPTs are expired, they shall be immediately counted, segregated and quarantined from the rest of the stock. The FP HPT manager shall then document this occurrence and record the details of the expired HPTs (Name, Batch Number, Expiry date and Quantity) in a chart or log book for recording expired FP HPTs. Once this is reported and the sub-county pharmacist notified, the sub-county pharmacist will notify the county pharmacist and the sub-county public health officer (PHO), who will fill out and complete the F.O. 58 form. The county pharmacist then forwards the expired HPTs to the county public health officer, who is responsible for the subsequent disposal of the expired HPTs.

Key Points to Note While Handling Expired FPHPTs

- Store expired RHPTs separately from the usable ones
- Keep a schedule to regularly check on and remove expired or damaged HPTs from shelves
- Set aside a designated space for damaged, expired or unusable HPTs
- F.O. 58 filled to document expired items

- Inform facility in-charge
- Expired or damaged shall be destroyed in accordance with the government PPDA regulations and NEMA guidelines
- Return to donor or manufacturer: Return unusable drugs for safe disposal by the manufacturer or unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date

Please refer to The Ministry of Health, National Guidelines for Safe Management of Health Care Waste, Second Edition, 2024 for the safe disposal of drugs at the county level[19].

SYNCHRONIZATION OF SERVICE DATA & CONSUMPTION

Service data refers to a record of the FP services offered at a health facility to a particular client at a particular time. This is reported in the FP register (MoH 512) and summarized through the MoH 731 form. Consumption data refers to RHPT use in a health facility for a specified period of time. This is reported through the FCDRR (MoH 747A). Synchronizing these two data reports is useful in ensuring that the services offered and commodities used tally. This can be done by comparing monthly commodity data and monthly service data. Services offered and RHPTs consumed should match, taking into account the number provided to a client for each service. This can be done monthly by using the DHIS2 Pivot table function to compare the two data sets.

Key Points to note while using MoH Registers and Reporting Tools

- 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 on a new page
- Ensure daily and monthly summaries
- Complete all rows and columns appropriately
- All monthly reports must have the reporting officer's name and

signature, supervisor's signature, facility name, date and stamp

- All monthly reports should reach the next level by 5th of the following month and be aggregated to KHIS by 15th of the following month

HPT Management in Community-Based Distribution

According to the WHO's global handbook for healthcare providers, the link health facility should work with the CBD agents, supervised by health facility clinical staff, reviewing their consumption records and assisting the CBDs to complete their order forms. The contraceptive supplies should be issued to community-based agents, based on their orders. A record of the date of expiry of these supplies can help with retrieving supplies that have not been distributed and are out of date.

LAST MILE ASSURANCE & IN-COUNTRY ASSESSMENT

Last mile assurance (LMA) in FP HPT management refers to a systematic and periodic process of conducting inspections or assessments to verify the status of FP HPTs within a supply chain. This is essential to ensure the quality, availability and proper handling/management of FP HPTs, including contraceptives and medical supplies.

LMA plays a crucial role in maintaining the quality and availability of FP HPTs, ultimately ensuring that individuals have access to safe and effective family planning products and services. LMA ICA helps to identify and address issues proactively to prevent stockouts, wastage and compromised product quality.

Purpose of LMA

- Verifying inventory accuracy: Confirming that the physical inventory matches the recorded inventory levels
- Ensuring product quality: Checking for any signs of damage, expiration, or tampering with RH commodities
- Monitoring storage conditions: Assessing whether commodities are stored in appropriate environmental conditions (e.g., temperature and humidity)

- Identifying potential issues: Detecting discrepancies or irregularities in the supply chain that may require corrective action
- Promoting accountability: Holding responsible parties accountable for maintaining the integrity of RH commodities

The LMA process aims to increase visibility on how RH Supplies are managed at different levels of the supply chain, allowing for better programming, targeted supply chain systems strengthening interventions, and increased MoH, UNFPA and Implementing Partner (IP) accountability.

The in-country assessment (ICA) is a critical component of the LMA process. It consists of on-site visits to health facilities to trace FP Programme Supplies at all levels of the supply chain, assess implementing partner capacity to safeguard and manage FP Programme Supplies, mentor facility personnel, and issue short- and long-term recommendations for strengthening supply chain systems.

The main aims of the ICA are to:

- Perform traceability exercises for MoH, UNFPA and implementing partner distributions
- Measure country stock on hand at Central Warehouses, Decentralized Warehouses and Service Delivery Points (SDPs)
- Assess if quality of products is safeguarded at facilities
- Measure product expiration, waste and loss
- Evaluate facility record-keeping and storage practices
- Mentor and build capacity of facility staff
- Verify information collected in previous LMA process activities
- Gather data for issuance of evidence-based recommendations for supply chain strengthening
- Monitor and evaluate progress of remedial actions issued in previous in-country assessments
- Ensure UNFPA and implementing partner accountability

- Improve MoH, UNFPA and implementing partner ability to discharge fiduciary obligations to donors.

The ICA includes four main activities, which are (1) Traceability, (2) Stock Verification, (3) Facilities Conditions and (4) Assessment of Irregularities.

Important notes on LMA-ICA

- Frequency and Randomization: LMA should be conducted regularly but on an irregular schedule to prevent predictability. Randomization in selecting which facilities or storage locations to check helps ensure that commodities are monitored across the supply chain without advance notice.
- Scope of LMA ICA: The scope can vary depending on the specific goals and needs of the RH commodity management program. It may include:
    - Physical counts of commodities to verify stock levels
    - Examination of packaging and labelling to ensure product integrity
    - Checking expiration dates and lot numbers to ensure compliance
    - Assessing storage conditions, such as temperature and humidity
    - Reviewing documentation, such as stock cards and inventory records
- Documentation and Reporting: The findings from LMA ICA should be thoroughly documented. This includes recording the date of the assessment, the specific commodities inspected, any discrepancies or issues discovered, and any corrective actions taken. Detailed reports should be generated and shared with relevant stakeholders.

- Corrective Actions: When discrepancies or issues are identified during LMA, appropriate corrective actions should be taken. This may involve restocking, reordering, disposing of expired commodities, or addressing issues with storage conditions. Tracking the implementation of corrective actions is crucial.
- Training and Capacity Building: Personnel responsible for conducting LMA should receive proper training to ensure that they can effectively carry out the assessments. Training should cover the criteria for assessing RH commodities, data collection methods and reporting procedures.
- Integration into FP HPT Supply Chain Management: LMA should be integrated into the overall FP HPT supply chain management system as a routine component. It should complement other monitoring and evaluation processes to ensure the overall integrity of the supply chain.
- Continuous Improvement: The results of assessments should be used to inform continuous improvement efforts in RH commodity management. This may involve revising standard operating procedures, adjusting inventory management practices, or enhancing staff training.

PHARMACOVIGILANCE

Introduction

The safety of modern FP methods on the health of 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. FP healthcare providers need to routinely document adverse events through collecting, monitoring, assessing and evaluating information on adverse drug reactions (ADRs).

All HPTs undergo testing for safety and efficacy through clinical trials before they are authorized for use. However, clinical trial processes involve studying these products in a relatively small number of individuals for a short period of time. Certain side effects may only emerge once these products have been used by a large heterogeneous population, including people with other concurrent diseases, and over a long period.

It is therefore imperative that regulators of HPTs put in place a process of evaluating and improving the safety of marketed medicines. The Pharmacy and Poisons Board's pharmacovigilance center is the hub for all pharmacovigilance (PV) activities in Kenya.

Table 10.4 provides definitions of terms used in pharmacovigilance.

Table 10.4 **Definition of terms in Pharmacovigilance**

Term	Definition
Pharmacovigilance	The science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with a view to: • Identifying new information about hazards, and • Preventing harm to patients.
Adverse Drug Reaction (ADR)	A response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.
Adverse Event	Any unpleasant medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.
Side Effect	Any unintended effect of a pharmaceutical product occurring at doses normally used in humans, which is related to the pharmacological properties of the product.
Toxicity	Adverse effects of a drug that occur because the dose or plasma concentration has risen above the therapeutic range, either unintentionally or intentionally (drug overdose).
Substandard and Falsified (SF) products	**Sub-standard** or "out of specification" products are authorized medical products that fail to meet either their quality standards or specifications, or both. **Falsified** medical products are those that deliberately/fraudulently misrepresent their identity, composition or source.

Importance of Pharmacovigilance

- Prevention of HPT-related morbidity and mortality
- Greater understanding and awareness of medicine-induced disorders
- Provides early signals/warnings on potentially serious ADRs
- Huge savings in health care costs
- Better patient confidence and trust in healthcare delivery

Scope of Pharmacovigilance

The scope of PV extends to medicines, medical devices, biologicals, herbal products, cosmetics, blood and blood products, poor-quality medicines and medication errors.

Goals of Pharmacovigilance

- Early detection of unknown safety problem
- Detection of change and frequency of ADRs
- Identification of risk factors
- Quantification of risks
- Minimizing the risk of ADRs to patients

Key Players in PV

- Regulatory bodies: The Pharmacy and Poisons Board (PPB) has a PV Centre that analyzes the PV data and communicates any 'signals' to all stakeholders. PPB also issues alerts to Market Authorization Holders (MAH) on any quality issues.
- Public health programs are responsible for capacity building, advocacy and technical assistance to the counties and health facilities on PV
- Pharmaceutical companies are required to have their own monitoring system for PV
- Healthcare professionals practice rational drug use, avoiding use of drugs that may cause ADRs in vulnerable patients, or combinations of drugs that may interact to precipitate an ADR. They are also responsible for detecting, assessing, managing and reporting any ADRs. They are also responsible for patient

education and form part of the investigation team.

- The patients and members of the public can also suspect and report an ADR, either directly to the PPB portal or to a healthcare worker.

Adverse Drug Reactions (ADRs)

An Adverse Drug Reaction is defined by the WHO as "A response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function."

ABCD Classification of ADRs

Type A are dose-dependent, predictable and therefore avoidable

Type B are unpredictable; include intolerance, hypersensitivity, pseudo-allergic and idiosyncratic reactions

Type C are ADRs that occur after a long period (months to years) of use of a drug

Type D occur as a result of carcinogenicity or teratogenicity

Classification of ADRs on Severity Scale

Severity classifications for ADRs are mild, moderate, severe and fatal (with fatal directly or indirectly leading to the death of the patient).

Reporting

All suspected ADRs and poor-quality RHPTs must be reported to the Pharmacy and Poisons Board PV Centre as soon as they are identified. Healthcare providers should note that no ADRs or suspected poor-quality HPTs are too minor or insignificant to be reported. In addition, one need not be certain, mere suspicion is sufficient.

When completing the ADR forms, the reporting person 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)

ADRs can be reported by healthcare workers, CHPs and members of the general public. Both suspected ADRs and suspected poor-quality HPTs should be reported on the PPB PV Electronic Reporting System (PvERS) portal:

https://web.pharmacyboardkenya.org/pharmacovigilance/

Otherwise, this can be done through the mobile app **mPvERs**, which can be downloaded free of charge from the Google Play Store. Alternatively, one may wish to download the reporting forms, fill them out, scan and email or deliver to the PPB Pharmacovigilance Centre.

There are six forms in the PvERS, namely:

1. Yellow form for reporting suspected ADRs
2. Off-white form for reporting Suspected Adverse Transfusion Reaction (ADR occurring after transfusion of blood and blood products)
3. White form for reporting suspected Adverse Events Following Immunization (AEFI)
4. Green form for reporting incidents arising from the use of medical devices and diagnostics
5. Blue form for medication error reporting
6. Pink form for reporting suspected poor-quality medicinal products

An ADR Alert Card is issued to clients who are hypersensitive or intolerant to a medication to alert healthcare givers against administering the offending medicine.

POST-MARKETING SURVEILLANCE (PMS)

Post-marketing surveillance (PMS) is the practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released into the market. It is an important practice in monitoring the quality of FP products and technologies after they are licensed and introduced into the market. Assuring the quality and safety of HPTs is needed to prevent harm to patients. Quality, safety and efficacy of health products and technologies can be compromised during the manufacturing process and/or in the supply chain.

Post-marketing surveillance enables the detection of Substandard and Falsified (SF) products, establishing registration status and the effects of storage conditions on the quality and stability of the products. In line with ensuring that the Kenyan public has continuous access to quality, safe and efficacious health products towards attaining UHC, PPB in collaboration with other relevant government agencies and development partners aims to conduct regular post-marketing surveillance surveys based on scientific protocols in order to assess the quality of medical products and health technologies circulating in the Kenyan market.

Importance of PMS

- HPTs do not necessarily retain their quality, safety and efficacy after registration throughout their shelf life
- Several factors can affect the quality of the medicines, including shipment, warehousing, distribution, handling, storage conditions and eventual dispensing to patients
- Unscrupulous individuals can compromise on these factors and the inherent quality of HPT by adopting unethical business practices
- Varying climatic conditions in the country may affect the quality of HPT

CHAPTER 11: CROSS-CUTTING ISSUES IN FAMILY PLANNING

INFERTILITY

Introduction

Infertility, defined as the inability to conceive after 12 months of regular, unprotected sexual intercourse, poses significant physical, emotional and social challenges. It affects approximately 10–15% of couples worldwide, with varying prevalence rates in different regions. In Kenya, cultural and social implications of infertility can add further complexity to the condition. The purpose of this guideline is to equip healthcare providers with comprehensive, evidence-based strategies for diagnosing, managing, and supporting individuals and couples experiencing infertility.

The WHO indicates that all human beings have a right to enjoy the highest attainable state of health, individuals and couples have a right to decide the timing, the number, and spacing of their children. Infertility can deter the realization of these human rights.

Although infertility affects both men and women, gender inequality is often propagated against women in a relationship with a man, sometimes perceived to suffer from infertility regardless of if they are infertile or not. Ensuring availability, access and quality interventions to address infertility has been recognized as a global priority that should be integrated within FP service provision as a core element of RH.

Healthcare systems should provide appropriate counselling and information including appropriate referrals for services.[20]

Effects Associated with Infertility

Infertility not only affects physical health but also has profound psychosocial and economic impacts.

Psychological risks include increased levels of stress, anxiety and depression, often exacerbated by social stigma and cultural pressures.

Economically, infertility treatments can be costly, leading to financial strain. It is essential for healthcare providers to understand these risks to provide holistic care that addresses both the medical and psychosocial aspects of infertility.

Known Causes of Infertility

a) Female Infertility Causes

Several factors can contribute to female infertility:

- **Ovarian Factors:** Conditions such as polycystic ovarian syndrome (PCOS), premature ovarian failure, and other ovulatory disorders. PCOS, for instance, affects ovulation and is characterized by irregular menstrual cycles, hyperandrogenism and polycystic ovaries. Premature ovarian failure involves early depletion of ovarian follicles before age 40, which can result in reduced fertility.
- **Tubal Factors:** Fallopian tube damage or blockage, often due to pelvic inflammatory disease (PID), sexually transmitted infections (STIs), or previous surgeries, can prevent sperm from reaching the egg or the fertilized egg from reaching the uterus.
- **Uterine Factors:** Abnormalities such as fibroids, polyps, congenital malformations, or adhesions can affect implantation or lead to recurrent pregnancy loss.

b) Male Infertility Causes

Male infertility can result from various issues:

- **Sperm Production Issues:** Low sperm count, poor sperm motility or abnormal sperm morphology. Conditions like varicocele or hormonal imbalances affecting testosterone can impair sperm production.
- **Obstructive Causes:** Blockages in the reproductive tract, such as those caused by infections or congenital absence of the vas deferens
- **Hormonal and Genetic Factors:** Imbalances in hormones like follicle-stimulating hormone (FSH), LH or testosterone and genetic conditions such as Klinefelter syndrome or Y chromosome microdeletions

c) Combined and Unexplained Infertility

In some cases, both partners may contribute to infertility, or no specific cause can be identified despite thorough evaluation, referred to as unexplained infertility.

Diagnosing Infertility

A comprehensive approach to diagnosing infertility involves a detailed medical history, physical examination and appropriate diagnostic tests.

Initial Assessment: Includes a detailed history-taking covering menstrual, sexual, medical, surgical and lifestyle factors. Physical examinations for women include a pelvic exam to assess any anatomical abnormalities, while for men, a genital exam is conducted to evaluate testicular size, presence of varicocele, or other abnormalities.

Diagnostic Tests for Women:

- **Hormonal Evaluation:** Blood tests to assess levels of FSH, LH, prolactin, TSH, and AMH (Anti-Müllerian Hormone) to evaluate ovarian reserve and function.
- **Imaging:** Pelvic ultrasound to assess ovarian and uterine health, hysterosalpingography (HSG) to evaluate tubal patency, and hysteroscopy or laparoscopy for direct visualization of the reproductive organs.
- **Ovulation Testing:** Use of ovulation predictor kits, basal body temperature charting, or serum progesterone levels on day 21 of the cycle to confirm ovulation.

Diagnostic Tests for Men:

- **Semen Analysis:** To assess sperm count, motility and morphology. Normal values are defined by WHO standards (e.g., sperm concentration ≥15 million/mL, total motility ≥40%).
- **Hormonal Evaluation:** Blood tests for testosterone, FSH, LH and prolactin to assess endocrine function.
- **Imaging:** Scrotal ultrasound to detect varicocele or other testicular abnormalities. Genetic testing may be indicated in cases of severe oligospermia or azoospermia.[21]

Self-care Interventions to Prevent Infertility

Prevention strategies are crucial in minimizing the risk of infertility and include lifestyle modifications, regular health checks, and safe sexual practices.

- **Lifestyle Modifications:** Encourage a balanced diet rich in antioxidants, maintaining a healthy weight, regular physical activity, and avoiding smoking, excessive alcohol and illicit drugs, all of which have been linked to improved reproductive outcomes.
- **Preventive Health Measures:** Regular screenings for sexually transmitted infections (STIs), timely management of infections, and appropriate vaccinations (e.g., HPV, rubella) can prevent conditions that may lead to infertility.

Non-Medical Interventions for Infertility

Non-medical interventions often complement medical treatments and can provide psychological and emotional support.

- **Complementary Therapies:** Acupuncture, herbal medicine, and nutritional supplements have been explored for their potential to enhance fertility, though evidence remains mixed. Healthcare providers should discuss the benefits and risks of these options with patients.
- **Behavioural Interventions:** Stress reduction techniques, such as yoga, meditation and mindfulness practices, can improve overall well-being and potentially enhance fertility outcomes.
- **Support Systems:** Establishing support groups and providing counselling services are vital in managing the emotional burden associated with infertility.

Medical Interventions for Infertility

Medical interventions range from pharmacological treatments to surgical procedures, depending on the underlying cause of infertility.

- **Pharmacological Interventions:**
    - **Ovulation Induction:** For women with ovulatory disorders, medications like Clomiphene citrate or Letrozole can stimulate ovulation. Gonadotropins (FSH, LH) may be used in more advanced cases, with dosage adjustments based on ovarian response monitored by ultrasound.
    - **Hyperprolactinemia:** Treated with dopamine agonists like Cabergolineorine
- **Surgical Interventions:**
    - **Laparoscopic Surgery:** For the treatment of endometriosis, removal of ovarian cysts, or adhesiolysis
    - **Hysteroscopic Surgery:** To remove uterine polyps, fibroids, or correct congenital uterine anomalies
    - **Tubal Surgery:** For tubal blockage or damage, though success rates are variable and often lower than ART
- **Assisted Reproductive Technologies (ART):**
    - **Intrauterine Insemination (IUI):** A less invasive procedure where sperm is washed and concentrated before being directly inserted into the uterus. Typically timed with ovulation, with or without ovulation induction medications.
    - **In Vitro Fertilization (IVF):** Involves ovarian stimulation with gonadotropins, egg retrieval, fertilization in a laboratory setting, and subsequent embryo transfer. Protocols vary, but commonly used regimens include a combination of FSH and LH or recombinant FSH with GnRH agonist or antagonist protocols. The starting dose of gonadotropins ranges from 150 to 450 IU daily.
    - **Intracytoplasmic Sperm Injection (ICSI):** A specialized form of IVF where a single sperm is injected directly into an egg, often used in cases of severe male infertility.[22],[23]

Counselling in Infertility Management

Counselling is integral to infertility management, offering emotional support and guiding patients through complex decision-making processes.

- **Pre-treatment Counselling:** Provides comprehensive information on diagnostic findings, available treatment options, success rates, potential risks, and costs. Informed consent must be obtained after discussing all aspects of proposed interventions.
- **Psychosocial Support:** Addressing the emotional impact of infertility, including feelings of guilt, blame and anxiety. Psychological support, including individual or couples therapy, can help manage stress and improve coping mechanisms.
- **Post-treatment Counselling:** Includes follow-up care after interventions, managing expectations regarding success rates, and providing guidance on next steps if treatment is unsuccessful. Alternative options like adoption, donor gametes, or surrogacy may be explored.

Referrals and Multidisciplinary Approach

Effective management of infertility often requires a multidisciplinary approach.

- **Referral Pathways:** Clear guidelines on when to refer patients to specialists such as reproductive endocrinologists, urologists or genetic counsellors. Referrals should be considered early in cases of complex infertility or when initial treatments fail.
- **Collaborative Care:** Infertility management may involve collaboration with various healthcare professionals, including gynecologists, andrologists, endocrinologists, mental health professionals, dietitians and social workers to address all aspects of patient care comprehensively.

Additional Topics

- **Ethical Considerations in Infertility Treatment:** Ethical challenges, including the use of ART, donor gametes, and surrogacy, should be addressed. Ethical principles such as autonomy, beneficence, non-maleficence and justice must guide
- **Health Education and Awareness:** Educating communities on infertility causes, prevention and treatment options can reduce stigma and encourage early consultation.
- **Impact of Age on Fertility:** Detailed information on how age affects fertility in both men and women, and guidance on egg and sperm preservation techniques for those who may wish to delay childbearing.
- **Stigma reduction**

Monitoring and Evaluation

Regular monitoring and evaluation of infertility services are essential for maintaining high standards of care and improving outcomes.

- **Data Collection and Reporting:** Establish protocols for systematic data collection on infertility cases, treatment outcomes, patient satisfaction and adverse events. Regularly analyze data to identify trends and improve service delivery.
- **Quality Assurance:** Implement regular audits, patient feedback mechanisms and continuous quality improvement initiatives to ensure adherence to best practices and high-quality care standards.

Infertility can be influenced by a variety of factors, such as:

- **Infections:** Pelvic inflammatory disease (PID), sexually transmitted infections (STIs)
- **Cultural Practices:** Certain cultural practices and beliefs can impact fertility, including early marriages and female genital mutilation
- **Healthcare Access:** Limited access to quality healthcare services can delay diagnosis and treatment of infertility

- **Environmental Factors:** Exposure to environmental toxins and pollutants can affect reproductive health
- **Socioeconomic Factors:** Poverty and lack of education can limit access to fertility treatments and healthcare
- **Lifestyle Factors:** Smoking, excessive alcohol consumption, and obesity can negatively impact fertility
- **Medical Conditions:** Conditions such as polycystic ovary syndrome (PCOS) and endometriosis are common causes of infertility

FP SERVICES IN HUMANITARIAN SETTINGS

Provision of FP services in Humanitarian Emergencies and Outbreaks

FP healthcare providers need to balance the demands of responding to outbreaks, while simultaneously maintaining FP services in all three phases of an epidemic response: mitigation and preparedness, emergency, and post-emergency.

Evidence-based practices, including multi-month scripting and supplies during humanitarian crises and epidemics, and integration of self-care, have been recommended. Based on WHO's global handbook for FP providers, many contraceptive methods can be self-administered safely and effectively in such circumstances without a physical examination: POPs, COCs, ECPs, spermicides, male and female condoms, some diaphragms, and LAM have been recommended.[7]

Key Points for Providers and Clients

- FP services should be made available throughout an epidemic
- MEC for safe use of contraceptive methods do not change during an epidemic
- Some contraceptive methods can be safely and effectively self-initiated and continued with or without support from healthcare providers
- More widespread use of digital health technologies and direct pharmacy access may improve access during an epidemic

Maintaining FP service provision during an Epidemic

Individuals' ability to access and effectively use FP services is time-sensitive, because incorrect or delayed contraceptive use greatly reduces effectiveness.

In providing FP services during an epidemic, providers should:

- Screen clients for symptoms of the epidemic disease and—if symptoms are present—manage or refer the client in accordance with the existing protocols
- Protect their own and their client's safety during interactions by following rules of infection prevention appropriate to the type of epidemic, including sanitizing equipment and rooms using the correct protocols
- Ensure that the client makes a voluntary and informed method choice, and that privacy and confidentiality are respected
- Provide the full range of methods when resources and circumstances permit, but be open about what is not available, and when additional methods may become available
- Provide multi-month supplies of oral contraceptives and subcutaneous depot medroxyprogesterone acetate (DMPA-SC) for self-injection as needed, to cover a longer duration of use

Safe use of contraceptive methods during an Epidemic

The medical eligibility criteria (MEC) for contraceptive use do not change during an epidemic.

Accounting Mechanisms for FP HPTs during Humanitarian Emergencies

FP HPTs supplied to service delivery points during humanitarian emergencies should be reported using the updated FCDRR reporting tool (MOH 747A) under the receipt's column labelled "Red Cross".

Use of Digital Health Technologies

Healthcare providers can maintain access to family planning for clients even in humanitarian settings. There are many formats and uses for digital health technologies, and they may be particularly valuable during an epidemic when clinic-based services are restricted.

Technologies used in a digital health framework to connect healthcare providers with clients include SMS or text messaging, phone or video "visits", informative podcasts, mobile apps, and web-based tools such as email or open medical records (medical records that clients can directly review or access themselves). With the exception of IUDs, implants, DMPA IM, some diaphragms, and permanent methods (male and female sterilization), contraceptive methods do not require a physical exam prior to initiation.[24]

In providing family planning services in humanitarian settings, healthcare providers are recommended to:

- Use digital health technologies to connect with clients, counsel them, and prescribe methods that do not require physical examination
- Leverage digital health technologies to share important information on the safety of contraceptive methods and how to access services.

FP GENDER EQUALITY AND GENDER INCLUSIVENESS

Gender Equality and Family Planning

Gender-related barriers to reproductive autonomy significantly undermine the effectiveness of sexual and reproductive health programs. These barriers include reproductive coercion by partners or family members, child marriage, patriarchal gender norms, and the underrepresentation of women in decision-making roles at national, regional and local levels.

FP products and interventions are crucial for advancing gender equality, as they provide women, girls and others with the tools they need to manage their fertility and protect their physical, mental and economic well-being. However, for sexual and reproductive health programs to succeed, it is essential to address gaps and disparities arising from gender norms and power dynamics.

Gender integration aims to understand and address structural and social barriers to reproductive health care. By tackling these barriers intentionally and safely, gender integration helps ensure that all individuals have the opportunity to exercise their reproductive autonomy and benefit from comprehensive sexual and reproductive health services. Gender equality and access to family planning are closely interconnected. From a human rights perspective, everyone has the right to decide "whether and when to have

children, how many, and with whom." This right is essential for personal empowerment and control over one's own body and life.

To ensure gender-responsive care while adhering to the nine human rights principles outlined in the Human Rights section, providers should focus on empowering all individuals—women, men, and gender-diverse people—to:

- Access comprehensive sexual and reproductive health care, information and education: Ensure that everyone has equal opportunities to obtain the resources and support they need
- Make informed decisions about their health care: Respect each individual's autonomy to make choices about their health care, including contraceptive use and consent to sexual activity. This includes supporting the right to make decisions independently or collaboratively with a partner.

Key Gender Equality Definitions

- Sex refers to the biological and physiological characteristics that differentiate males and females, such as reproductive organs, chromosomes and hormones.
- Gender denotes the socially constructed characteristics associated with being male or female, including norms, roles and relationships within and between groups of women and men.
- Gender equality involves providing equal opportunities for all individuals, regardless of gender, to access and control social, economic and political resources, including protection under the law, such as health services, education and voting rights.
- Gender equity recognizes that individuals have different needs, preferences and interests based on gender. It may involve providing different treatments or resources to ensure equal opportunities by addressing the specific realities faced by different genders.
- Gender-responsive policies, practices and programs aim to address and reduce gender inequality and inequity by actively working to mitigate their negative effects.

Key Gender Inclusion and Diversity Definitions

- Gender identity refers to an individual's deeply felt internal sense of their own gender, which may or may not align with the sex they were assigned at birth.
- Transgender, nonbinary, gender fluid and genderqueer are terms used to describe gender identities that differ from the sex assigned at birth.
- Cisgender describes individuals whose gender identity aligns with the sex they were assigned at birth.
- Gender expression pertains to the external presentation of one's gender, including choices in dress, speech and behaviour. This expression may not always correspond to one's gender identity.
- Intersex refers to a range of conditions where an individual is born with physical sex characteristics that do not fit typical definitions of male or female. These can include variations in chromosomes, hormones or reproductive anatomy, and may be apparent at birth or later in life.

Providers need to be mindful of the diverse needs and experiences of women, men and gender-diverse individuals. It is essential to consider how social, cultural, and economic circumstances—particularly harmful gender norms and inequalities—impact individuals' contraceptive decision-making, access to care and ongoing use of their chosen method. Providers should ensure that their approach to care empowers all individuals, regardless of these circumstances, to make informed choices and access the support they need.

Gender Inclusiveness

Gender inclusiveness in family planning means creating and implementing practices, policies and services that are respectful, accessible and supportive of all gender identities. It involves recognizing and addressing the diverse needs of individuals beyond the traditional binary gender categories of male and female. Key aspects include:

- **Recognizing Diverse Identities:** Gender inclusiveness acknowledges that people may identify as transgender, nonbinary, gender fluid, genderqueer, or in other ways that do not fit within the traditional male-female binary. Family planning services should be designed to meet the needs of all gender identities.
- **Access to Services:** Ensure that family planning services are accessible to everyone, regardless of their gender identity. This includes providing contraceptive options, reproductive health care, and support services that accommodate the needs of transgender and gender-diverse individuals.
- **Respecting Gender Identity:** Respect each individual's gender identity by using their preferred names and pronouns. This respect should extend to all aspects of the service, from initial consultations to medical records and interactions with staff.
- **Inclusive Education and Counselling:** Provide educational materials and counselling services that are inclusive of all genders. This includes offering information about contraception and reproductive health that is relevant to transgender and nonbinary individuals, and addressing any specific needs or concerns they may have.
- **Addressing Barriers:** Identify and mitigate barriers that may prevent gender-diverse individuals from accessing family planning services. This could include financial barriers, discrimination, lack of knowledgeable providers or inadequate facilities.
- **Gender-Sensitive Approaches:** Adapt family planning approaches to be sensitive to the different needs and experiences of various genders. This includes understanding

how hormone therapies used by transgender individuals might interact with contraceptive methods, and addressing specific health concerns related to gender transition.

- **Confidentiality and Privacy:** Maintain confidentiality and privacy, particularly when dealing with sensitive information about gender identity and reproductive health. Avoid disclosing gender history or personal details without explicit consent.
- **Training and Education for Providers:** Ensure that family planning providers are trained in gender inclusivity and are aware of the specific needs of gender-diverse populations. This training should include how to provide respectful and knowledgeable care to all individuals.

By integrating these principles, family planning services can become more inclusive, ensuring that everyone has equitable access to the care and support they need to make informed decisions about their reproductive health.[7],[3]

CHAPTER 12: CURRENT HIGH-IMPACT PRACTICES IN FAMILY PLANNING

HIGH-IMPACT PRACTICES IN FAMILY PLANNING

According to the World Health Organization, high-impact practices (HIPs) are a set of evidence-based family planning practices vetted by experts against specific criteria and documented in an easy-to-use format [25]. HIPs are measurable practices that should have a demonstrable impact in achieving various FP outcomes, such as increased modern contraceptive uptake, reduction in unintended pregnancy, and reduction in overall fertility or in at least one primary proximate determinants of fertility (delay of marriage or sexual initiation for adolescents, birth spacing, exclusive breastfeeding and postpartum abstinence). HIPs are categorized as:

- **Enabling environment:** Enabling environment HIPs address systemic barriers that affect an individual's ability to access FP information and services.
- **Service delivery:** Service delivery HIPs improve the availability, accessibility, acceptability, and quality of FP services.
- **Social and behaviour change (SBCC):** SBCC HIPs influence knowledge, beliefs, behaviours, and social norms associated with FP.

Enhancements: A HIP enhancement is a tool or an approach that is not a standalone practice, but often used in conjunction with at least two or more HIPs in the other three areas to maximize the impact of HIP implementation or increase the reach and access for specific audiences. The intended purpose and impact of enhancements are focused, and therefore the evidence-base and impact of an enhancement is subject to different standards than a HIP.

POST-PREGNANCY FAMILY PLANNING

Introduction

Post-pregnancy family planning includes both postpartum FP as well as post-abortion FP.

- **Postpartum FP:** Refers to the prevention of unintended and closely-spaced pregnancies through the first 12 months following childbirth, for women and their partners.[14]
- **Post-abortion FP:** Refers to the prevention of unintended and closely spaced pregnancies following an abortion.

Post-Pregnancy Family Planning (PPFP) focuses on enhancing the spacing of pregnancy in the first 12 months following childbirth or abortion. The provision of family planning following pregnancy is a life-saving intervention that not only prevents unintended pregnancies, but also improves postnatal outcomes for mothers and infants and perinatal outcomes in subsequent pregnancies. The WHO recommends spacing pregnancies by 2 years or more following childbirth and at least six months following abortion.

Strong evidence demonstrates that the provision of PPFP at the same time and location as the Post-Abortion Care (PAC) services improves the feasibility, acceptability and effectiveness of PPFP services. Despite the evidence, many post-abortion clients who need PPFP leave facilities without a contraceptive method or counselling services.

Research has demonstrated that more than 90% of women during their first-year postpartum want to either delay the next pregnancy for at least two years or avoid future pregnancies altogether.

Women are much more likely to take up postpartum family planning if they have made a decision before going into labour.

Figure 12.1 **The Periods of Post-Pregnancy Family Planning**

Rationale for PPFP

Post-Pregnancy Family Planning has an important role to play in strategies to reduce the unmet need for FP. It addresses the needs of those who wish to have children in the future (referred to as 'spacers'), as well as those who have reached their desired family size and wish to avoid future pregnancies (referred to as 'limiters'). Further rationale for PPFP includes the following:

- 24 months is the recommended interval before attempting the next pregnancy, based on a consultation convened by the World Health Organization.
- According to a DHS survey analysis from 8 sub-Saharan countries, 95% of women who are 0–12 months postpartum want to avoid a pregnancy in the next 24 months, but 70% of them are not using contraception[26]
- 63% of women in Kenya have an unmet need for family planning during the postpartum period[27]
- More than 4 in 10 currently married women in Kenya want to limit childbearing, and 43% want no more children[1]
- FP can avert more than 30% of maternal deaths and 10% of child mortality if couples space their pregnancies more than 2 years apart
- Closely spaced pregnancies within the first year postpartum are the riskiest for mother and baby, resulting in increased risks for adverse outcomes, such as preterm, low birth weight and small for gestational age
- Risk of child mortality is highest for very short birth-to-pregnancy intervals (<12 months). If all couples waited 24

months to conceive again, under-five mortality would decrease by 13%. If couples waited 36 months, the decrease would be 25%.

- 18% of births in Kenya occur less than 24 months after previous childbirth.[2]
- Many women and couples have reached their desired family size and would like to prevent future pregnancies. Ensuring that every woman has only the number of children she desires is an important means of decreasing maternal mortality.
- Studies have demonstrated that the risk of maternal death increases as the number of children per woman rises to four or more. Maternal deaths have been shown to decline as the number of children per woman falls. PPFP, therefore, helps women who have an unmet need to space and limit future pregnancies, while helping to lower rates of maternal and child death.
- Fertility returns quickly. Following an induced or spontaneous abortion, ovulation can return as early as 8–10 days later and usually within 1 month. Hence, initiating a family planning method immediately after abortion if possible, or as soon as possible within the first month, is important for women who desire to delay or prevent a future pregnancy.

Post-Pregnancy Family Planning Strategic Objectives are to:

- **Improve Access:** Ensure that all women have access to post-pregnancy family planning information and services, regardless of their geographic location or socio-economic status
- **Increase Awareness:** Conduct awareness campaigns to promote the importance of post-pregnancy FP and dispel misconceptions
- **Strengthen Healthcare Systems**: Develop the capacity of healthcare providers to offer high-quality post-pregnancy family planning services
- **Monitor and Evaluate:** Establish a robust monitoring and evaluation framework to track the progress and impact of the scale-up roadmap

Increasing PPFP Uptake along the maternal, newborn and child health MNCH continuum of care

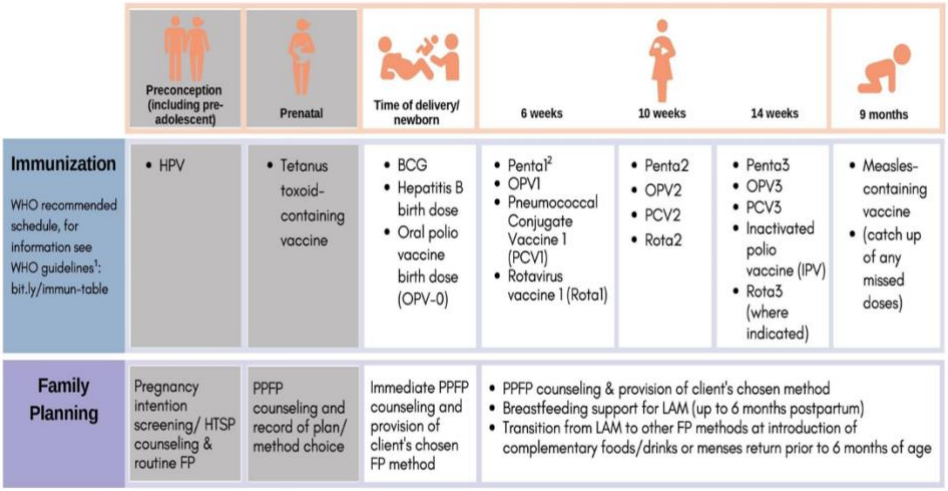
The foundation for postpartum FP should be established during the antenatal period. Women are much more likely to take up postpartum FP if they have made a decision before going into labour. FP information and services or referral should be a key component of the post-abortion care package and postnatal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

There exist opportunities for integrating FP through the MNCH continuum of care following the recommended vaccination schedule during the first year of an infant's life. Integration offers benefits such as mitigating constraints related to transportation costs and time while also reducing the burden on the overall health system and, potentially, on individual workloads.

The existing evidence suggests that when well planned and executed, family planning and immunization integration services can lead to increased family planning uptake with no negative impact on immunization, as shown in **Figure 12.2** below.

Figure 12.2 **Opportunities to integrate FP at various immunization contacts from preconception through first year of life**

Figure 3. Opportunities to integrate family planning at various immunization contacts from preconception through first year of life



[1] Vaccination schedules may vary across countries.

[2] Pentavalent vaccine protects against the following five diseases: diphtheria, tetanus, pertussis (whooping cough), hepatitis B and *Haemophilus influenzae* type b (DTP-hepB-Hib)

Shaded columns are outside the postpartum period and therefore do not pertain to periods relevant to this brief.

Postpartum women and their infants are recommended to receive at least five assessments by a skilled attendant within the first year of childbirth. (See **Table 12.1.**) During the visits, healthcare providers 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 healthcare facility after delivery, service providers should ensure that clients have been offered the opportunity to receive immediate postpartum family planning before being discharged home.

Table 12.1 **FP counselling and services during the continuum of care from antenatal through postpartum phases**

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 cesarean 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
Within 2 weeks (preferably within one week) after birth	• Provide counselling on vasectomy where applicable • 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 women's choice). • 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 of genital trauma

Family Planning methods during the post-pregnancy period

An important consideration when planning a PPFP Programme or intervention is clinical safety; that is, which methods can be used at what point in time following birth and given the mother's breastfeeding status.

The following are WHO recommendations for method use during the first year postpartum (and beyond) within the medical eligibility criteria for contraceptive use (MEC) [(14)]. Note that these recommendations are also applicable to women living with HIV.

- Immediately after birth and for up to 6 months following, a woman who is exclusively breastfeeding can use the lactational amenorrhoea method (LAM) and several other methods safely. If a mother chooses LAM, she should transition from LAM to another modern contraceptive method by the time the infant reaches 6 months of age, or sooner if LAM criteria [(14)] are not met. She should be provided information in a timely manner to enable her to choose another modern contraceptive method.

- A copper-bearing intrauterine contraceptive device (IUD) can be inserted immediately or up to 48 hours after birth, or any time after 4 weeks postpartum.
- A female sterilization procedure or tubal ligation (BTL) can be performed immediately or up to 4 days after birth, or any time after 6 weeks postpartum.
- For non-breastfeeding women, in addition to IUD and BTL, progestin only methods can be initiated immediately following birth.
- Combined oral contraceptives can be initiated at 3 weeks after birth.
- For breastfeeding women, all progestin-only methods; pills, injections, implants – can be initiated at 6 weeks following birth, as per WHO MEC.
- Combined oestrogen and progestin pills cannot be initiated until 6 months after birth.
- All women, breastfeeding or not, can initiate use of condoms immediately after birth, emergency contraception after 4 weeks, and the diaphragm or cervical cap after 6 weeks, as illustrated in the **appendix 14.5.**

REDUCING STOCK-OUTS

Ensuring commodity security has been a priority for the ministry and the FP program through various approaches and focusing on strengthening key strategies. These include:

- Advocacy for sustainable financing, including domestic public financing, and
- Rolling out and scaling up of the integrated LMIS, targeting all 47 counties.

The iLMIS ensures commodity security through the commodity early warning and alert system (CEWAS) and electronic proof of delivery (EPOD). These tools enable proactive FP commodity management with real-time visualization of stocks throughout all levels of the FP supply chain (KEMSA, county, sub-county, health facility).

SOCIAL BEHAVIOUR CHANGE AND COMMUNICATION (SBCC)

SBCC is an essential component in achieving global development goals, including family planning. It is a discipline that uses a deep understanding of human and societal behaviour and evidence-based interventions—such as mass media, community engagement, and interpersonal communication—to increase the adoption of healthy behaviours and influence the social norms that underpin those behaviours.

SELF-CARE

Self-care refers to the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope will illness and disability with or without the support of a health worker. It helps enable people to exercise greater autonomy, power and control of their health and improve their wellbeing. Self-care encompasses self-awareness, self-testing and self-managed care.

Self-care in FP provides an opportunity for individuals to take responsibility for their own health, take charge of their reproductive health goal(s) and fertility, and accessing FP contraception.[28]

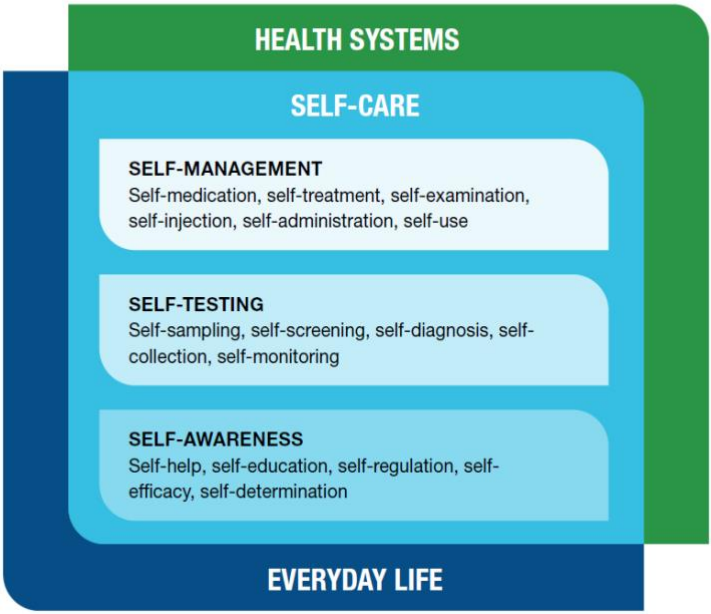
This section addresses the FP priority areas for self-care.

Self-care interventions:

- Help improve health and well-being, both from a health systems perspective and for the users of these interventions, and hold the promise to be good for everyone and to move us closer to realizing universal health coverage
- Have the potential to increase choice and autonomy when they are accessible, acceptable and affordable
- Represent a significant push towards greater self-determination, self-efficacy, autonomy and engagement in health for self-carers and caregivers
- Promote the active participation of individuals in their health care and are an exciting way forward to reach improved health outcomes by addressing various aspects of health care
- Can play a significant role in humanitarian settings, for example due to lack of or limited health infrastructure and medical services in the crisis-affected areas
- Could play an important role in improving health-related outcomes
- Build upon existing movements, such as task sharing and ask shifting, which are powerful strategies to support health systems

Figure 12.3

SELF-CARE IN THE CONTEXT OF INTERVENTIONS LINKED TO HEALTH SYSTEMS



Adapted from (WHO self-care guideline 2023)

Self-care in Family Planning consists of 3 components:

1. Self-awareness,
2. Self-examination/diagnosis/testing, and
3. Self-Management.

a) Self-Awareness

Self-awareness in FP covers matters such as normal menstrual cycle, when and how to initiate contraception, FP method change, method discontinuation and return to fertility. Knowledge of the different methods of contraception, together with their effectiveness and common side effects, is key in ensuring that the client makes an informed choice on a method.

Clients should be educated on their eligibility for various self-care contraceptive options, on drug interactions (especially for those on management for other conditions) and proper use of self-care contraceptive methods, adherence to the contraceptive schedule, where to acquire contraceptives, and the management and disposal of contraceptive waste.

Lactating mothers should be provided with the options—when to initiate contraception and which contraception method to use, their contraindications and proper use of methods like LAM.

People living with HIV and AIDS (PLWHA) require comprehensive counselling and knowledge of contraception, infection transmission prevention, drug interactions between ART and contraceptives and how to detect side effects and warning signs, and when to seek help.

Self-Awareness: Self Care for DMPA-SC

DMPA self-injection is a safe, high-quality intervention for increasing access to FP. DMPA (also called "Depo-Provera" or "the shot") is a 3-month Progestin-Only injectable contraceptive that can be administered subcutaneously (SC) or intramuscularly (IM) that can be self-administered safely by anyone trained including women themselves.

Self-injected contraception is now an option with the innovative, easy-to-use injectable DMPA-SC that has revolutionized contraceptive access and use, overcoming potential barriers related to access.

b) Self-Examination/Diagnosis/Testing

Clients can self-monitor for common contraceptive side effects. They can conduct self-examination for blood pressure, pregnancy testing and interpretation of the results.

c) Self-Management

Proper use of and compliance with self-care contraceptives; The healthcare provider should demonstrate to client's self-injection and self-medication.

DMPA-SC injection is one of the approved forms of self-care. This is dependent on the training of healthcare providers 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.

DMPA-SC Self-injection: Initiation – 1st visit guidelines

- For clients who are counselled and choose DMPA-SC injectable contraceptive as the preferred method, the HCP should introduce DMPA-SC for self-injection
- The first self-injection is to be done under direct supervision of the HCP at the health facility
- During the first visit, the healthcare provider shall observe that the client can self-inject using the steps outlined in Table 12.2:

Table 12.2 **Client self-injection steps**

Steps to observe and rate client	
1.	Checks the expiry date on the package and any visible damage to the packaging.
2.	Washes hands thoroughly and dries them.
3.	Correctly identifies the injection site.
4.	Correctly cleans the injection site.
5.	Correctly holds and shakes the DMPA-SC unject system for 30 seconds.
6.	Correctly activates the unject system.
7.	Correctly pinches the skin fold at the injection site.
8.	Correctly inserts the needle to puncture the skin at a downward angle until the port comes into the contact with the skin.
9.	Correctly squeeze the reservoir slowly for 5-7 seconds to administer the DMPA-SC.
10.	Documents on the record card/re-injection calendar the date of current dose administered and the due date for the next dose.

Client refills – 2nd, 3rd & subsequent visits

During these visits, the HCPs shall take the following steps for clients who are eligible and want to continue with DMPA-SC.

- Collect any used DMPA-SC kits from the clients for disposal through the health facility medical waste system, if not collected by the CBD. Note that the return of the used DMPA-SC kit is not linked to the dispensing of subsequent doses.
- Review the self-injection technique with the client to ascertain whether they can remember the correct procedure
- Dispense 4 doses of DMPA-SC for self-injection at home
- Capture the resupply details of the client on the daily activity register and on the client's revisit card
- Advise the client to return to the healthcare facility for a check-up at least once a year
- Emphasize the importance of adhering to the subsequent dates for self-injection
- Provide the client with the appropriate brochure and job aid, including the reinjection calendar for injection reminders during each subsequent reinjection
- Emphasize key take-home messages, including reinjection window, return dates, safe disposal of the self-care products, danger signs, and use of dual method
- Provide a follow-up card to the client, clearly indicating the revisit dates and emphasizing that the client is free to consult the HCPs at any time
- Remind the client not to share dispensed doses and to return the doses in case of damage. Note that any returned doses shall be disposed of through the health facility's medical waste systems.
- Provide or link the client to other integrated services, such as cancer screening and HIV testing
- In case the client has missed the injection date by more than 4 weeks, the HCP should rule out pregnancy and switch to provider-administered DMPA-IM

- If the client is uncomfortable continuing with self-injection but still prefers an injectable contraceptive, give DMPA-IM

DMPA-SC Storage and Waste Disposal

Instruct the client to:

- Store DMPA-SC in a cool dry place, out of reach from children, and in a clean environment illustrated below in figure 12.5
- Discard the Uniject in a readily available puncture-proof container with a well-fitting lid, immediately after self-injection
- DO NOT recap the needle after injection.
- Store the puncture-proof container with used DMPA-SC in a safe and secure place out of children's reach
- Dispose of the used DMPA-SC packaging material in general household waste
- Return the puncture-proof container (with the used Uniject) to the HCPs at their convenience or engage CBDs to collect the puncture-proof container for disposal

Figure 12.4 **Storage instructions for DMPA-SC clients self-injecting at home**

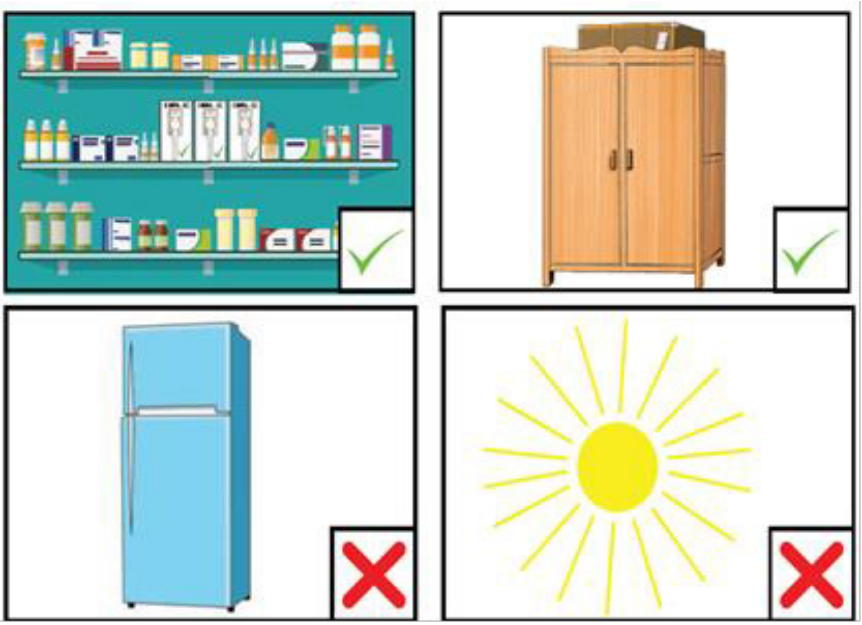


Figure 12.5 **DMPA-SC Waste Disposal**

Figure 12.6 **Required supplies and equipment for DMPA-SC injection**

- Make sure that you have all the supplies and equipment you need.

Figure 12.7 **Hand washing and safety instructions before handling the injection**

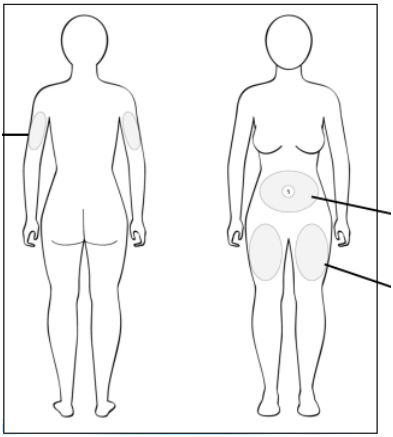
Hand hygiene

- Wash your hands after you have set out your supplies and before you give the injection. This helps prevent infection.
- Wash your hands well with soap and running water.
- Let your hands air dry.

Injection Sites

The following are the injection sites.

Figure 12.8 **Possible injection sites for DMPA-SC**



Ask your client which site she prefers:

- In the back of the upper arm.
- In the abdomen (not at the navel).
- On the front of the thigh.

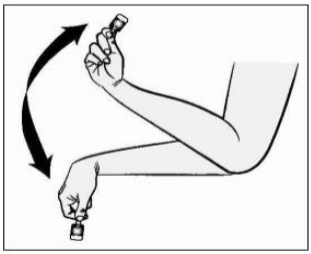
Figure 12.9 **Instructions for sealing open the DMPA-SC package**

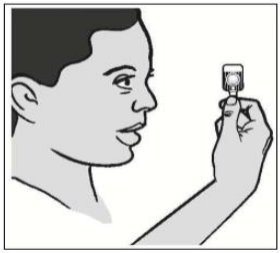
The pouch should be opened as follows

- Check the expiration date on the pouch.
- Open the foil pouch and remove Uniject.
- Make sure it is at room temperature.

Figure 12.10 **Mixing technique for the active ingredient (DMPA-SC)**

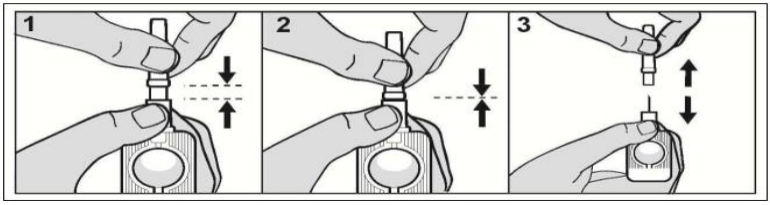
Mix the solution





- Hold the Uniject by the port.
- Shake it for 30 seconds.
- Check to make sure the solution is mixed and there is no damage or leakage.

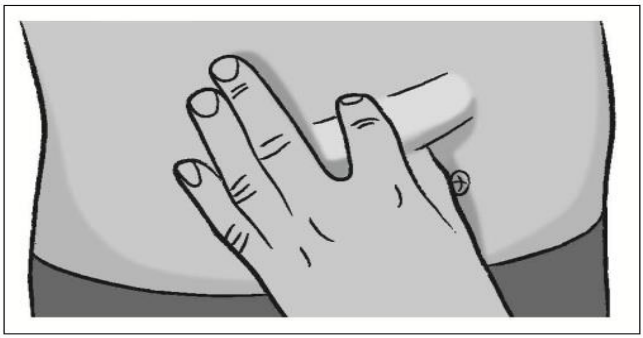
Figure 12.11 **Preparation and activation technique for the Uniject**
Activate the Uniject



- Hold the Uniject by the port.
- Keep the Uniject pointed upward during activation to prevent spilling the drug.
- Push the needle shield into the port.
- Continue to push firmly until the gap between the needle shield and port is closed.
- Remove the needle shield.

Figure 12.12 **Skin pinching technique**

Gently pinch the skin at the injection site



- The pinch is important to make sure DMPA-SC is injected into the fat, and not the muscle

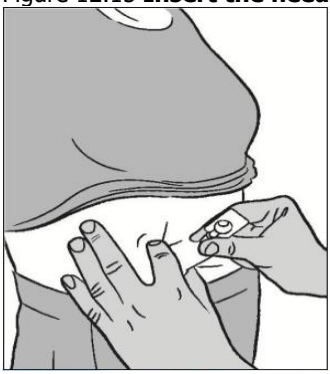
Figure 12.13 **Positioning the needle for injection**

- Insert straight into the skin at a downward angle.
- A slight downward angle helps prevent injection of air.
- Needle should never be pointed upward during injection.

Figure 12.14 **Insert the needle (arm)**

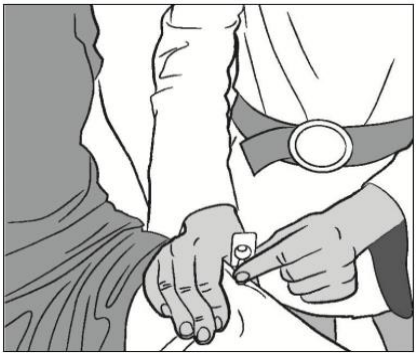
- Hold port while inserting.
- Insert at a downward angle.
- Port should touch the skin.

Figure 12.15 **Insert the needle (abdomen)**



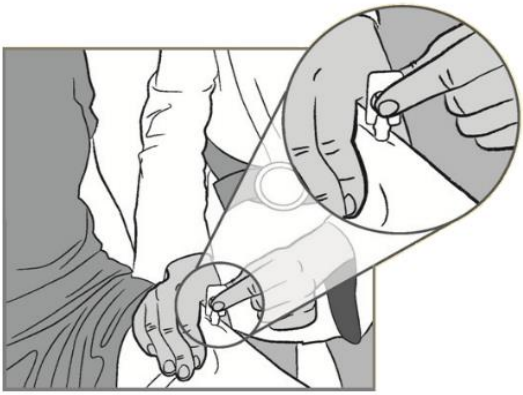
- Hold port while inserting.
- Insert at a downward angle.
- Port should touch the skin.
- **Avoid the navel.**

Figure 12.16 **Insert the needle (thigh)**



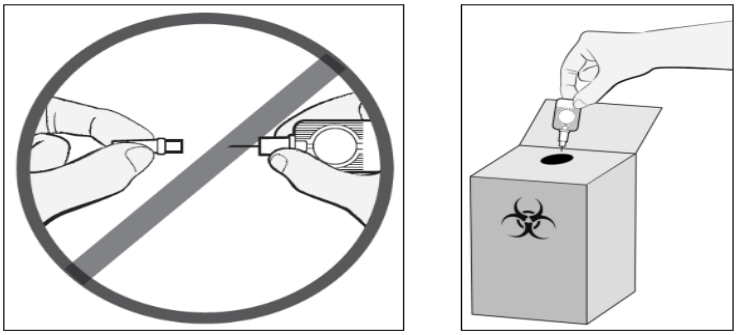
- Hold port while inserting.
- Insert at a downward angle.
- Port should touch the skin.

Figure 12.17 **Squeezing the reservoir**



- Squeeze the reservoir slowly – 5 to 7 seconds.
- **Do not** clean or massage the site after injecting.

Figure 12.18 **Discarding the Uniject**



- Do not replace the needle shield into the Uniject.
- Place in safety box.

QUALITY OF CARE

Quality of care forms a critical and accepted part of contraceptive services. The WHO defined quality of care as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes. Quality of care is based on evidence-based professional knowledge and is necessary to achieve the country's sustainable development goals and universal health coverage. Kenya responded to the global call for action and has witnessed increased access to and utilization of reproductive and other maternal, adolescent, and child health services [29]. Despite this increase in access to services, adverse outcomes; persisting high rates of unmet contraceptive needs, gender inequalities, teenage pregnancies persist as a reflection of the quality of RH/FP services. There has been a growing acknowledgment that quality health services should be:

- **Effective** – providing evidence-based healthcare services to those who need them;
- **Safe** – avoiding harm to people for whom the care is intended; and
- **People-centered** – providing care that responds to individual preferences, needs, and values.

The WHO states that to realize the full benefits of quality of health services, health services must be;

- **Timely** – reducing waiting times and sometimes harmful delays;
- **Equitable** – providing care that does not vary in quality on account of gender, ethnicity, geographic location, and socio-economic status;
- **Integrated** – providing care that makes available the full range of

health services throughout the life course;
- **Efficient** – maximizing the benefit of available resources and avoiding waste.

HUMAN RIGHTS-BASED APPROACH (HRBA)

The right to access the highest attainable standard of physical and mental health remains the backbone for health programs. The provision of FP services is also anchored on fundamental rights. The human rights-based approach (HRBA) to FP is a systematic process to ensuring that FP programmes maintain a focus on human rights-related principles and standards that apply to FP. It aims to ensure that the care provided is respectful, person-centered, equitable, and responsive to the needs and rights of clients.

The HRBA provision of FP services ensures:

- **Dignity and respect**—clients are provided with non-judgmental, client-centered care, with ensured privacy and confidentiality
- **Autonomy and informed choice**—where clients are given an opportunity for voluntariness in decision-making and informed consent while choosing an FP method
- **Empowerment and support—**that clients are empowered through proper information giving and counselling, and that clients receive a full range of comprehensive FP services. In addition to this, that service provision is based on evidence-based practices, and healthcare providers are regularly trained and remain competent in delivering FP services.
- **Participation and accountability**—where clients and communities are engaged in planning and evaluating FP programs, and program feedback mechanisms for users are established
- **Integration and coordination**—ensuring that FP is integrated with other services (HIV/AIDS, maternal and child health, STI) to ensure holistic care

DIGITAL HEALTH AND FAMILY PLANNING

The division RMNCAH is utilizing digital health as an opportunity to increase access and provide convenience in the utilization of RH services, including FP. The FP program is engaging online pharmacy and telehealth platforms in offering quality information and services.

Digital counselling (DC) and direct-to-consumer (DTC) platforms are transforming access to quality FP information, counselling and products. These platforms have the potential to offer an on-demand, user-centered experience that addresses logistical, privacy, stigma, and cost challenges, particularly for women and adolescent girls making contraceptive decisions. By increasing the visibility and acceptability of contraceptive products through mainstream digital channels, these platforms can unlock latent demand and promote integration.

The delivery of contraceptive services through telecommunication technologies on virtual platforms aims to enhance accessibility and convenience for individuals facing challenges with in-person services. These online and telehealth services are provided by authorized and trained providers for FP counselling.

The online/telehealth package for FP services may include:

- Online counselling with trained providers
- Enhanced self-care services, such as self-testing for pregnancy, DMPA-SC self-injection
- Direct-to-consumer services, including provision of short-term contraceptive commodities
- Digital counselling and referrals for long-term contraceptive services
- Data tracking and digital reporting to monitor service utilization, client satisfaction and feedback, such as through pharmacy service provision channels

CHAPTER 13; MONITORING, EVALUATION, RESEARCH & LEARNING

MONITORING AND EVALUATION (M&E)

Monitoring in the Family Planning program refers to the systematic and routine tracking of key indicators. Evaluation is the episodic assessment of the change in targeted results that can be attributed to the FP program. The MoH provides overall strategic leadership in M&E of the FP program with technical assistance from a multi-sectoral technical working group that includes implementing partners.

County governments shall also establish similar accountability mechanisms to provide close monitoring of the FP program. The MoH and partners shall mobilize sufficient resources to support M&E functions of the FP program and in implementation of its Plan of Action. Indicators for monitoring will be drawn from and aligned with the National Health Management Information System (HMIS). Monitoring will be led by the DRMNCAH with all other stakeholders ensuring the FP program reporting is coordinated with the MoH.

Evaluation of the FP program will be conducted through periodic surveys, including the Kenya Demographic and Health Survey (KDHS) every five years. These evaluations will assess the effectiveness and impact of family planning interventions, identify what works and what doesn't, and provide insights to guide necessary adjustments to the FP program. Additionally, other relevant data sources and targeted studies may be leveraged to ensure a comprehensive evaluation. The findings will support policy refinement, optimize resource allocation, and ensure the program continues to meet the evolving needs of the population. Stakeholders at all levels will be engaged in the evaluation process to ensure that the results are actionable and aligned with national priorities.

Integrated Logistics Management Information System (i-LMIS)

Timely and accurate logistics data are essential for the effective management of the family planning health products and technologies (HPT) supply chain. The i-LMIS is instrumental in monitoring, planning and informing procurement processes, ensuring that FP HPTs are available in the right place and at the right time. In addition to enhancing supply chain efficiency, data on FP HPTs consumption patterns and service utilization provides valuable insights for monitoring and evaluation. This information helps identify trends, forecast demand and assess the impact of FP services, ultimately leading to improvement in decision-making and effective resource allocation.

It is imperative that both national and county FP HPT management teams ensure the timely and accurate collection, reporting and analysis of all FP HPT data. This commitment to data integrity will enhance the overall effectiveness of FP programs and ensure that they continue to meet the reproductive health needs of the population.

Indicators for FP Services and HPT Management

Table 13.1 **FP Service Indicators**

Indicator	Indicator definition
Uptake of FP modern methods	Number of new acceptors of 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 women of reproductive age (WRA) who are currently using at least one method of contraception regardless of the method use **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 regardless of the method use **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 were she to live to the end of her childbearing years and bear children in accordance with current age-specific fertility rates

Indicator	Indicator definition
Discontinuation rate (per method)	% of WRA who stop using contraceptive method(s) within the first year of use
Unmet need for FP	% of women currently married or in union who are fecund and who desire to either stop or postpone childbearing, but who are not currently using a modern contraceptive method
Total Demand for FP	% of women using FP + % ow omen with unmet need for FP
Met need for FP	% women using FP / % women with demand for FP
Unintended Birth Rate	% of births that resulted from pregnancies that were reported to be either unplanned or unintended **Numerator**: # of births reported as unintended **Denominator:** total # births reported

Table 13.2 **FP HPT Management Indicators**

Indicator	Indicator definition
Reporting (Rate)	% of facilities submitting (timely, complete, accurate) commodity consumption reports to the central lev
Stock Status	% of facilities with current stocks within the Min (1 MOS) and Max (4 MOS) level (not overstocked, under-stocked or stocked out)- in the last 3 months
Stock Outs	% of facilities providing a service judged by the figure of those 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

RESEARCH IN FAMILY PLANNING SERVICE DELIVERY

Research is defined as a systematic investigation, including concept development, testing and evaluation, aimed at generating or contributing to generalizable knowledge. In the context of family planning, research is critical for advancing the field, particularly as new innovations, digital platforms, products and technologies continue to emerge.

With the rapid expansion of FP services and the integration of innovative

solutions, this guideline encourages FP healthcare providers to systematically explore, test and refine new ideas. It emphasizes the importance of using implementation science and operations research. This approach encourages the documentation of best practices in service delivery and prompt communication of such to the DRMNCAH. At the national level, DRMNCAH is committed to promoting research within the FP program by strengthening centres of excellence—entities or teams that provide leadership, best practices, research, support and training in specific focus areas. These centres of excellence play a pivotal role in advancing FP research and ensuring that new knowledge is translated into improved practices.

To further streamline and prioritize FP research efforts, MoH has developed the National Reproductive Health Priority Research and Learning Agenda (2022–2027). This agenda aims to harmonize reproductive health research across the country, fostering collective synergy, improving efficiency, and facilitating the rapid absorption of research findings into policy and programmatic decisions. By aligning research activities with this agenda, Kenya can more effectively address the reproductive health needs of its population and drive impactful change in the FP sector [(30)].

The goal of health-facility-based research is to improve patient care and safety through systematic evaluation and analysis of medication use and healthcare practices.

Specifically, the operational research objectives are to:

1. **Enhance Patient Safety**: Identify potential drug interactions, contraindications and adverse drug reactions (ADRs) to minimize risks associated with medication use
2. **Optimize Therapeutic Outcomes**: Ensure that patients receive the most effective method appropriate for their needs, considering efficacy, safety and client preferences
3. **Promote cost-effectiveness**: Evaluate the appropriateness of the family planning methods to avoid unnecessary costs associated with the wrong method choice
4. **Improve Quality of Care**: Support healthcare providers in making informed decisions about quality family planning service delivery, ultimately leading to better patient outcomes

TYPES OF HEALTH-FACILITY-BASED FP RESEARCH

Drug Use Reviews (DURs)

Drug Use Reviews (DURs) play a crucial role in the healthcare system, particularly in family planning services. By systematically evaluating medication use, DURs enhance patient safety, optimize therapeutic outcomes and improve the overall quality of care. Implementing DURs within family planning can lead to better-informed counselling and method choice and increased client satisfaction.

Healthcare providers should prioritize the integration of DURs into their practice to ensure that family planning services are not only effective but also responsive to the evolving needs of their clients. Continuous education and training on DUR processes will empower healthcare workers to utilize this valuable tool effectively, fostering a culture of safety and quality in medication management.

Process of Conducting DURs

1. **Data Collection**: Gather relevant patient data, including medication history, diagnoses, laboratory results and other pertinent health information
2. **Evaluation**: Assess the appropriateness of the FP method given based on Medical Eligibility Criteria (MEC), clinical guidelines and individual patient factors
3. **Identification of Issues**: Identify any potential problems, such as drug interactions, inappropriate methods or non-adherence
4. **Intervention**: Communicate findings to other healthcare providers to avoid future issues and improve client experience and FP outcomes
5. **Follow-Up**: Monitor the implementation of the recommendations from the DUR

Importance of DUR in Family Planning Services

In the context of family planning services, DURs can be particularly valuable for:

- **Monitoring Contraceptive Use**: Evaluating the effectiveness

and safety of various contraceptive methods prescribed to clients

- **Identifying Adverse Drug Reactions**: Gathering data on any adverse effects experienced by clients using specific contraceptives, which can inform future prescribing practices
- **Enhancing Client Education**: Providing insights that can help healthcare providers educate clients about potential side effects and the importance of adherence to prescribed contraceptive methods
- **Personalizing Care**: DURs can help tailor contraceptive options to individual client needs, preferences, and health conditions, ensuring that the chosen method aligns with their overall health goals
- **Improving Access to Services**: By identifying barriers to effective contraceptive use, such as cost or availability, DURs can inform strategies to enhance access to family planning services

Clinical Audits

Clinical audits are essential for ensuring the quality and safety of family planning services. By systematically reviewing practices against established standards and implementing changes based on audit findings, healthcare providers can improve service delivery, enhance client experience, and maintain high standards of service.

A clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review against explicit criteria and the implementation of change. Its objective is to identify gaps in service delivery, improve clinical practices, ensure adherence to guidelines, and enhance overall patient safety in family planning services.

Steps in Conducting Clinical Audits in Family Planning

1. **Preparation and Planning**
    - **Define the scope**: Identify the specific area of family planning to be audited, such as contraceptive management, patient counselling or follow-up care.
    - **Set Objectives**: Establish clear objectives for the audit, such as improving adherence to contraceptive guidelines or reducing the incidence of adverse drug reactions.
    - **Select Criteria and Standards**: Choose relevant criteria and standards based on national guideline, evidence-based practices, or local protocols.
2. **Data Collection**
    - **Identify Data Sources**: Determine sources of data, such as patient records, electronic health records (EHRs) and Daily Activity Registers.
    - **Data Collection Tools**: Develop or use existing tools, such as checklists or data collection forms, to systematically gather information.
    - **Collect Data**: Collect data on a representative sample of patients over a defined period to ensure the audit results are meaningful and applicable.
3. **Data Analysis and Interpretation**
    - **Compare Against Standards**: Compare collected data against established standards to identify discrepancies, non-compliance and areas needing improvement.
    - **Root Cause Analysis**: Conduct a root cause analysis to understand the reasons behind any identified gaps in practice or non-compliance with standards.
    - **Identify Areas for Improvement**: Highlight key areas where changes are needed to improve family planning services and patient outcomes.

4. **Implementing Changes**
    - **Develop an Action Plan**: Create a detailed action plan to address the identified gaps, including specific interventions, timelines and responsible personnel.
    - **Training and Education**: Provide training and education to healthcare providers on the new practices or guidelines to be implemented.
    - **Monitor Progress**: Monitor the implementation of changes to ensure adherence and to evaluate the impact on service quality and patient outcomes.
5. **Re-audit and Continuous Improvement**
    - **Conduct a Re-audit**: Re-audit the service after implementing changes to assess the effectiveness of interventions and ensure sustained improvements.
    - **Evaluate Outcomes**: Evaluate the outcomes of the re-audit and make further adjustments as needed to maintain high-quality care.
    - **Document and Share Findings**: Document the audit findings, lessons learned and improvements made, and share them with the healthcare team and relevant stakeholders.

Types of Clinical Audits in Family Planning

- **Clinical Practice Audits**: Review adherence to clinical guidelines, such as those for contraceptive counselling, selection and follow-up.
- **Medication Management Audits**: Assess the appropriateness of contraceptive prescriptions, management of drug interactions and monitoring of adverse drug reactions.
- **Patient Safety Audits**: Evaluate safety practices related to family planning services, such as infection prevention in procedures like IUD insertions.
- **Documentation Audits**: Review the completeness and accuracy of documentation related to family planning, including patient records and consent forms.

Quality Assurance and Continuous Improvement

- **Regular Audits**: Conduct regular clinical audits as part of a continuous quality improvement program to ensure high standards of care.
- **Learning from Best Practices**: Identify and adopt best practices from other healthcare facilities to enhance FP services.

Criteria for Effective Research in Family Planning

For a research activity to be valuable and impactful in the field of family planning, several key criteria must be met:

1. **Relevance and alignment with priority issues:** The research topic must address a priority issue within family planning. It should be aligned with the needs of the population and the strategic objectives outlined in the National Reproductive Health Research Agenda (2022–2027).
2. **Stakeholder engagement:** Stakeholders, including policymakers, healthcare providers and community representatives, must be involved from the outset. Their engagement is essential in reviewing the research question, justification and study design to ensure that the research is contextually appropriate and addresses real-world challenges.
3. **Ethical approval:** All research activities must receive approval from an accredited research ethics committee to ensure they meet ethical standards. Additionally, approval must be obtained from the National Commission for Science, Technology and Innovation (NACOSTI) to ensure compliance with national regulations and standards.
4. **Dissemination of findings:** The results of the research must be disseminated widely at local, national and international levels. This dissemination ensures that the knowledge generated reaches all relevant stakeholders and can inform broader discussions and actions within the FP community.
5. **Utilization of findings:** Deliberate efforts must be made to promote the utilization of study findings to influence improvements in family planning programs, practices and policies. The research should not just end with publication but should lead to tangible changes that

enhance the effectiveness and impact of FP services.

Family planning priorities for the National Reproductive Health Research Agenda (2022-2027)

The National Reproductive Health Research Agenda (2022–2027) has identified several priority areas within family planning that require focused research efforts:

1. **Data recording and documentation:** Enhancing the accuracy and completeness of data collection to inform decision-making and program evaluation
2. **Self-Care:** Exploring the potential of self-care interventions in family planning, including the use of digital tools and remote services
3. **Pharmacovigilance:** Monitoring and evaluating the safety and efficacy of FP products, with a focus on minimizing adverse effects and ensuring consumer safety
4. **Consumer Knowledge, Attitude and Practice:** Understanding the knowledge, attitudes and practices of consumers regarding FP to inform more effective communication and education strategies
5. **Uptake of FP:** Investigating accessibility and availability of services; impact of innovations and digital platforms; barriers to consistent use; equity and inclusion; and factors that influence the uptake of family planning services, particularly among underserved populations
6. **Method Mix/Market:** Analyzing the distribution and availability of different FP methods to ensure a balanced method mix that meets the diverse needs of the population
7. **Infertility:** Addressing infertility within the FP context, including prevention, management and the social implications of infertility

By focusing on these priority areas, the research conducted will contribute to the continuous improvement of family planning services, ensuring they are effective, accessible and responsive to the needs of all users.

CHAPTER 14: APPENDICES

APPENDIX 14.1: EFFECTIVENESS OF FP METHODS

Pregnancy Rates per 100 Women during First Year of Use

Method	Pregnancy Rate as commonly used	Pregnancy Rate when used correctly and consistently
Contraceptive Implants	0.05	0.05
Male sterilization-Vasectomy	0.15	0.1
LNG-IUD (Mirena)	0.2	0.2
Female sterilization-Tubal Occlusion	0.5	0.5
Copper IUCD (380A IUD)	0.8	0.6
Lactational Amenorrhoea 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
Two Day method		4
Standard Days Method (SDM)	25	5
Female condoms	21	5
Withdrawal (Coitus Interruptus)	27	4
NO METHOD OF CONTRACEPTION	85	85

APPENDIX 14.2: HOW TO IDENTIFY MIGRAINE HEADACHES AND AURAS

For women who want or are using a hormonal method, identifying whether or not they suffer from migraine headaches, with or without auras, is important because migraines, and aura in particular, are linked to a 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 experience aura, she can start or continue hormonal methods if she is otherwise medically eligible. Any later changes in her headaches should be evaluated.

APPENDIX 14.3: 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:

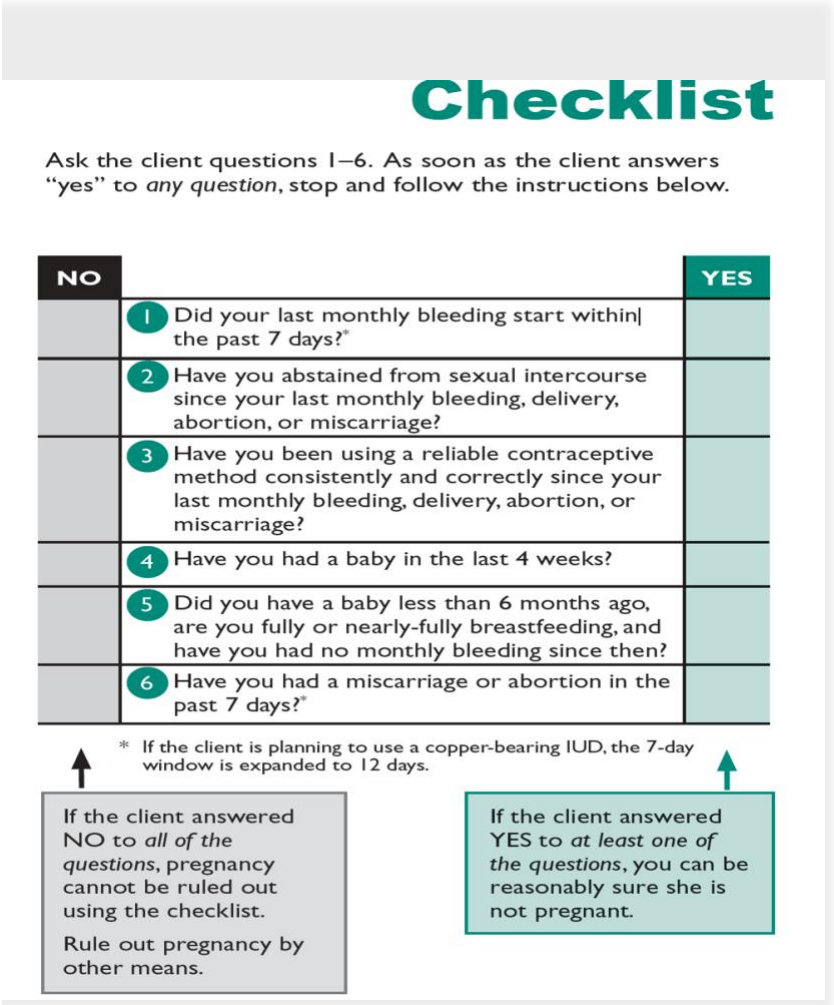
……..……

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 14.4: 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?*	

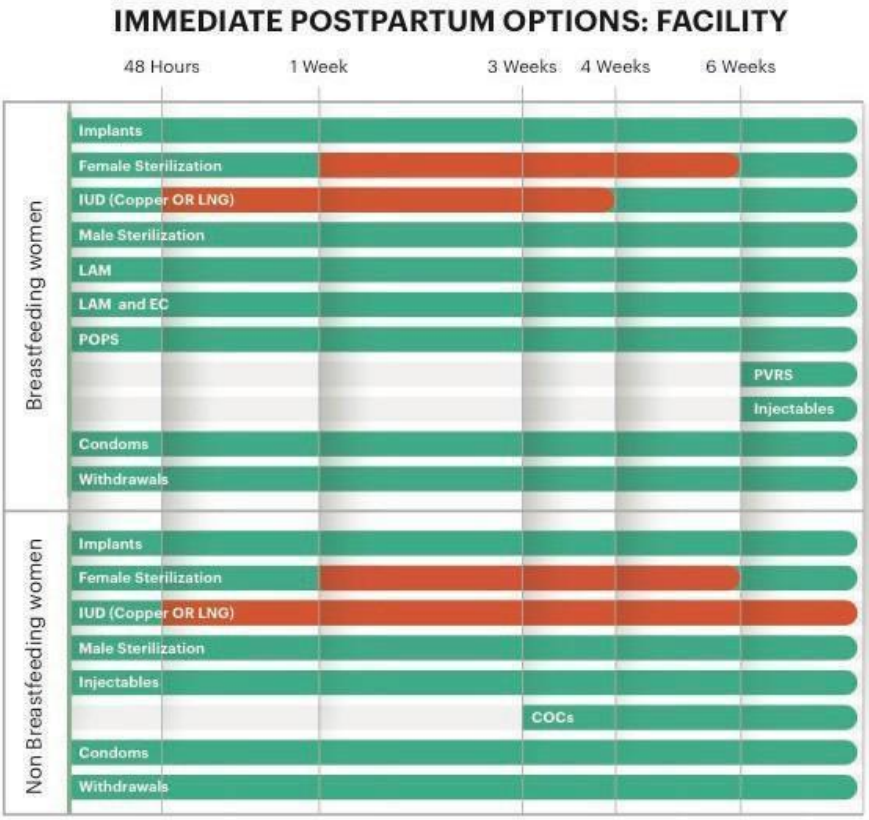
* If the client is planning to use a copper-bearing IUD, the 7-day window is expanded to 12 days.

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 14.5: 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 14.6: PHARMACOVIGILANCE FORMS

There are six (6) pharmacovigilance forms that are used to report drug reactions, or any reactions occurring when using any of the FP products.

1. Suspected Adverse Drug Reaction Reporting Form (Yellow Form)
2. Suspected Poor Quality Health Products & Technologies Reporting Form (Pink Form)
3. Suspected Adverse Event Following Immunization Reporting Form (White Form)
4. Medical Devices Incident Reporting Form (Green Form)
5. Medication Error Reporting Form (Blue Form)
6. Adverse Transfusion Reaction Form (Off White Form)

The forms can be accessed at: http://www.pv.pharmacyboardkenya.org/

Pre-Choice Stage

1. **Establish and maintain a warm, cordial relationship. Listen to the client's contraceptive needs.**

2. **Rule out pregnancy using the pregnancy checklist card with 6 questions.**

If client answers:	Then:
"Yes" to any of the questions and she is free of signs and symptoms of pregnancy	1) Pregnancy is unlikely. 2) Continue to **Step 3.**
"No" to all of the questions	1) Pregnancy cannot be ruled out. 2) Give client a pregnancy test, if available, or refer her to an antenatal clinic. 3) Ask her to return when she has her menstrual bleeding. 4) Provide her with a backup method, such as condoms, to use until then. 5) Go to **Steps 12 to 19.**

3. **Display all of the method cards. Determine whether the client wants a particular method.**

4. **Ask <u>all</u> of the following questions. Set aside method cards based on the client's responses.**

   a) **Do you wish to have children in the future?**
   If "Yes," set aside vasectomy and tubal ligation cards. Explain why. If "No," keep all cards and continue.

   b) **Are you breastfeeding an infant less than 6 months old?**
   If "Yes," set aside the combined oral contraceptives (the Pill) and combined injectable contraceptive (CIC) cards. Explain why.
   If "No," or she has begun her monthly bleeding again, set aside the lactational amenorrhoea method (LAM) card. Explain why.

   c) **Does your partner support you in family planning?**
   If "Yes," continue with the next question.
   If "No," set aside the following cards: Standard Days Method© and TwoDay Method©. Explain why.

   d) **Are there any methods that you do not want to use or have not tolerated in the past?**
   If "Yes," set aside the cards the client does not want. If "No," keep the rest of the cards.

Method Choice Stage

5. **Give information on the methods that have <u>not</u> been set aside and indicate their effectiveness.**
   a) Arrange the remaining cards in order of effectiveness (number on back of each card).
   b) In order of effectiveness (lowest number to highest), read the 5 to 7 attributes on each method card not set aside. Ensure that client fully understands the information given on the method before proceeding to the next card.

6. **Ask the client to choose the method that is most convenient for her/him.**

7. **Using the method-specific brochure, determine whether the client has any conditions for which the method is not advised.**
   a) Together with the client, review the section under "Method not advised if you…" in the brochure of the method chosen.
   b) If the method is not advisable for the client, ask the client to select another method from the cards that remain. Repeat the process from **Step 6** (**Step 4** if the client already had a method in mind).

Post-Choice Stage

8. **Discuss the method chosen with the client using the method brochures as a counselling tool.**

9. **Determine the client's comprehension and reinforce key information.**

10. **Make sure the client has made a definite decision. Give her/him the method chosen and/or a referral and backup method, depending on the method selected.**

11. **Encourage the client to involve partner(s) in decisions about / practice of contraception through discussion or a visit to the clinic.**

STI/HIV Prevention, Risk Assessment, and Counselling and Testing Stage

12. **Discuss STI/HIV transmission and prevention and the client's HIV status using the counselling card.**

13. **Conduct STI/HIV risk assessment using the counselling card. If the client has STI symptoms, treat her/him syndromically.**

14. **Discuss dual protection using the counselling card. Offer condoms and instruct the client in correct and consistent use.**

15. **Conduct HIV counselling and testing (C&T) awareness using the counselling card. If the client is known to be HIV positive, skip to Step 17.**

16. **Discuss and offer the client an opportunity for HIV C&T. If willing, test the client and counsel her/him on the test results according to national protocols.**

17. **Encourage the client to disclose HIV status to her/his partner(s). Let the client know the benefits and risks of disclosure.**

18. **Give follow-up instructions, a condom brochure, and the brochure of the method chosen.**

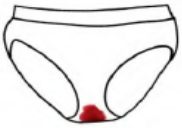
19. **Complete the counselling session. Invite the client to return at any time. Thank her/him for the visit. End the session.**

APPENDIX 14.8: NORMAL COUNSELING TOOL FOR MENSTRUAL BLEEDING CHANGES

Changes to your monthly periods are **NORMAL** while using family planning

It is common to have changes to your menstruation (monthly periods)* when you use some family planning methods.**

Review this guide as part of family planning counseling when you choose a method.

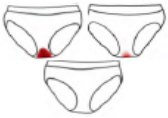


*See the back page for more information about your monthly periods

**Normal changes in your monthly periods can include lighter bleeding or less bleeding, shorter bleeding, heavier bleeding or more bleeding, longer bleeding, bleeding when you don't expect it, or a pause in your bleeding. Paused bleeding is when your bleeding stops for some or all of the time you're using a family planning method.

Talk to your doctor if you have any questions or concerns at any point.

N It is **NORMAL** and safe to have changes in your monthly periods when you use some family planning methods.**



O Lighter bleeding or a pause in bleeding** can provide **OPPORTUNITIES** by giving you strength and freedom to go on with your daily activities.

R Your monthly periods and fertility will **RETURN** after you stop using family planning.

M Different family planning **METHODS** can cause different bleeding changes. Talk to your doctor about what you want.

A **ABSENCE** of monthly bleeding by itself does not mean you are pregnant.

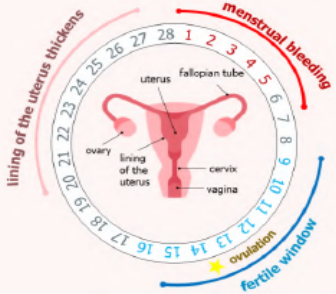
L Talk to your doctor if changes to your monthly periods **LIMIT** your activities. There may be treatments that can help.

Different family planning methods can cause different menstrual changes

Below are some common bleeding changes, **but everyone is different.**
You may experience none of these changes, some of them, or all of them.

INJECTABLES	• Bleeding when you don't expect it • Spotting (dots of blood) • Less bleeding (lighter bleeding) • More bleeding (heavier bleeding) • Paused bleeding (bleeding stops for some or all of the time while using the method)
IMPLANTS	• Bleeding when you don't expect it • Spotting (dots of blood) • Less bleeding (lighter bleeding) • More bleeding (heavier bleeding) • Paused bleeding (bleeding stops for some or all of the time while using the method)
PILLS (Progestin-Only Pills)	• Shorter bleeding • Less bleeding (lighter bleeding) • Spotting (dots of blood) • Paused bleeding if breastfeeding • Bleeding when you don't expect it • Longer bleeding
PILLS (Combined Oral Pills)	• Shorter bleeding • Less bleeding (lighter bleeding) • Spotting (dots of blood)
COPPER IUD	• No change in bleeding • More bleeding (heavier bleeding) • Longer bleeding
HORMONAL IUD	• Bleeding when you don't expect it • Spotting (dots of blood) • Less bleeding (lighter bleeding) • Less frequent bleeding • Paused bleeding (bleeding stops for some or all of the time while using the method)

f your bleeding stops while you are using family planning, this is NORMAL. There can even be benefits to your health or life.



This is what a 28-day menstrual cycle looks like.
Yours may be longer or shorter; this is normal.

WHAT IS YOUR MONTHLY PERIOD?

- A monthly period (menstruation) is normally 3-7 days when the lining of the uterus in the form of blood flows from the uterus out the vagina each month.
- You usually lose about 6-8 teaspoons of blood during the monthly period.
- Cramps, headaches, or sore breasts are all common during and just before bleeding starts.
- Use of the family planning methods above can change the menstrual cycle (pictured here). This is normal and does not cause health problems. For example, some methods keep the lining of the uterus from growing.

Talk to your doctor if you have any questions or concerns.

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