



Ministry of Health Kenya

Expanding Access and Choice to Family Planning Services in Kenya

Package for Training Pharmacists & Pharmaceutical Technologists on Provision of Quality, Integrated Family Planning Services

**PARTICIPANTS'
MANUAL**

2019



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FOREWORD

The Ministry of Health is committed to ensuring provision of 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)*, in 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.’

Contraceptives use has increased over the years in Kenya. There has been an increase in the contraceptive prevalence for all methods among currently married women. The Total Fertility Rate (TFR) has declined to less than four as more women use voluntary family planning with Contraceptive Prevalence Rate (CPR) now estimated at 61% among married women.

It is already known that 10% of clients seeking family planning services obtain their method of choice from pharmacies (*KDHS 2014*), and that pharmacies are the single largest source of contraceptive pills. However, only about a third of Pharmacists have had comprehensive training on provision of family planning (*KURHI, KSDP Survey 2011*).

The Ministry of Health, therefore, deems it necessary to equip Pharmacist and Pharmaceutical Technologists with up-to-date knowledge and skills, in order for them to provide quality family planning services to clients seeking information and services from them. The development of this training package is the first step towards this objective.

This training package is intended to serve as a resource and guide to pharmaceutical personnel in both public and private sectors (including retail pharmacies) in the provision of family planning services. The training package consists of a trainers’ manual, a participants’ manual and a participants’ logbook. The trainers’ manual is a tool for facilitators to guide them throughout the training exercise to enable active learning by employing various adult learning techniques.

We believe that with this resource, Pharmacists and Pharmaceutical Technologists will acquire new knowledge and skills required to competently provide family planning information and services.



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LIST OF ABBREVIATIONS

ABHR	Alcohol Based Hand Rub
ADR	Adverse Drug Reactions
AIDS	Acquired Immunodeficiency Syndrome
COC	Combined Oral Contraceptive
CI	Coitus Interruptus
CPR	Contraceptive Prevalence Rate
Cu IUD	Copper Intra Uterine Device
CYP3A4	Cytochrome P450 3A4
DMPA-IM	Depot-Medroxyprogesterone Acetate, Intramuscular
DMPA-SC	Depot-Medroxyprogesterone Acetate, Subcutaneous
EC	Emergency Contraception
ECP	Emergency Contraceptive Pill
ENG	Etonogestrel
FAbM	Fertility Awareness-Based Methods
FP	Family Planning
FSH	Follicular Stimulating Hormone
GBV	Gender Based Violence
GRH	Gonadotropin Releasing Hormone
HIV	Human Immunodeficiency Virus
HIVST	HIV-Self Testing
HTS	HIV Testing Services
IPC	Infection Prevention & Control
IPV	Intimate Partner Violence
IUCD	Intra Uterine Contraceptive Device
POP	Progestin Only Pills
KDHS	Kenya Demographic and Health Survey

KHIS	Kenya Health Information System
KNBS	Kenya National Bureau of Statistics
LAPM	Long Acting and Permanent Methods
LH	Luteinizing Hormone
LMIS	Logistics Management Information System
LNG IUS	Levonorgestrel Intra-Uterine System
HCP	Health Care Providers
MEC	Medical Eligibility Criteria
PMS	Post-Marketing Surveillance
PPB	Pharmacy and Poisons Board
PPE	Personal Protection Equipment
PV	Pharmacovigilance
RC	Reproductive Coercion
RH	Reproductive Health
STI	Sexually Transmitted Infections
UPA	Ulipristal Acetate
USFDA	United States Food and Drug Authority
WHO	World Health Organization



PREFACE

The participant's manual has been designed for pharmacy and pharmaceutical technologists attending the Family planning/contraceptive methods training course. It provides all essential information required by the participant and the trainer to effectively achieve the intended course outcomes. The structure of the manual is similar to that of the trainer's manual which follows the flow or sequence of the units as they appear in the course agenda or program.

For each topic covered, the manual begins by presenting a brief introduction followed by the objectives of the units. Other areas covered include specific information on the topic, instructions on group work units, and step by step instructions on how to perform various procedures on the humanistic models and on clients, links to videos used by the trainers or guest speakers and suggested reading or additional reference materials.

As a participant, you will be provided with handouts of reference manuals, PowerPoint presentations, case studies, and other materials such as group assignments and a booklet of log forms. The booklet of log forms is an accompanying document that allows participants to document the procedures that they have performed without assistance while being supervised by the trainer (s). In almost all units, the specified procedures are to be performed on humanistic models, family planning clients or when preparing the procedure room, equipment and supplies in readiness to offer a method. The participants will be signed off by the trainer upon competently mastering the required skills listed on the log forms.

This manual emphasizes on a holistic approach to family planning with modules on short, long acting reversible methods and permanent methods. The aim is to improve on the skills of pharmacists and pharmaceutical technologists to offer quality contraceptive information and selected methods. This course is timely in facilitating rational use of contraceptives among clients seeking services from pharmaceutical outlets.

In addition, it is intended to serve as a useful reference for the providers long after the training. Those who have not undergone this course should not use the manual as the only source of information.

UNIT 1:

INTRODUCTION TO THE COURSE



Introduction

This is a Skill-based training course focusing in the acquisition of practical skills that will be required in the delivery of quality family planning services and other preventive health related services.



Goal

To expand access to and choice of family planning services and HIV preventive services through integration in pharmaceutical outlets.



Objectives

By the end of this course you will be able to gain the following:

1. Knowledge on the FP program in Kenya
2. Knowledge on the basic anatomy and physiology of the human reproductive system
3. Skills and competencies in counselling for FP methods and HIV prevention
4. Skills and competencies in the Medical Eligibility Criteria (MEC) for FP
5. Skills and competencies in FP infection prevention and control practices
6. Skills and competencies in FP methods
7. Knowledge on integration and referral
8. Skills and competencies in documentation, reporting, monitoring and evaluation
9. Knowledge on reproductive health commodity management and pharmacovigilance

Expected Outcomes

As you undertake this unit you will:

- Undergo introduction to the course
- Understand how to navigate through different materials and documents
- Undertake course pre-test/skill assesment and post-test/skill assesment

UNIT 2

OVERVIEW OF FAMILY PLANNING IN KENYA



Introduction

This unit covers an overview of family planning program in Kenya and provides the participants with an insight into the Kenyan Family Planning landscape. In addition, it will enable the participants understand the existing regional disparities in terms of the current trends in contraceptive prevalence and total fertility rates.



Objectives

By the end of this unit participants will be able to:

1. Describe family planning background information
2. Define common terms used in family planning
3. Discuss the general trends and disparities in Family Planning Indicators across the country
4. Discuss the current policy and legal framework guiding family planning in Kenya

2.1 Background Information

Kenya was the first country in sub Saharan Africa to establish a national Family Planning program in 1967. The government of Kenya recognizes the importance of population management and the central role of Family Planning in socio-economic development at the individual family level and also the national level.

Family planning (FP) is a central pillar of Kenya's reproductive health (RH) program and wider national health priorities as outlined in the Vision 2030, Kenya Health Sector Policy and Population Policy for National Development (Republic of Kenya, 2012). The use of family planning in Kenya has been increasing steadily over recent years. The Government and the health sector stakeholders have integrated Family Planning program within the wider Reproductive Health and HIV/AIDS services. Integration of these services is a cost-effective way of providing better health services to the population including sexually active unmarried youths.

The Kenya Demographic and Health Survey (KDHS) 2014, findings show that 53.2 percent of married women in Kenya use a modern method of family planning (KNBS *et al.*, 2015). Further, the report indicates a total fertility rate of 3.9. Current fertility rates (KDHS 2014) differ for urban and rural areas and across the regions in Kenya. The TFR in rural areas (4.5) is significantly higher than in urban areas (3.1). These urban-rural differences in fertility rates are evident throughout all age groups, including adolescents, which illustrates the need to address the unmet need for FP particularly among rural adolescents and youths

There has been a significant increase in contraceptive use, among married women from 46% in 2008-9 to 58% in 2014 for any method. Between 2008-9 and 2014, use of modern methods increased from 39% to 53 % among married women. Analysis of trends by method shows that the overall CPR is driven by the increased use of modern methods. For the modern methods there has been a significant change in the method mix. In 2014 short acting methods accounted for 69% of the method mix as compared to 78% in 2008-9. The long acting methods accounted for 25% and 9% for the two periods respectively. Use of traditional methods over the same time period actually decreased from 6 to 4.8% among married women. Despite the overall increase in CPR, the level of unmet need for FP still remains high, estimated at 18%.

The data showed an increased uptake for implants, slight increase for IUCDs and erosion of permanent methods (figure 5).

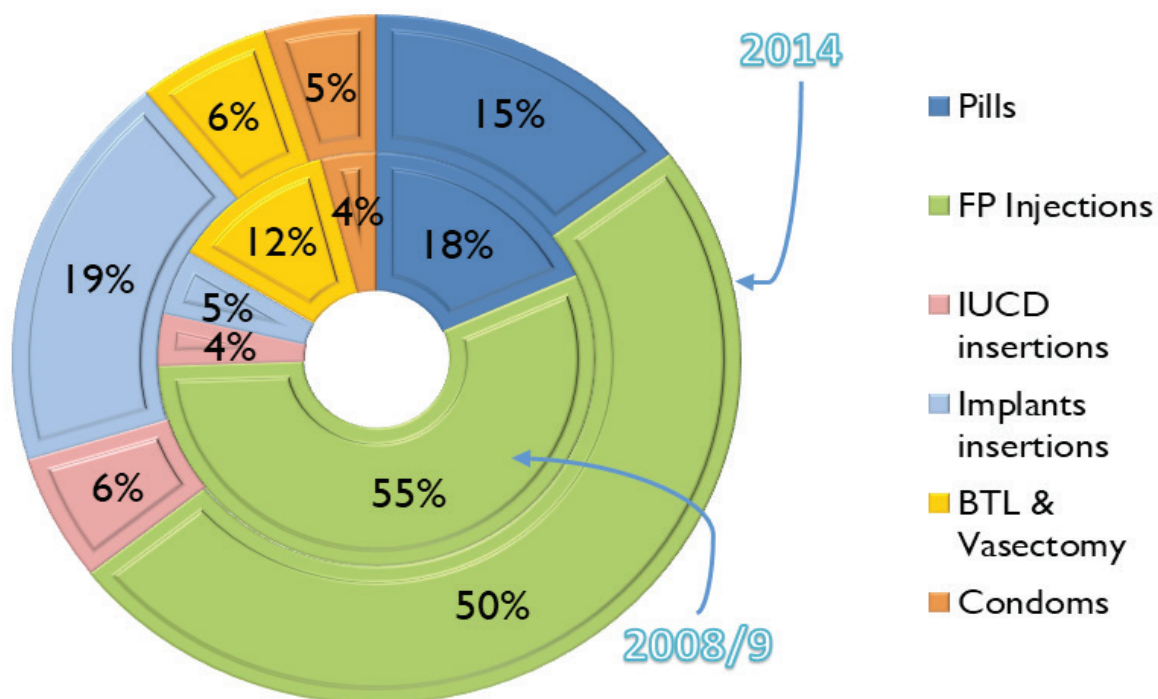


Figure 1: METHOD MIX CHANGES FOR MODERN METHODS BETWEEN 2008/9 & 2014

KDHS 2014, indicates that 34% of modern contraceptive users obtained their method from the private sector of which pharmacies provided 10%. Private pharmacies mainly provided pills (45.4%), condoms (16.1%) and injectables (5.4%). With the introduction of new products (subcutaneous DMPA injectables) in the Kenyan market, we foresee opportunity for Private pharmacies to play a greater role in provision of injectable contraceptives, thereby expanding choice and hence the need for this participants' manual.

Kenya has revised her Family planning goals to 58% by 2020, 66% by 2030 and 70% by 2050, hence health providers should place more emphasis on improving access to quality FP services including expansion of method mix, reduction of missed opportunities and unmet FP need, sustaining the gains made and increasing the numbers of new users.

The WHO Factsheet (2018) outlines various benefits of Family planning as follows:

1. Preventing pregnancy related health risks in women

2. Reducing infant mortality
3. Helping prevent HIV/AIDS
4. Empowering people and enhancing education
5. Reducing adolescent pregnancies
6. Slowing population growth

2.2 Definition of common terms

Family Planning: The ability of individuals and couples to anticipate and attain their desired number of children, as well as the spacing and timing of their births.

Total Fertility Rate (TFR): The number of children who would be born per woman (or per 1,000 women) if she/they were to pass through the childbearing years bearing children according to a current schedule of age-specific fertility rates.

Contraceptive Prevalence Rate (CPR): Contraceptive prevalence is the percentage of women who are currently using, or whose sexual partner is currently using, at least one method of contraception, regardless of the method used. It is usually reported for married or in-union women aged 15 to 49. CPR can also be calculated for all women.

Modern Contraceptive Prevalence Rate (mCPR): Contraceptive prevalence is the percentage of women who are currently using, or whose sexual partner is currently using, at least one modern method of contraception. It is usually reported for married or in-union women aged 15 to 49. mCPR can also be calculated for all women.

Unmet need: Is the percentage of fecund women of reproductive age who want no more children or want to space the pregnancy, but are not using a contraceptive method, (the woman does not intend to get pregnant but is not on any FP method).

2.3 National Family Planning Program Goal

The National Family Planning program aims to achieve an increase in mCPR from the current 53 to 58 by the year 2020, mCPR of 66 by 2030 and mCPR of 70 by the year 2050. Every county contributes to the national goal.

2.4 Trends in Fertility and contraceptive use in Kenya

Significant decline in fertility trends in Kenya was documented between 1977 and 1993. The total fertility rates were 8.1 and 4.7 in 1977 and 1998 respectively. This decline however began to slow down from 1998 and by 2003 the decline in fertility had stalled. In the period when there was marked decline in fertility, the contraceptive use among currently married women steadily increased from about seven percent in 1978 to 39 percent in 1998 and 58 percent in 2014. The trends are demonstrated clearly in figures below.

2.5 Kenya S-Curve for Family Planning

The 2014 KDHS variations in mCPR across counties, when the data from the counties were plotted, an S- Curve distribution emerged indicating that just a few counties were at a level where they would experience high growth rates, while others would experience low growth rates (figure 1).

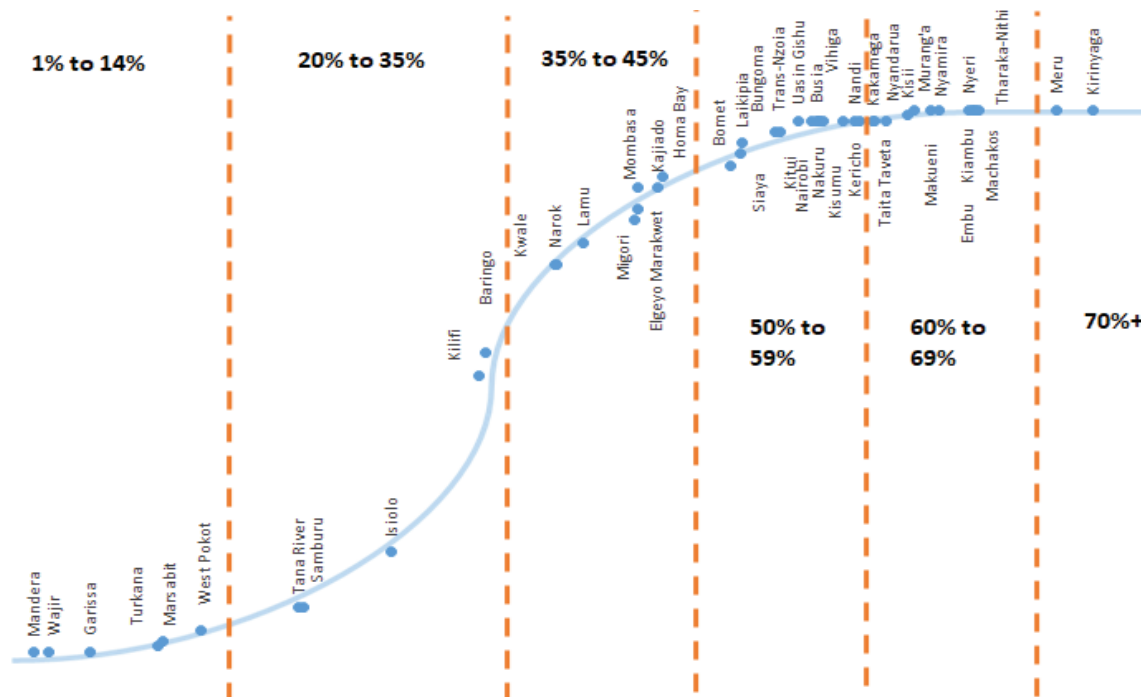


Figure 2: KENYA'S S-CURVE - DIFFERENTIALS IN COUNTY mCPR (2014 KDHS)

2.6 Demand for Family Planning in Kenya

It is observed that there is a higher demand for contraceptive services in counties where women of reproductive age desire fewer children as shown in figure 2.

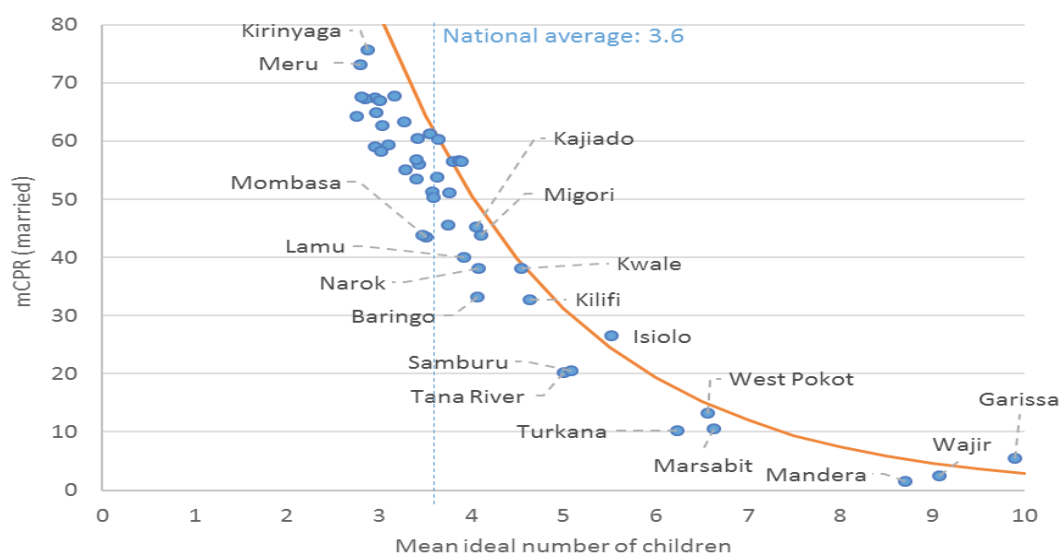


Figure 3: DEMAND FOR FAMILY PLANNING (2014 KDHS)

2.7 Trends in unmet need for Family Planning

Unmet need is the percentage of fecund women of reproductive age who want no more children or want to postpone having the next child, but are not using a contraceptive method, (the woman does not intend to get pregnant but is not on any FP method). According to KDHS 2014, 18% of the currently married women have an unmet need for family planning of which 9% are in need of spacing and 8% are in need of limiting (figure 3).

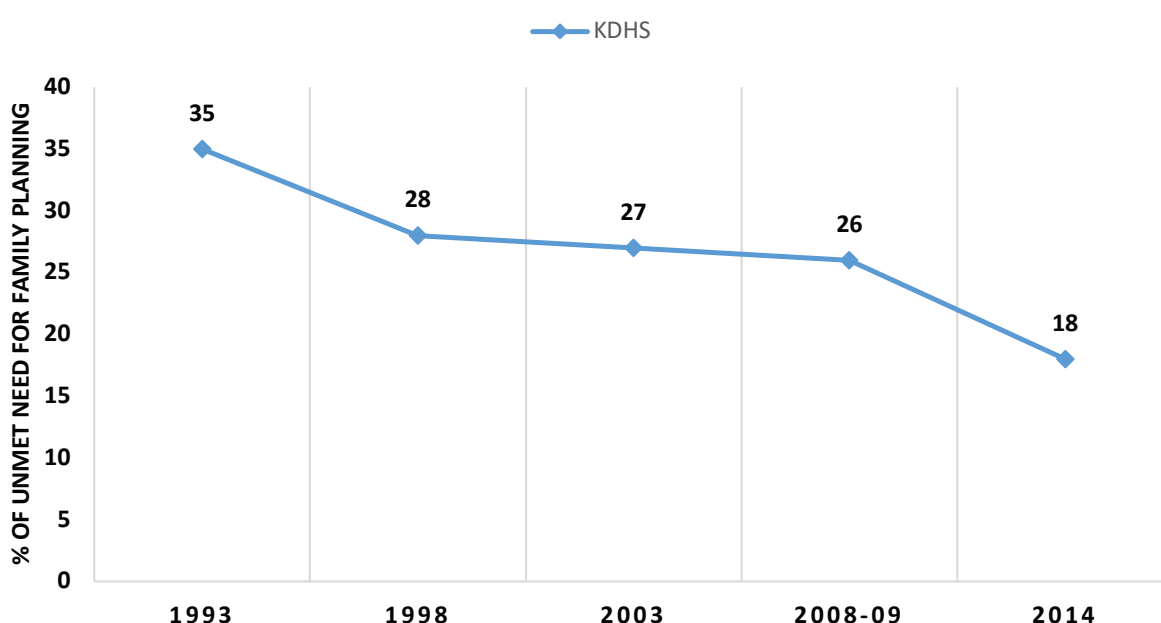


Figure 4: TRENDS OF UNMET NEED OF FAMILY PLANNING IN KENYA

2.7.1 Fertility and contraception by level of education

The TFR and CPR are affected by the level of education. Women with higher education levels (secondary and above) are reported to have low TFR and high CPR. On the other hand, women with low education levels (Primary school and below) are reported to have high TFR and Low CPR. In 2008-2009, contraceptive prevalence rate for currently married women with at least secondary education was 60 percent, compared to 40 percent for women with primary incomplete education and 14 percent for married women who had never attended school.

2.7.2 Teenage Pregnancies

According to KDHS 2014, teenage pregnancies varies according to age with the highest prevalence being amongst young people aged 19 years (39.9%).

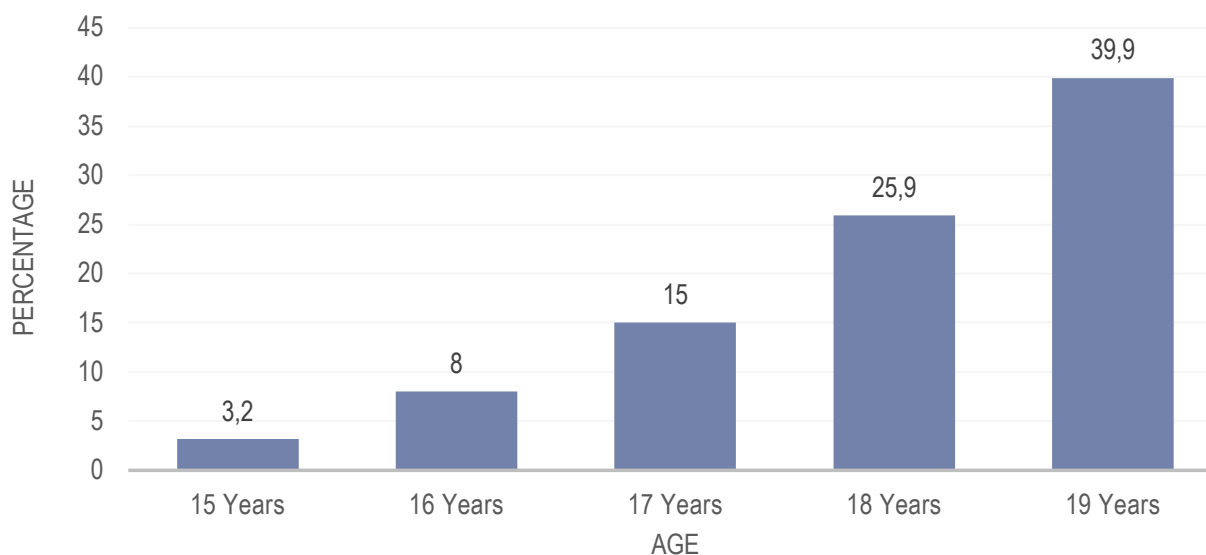


Figure 4: % OF TEENAGE PREGNANCIES IN KENYA

2.7.3 Contraceptives and Young People

The unmet need for contraceptives among adolescents is higher than the national average (18%) at 23%. Service providers can encourage utilization of contraceptive services among adolescents and youth by:

- Adopting positive attitudes
- Ensuring privacy and confidentiality
- Providing convenient hours of service and factual information

2.7.4 National Family Planning Priority Areas

The Ministry of Health has prioritized the following areas towards universal access to family planning services:

- Advocacy for family planning services
- Family planning commodity security
- Demand creation for FP

- Focus on adolescents, the youth and vulnerable populations
- Integration of family planning into other services
- Capacity building for FP
- Total Market Approach (TMA) where both private and public sectors collaborate in provision of Family Planning services

2.7.5 Current Challenges in The Realization of National Family Planning Goals

The following challenges are still impediments in the realization of FP goals and objectives:

- Wide county and socio-economic disparities in CPR
- Lack of contraceptive commodity security and sustained demand creation for family planning services
- Relatively low community and private sector participation in family planning service provision and low male engagement
- Low uptake of cost-effective methods such as LARCs and permanent methods
- Inadequate capacity for provision of quality family planning services including provider skills, equipment and supplies
- Low level of integration of family planning into other services
- Access to contraceptive services for the adolescents, youth, hard to reach populations and people living with disability

2.8 Family Planning Methods Available in Kenya

Table 1: COMMONLY AVAILABLE FAMILY PLANNING METHODS IN KENYA

	Short term methods	Long term methods
Hormonal methods	<ul style="list-style-type: none"> • Combined oral Contraceptives (COCs) • Progesterone only pills (POP) • High dose Progesterone Only Pills (for ECP) • Injectables: Progesterone only injectable (DMPA IM/SC) • Combined injectable contraceptives (CIC) • Combined contraceptive skin patch • Combined vaginal contraceptive ring 	<ul style="list-style-type: none"> • Contraceptive implants: One rod (Etonogestrel 68mg) and two rods (Levonorgestrel 75mg) • Hormone releasing IUCDs (LNG-20IUS, LNG-4IUS)
Non-Hormonal methods	<ul style="list-style-type: none"> • Barrier methods: Condoms (male and female) • Natural FP: Lactation Amenorrhea Method (LAM), Fertility Awareness methods (Cycle beads, calendar method, Menstrual Apps), Withdrawal method 	<ul style="list-style-type: none"> • Intrauterine contraceptive devices: Copper based IUCDs (Copper T 380A TCu380S, Copper 300T, Copper T230) • Surgical contraceptives: Tubal ligation, Vasectomy

Source: NATIONAL FAMILY PLANNING GUIDELINES FOR SERVICE PROVIDERS

2.9 Essentials of Family Planning Service Provision

The following consideration are essential for the provision of family planning services:

- Increasing demand and utilization of family planning services
- Counselling for family planning
- Infection prevention and control
- Integration of services

- Provision of contraceptives including dual protection
- Follow up and referral systems
- Record keeping/ M&E
- Supportive supervision and mentorship
- Logistics management
- Cost consideration for clients

Table 2: **BENEFITS OF FAMILY PLANNING**

Benefits to Women	Benefits to children	Benefits to families and communities
<ul style="list-style-type: none"> • Low risk of maternal death 	<ul style="list-style-type: none"> • Longer breastfeeding 	<ul style="list-style-type: none"> • Families can devote more resources to providing for each child
<ul style="list-style-type: none"> • Low risk of anaemia, poor pregnancy outcomes and complications related to miscarriage or unsafe abortion 	<ul style="list-style-type: none"> • Allows more time and resources for parents to meet the needs of each child 	<ul style="list-style-type: none"> • Reduced maternal deaths strengthen families and communities
<ul style="list-style-type: none"> • Protection from Disease transmission/ acquisition e.g HIV • Protects from childhood illnesses • Relieves economic, social and environmental pressures 		
<ul style="list-style-type: none"> • Low risk of certain cancers and other gynaecological problems 	<ul style="list-style-type: none"> • Improves mother/child bonding 	<ul style="list-style-type: none"> • Enhances women's status and promotes equality between men and women
	<ul style="list-style-type: none"> • Reduces child illnesses and death 	<ul style="list-style-type: none"> • Improves education and economic opportunities
	<ul style="list-style-type: none"> • Provides nutrition 	



Key Facts

- 214 million women of reproductive age in developing countries who want to avoid pregnancy are not using a modern contraceptive method.
- Some FP methods, such as condoms, help prevent the transmission of HIV and other sexually transmitted infections.
- Contraceptive use reduces the need for abortion, especially unsafe abortion.
- FP reinforces people's rights to determine the number and spacing of their children.
- By preventing unintended pregnancy, FP /contraception prevents deaths of mothers and children.

UNIT 3

BASIC ANATOMY & PHYSIOLOGY OF THE HUMAN REPRODUCTIVE SYSTEM



Introduction

This unit covers the basic anatomy and physiology of the female and male reproductive systems. Knowledge on anatomy and physiology is important in understanding the structures and the functions of reproductive system in relation to contraceptive use.



Objectives

By the end of this session, participants should be able to describe the:

1. Anatomy of the female and male reproductive systems
2. Physiology of the female and male reproductive systems
3. Menstrual cycle
4. Process of fertilization and implantation

3.1 Definition of Anatomy and Physiology

The term **anatomy** refers to the structure, composition, make up or frame of the reproductive system while **physiology** refers to the functioning or working of the bodily processes pertaining to the reproductive system and conception.

3.1.1 The Female Reproductive System

The female reproductive system is made up of the internal and external sex organs that function in reproduction of new offspring. female reproductive system is immature at birth and develops to maturity at puberty to be able to produce gametes, and to carry a foetus to full term.

The internal sex organs are the uterus, Fallopian tubes, and ovaries. The uterus or womb accommodates the embryo which develops into the foetus. The uterus also produces vaginal and uterine secretions which help the transit of sperm to the Fallopian tubes.

The ovaries produce the ova (egg cells). The external sex organs are also known as the genitals and these are the organs of the vulva including the labia, clitoris, and vaginal opening.

3.1.1.1 External Female Genitalia

The external genital organs include mons pubis, labia majora, labia minora, Bartholin glands, and clitoris. The area containing these organs is called the vulva. The external genital organs have three main functions:

- Enabling sperm to enter the body
- Protecting the internal genital organs from infectious organisms
- Providing sexual pleasure

Table 3: SHOWS THE FEMALE EXTERNAL GENITALIA

Organs	Functions
Pudendum	The area in the body where the sex organs are located
Vulva	The general term to describe all the external female sex organs
Mons pubis	A mound of fatty tissue which covers the pubic bone. At puberty this area is covered with coarse pubic hair. The mons contains many touch-sensitive receptors
Labia Majora (Major lip)	The outer lips of vulva covered with hair that protects labia minora and internal structures

Organs	Functions
Labia minora (Minor lip)	The two inner lips without hair that covers and protects the vaginal opening
Clitoris	It is a small, sensitive organ above the urethra that responds to stimulation during sexual intercourse
Urethra	The opening to the bladder located below the clitoris for passage of urine
Bartholin's glands	Located near the vaginal opening, it produces a lubricating fluid to keep the vagina moist. It can form a Bartholin's abscess when infected
Hymen	Thin membrane covering the opening of the vagina
Vaginal Orifice	The opening into the vaginal canal

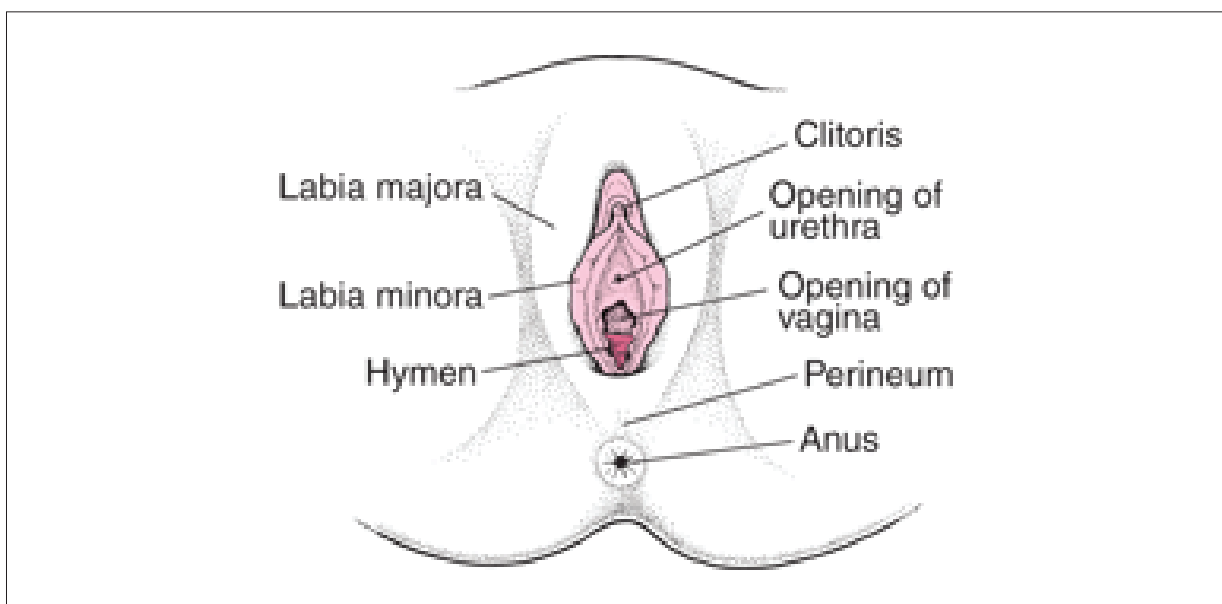


Figure 5: FEMALE EXTERNAL GENITAL

3.3.1.2 Internal Female Reproductive Organs

Internal reproductive organs include vagina, uterus, fallopian tubes, cervix, and ovary. The internal genital organs have five main functions:

- Production of the female egg cells (ova or oocytes) for reproduction.
- Transportation of the ova to in the fallopian tubes for fertilization.
- Implantation of fertilized egg into the walls of the uterus

- Production of female sex hormones that maintain the reproductive cycle.
- Menstrual cycle (the monthly shedding of the uterine lining).

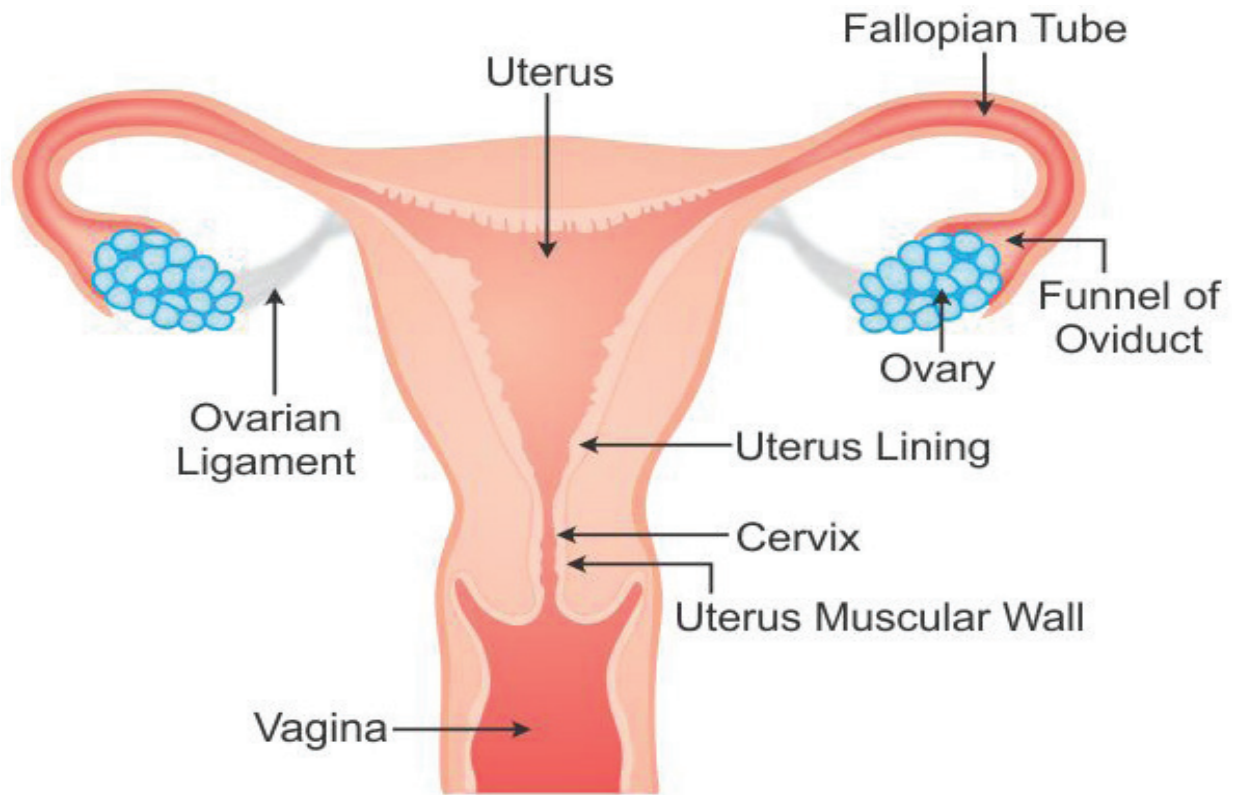


Figure 6: THE INTERNAL FEMALE REPRODUCTIVE ORGANS

Table 4: SUMMARY OF FUNCTIONS OF FEMALE REPRODUCTIVE ORGANS

Organ	Description	Functions
Vagina	<ul style="list-style-type: none"> It is a stretchy fibro muscular tube extending from the vulva upward and backward toward the cervix and uterus: It is widest at the upper area (near the cervix) and narrower near the opening on the vulva. Anterior wall is related to the bladder superiorly and urethra inferiorly Posterior wall is related to the rectum The cervix invaginates into the vagina through the anterior wall forming clefts called fornices (anterior and posterior fornices) 	<ul style="list-style-type: none"> Channel for the menstrual flow Receptacle for the penis during intercourse Birth canal
Cervix	<ul style="list-style-type: none"> The cervix is the opening of the uterus. It is cylindrical in shape and is normally 3–4 cm long and 2.5–3.5 cm in diameter. The external os of the cervix opens into the vagina. The internal os is the point at which the cervix and uterus meet, cervix is normally plugged by mucus. 	<ul style="list-style-type: none"> It stays tightly closed during pregnancy but thins and opens for the delivery of the baby (dilatation).
	<ul style="list-style-type: none"> Internal os: Located in the endocervical canal 	<ul style="list-style-type: none"> Act as opening into the uterus
	<ul style="list-style-type: none"> Uterus: A hollow, muscular organ shaped like an upside-down pear. Can be divided into three parts, the fundus, the body and the cervix. 	<ul style="list-style-type: none"> It protects and nourishes the foetus during pregnancy and also contracts to expel the baby during delivery
Oviduct (fallopian tubes)	<ul style="list-style-type: none"> These are two funnel-shaped tubes on either side of the uterus, near the ovaries. They are the location for fertilization. 	<ul style="list-style-type: none"> They are the passageway through which the ova travel from the ovaries to the uterus and sperm toward the egg cell
Ovaries	<ul style="list-style-type: none"> Two solid egg-shaped structures attached to the uterus by ligaments. They are the primary sex gland of a woman. 	<ul style="list-style-type: none"> Production of ova during the reproductive phase Production of female sex hormones (estrogen and progesterone)

Note:

Other organs that form part of the reproductive system include:

- Hypothalamus
- Pituitary gland in the brain

The two organs are responsible for the release of various hormones such as the gonadotropin releasing hormone (GRH) luteinizing hormone (LH), follicular stimulating hormone (FSH), prolactin, oxytocin etc. that regulate the reproductive system.

3.1.1.3 Menstrual Cycle

Menstruation is characterized by vaginal bleeding which lasts for a period of **2-7 days**. It's the terminal phase of the cycle and is the period during which the endometrium is shed down up to the basal layer together with blood from the capillaries and the unfertilised ovum.

These are cyclical changes in the endometrium caused by alterations in progesterone and oestrogen levels.

The menstrual cycle is primarily controlled by hormones released from three organs namely, the hypothalamus, the pituitary, and the ovaries. The cycle has two phases,

Proliferative: The proliferative phase is oestrogen-driven and is characterized by the thickening of the endometrium which reaches its optimum height at ovulation time.

Secretory phase: Is predominantly progesterone- driven and is characterized with vascular and glandular changes which occur in the endometrium. During this phase, glycogen also accumulates in the endometrium.

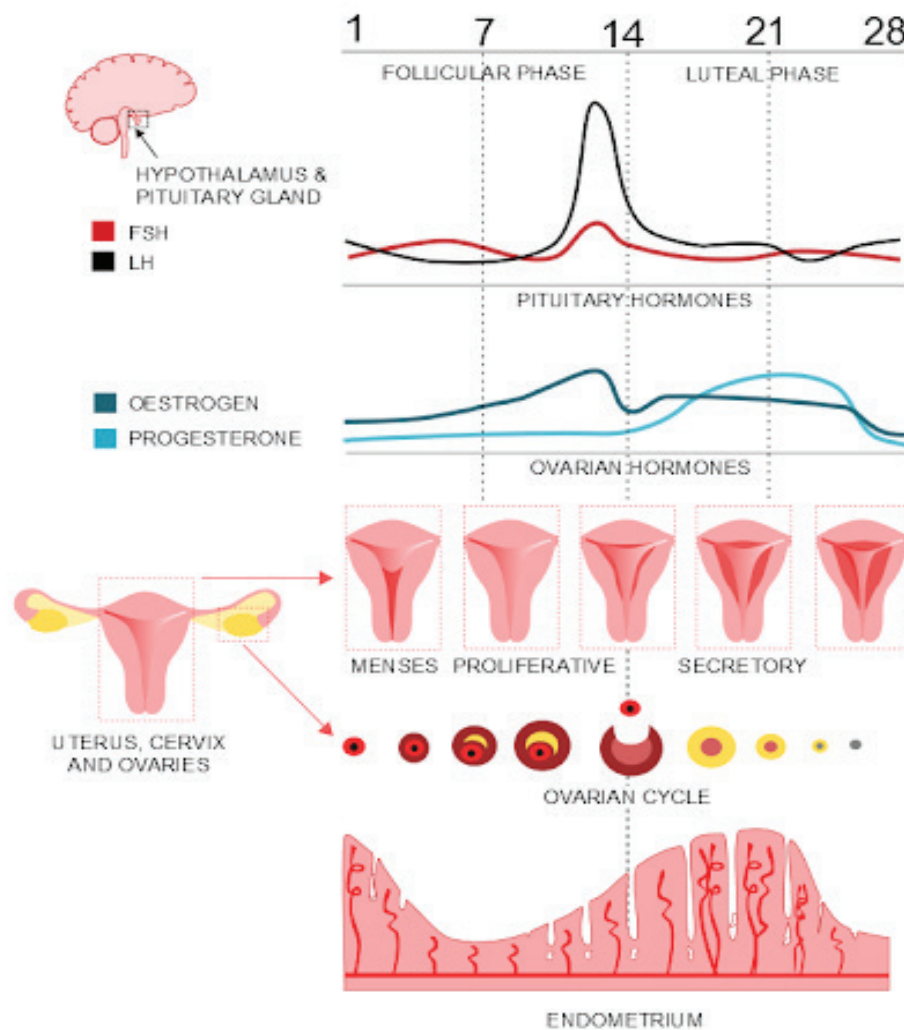


Figure7: THE MENSTRUAL CYCLE

3.1.1.4 Pregnancy and Implantation

Following the deposition of sperms into the vagina, healthy sperms swim upstream through the cervix and the uterine cavity into the tubes. If ovulation had occurred and the ovum is within the fallopian tubes, then fertilization can occur.

The fertilized ovum also called **zygote** moves towards the uterine cavity aided by contractions of the fallopian tube for implantation. The implantation process is aided by the trophoblastic cells surrounding the embryo.

3.1.1.5 Anatomy of the Breast

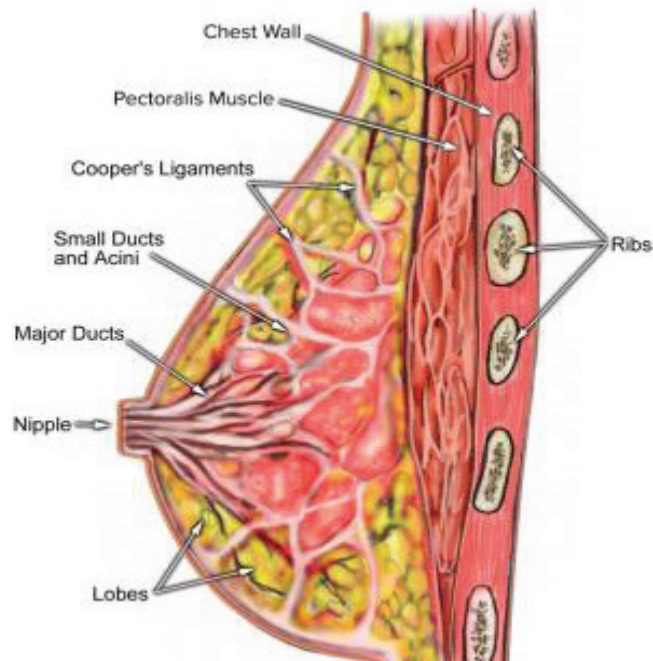


Figure 8: [ANATOMY OF THE BREAST](#)

Table 5: [FUNCTIONS OF THE BREAST](#)

Organ	Description	Functions
Breast	<p>It is the tissue overlying the chest (pectoral) muscles. Women's breasts are made of specialized tissue producing milk (glandular tissue) as well as fatty tissue. The amount of fat determines the size of the breast.</p> <p>The milk-producing part of the breast is organized into 15 to 20 sections, called lobes. Within each lobe are smaller structures, called lobules, where milk is produced. The dark area of skin surrounding the nipple is called the areola.</p> <p>Connective tissue and ligaments provide support to the breast and give it its shape. Nerves provide sensation to the breast. The breast also contains blood vessels, lymph vessels, and lymph nodes.</p>	<p>Produce milk</p> <p>Glands on the areola (the shaded circle of skin around the nipple) secrete small amounts of fluid to lubricate the nipple when breastfeeding.</p>

3.2.1 The Male Reproductive System

The male reproductive system consists of a number of sex organs that play a role in the process of human reproduction. These organs are located on the outside of the body and within the pelvis. The main male sex organs are the penis and the testicles which produce semen and sperm, which, as part of sexual intercourse, fertilize an ovum in the female's body; the fertilized ovum (zygote) develops into a foetus, which is later born as an infant.

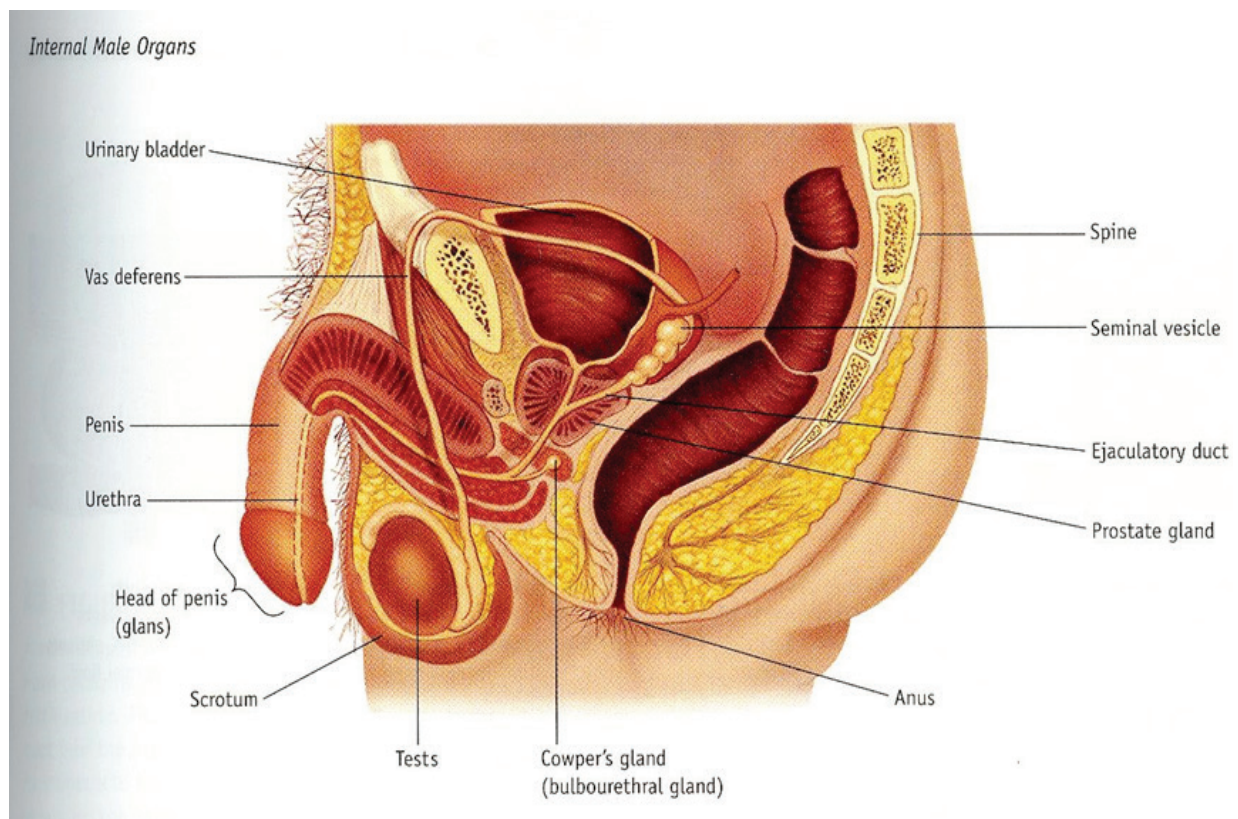


Figure 8: THE MALE REPRODUCTIVE SYSTEM

3.3.1.5 Structure and functions of male reproductive organs

The structure and functions of the male reproductive organs are summarized in the table below;

Table 6: SUMMARY OF FUNCTIONS OF MALE REPRODUCTIVE ORGANS

MALE REPRODUCTIVE ORGAN	CORRESPONDING DESCRIPTION/ FUNCTION
Penis	Male organ for sex used for placing sperms into the vagina and for passing urine
Prepuce	Foreskin that protects the head of the penis
Urethra	Long narrow tube inside the penis through which both sperms and urine pass
Testes	Two sex glands that produce sperm and male hormones. They are responsible for the development of secondary sexual characteristics in a man
Seminal vesicles	Are like pockets or glands where the white fluid (semen) is produced and the sperms stored
Prostate	Produces fluid, which helps create a good environment for the sperms in the vagina
Vas deferens	Are tubes through which the man's sperms pass from the testicles to the penis
Scrotum	It is a sac which holds the testes, and protects them against extreme temperature
Epididymis	Coiled tubes leading from the testes to the vas deferens where sperm mature
Cowper's gland	Produces fluid, which helps create a good environment for the sperm in the penile urethra

Note: Other structures related to the male reproductive systems are the urinary bladder and urethral sphincter.

UNIT 4

COUNSELING FOR FAMILY PLANNING



Introduction

This unit consists of counselling for contraceptive methods and HIV prevention.



Objectives

By the end of this unit participants will be able to:

1. Gain knowledge and competency in counselling skills while offering contraceptive methods
2. Demonstrate competency in use of Balanced Counselling Strategy plus (BCS+) as a counselling method
3. Screen for Reproductive Coercion (RC) and Intimate Partner Violence (IPV) in relation to FP services
4. Dispel common myths and misconceptions on FP

4.1 Definition of Counselling

Counselling is a person to person interaction in which the counsellor provides adequate information to enable the client to:

- Work through particular problems conflicts, feelings and helps find ways to resolve or cope with them
- Make informed choice and guidance on making the choice that best meets client's needs and concerns

Counselling is one of the critical elements in the provision of quality family

planning Services and HIV prevention. Effective counselling leads to improved client satisfaction. A satisfied user promotes family planning and HIV prevention, returns when she or he needs to and continues to use the chosen method.

4.3.1 Clients' rights and informed choice

This is defined as a voluntary choice or decision, based on the knowledge of all available information relevant to the choice or decision. In order to allow clients to make an informed choice about family planning and HIV prevention, you must make them aware of all the available methods, the benefits, limitations and side effects. Below are client's rights;

1. Right to information and services
2. Right to privacy and confidentiality
3. Right to participation and informed decision making
4. Right to quality services
5. Right to non-discrimination

4.3.2 Communication

This is a process of exchanging information between two or more individuals. Communication is about much more than the words we say. The tone of our voice when we speak, the attention we give to what the other person is saying, the messages we give out by the way we move and position our bodies and the accuracy and clarity of what we write are also key elements of good communication. The five important communication aspects are; listening and attending (including patient/family complaints), non-verbal, verbal, questioning, written.

Verbal communication: It involves the use of words and phrases that indicate attention and the wish for the person to continue speaking.

Non-verbal communication: Body gestures that communicates some information.

- Head Nodding
- Smiling

- Crying
- Frowning
- Laughing
- Gestures
- Sign language

Why communication is important

- Good communication helps patients/clients feel at ease
- Good communication helps patients/clients to feel in control of their own health care
- Good communication makes patients/clients feel valued
- Good communication allows patient/client take control of their health care

General Principles of Counselling	Characteristics of a Counsellor
Principles and conditions necessary for effective counselling include:	The most important characteristics are:
<ul style="list-style-type: none"> • Customize the information to client needs (BCS plus strategy) • Privacy - find a quiet place to talk • Take sufficient time • Maintain confidentiality • Conduct the discussion with a goal of assisting the client • Keep it simple - use words people in your village will understand • First things first - do not cause confusion by giving too much information • Say it again - repeat the most important instructions again and again • Use available visual aids like posters and flip charts, etc. • Counsel clients on possible side effects and what to do (<i>counselling on side effects reduces discontinuation</i>) 	<ul style="list-style-type: none"> • Respect the dignity, concerns and ideas of the clients • Non-judgmental and open minded • Active listener • Be empathetic and caring • Be honest and sensitive • Should be aware of their own biases and put them aside (value clarification)

Table 7: BASIC COUNSELLING SKILLS

SOLER	CLEAR
S - Sit squarely	C - Clarity
O - Open posture	L - Listen attentively
L - Lean forward	E - Encourage
E - Eye contact	A - Acknowledge
R - Relax	R - Repeat/ reflect

4.3.4 Counselling Approaches

There are three approaches used for counselling in Kenya. These have been summarized with use of mnemonics and acronym as indicated below.

Balanced Counselling Strategy plus (BCS+) has been shown to be an effective and focused approach according to previous studies (WHO, 2015)

The four approaches are:

GATHER	REDI	BCS	BCS plus
G - Greeting	R - Rapport	B - Balanced	B - Balanced
A - Ask	E - Explore	C - Counselling	C - Counselling
T - Tell	D - Decide	S - Strategies	S - Strategies
H - Help	I - Implement		Plus , other RH related conditions including HIV
E - Explain			
R - Return date/ Refer			

4.4 Balanced Counselling Strategy Plus (BCS+)

This is a practical, interactive, and client-friendly counselling approach that uses job aids to facilitate consultation. It was adapted from the original BCS that aimed at improving the quality of consultations, hence the term “BCS – Plus”. The adaption was necessary to make the strategy appropriate for settings that have high HIV & STI prevalence e.g. Southern, Central and East Africa.

NOTE:

Currently BCS+ is the recommended approach for FP counselling.

4.4.1 Why BCS+

The two most commonly used FP counselling approaches: GATHER and REDI counselling models were found to have limitations that included the following, the providers were:

- i. Failing to discuss client's wishes
- ii. Mainly asking medical questions (such as date of client's last menstruation)
- iii. Failing to ask the client basic questions about the client's reproductive intentions such as:
 - Whether she wants more children
 - Whether her partner cooperates in contraceptive use
 - Giving excessive details on most of the methods available in the clinics - whether or not the methods are suitable for the client's needs
 - Often tending to overload clients with more information than they can remember and much of it is not used
 - Providing sparse information on the chosen method
 - Spending most of the counselling time describing numerous FP options
 - Evidence show that clients interviewed after the consultations know little about the method they had chosen (León 1999 and León, et al. 2001)



4.4.2 What Is Different in BCS+?

The BSC+ has benefits for both clients and providers:

- i. Use of BCS Plus simplifies decision-making
- ii. Responds to the client's needs and reproductive intentions in family planning counselling sessions
- iii. More reliable than memory and designed to minimize trial and error
- iv. Reduce the amount of recall necessary to perform a task
- v. Screening for RC and IPV in relation to FP use

The BCS toolkit has three main job aids-the algorithm, counselling cards and brochures.

4.4.3 How to use BCS Plus Counselling Strategy

The BCS Plus is divided into four stages and each stage has its steps to follow (refer to Algorithm Job Aid in the annex). Follow the steps by step guide to BCS plus on the Algorithm.

Stage 1: Pre-Choice

In this stage, the provider creates the conditions that help a client select a family planning method. The provider emphasizes to the client that, during the consultation, other reproductive health issues will be addressed depending on her/his individual circumstance. (Establish Rapport and assess client's needs).

Stage 2: Method Choice

During this stage, the provider offers more extensive information about the methods that have not been set aside, including their effectiveness. This helps the client select a method suited to her/his reproductive needs. Following the steps in the BCS+ algorithm, the provider continues to narrow down the number of counselling method cards until a method is chosen. (Help Client Make an Informed Decision).

Stage 3: Post-Choice

During this stage, the provider uses the method brochure to give the client complete information about the method that s/he has chosen. If the client

has conditions where the method is not advised or is not satisfied with the method, the provider returns to the Method Choice Stage to help the client select another method. The provider also encourages the client to involve her/his partner(s) in decisions about contraception, either through discussion or visit to the clinic. (Help Carry out Client's Decision).

Stage 4: Systematic Screening for other Services

During this stage, using information collected previously, determine client's need for:

Postpartum, new-born, infant care, well-child services or post abortion care.

Discuss with the client regarding screening for;

- Cervical cancer (VIA/VILI or Pap smear)
- Breast cancer
- STI and HIV to consider dual protection.
- RC and IPV

Have partner's status in mind. Thank her/him for the visit as you inform them on the return date. Complete the counselling session.

4.4.4 Screening for Reproductive Coercion

4.4.4.1 Definition

Reproductive Coercion (RC) involves behaviour intended to maintain power and control in a relationship related to reproductive health by someone who is, was, or wishes to be involved in an intimate or dating relationship with an adult or adolescent. This behaviour includes explicit attempts to impregnate a partner against her will, control outcomes of a pregnancy, coerce a partner to have unprotected sex, and interfere with contraceptive methods (ACOG). RC is a form of gender-based violence (GBV) that consists of specific behaviours, perpetrated by a partner, intended to reduce access to or use of family planning (FP).

4.4.4.2 Common Forms of Reproductive Coercion

There are three common forms of Reproductive Coercion

- **Pregnancy Coercion:** Forcing pregnancy and/or not supporting partner's decision about when or if they want to have a child.
- **Contraceptive Sabotage:** Hiding, withholding, destroying, or removing family planning methods against a partner's will.
- **Limiting Contraceptive Choice:** Negative stigmatizing perceptions of family planning that are intentionally communicated to a partner to dissuade them from FP use.

4.4.4.3 Other Forms Reproductive Coercion

- Use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally.
- Refusing to use a condom or other type of birth control
- Breaking or removing a condom during intercourse
- Lying about their methods of contraception (ex. lying about having a vasectomy, lying about being on the pill)
- Refusing withdrawal during coitus Interruptus
- Removing birth control methods (ex. rings, IUDs, contraceptive patches)
- Withholding finances needed to access contraceptives
- Monitoring their partner's menstrual cycles with the intention of RC
- Forcing their partner to get an abortion.
- Continually keeping their partner pregnant (getting them pregnant again shortly after they give birth)

NOTE:

- RC is associated with intimate partner violence (IPV) but also occurs independently
- The link below provides participants with additional resources on RC <https://www.loveisrespect.org/content/reproductive-coercion/>

4.4.5 Screening for Reproductive Coercion

Take the time to assess the client's risk for RC and counsel on strategies to help control client's FP use and pregnancy decisions.

1. Begin by sharing some information on RC with the client:
 - As many as 1 in 2 women and girls in Kenya have experienced male partners or family members who make it difficult for them to use FP (e.g. destroy, take away or hide their FP methods), prevent them from getting FP, or force or pressure them to become pregnant.
 - We want to ensure that our clients feel empowered to control their FP decisions and use so we share the following information with our clients and ask some confidential questions.
 - Opposition to use FP by partners, family members or community opinion leaders has negative health consequences such as unintended pregnancy and unsafe abortion.
 - Clients have a right to make their own FP and pregnancy decisions. There are FP methods that can be used privately especially if a partner or family member is making it difficult.
2. Ask the following questions to screen for RC
 - Have you ever felt pressured or forced by your partner/ any other person to become pregnant or impregnate when you did not want?
 - Has your partner or any other person ever made it difficult for you to get or use FP? (e.g. destroy, take away or hide your contraception)
 - Clients that screen positive for RC are identified as survivors, and often, more prepared to seek and receive help and/or safety. Clients, however, still require a supportive, non-judgmental, and helpful response.

Positive Reproductive Coercion Clients

When a client screens positive for RC, ensure you do the following;

- Thank them for sharing this experience with you and emphasize you know these issues are difficult to talk about.

- If positive, inform clients that these experiences are not their fault and that they have a right to have control over their reproductive choices.
- Assure the client of confidentiality

If helpful, you can refer to the following script:

“Thank you for sharing this with me, I know these situations can be difficult to talk about. You have the right to be in control of your reproductive choices, no matter your situation. We can help and give you information and strategies to help you make the right FP decisions for yourself.”



Negative Reproductive Coercion Clients

Clients that Screen Negative for RC just because a client screens negative for coercion does not mean it is not occurring in their relationship. When a client screens negative for RC, ensure you do the following:

- Explain that you are pleased to hear this is not happening in their relationship at this time.
- Let the client know they can come to the clinic to talk about this and seek help in the future if their situation changes.
- Ask clients if they have or are experiencing abuse from any family members or other persons, this is especially important for young women and adolescent girls.

If helpful, you can refer to the following script:

“I am glad to hear that you are not experiencing any of these issues in your relationship today. If your situation ever changes, I want to assure you that you have a safe space here to talk about these issues and receive help.”



Clients on Denial

Some clients that are experiencing the signs and symptoms of abuse may

not believe that they are experiencing RC or may not wish to talk about their experience.

It is important not to pressure clients but to encourage them and let them know there is a safe, supportive space at the clinic. Providers should offer all clients information and resources on FP methods to help their situation regardless of disclosure status.

If this situation occurs, ask a follow-up question:

- a. Does your partner approve of your FP use? You can also use an example, “Does he throw your contraceptive out or prevent you from coming to the clinic?”
- b. “Would you be frightened to tell him that you are using FP?”

Providers should use their expertise in FP counselling to judge the situation and their follow-up question. Providers should not ask or repeat follow-up questions that make clients upset or uncomfortable. It is okay for the client to refuse to answer! Do not pressure them. Establish the clinic as a safe space to talk about this and seek help if this occurs in the future.

If helpful, you can refer to the following script:

“I understand that these questions may be difficult to understand and talk about. If you ever want to talk about these issues more, you can come to the clinic at any time for support and help with FP methods. Do you have any questions for me about this?”



4.5 Management of Reproductive Coercion

Interventions can include;

- a. Educating clients about safety planning and support services,
- b. Offering harm-reduction strategies
- c. Providing discreet and confidential methods of contraception such as IUDs, emergency contraception, depot medroxyprogesterone acetate injections, and Etonogestrel implants

4.5.1 Intimate Partner Violence

4.5.1.1 Definition

Intimate partner violence (IPV) is violence or aggression that occurs in a close relationship. The term “intimate partner” includes current and former spouses and dating partners. IPV can vary in frequency and severity and occurs on a continuum, ranging from one episode that might or might not have lasting impact, to chronic and severe episodes over a period of years.

IPV includes four types of behaviour;

- **Physical violence** is when a person hurts or tries to hurt a partner by hitting, kicking, or using another type of physical force.
- **Sexual violence** is forcing or attempting to force a partner to take part in a sex act, sexual touching, or a non-physical sexual event (e.g., sexting) when the partner does not or cannot consent.
- **Stalking** is a pattern of repeated, unwanted attention and contact by a partner that causes fear or concern for one’s own safety or the safety of someone close to the victim.
- **Psychological aggression** is the use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally and/or exert control over another person.

Several types of IPV can occur together. IPV is associated with several risk and protective factors. It is connected to other forms of violence, and causes serious health and economic consequences. By using a public health approach that addresses risk and protective factors for multiple types of violence, IPV and other forms of violence can be prevented

Source - CDC

- https://www.cdc.gov/violenceprevention/intimatepartnerviolence/fastfact.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fviolenceprevention%2Fintimatepartnerviolence%2Fdefinitions.html
- Refer to Annex 4 - The Algorithm (BCS card on Women’s support and safety)

4.5.1.2 Management of Reproductive Coercion and Intimate Partner Violence, Referral and Linkages

Talk to the client about Intimate Partner Violence (IPV) Before screening, always remember to normalize screening for IPV with the client by providing a brief introduction.

If helpful, you can refer to the following script:

“Because some of the clients that we talk to are treated badly by their partners, we talk about these experiences with all of our clients in confidence (without exposing their identities). We can connect our clients to helpful services in case they experience violence.”



4.5.1.3 Screening for Intimate Partner Violence

IPV Guiding Questions

1. “Are you currently in a relationship with a partner who physically hurts you because of using contraceptives?”
2. “Are you currently in a relationship with a partner who threatens, frightens, insults you, or treats you badly because of using contraceptives?”
3. “Are you currently in a relationship with a partner who forces you to have sex or to do something sexual that makes you feel uncomfortable because of using contraceptives?”

Now, respond to her according to the client answer (yes/no/unsure) using the guidelines for response highlighted in the section IPV: Communication & Responding to Clients. After responding, move on to providing referrals if positive and the “My FP Choice, My Right” mini-booklet for all clients. IPV: Communication & Responding to Clients.

Providers should follow the same protocols as for RC except emphasize the referral options for women and girls who screen positive for physical or sexual abuse.

4.5.1.4 Clients on Denial

Some clients that are experiencing the signs and symptoms of abuse may not self-identify as survivors of violence or may not wish to talk about their experience. It is important that providers do not pressure them but encourage that they have safe and supportive services at the clinic. If this situation occurs, ensure you ask follow-up question;

1. Does your partner ever hurt you or make you feel badly about yourself because of contraceptive use?
2. You can also use an example: “Does your partner ever slap you or use his strength to intimidate you?” “Would you be frightened to tell your partner that you are using family planning for fear of being hurt or raped?” “Does your partner ever pressure you to have sex when you have said you do not want to?”

Note: Providers should use their expertise in FP counselling to judge the situation and their follow-up question.

- Allow the client to refuse to answer; do not pressure them to respond.
- Establish the clinic as safe and connected with helpful people to talk to if they ever want to access services in the future.

If helpful, you can refer to the following script:

“I understand that these questions may be difficult to understand and talk about. I want to assure you that you are in a safe place and that anything you discuss here will be kept completely private and confidential. You can come to the clinic to talk about these issues in the future and access contraceptive services safely.”



4.5.1.5 Summary

1. It is important to identify and manage clients with RC and IPV concerns regarding contraceptive use
2. Helping clients with concerns on safely accessing contraceptives requires providers to discuss their needs, situations and explore options and available resources.

3. It is important to have a list of referrals readily handy and help the client think through what barriers they might face in accessing referral services.
4. Prior arrangements with facilities that clients are referred to can be helpful.
5. See link below for Job aids for BCS+ in <https://www.popcouncil.org/research/the-balanced-counseling-strategy-plus-a-toolkit>

4.6 Counselling for Diverse groups

FP service providers have a duty to ensure acceptable and equitable access of services to all, including groups with special needs. Therefore, there is need to focus on counselling for special groups. In this section we shall be looking at Adolescents and men though the list is large to include people living in humanitarian settings as well as those living with disability.

4.6.1 Adolescents

Adolescents are young heterogeneous group - married, unmarried, parents, non-parents. In-school or out of school. Young people deserve non-judgmental and respectful care no matter their age, marital status, school-status, parenting status, or otherwise. Criticism or unwelcoming attitudes will keep young people away from the care they need. Research has shown that family planning counselling and services do not encourage young people to have sex. Instead, they help young people make better decisions and protect their health. To serve the needs of adolescents, you can:

- i. Show young people that you enjoy working with them
- ii. Use terms that suit young people. Avoid such terms as “family planning,” which may not make sense to unmarried adolescents. Use terms like contraception or “future planning” as an alternate
- iii. Try to make sure that a young woman’s choices are her own and are not pressured by her partner or her family. In particular, if she is being pressured to have sex, help a young woman think about what she can say and do to resist and reduce that pressure
- iv. Practice skills to negotiate condom use

- v. Speak without expressing judgment (for example, say “You can” rather than “You should”). Do not criticize even if you do not approve of what the young person is saying or doing. Help young clients make decisions that are in their best interest
- vi. Reassure her/him that anything she/he shares with you is confidential, and you will not share her/ his information with anyone
- vii. Take time to fully address questions, fears, and misinformation about sex, sexually transmitted infections (STIs), and contraceptives. Many young people want reassurance that the changes in their bodies and their feelings are normal
- viii. Reassure her/him that the contraceptive methods used are reversible and will not affect their future fertility

4.6.2 Men

It is important to engage men in FP. The first reason is the influence that men have on women. Some men care about their partner’s reproductive health and support them. Others stand in their way or make decisions for them. Thus, men’s attitudes can determine whether women can practice healthy behaviours. In some situations, such as needing to avoid HIV infection or getting help quickly in a medical emergency, a man’s actions can determine whether a woman lives or dies.

Men are also important as clients. They use family planning methods such as natural methods, male condoms, vasectomy. Men also have their own sexual and reproductive health needs and concerns about sexually transmitted infections (STIs) - that deserve the attention of health care providers.

4.6.2.1 Approaches for providing information

Meeting the needs of male clients

- Coach men and women on how to talk with their partners about family planning and STIs
- Encourage men to make decisions about sexual and reproductive health jointly with their partners

- Encourage women to bring their partners to see clinical providers for joint counselling, decision-making, and care
- Suggest to female clients that they tell their partners about health services for men
- Give female clients informational materials to take home, if available
- Correct men's misperceptions and give them information to inform their decisions and opinions. Topics important to men include:
 - Family planning methods for men and for women, including safety and effectiveness
 - STIs including HIV/AIDS - how they are and are not transmitted and where to go for testing and treatment
 - The benefits of waiting until the youngest child is two years old before a woman becomes pregnant again
 - Male and female sexual and reproductive anatomy and function
 - Where to learn about safe pregnancy and childbirth

4.6.2.2 Counteracting myths and misconceptions

Rumours are unconfirmed stories that are transferred from one person to another by word of mouth. In general, rumours arise when:

- An issue or information is important to people, but it has not been clearly explained
- A person who can clarify or provide the correct information is not available
- The original source is perceived to be credible
- Clients have not been given enough options for contraceptive methods
- People are motivated to spread them for political reasons

A misconception is a mistaken interpretation of ideas or information. If a misconception is imbued with elaborate details and becomes a fanciful story, then it acquires the characteristics of a rumour. Unfortunately, rumours or misconceptions are sometimes spread by health care workers who may be

misinformed about certain methods or who have religious or cultural beliefs pertaining to family planning that they allow to have an impact on their professional conduct.

The underlying causes of rumours have to do with people's knowledge and understanding of their bodies, health, medicine, and the world around them. Often, rumours and misconceptions about family planning make rational sense to clients and potential clients. People usually believe a given rumour or piece of misinformation due to immediate causes (e.g., confusion about anatomy and physiology).

4.6.2.3 Methods for Counteracting Rumours and Misinformation

1. When a client mentions a rumour, always listen politely. Don't laugh
2. Define what a rumour or misconception is
3. Find out where the rumour came from and talk with the people who started it or repeated it
4. Check whether there is some basis for the rumour
5. Explain the facts
6. Use strong scientific facts about family planning methods to counteract misinformation
7. Always tell the truth. Never try to hide side effects or problems that might occur with various methods
8. Clarify information with the use of demonstrations and visual aids
9. Give examples of people who are satisfied users of the method (only if they are willing to have their names used). This kind of personal testimonial is most convincing
10. Reassure the client by examining her and telling her your findings
11. Counsel the client about all available family planning method
12. Reassure and let the client know that you care by conducting home visits.

UNIT 5:

MEDICAL ELIGIBILITY CRITERIA FOR FAMILY PLANNING



Introduction

This unit introduces the participant to the Medical Eligibility Criteria applied for family planning



Objectives

1. To define and outline the WHO Medical Eligibility Criteria (MEC)
2. To describe the components of MEC Wheel
3. To demonstrate skills in the use of the MEC Wheel

5.1 WHO Medical Eligibility Criteria (MEC) Wheel

5.1.1 Introduction

A medical Eligibility criterion, for starting use of contraceptive methods is based on World Health Organization (WHO) guidelines. MEC helps a provider to decide whether a particular contraceptive method can be used, in the presence of a given individual characteristic or medical condition. Each condition is defined as representing either an individual's characteristics (e.g., *age, history of pregnancy or known pre-existing medical conditions such as diabetes, hypertension*).

- 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.
- With 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) and medication used.

- The latest Edition (5th Edition) of the WHO MEC was updated in 2015 and the new recommendations have been incorporated in the present guidelines. (https://www.who.int/reproductivehealth/publications/family_planning/Ex-Summ-MEC-5/en)

Compared to the fourth edition, the current edition provides recommendations for the following new methods:

- i. Subcutaneously administered depot medroxyprogesterone acetate (DMPA-SC)
- ii. Sino-implant (II)
- iii. Emergency contraceptive pills (ECPs) – Ulipristal acetate (UPA) as a new method added to the guideline; use of CYP3A4 inducers and obesity as new conditions for ECP use
- iv. Vaginal rings

5.1.2 The Purpose of MEC

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

The WHO groups medical conditions into the following four categories:

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

Category 2: Conditions for which the advantages of using the method generally outweigh the theoretical or proven risks. In most situations, the method can be used freely, but careful follow-up might be required

Category 3: Conditions for which the theoretical or proven risks usually outweigh the advantages of using the method. In this case, use of the method is not usually recommended unless other more appropriate alternative methods are not available or acceptable

Category 4: Conditions that present an unacceptable health risk if the contraceptive method is used, (*i.e. the method should not be used*)

Table 8: THE MEC WHEEL CLASSIFICATIONS SUMMARY

Classification	With clinical judgment	With limited clinical judgment
1	Use method in any circumstances	Yes, Use the method
2	Generally, use: advantages outweigh risks	Yes, Use the method
3	Generally, do not use: Risks outweigh advantages	No, do not use the method
4	Method not to be used	No, do not use the method

5.2 The WHO MEC Application in Kenya

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

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

Category 2: Conditions for which the advantages of using the method generally outweigh the theoretical or proven risks. Recommendation: Where clinical 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 9: SUMMARY TABLE FOR MEC IN RELATION TO CLINICAL JUDGMENT

Category	Description	Recommendation	
		Where Clinical Judgment is possible	Where Clinical Judgment is NOT possible
1	A condition for which there is no restriction for the use of the method	Use method in any circumstances	Use the method
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks	Use the method with care—close follow-up might be required in some cases	Initiate the method and refer the client for evaluation as soon as possible
3	A condition where the theoretical or proven risks usually outweighs the advantages of using the method	Generally, advise suitable alternative. Method may be used only if no others are available or acceptable to the client and careful follow-up can be assured.	Do not use the method. Refer the client or help her to choose another method
4	A condition that presents an unacceptable health risk if the contraceptive method is used	Do not use the method	Do not use the method. Refer as needed

Table 10: MEC CATEGORIES FOR PERMANENT METHODS

CATEGORY	EXPLANATION
Accept	<ul style="list-style-type: none"> There is no medical reason to deny sterilization to a person with this condition
Caution	<ul style="list-style-type: none"> The procedure is normally conducted in a routine setting, but with extra preparation and precautions.
Delay	<ul style="list-style-type: none"> The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods of contraception should be provided.
S - Special	<ul style="list-style-type: none"> The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the 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.

5.3 MEC Criteria for Fertility Awareness-based Methods (FAMs) of FP

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

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



Table 11: MEC CATEGORIZES FOR FERTILITY AWARENESS-BASED METHODS

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

UNIT 6:

INFECTION PREVENTION & CONTROL



Introduction

The unit is to help participants gain knowledge, skills and competencies on the basic principles of infection prevention and control; recommended processes and practices.



Objectives

By the end of this unit the participants will be able to: -

1. Describe the basic infection prevention practices
2. Gain skills and competencies on hand washing and use of gloves
3. Demonstrate proper waste management practices

6.1 Definition

A set of practices, protocols, and procedures that are put in place to prevent infections.

6.1.1 Standard Precautions for Infection Prevention and Control

Preventing and controlling infection in health care facilities involves two levels of approach: standard precautions and additional (transmission-based) precautions. Standard precautions are practices taken to reduce the risk of transmitting blood-borne pathogens from both recognized and unrecognized sources. These precautions should be used, as a minimum

requirement, in the care of all clients in the health care settings, regardless of their diagnoses or presumed infection status.

6.1.2 Importance of Infection Prevention and control

Infection prevention practices protect not only clients, but also the Health care providers (HCPs) and the community. It is important to remember that all HCPs including cleaners who come in contact with blood and body fluids are at risk of infection. Most infections can be prevented and controlled if IPC procedures are followed. The Health care providers are responsible for ensuring their safety and that of their clients by observing IPC practices.

Strategies for standard precautions include:

- Hand hygiene
- Use of personal protective equipment (PPE)
- Prevention of needle stick and injuries from other sharp instruments
- Respiratory hygiene and cough etiquette
- Environmental cleaning
- Management of linen
- Management of healthcare waste
- Management of patient care equipment

6.1.3 Hand hygiene

Refers to washing hands with soap and running water or use of alcohol-based hand rub, for the purpose of the removal of visible soil/dirt and the removal or killing of micro-organisms. Good hand washing requires focusing on the palms, back of the hands and also the fingertips. **Lack of Hand Hygiene + patient care = Increases risks**


Types of Hand Hygiene Procedures

- Routine hand washing
- Alcohol based hand rub (ABHR)
- Surgical hand scrub

6.2 Routine Hand Washing

Knowing the positive impact of handwashing in life it is generally a good motivating factor to keep up with good hygienic habits. Involves washing hands with soap and clean running water. wash your hands:

- On arrival at workplace
- Before & after gloving
- Before and after visiting the toilet
- When hands are visibly soiled
- After any situation in which hands might become contaminated, such as:
 - Handling contaminated objects, including used instruments
 - Diapering or toileting children
 - Using the toilet, wiping or blowing one's nose, or performing other personal functions
 - Touching mucous membranes, blood, body fluids, secretions, or excretions



To effectively reduce the growth of germs on hands, handwashing must be performed by following all 11 steps illustrated above.

This takes 40-60 seconds!

6.3 Alcohol Based Hand Rub

An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol.

- Alcohol-based gels, sprays, and solutions
- Kills 99% of microorganisms
- Takes 60 seconds to dry
- Quicker and easier to perform
- To be effective, an adequate amount (5 ml) solution should be used
- Should not be used when hands are visibly soiled. Instead hand wash with soap and water

6.3.1 Right Way

To avoid prolonged hand contamination:

- Use the appropriate technique
- Use an adequate quantity
- Use for recommended length of time

6.3.2 Proper Hand Washing/Rubbing Technique



STEP 1
Rub palms together.



STEP 2
Rub the back of both hands.



STEP 3
Interlace fingers and rub hands together.



STEP 4
Interlock fingers and rub the back of fingers of both hands



STEP 5
Rub thumb in a rotating manner followed by the area between index finger and thumb for both hands.

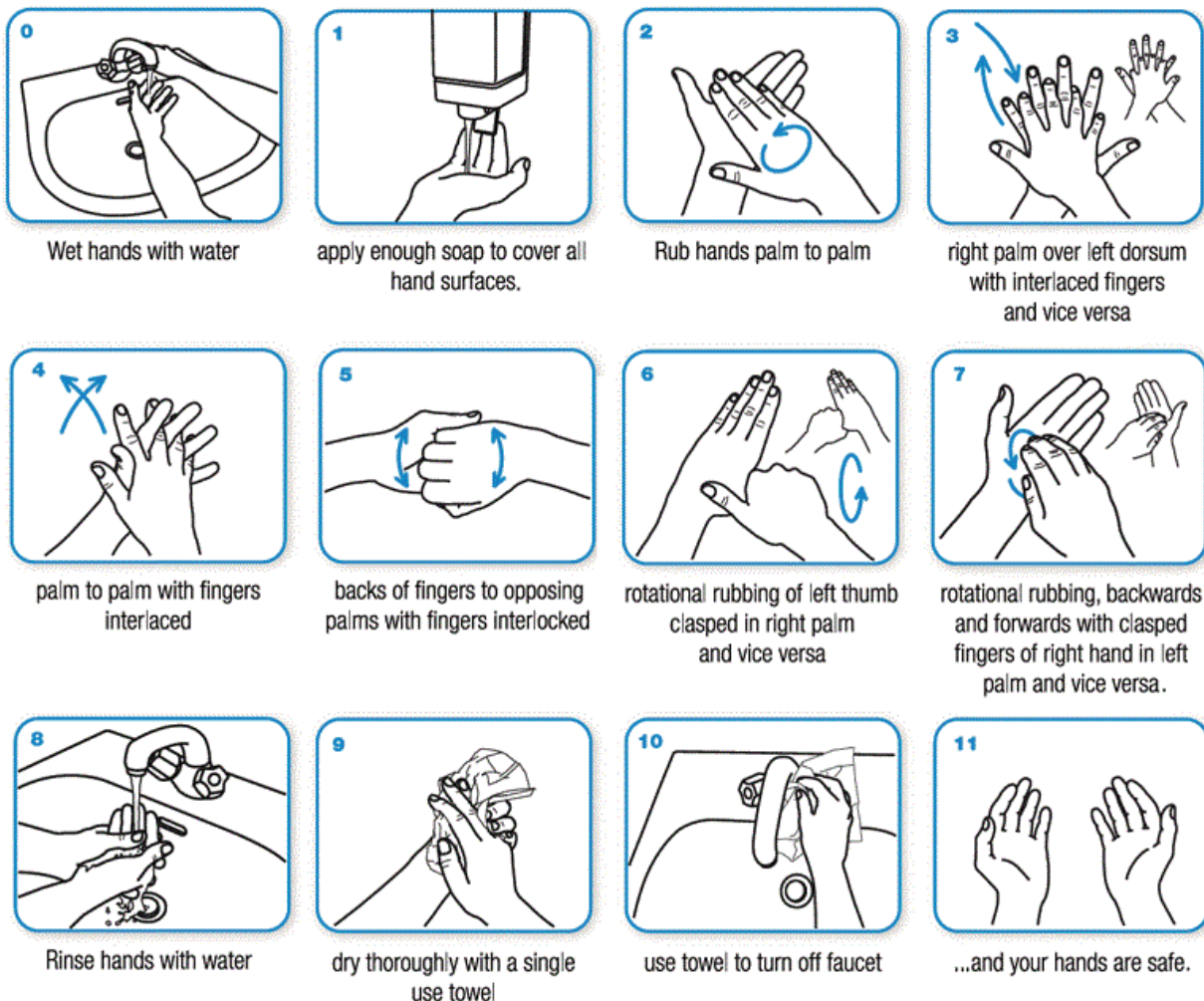


STEP 6
Rub fingertips on palm for both hands.



STEP 7
Rub both wrists in a rotating manner. Rinse and dry thoroughly.

How to Handwash



Source: WHO

How to Use Handrub

1. An alcohol hand rub kills or inhibits the growth of both transient and resident microorganisms, but does not remove microorganisms or soil.
2. Such a hand rub can be used when hand washing with soap and running water is not possible or practical (such as when running water is not available).
3. For an alcohol hand rub, rinse hands twice with 3–5 ml of alcohol and follow the steps as in hand washing. (if you do not have a readily available alcohol hand rub use this formula to make a glycerine solution ;100 ml of 60–90% ethyl or isopropyl alcohol mixed with 2–3 ml of glycerine).



Figure 10: USING ALCOHOL HAND RUB

6.4 Personal Protective Equipment

6.4.1 Definition

“Specialized clothing or equipment worn by an employee for protection against infectious materials” (Occupational Safety and Health Act)

TYPES OF PPE USED IN HEALTHCARE SETTINGS

Types of PPE	Description
Gloves	<ul style="list-style-type: none">• Protect hands• Glove materials include vinyl, latex and nitrile.• They could be sterile or nonsterile, for single use (disposable).• Environmental services personnel must wear reusable heavy duty gloves made of latex or nitrile to work with caustic disinfectants when cleaning environmental surfaces. <p>NB: Most patient care activities require the use of a single pair of nonsterile gloves made of either latex, nitrile, or vinyl.</p>

Types of PPE	Description
Gowns/aprons	Protect skin and/ or clothing
Masks	Protect mouth/ nose
Respirators	Also protect the respiratory tract from airborne infectious agents
Goggles	Protect eyes
Face shields	Protect face, mouth, nose, and eyes

6.5 Waste Disposal

Healthcare waste contains potentially harmful microorganisms which can infect clients, health-care workers and the general public.

Importance of Safe Waste Management

- Reduces risk of healthcare-associated infections (HAI)
- Reduces risk of injury
- Creates clean and safe workplaces in the healthcare facilities
- Reduces waste-related odours and attraction for vermin
- Clean and well protected environment (soil, water, and air)

All staff have a responsibility to dispose off healthcare waste in a manner that poses minimal hazard to patients, visitors, other healthcare workers, and the community.

6.5.1 Categories of Waste

Non-hazardous	Hazardous
<p>Non-hazardous waste comprises of: General waste which has not been mixed with any infectious material.</p> <p>Examples</p> <ul style="list-style-type: none"> • Paper, boxes, bottles, and plastic containers • PPE that is not contaminated with bodily fluids or from an isolation area 	<p>Hazardous waste comprises of:</p> <ul style="list-style-type: none"> • Sharps (needles) • Infectious (items contaminated with body fluids) • Pathological (human tissue, placentas) • Pharmaceutical (medications) • Chemical (lab reagents, disinfectants) • Radioactive (unused radiation liquids, urine from radiation patient)

6.5.1.1 Key Steps in Waste Management

1. Waste minimization
2. Segregation (separation)
3. Handling and Storage
4. Collection
5. Transportation
6. Treatment
7. Disposal

6.5.2 Waste Minimization

Significant reduction of the waste generated in health-care establishments and research facilities may be encouraged by the implementation of certain policies and practices, including the following:

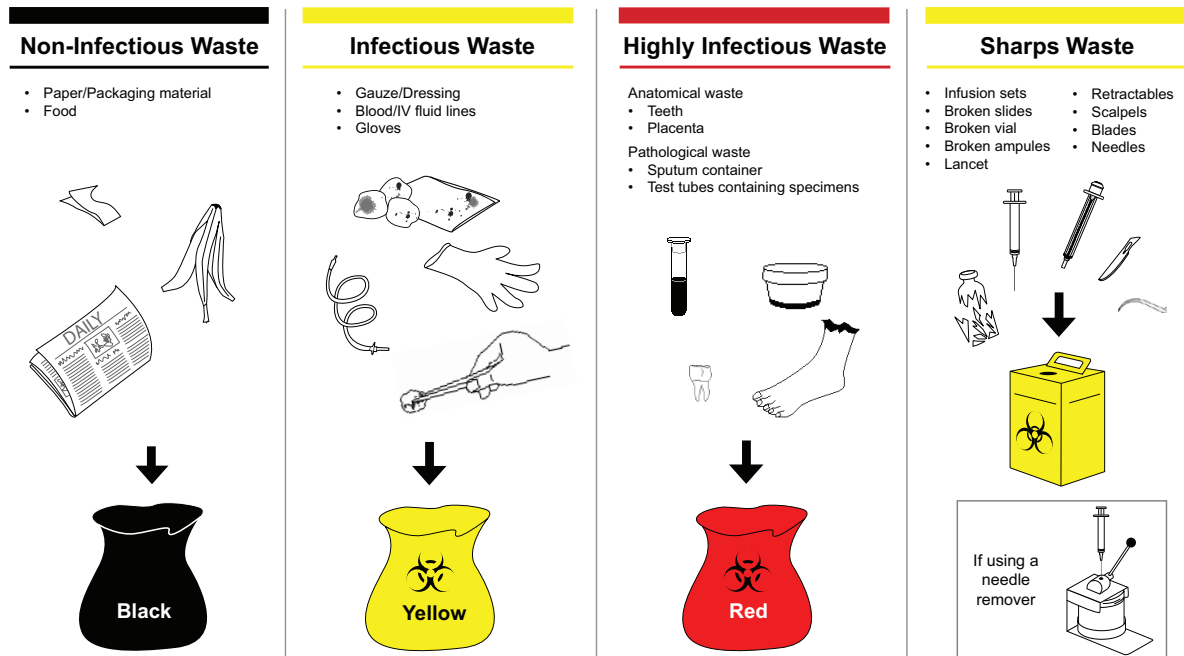
- Source reduction: measures such as purchasing restrictions to ensure the selection of methods or supplies that are less wasteful or generate less hazardous waste.
- Recyclable products: use of materials that may be recycled, either on-site or off-site.
- Good management and control practices: apply particularly to the purchase and use of chemicals and pharmaceuticals.

6.6.2 Waste Segregation

- Waste **should be segregated** at **point of generation** by ALL personnel
- Waste **should** be segregated in the correct color-coded bins based on their potential hazard (Red, yellow, black and Sharps container)
- Minimizes infection

To make separate collection possible, personnel at all levels should be trained to segregate the waste they produce.

Figure: EXAMPLE OF WASTE SEGREGATION IN COLOUR CODED BIN/LINERS



6.6.3 Waste Bins

- The bin must be sufficiently large to contain the types of waste generated.
 - Bins that are too large are difficult to handle
 - Bins that are too small increases frequency of handling of waste
- Bin liners must fit the bin and be leak proof.
- If no bin liners, bins must be cleaned and disinfected using 0.5% chlorine after disposal of waste and before re-use.
- This must be done AWAY from the patient care area

NOTE:

A separate color-coded bin for radioactive waste and food waste should be made available.

6.6.4 Sharps Waste

Sharps waste is a form of biomedical waste composed of used “sharps”, which includes any device or object used to puncture or lacerate the skin. Common medical materials treated as sharps waste are: Hypodermic needles, disposable scalpels and blades, contaminated glass and some plastics that can cause cuts or puncture wounds.

6.6.5 Type of Sharps

- Needles
- Scalpel
- Blades
- Knives
- Saws
- Broken glass

To reduce the risk of sharp injuries, all sharps must be used and disposed of safely in accordance with this guidance. It is the responsibility of the user to ensure compliance. Where this task is delegated, e.g. support staff, the user must be sure that ‘at risk’ staff are aware of the presence of the hazard and their responsibility for disposal.

Table: PROVIDES THE DOS’ AND DON’TS’ WHEN HANDLING SHARPS

DOS’	DON’TS’
<ul style="list-style-type: none">• Immediately place used needles/ other sharps in a sharps disposal container to reduce the risk of needle sticks, cuts or punctures from loose sharps.• Keep all sharps and sharps disposal containers out of reach of children.• Dispose of all contents of disposal containers at drop-off locations for incineration.	<ul style="list-style-type: none">• Do not throw needles and other sharps into the trash.• Do not flush needles and other sharps down the toilet.• Do not put needles and other sharps in your recycling bin – they are not recyclable.• Do not try to remove, bend, break or recap used needles.

6.6.5.1 Waste Handling

- **Always** wear personal protective equipment (**PPE**)
 - A minimum of gloves, heavy duty apron and boots
- Maintain segregation patterns and NEVER re-sort waste
- Keep written records of the quantities received and treated
- Collect and remove waste daily from the premises.

6.6.5.2 Waste Storage

- Designate an area/room within the premises for holding the waste containers
- Storage time must not exceed 24 hours
- Mark storage areas with the biohazard symbol

6.6.5.3 Waste Storage Requirements

- Waste must be stored in a secure location
 - i. To restrict access of unauthorized persons
 - ii. To secure against scavengers
- Waste must be sheltered from weather (e.g., rain)

NB: Storage area should be easily accessible from all points of waste generation

6.5.5.4 Transporting to Treatment/Disposal Site

All waste generated from the premises shall be collected and transported by licensed waste disposal companies to areas approved by **NEMA**.

CONTRACEPTIVE METHODS



Introduction

This unit introduces the participant to available contraceptive methods in Kenya. It further narrows down to details on short-acting methods.

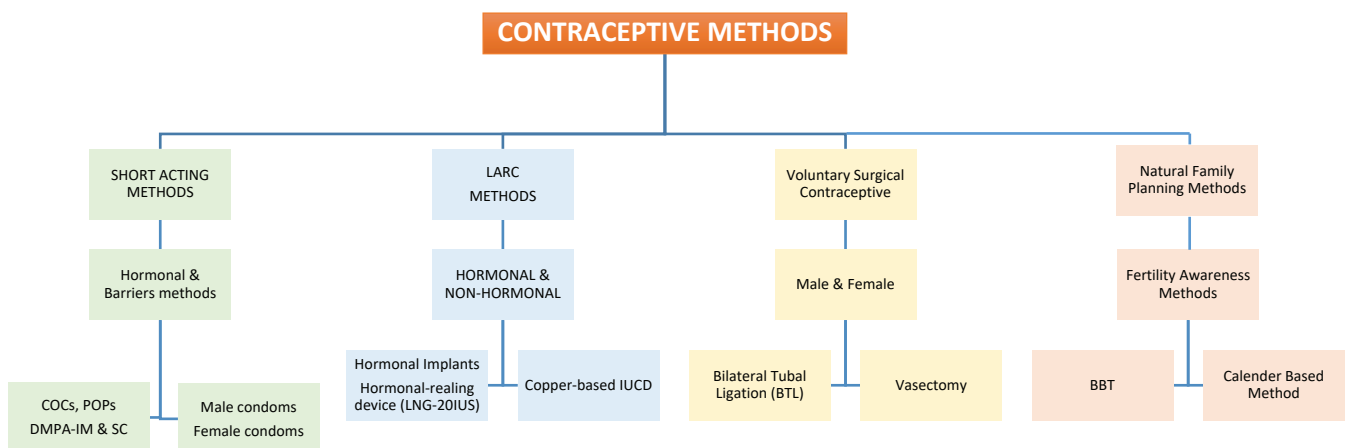


Broad objectives

1. Describe the contraceptive methods appropriately categorizing them into short and long acting (reversible and permanent) methods
2. Demonstrate competence in provision of the short acting methods
3. Attain clinical experience on the short-acting methods

Family planning allows people to attain their desired number of children and determine the spacing of pregnancies. One of the methods to achieve this is through use of contraceptive methods. Contraceptive methods are divided into different categories as illustrated in the figure below.

Figure 11: CATEGORIES OF AVAILABLE CONTRACEPTIVE METHODS IN KENYA



7.1 Short Acting Methods

7.1.1 Introduction

Short acting methods are a category of contraception methods that are effective and have to be used repetitively at short time intervals from single use, daily use or up to 3 months injections.

NOTE:

It is important to note that, except for the barrier methods, they do not protect against STIs including HIV.

By the end of this unit participants will be able to gain knowledge and acquire the competencies in offering the following methods to clients:

- Combined Hormonal contraceptives
- Progestin only pills
- Emergency pills
- Injectable contraceptives
- Barrier methods
- Natural methods

NOTE:

- Effectively counsel and administer to at least 5 clients, on short acting contraceptive method in the clinical training practicum (*To be done during the clinical practicum*)
- Effectively counsel and administer to at least 10 (5 IM, 5SC) clients short acting contraceptive methods in their duty station in preparation for certification (*To be done in the duty station/ pharmacy outlet & recorded in the logbook*)

7.1.1 Combined Hormonal Contraceptives

This entails contraceptive methods with both estrogen and progestin. They include Patch, COCs, CICs, and CVRs.

7.1.1.1 Combined Oral Contraceptives

Combined Oral Contraceptives: They are Pills that contain low doses of 2 hormones: a progestin and an estrogen like the natural hormones progesterone and estrogen in a woman's body. Combined oral contraceptives (COCs) are also called "the Pill," low-dose combined pills, oral contraceptive pills, and COCs. They work primarily by preventing the release of eggs from the ovaries (ovulation).

Effectiveness: This depends on the user. 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 end of a pill pack.

- The failure rate is 1 pregnancy per 100 women when taken correctly
- There is **immediate return to fertility** following discontinuation
- Does not protect against sexually transmitted infections (STIs)

Mode of action of Combined Oral Contraceptives

- Suppress ovulation
- Thickens the cervical mucus thus interfering with sperm transport



7.2.1 Providing Combined Oral Contraceptives

Table 8: HOW TO PROVIDE COCs TO A CLIENT

When to start	<ul style="list-style-type: none"> A woman can be given COCs at any time and told when to start taking them A woman can start using COCs any time she wants if it is reasonably certain she is not pregnant <ul style="list-style-type: none"> To be reasonably certain she is not pregnant, use the Pregnancy Checklist (see annex) If she begins using COCs within five days after the start of her monthly bleeding, she will not need a back-up contraceptive method If she begins using COCs more than five days after the start of her monthly bleeding, during the first seven days when she takes COCs she should also use a backup method For postpartum women <ul style="list-style-type: none"> Use of COCs is not usually recommended for breastfeeding women until after 6 months postpartum For Non-Breastfeeding women, if a woman is 21 or more days postpartum, amenorrhea and it is certain that she is not pregnant, she can start COCs immediately. Use of a backup method is required for the next 7 days. If her menstrual bleeding has returned, she can start COCs as for other women having menstrual bleeding Post Abortion women can start COCs immediately
Switching of FP methods	<ul style="list-style-type: none"> Switching from another hormonal method <ul style="list-style-type: none"> Can start COCs immediately if she has been using her hormonal method consistently and correctly or if certain that she is not pregnant If her previous method was an injectable, start COCs when the next injection is due Switching from a non-hormonal method (other than the IUCD) <ul style="list-style-type: none"> Start within 5 days of menstrual bleeding Start immediately or at any other time, if certain that she is not pregnant After 5 days of menstrual bleeding there is need to use a backup method for the next 2 days Switching from an IUCD (including a hormone-releasing IUCD) <ul style="list-style-type: none"> Start within 5 days of menstrual bleeding and the IUCD can be removed at the same time Start at any time if certain that she is not pregnant After 5 days of menstrual bleeding start COC and remove the IUCD on the next menstrual bleeding

Providers can give COCs to women at any time to start later. If pregnancy cannot be ruled out, but the woman is otherwise medically eligible to receive COCs, a provider may give her one or more packs of pills to take later (i.e., when her monthly period begins). This eliminates the need for clients to return at 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 ensure clients get regular follow up, and obtain optimally stored fresh products.

Providers should refer to the medical eligibility criteria (MEC) wheel and appropriate manual and job aids for instructions on pill usage.

7.2.2 Management for Missed Pills

For greatest effectiveness, a woman must take one pill every day and start each new pack of pills on time. Any missed pill should be taken as soon as possible. Missing pills increase the risk of pregnancy and could worsen side effects. Table 8 below summarizes actions to take for missed COCs pills.

Table 9: ACTIONS TO TAKE FOR MISSED COMBINED ORAL CONTRACEPTIVES

Number of Pills Missed	Advice to be given
One pill	Take the pill as soon as she can then continue at the usual time (this might mean taking 2 pills at the same time). Use a backup method for 2 days after the missed pill
Two pills	Take 2 pills as soon as she can and take another 2 pills the next day then return to her regular schedule on the third day. Use a backup method for 2 days after two missed pills
Three pills	Use a backup method and report to the health facility for professional help as soon as possible
Severe vomiting or Diarrhoea	If she vomits within two hours after taking a pill, she should take another pill from her pack as soon as possible, then keep taking pills as usual If she has vomiting or diarrhoea for more than two days, follow instructions for one or two missed pills, above

NOTE:

If three or more pills are missed, discard the packet and use a barrier method until next menstrual period then start a new packet. Supply an extra packet of pills with condoms for dual protection.

7.2.3 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.

7.2.4 “Come Back Any Time”: Reasons to Return

Assure every client that she is welcome to come back any time, for example, if she has problems, questions, or wants another method, she has any major change in health status, or she thinks she might be pregnant. Also, if:

- She lost her pills or started a new pack more than 3 days late and also had sex during this time. She may wish to consider emergency contraceptive pills.
- **General health advice:** Anyone who suddenly feels that something is seriously wrong with her health should immediately seek medical care from a nurse or doctor. Her contraceptive method is most likely not the cause of the condition, but she should tell the nurse or doctor what method she is using.

7.2.5 Planning the Next Visit

- Encourage her to come back for more pills before she uses up her supply of pills.
- An annual visit is recommended
- Some women can benefit from contact after 3 months of COC use. This offers an opportunity to answer any questions, help with any problems, and check on correct use

7.2.6 Side Effects Combined Oral Contraceptives

Some users report the following:	<ul style="list-style-type: none"> Changes in bleeding patterns including: <ul style="list-style-type: none"> Lighter bleeding and fewer days of bleeding Irregular bleeding Infrequent bleeding No monthly bleeding 	
	<ul style="list-style-type: none"> Headaches Dizziness Nausea Breast tenderness 	<ul style="list-style-type: none"> Weight change Mood changes Acne (can improve or worsen, but usually improves)
Other possible physical changes:	<ul style="list-style-type: none"> Blood pressure increases a few points (mm Hg). When increase is due to COCs, blood pressure declines quickly after discontinuation of COCs 	

7.2.7 Management of Side Effects

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

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

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

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 clinician. Table 9 shows the side effects of combined oral contraceptives and their management.

Table 10: SIDE EFFECTS OF COMBINED ORAL CONTRACEPTIVES AND THEIR MANAGEMENT

Side Effect	Management
Amenorrhea	<ul style="list-style-type: none"> • If the client is taking COCs correctly, reassure • If she has not been taking the pills correctly assess for pregnancy <ol style="list-style-type: none"> a. If not pregnant advise her to take the pills correctly b. If pregnant, discontinue COCs and refer for antenatal care
Nausea, Dizziness, Vomiting	<ul style="list-style-type: none"> • Advise the client that this is a common side effect in COCs users in the first few months and may diminish in a few months • Advise client to take pill with evening meal or before bedtime • If symptoms persist, assess for pregnancy <ol style="list-style-type: none"> a. If pregnant, discontinue COCs & refer for antenatal care b. If not pregnant, reassure • If the problem is intolerable stop COCs and help client choose another method
Breast tenderness	<ul style="list-style-type: none"> • Assess for pregnancy <ol style="list-style-type: none"> a. If pregnant, discontinue COCs a. If not pregnant, reassure and give analgesics • If physical examination shows signs of sepsis, treat with antibiotics and analgesics
Bleeding/ Spotting	<ul style="list-style-type: none"> • Reassure the client that break-through bleeding/spotting is common during the first 3 months of COC use • If this is a result of missed pills, review instructions • If the problem persists, assess for gynaecological problems and manage accordingly • If no gynaecological problems are found and spotting is persistent, help client choose another method
Headache	<ul style="list-style-type: none"> • If headaches are mild, treat with analgesics and reassure • If headaches persist or are associated with blurring of vision, discontinue COCs and help the client to choose another method

7.2.8 Health benefits and risks of combined oral contraceptives

Table 11: HEALTH BENEFITS AND RISKS OF COMBINED ORAL CONTRACEPTIVES

Health Benefits of COCs	
Help protect against	Risks of pregnancy <ul style="list-style-type: none"> • Cancer of the lining of the uterus (endometrial cancer) • Cancer of the ovary • Symptomatic pelvic inflammatory disease
May help protect against	Ovarian cysts Iron-deficiency anaemia
Reduce	Menstrual cramps Menstrual bleeding problems <ul style="list-style-type: none"> • Ovulation pain • Excess hair on face or body Symptoms of polycystic ovarian syndrome (irregular bleeding, acne, excess hair on face or body) Symptoms of endometriosis (pelvic pain, irregular bleeding)
Health Risks Associated with COCs	
Very rare	Blood clot in deep veins of legs or lungs (deep vein thrombosis or pulmonary embolism)
Extremely rare	Stroke Heart attack

7.3 Combined patch

- A small, thin, square of flexible plastic worn on the body.
- Continuously releases 2 hormones—a progestin and an estrogen, like the natural hormones progesterone and estrogen 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.
- Works primarily by preventing the release of eggs from the ovaries (ovulation).

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 for the first few months and then lighter and more regular bleeding.

NOTE:

Medical eligibility criteria guidelines for when to start and helping continuing users for the combined patch are the same as for combined oral contraceptives.

7.4 Combined Vaginal Ring

A flexible ring that a woman places in her vagina.

- Continuously releases 2 hormones—a progestin and an estrogen, like the natural hormones progesterone and estrogen 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.
- Works primarily by preventing the release of eggs from the ovaries (ovulation).



Key points for providers and clients

- A woman places a flexible ring in her vagina. She leaves it there at all times, every day and night for 3 weeks. Then, she removes the ring. Seven days later she inserts a new ring.
- Start each new ring on time for greatest effectiveness.
- Bleeding changes are common but not harmful. Typically, irregular bleeding for the first few months and then lighter and more regular bleeding.

NOTE:

Medical eligibility criteria, guidelines for when to start, and helping continuing users for the combined ring are the same as for combined oral contraceptives.

7.5 Progestin-Only Contraceptive

This entails contraceptive methods with only progesterone/progestin hormone. They include Progesterone Only Pills (POPs), Progesterone - Releasing Vaginal Ring (PVR), Depot Medroxy Progesterone Acetate (DMPA).

7.5.1 Progestin-Only Pills (Pop)

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

7.6.1 Effectiveness of Progestin Only Pill

POPs are 99.5 % effective if used correctly and consistently. They are most effective when taken at the same time every day.

7.6.2 Types of Progestin Only Pills

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

7.6.3 Mode of Action of Progestin Only Pills

- i. Thicken cervical mucus thus interfering with sperm transport
- ii. Suppressing ovulation in about 50 percent of cycles.

7.6.4 Advantages and Limitations of Progestin Only Pills

Contraceptive benefits	Non-contraceptive benefits of POP's
<ul style="list-style-type: none">• Effective and safe• Do 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	<ul style="list-style-type: none">• Less side effects such as acne and weight gain• Taking POPs does not increase risk of blood clotting• May prevent endometrial cancer• May help to prevent anaemia

Side effects of Progestin Only Pills

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

Limitations of Progestin Only Pills

- They provide a slightly lower level of contraceptive protection than COCs
- They require strict daily pill-taking, preferably at the same time each day
- They do not protect against STIs, including hepatitis B and HIV/ AIDS. Therefore, at-risk individuals should use a barrier method to ensure protection against STIs and HIV/AIDS
- Effectiveness may decrease if clients are also taking some other medications (anti-TB drugs, anticonvulsants and antiretroviral) so a client should use a backup method
- Less effective in women who are not breastfeeding
- Effectiveness may also be lowered in the presence of diarrhoea and vomiting

7.6.5 Counselling for Informed Choice

Counselling for all methods should be done with reference to the current National Family Planning Guidelines and MEC for Contraceptives to establish eligibility of clients for methods and facilitate consent and informed choice by the clients.

7.6.6 Management of common side effects for progestin only pills

Table 12: MANAGEMENT OF COMMON SIDE EFFECTS FOR PROGESTIN ONLY PILLS

Side Effect	Management
Spotting	<ul style="list-style-type: none">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 POPsIf 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	<ul style="list-style-type: none">Assess for underlying gynaecological problems and manage accordinglyIf there are no underlying gynaecological problems: give NSAIDs and COCsIf bleeding persists and becomes a threat to her life, remove the implants and help her choose another method
Amenorrhea	<ul style="list-style-type: none">If client is breastfeeding, reassure her that it is normal not to have monthly bleeding while breastfeedingIf client is not breastfeeding, reassure her that some women stop having monthly bleeding while taking POPsIf there are reasons to suspect pregnancy (e.g., the woman has missed pills), assess for pregnancy<ul style="list-style-type: none">If client is pregnant, advise her to stop using POPs and refer for antenatal care (ANC)If she is not pregnant, reassure her to continue POPs

Side Effect	Management
Headache or dizziness	<ul style="list-style-type: none"> Determine cause. If no cause is found, counsel client and recommend common painkillers If headaches worsen while using POPs (e.g., she develops migraines with aura), discontinue POPs and help client select alternative method. Refer if need be
Breast fullness or tenderness	<ul style="list-style-type: none"> Assess for pregnancy <ul style="list-style-type: none"> 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
Mood changes or nervousness	<ul style="list-style-type: none"> Counsel the clients If the condition worsens, discontinue POPs and help her to select an alternative method

Women can safely use POPs even if they are infected with HIV, have AIDS, or are on antiretroviral (ARV) therapy unless their therapy includes ritonavir. Ritonavir may reduce the effectiveness of POPs. Urge these women to use condoms along with POPs. Used consistently and correctly, condoms help prevent transmission of HIV and other STIs. Condoms also provide extra contraceptive protection for women on ARV therapy.

For appropriate breastfeeding practices for women with HIV, (see Maternal and New-born Health, Preventing Mother-to-Child Transmission of HIV)

7.6.7 Method Prescription and Use

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

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

If a woman misses one or more hormonal pills, the primary advice is to take the missed pill as soon as possible and keep taking pills as usual, one each day. She may take two pills at the same time or on the same day. Specific instructions are provided in the table below. CHVs and CBDs should be instructed to refer clients that miss pills to a health facility for evaluation and advice by a clinician. Table 6e shows actions to take for missed POPs.

Table 13: ACTIONS TO TAKE FOR MISSED PROGESTIN ONLY PILLS

Number of Pills Missed	Advice to be given
Client's menses have returned and she misses one or more pills by more than three hours (or 12 hours in the case of the 75 µg Desogestrel-containing pill), regardless of whether or not she is breastfeeding	<ul style="list-style-type: none">• Take one pill as soon as possible and continue taking the pills as usual, one each day• Abstain from sex or use a back-up method (e.g., a condom) for the next two days
Client is breastfeeding and is amenorrhoeic, and she misses one or more pills by more than three hours (or 12 hours in the case of the 75 mcg Desogestrel-containing pill)	<ul style="list-style-type: none">• Take one pill as soon as possible and continue taking the pills as usual, one each day• If she is less than six months postpartum, no back up method is needed
In case of diarrhoea and vomiting	<ul style="list-style-type: none">• The client should use a backup method during and up to 2 days after cessation of diarrhoea and vomiting

7.6.9 Method supply

Non-clinical providers can:

- Initiate use of POPs and re-supply, using the approved MOH Checklist for MEC Category 1 conditions
- Except where otherwise stated, trained CHVs and CBDs may initiate supply to clients with MEC category 2 conditions, and refer them for evaluation as soon as possible, as in the case of COCs (see above). They should not initiate supply to clients with conditions falling in category 3 or 4.

- Supply not more than three cycles to women with category 2 conditions before evaluation by a clinical provider. After evaluation non-clinical providers may re-supply up to three cycles per visit.

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

7.6.10 “Come Back Any Time”: Reasons to Return

Assure every client that she is welcome to come back any time for example, if she has problems, questions, or wants another method, she has a major change in health status, or she thinks she might be pregnant. Also, if:

- She has stopped breastfeeding and wants to switch to another method
- For a woman who has monthly bleeding: If she took a pill more than 3 hours late or missed one completely, and also had sex during this time, she may wish to consider ECs (see Emergency Contraception)

General health advice: Anyone who suddenly feels that something is seriously wrong with her health should immediately seek medical care from a nurse or doctor. Her contraceptive method is most likely not the cause of the condition, but she should tell the nurse or doctor what method she is using.

Planning the Next Visit

- Encourage her to come back for more pills before she uses up her supply of pills
- Contacting women after the first 3 months of POP use is recommended. This offers an opportunity to answer any questions, help with any problems, and check on correct use.

7.7 Progesterone-Releasing Vaginal Ring

- A smooth, soft, flexible silicone ring placed in the vagina to prolong lactational amenorrhea (postponing the return of monthly bleeding) and

help breastfeeding women space pregnancies.

- Continuously releases natural progesterone hormone—like that in a woman’s body—from inside the ring. The hormone passes through the wall of the vagina directly into the bloodstream.
- This ring does not contain estrogen.
- Use of the ring starts 4 to 9 weeks after giving birth. Each ring is kept in place for 90 days.
- The woman can then replace it with a new ring immediately. Up to 4 rings can be used, one after another, with no breaks.
- Works by preventing release of an egg from the ovaries (ovulation).
- Progesterone extends the postpartum amenorrhea of the breastfeeding woman. That is, it delays the return of monthly bleeding.

Key points for providers and clients

- Suitable for postpartum women who are actively breastfeeding, at least 4 times per day.
- A woman places a flexible ring in her vagina. She leaves it in place at all times, every day and night for 90 days. Four rings can be used, one after another, for approximately one year after giving birth.
- Start each new ring immediately after removal of the previous ring for greatest effectiveness.
- Easy for a woman to insert and remove from her vagina.
- If her reproductive plans change, she can take out the ring at any time without a provider’s help.

7.9 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 percent of those at risk. EC can reduce unwanted pregnancies that might lead to child neglect, abandonment, unsafe abortions, and maternal deaths. EC is an important element in post-rape care and PMTCT of HIV, and it is an essential component of quality FP service provision.


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

Effectiveness of emergency hormonal contraceptive pills

- ECs are 98% effective if used correctly; that is taking the ECPs within 72 hours and up to 120 hours, however the earlier the more effective, for IUCD it should be inserted within 5 days.
- 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. It is important to note that emergency hormonal contraceptives employ unusually high doses of hormones which may lead to unwanted side effects

Mode of action of emergency hormonal contraceptive pill

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



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

NOTE:

- ECs do not work once a woman is pregnant women and girls who are already pregnant should not take ECs.
- It is important to note that, except for the barrier methods, they do not protect against STIs including HIV.

7.9.1 Types and dosage of emergency hormonal contraceptive pills

7.9.1.1 Progestin only pills

These dedicated ECPs contain the same progestin hormone (Levonorgestrel) as some other progestin-only pills, although in higher doses. They are more effective than the combined pills, preventing up to 95 percent of expected pregnancies.

The standard dosage is as follows:

- **One 750 mcg Levonorgestrel pill** - To be taken as soon as possible after unprotected intercourse, but within 120 hours. Repeat the same dose in 12 hours. A total of two pills are required or
- **Two 750 mcg Levonorgestrel pills** - To be taken as a single dose as soon as possible after unprotected intercourse, but within 120 hours. This regimen is to be preferred because it 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.

7.9.1.2 Combined hormonal contraceptives

- These contain the hormones estrogen and progestin, and they prevent about 75 percent of expected pregnancies.



Key Fact:

Two standard dosage options are available:

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

NB: EC contains unconventionally high dosage of the active ingredients with the attendant compounded side effects



7.9.1.3 Ulipristal acetate

Ulipristal Acetate (UPA) is a new oral emergency contraceptive that works by delaying ovulation. The dosage is 30 mg of Ulipristal acetate in a single dose within 120 hours after unprotected sex. It is currently registered in 72 countries but not yet in Kenya.

7.9.1.4 Advantages of emergency hormonal contraceptive pills

- 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

7.9.1.5 Limitations of Emergency Hormonal Contraceptive Pills

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

7.9.1.6 Counselling for Informed Choice

Counselling for all methods should be done with reference to the current National Family Planning Guidelines and MEC for Contraceptives to establish eligibility of clients for methods and facilitate consent and informed choice by the clients.

7.9.1.7 Management of Common Side Effects of Emergency Contraceptive Pill

Table 14: MANAGEMENT OF COMMON SIDE EFFECTS FOR EMERGENCY CONTRACEPTIVE PILL

Side effects	Management
Nausea & vomiting	<ul style="list-style-type: none">• If mild reassure and advise to take milk or eat snack• If vomiting is severe, put on antiemetic• If the woman vomits within 2 hours after taking ECPs, she should take another dose. (She can use anti-nausea medication with this repeat dose)• If vomiting continues, she can take the repeat dose by placing the pills high in her vagina• If vomiting occurs more than 2 hours after taking ECPs, she does not need to take any extra pills
Breast tenderness	<ul style="list-style-type: none">• If not pregnant, reassure
Irregular bleeding	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• If BP is normal, reassure and prescribe/give a mild analgesic• If BP is high, refer for further evaluation and management

7.9.1.8 Method Prescription and Use for Emergency Contraceptive Pill

Emergency contraceptive 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.

7.9.1.9 When to start Emergency Contraceptive Pill

Within **120 hours** for ECP and within **5 days** for IUCD, following unprotected sexual intercourse. The earlier the EC is used after unprotected sexual intercourse, the more effective they are.

7.9.1.10 Indications for Emergency Contraceptive Pill 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

7.9.1.11 Starting FP Methods after Emergency Contraceptive Pill

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 inform users of all FP methods available.

7.10.1 “Come Back Any Time”: Reasons to Return

- No routine return visit is required. Assure every client that she is welcome to come back any time, however, and also if:
 - She thinks she might be pregnant, especially if she has no monthly bleeding or her next monthly bleeding is delayed by more than one week.

7.10.2.1 Side effects of Emergency Contraceptive Pill

Nausea: Routine use of anti-nausea medications is not recommended. Women who have had nausea with previous ECP use or with the first dose of a 2-dose regimen can take anti-nausea medication such as 50 mg meclizine one-half to one hour before taking ECPs.

Vomiting: If the woman vomits within 2 hours after taking ECPs, she should take another dose. (She can use anti-nausea medication with this repeat dose, as above.) If vomiting continues, she can take the repeat dose by

placing the pills high in her vagina. If vomiting occurs more than 2 hours after taking ECPs, she does not need to take any extra pills.

7.10.2.2 Planning Ongoing contraception

- Explain that ECPs will not protect her from pregnancy for any future sex, even the next day. Discuss the need for and choice of ongoing pregnancy prevention and, if at risk, protection from STIs including HIV (see Sexually Transmitted Infections, Including HIV)
- If she does not want to start a contraceptive method now, give her condoms or oral contraceptives and ask her to use them if she changes her mind. Give instructions on use. Invite her to come back any time if she wants another method or has any questions or problems.

NOTE:

IUCD is also used for emergency contraception, if inserted within seven days. It is over 99% effective to prevent pregnancies.

7.10 Injectable Contraceptives

Injectable contraceptives contain one or two contraceptive hormones and provide protection from pregnancy for one, two, or three months (depending on the type) following an injection. About 50 percent of all women in Kenya who use modern contraceptive methods choose injectable contraceptives. The most widely used injectable methods contain only progestin (Progestin-only Injectable Contraceptives or POIs). Less common methods are those that contain both progestin and estrogen (Combined Injectable Contraceptives or CIC).

7.10.1 Progestin-Only Injectable Contraceptives (POIs)

The most widely available POICs are:

- Depot-medroxyprogesterone acetate-(DMPA) given at three monthly intervals (13 weeks)
- Norethisterone Enanthate (NET-EN) given at two monthly intervals

Both of these injectables are given by an intramuscular (IM) injection. DMPA has also been formulated for sub-cutaneous injection at three-month intervals (DMPA-SC).

7.10.1.1 Mode of action for injectable contraceptives

POIs Progestin only injectable prevent pregnancy by:

- Suppressing ovulation
- Thickening cervical mucus and thereby preventing sperm from passing through it
- Thinning the endometrium, which could theoretically prevent implantation
- CICs prevent pregnancy mainly through the inhibition of ovulation

7.10.2 Combined Injectable Contraceptives (CICs)

The CICs consist of a natural estrogen plus a progestogen. They prevent pregnancy mainly through the inhibition of ovulation. There are two CIC formulations both given at four-week intervals are on the market:

1. Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg
2. Norethisterone Enanthate 50mg plus estradiol valerate 5mg

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

7.10.2.1 Mode of action of combined injectable contraceptives

Combined injectable prevent pregnancy by:

- Thickening cervical mucus and thereby preventing sperm penetration
- Thinning the endometrium, which could theoretically prevent implantation
- CICs prevent pregnancy mainly through the inhibition of ovulation

7.10.2.2 Effectiveness of Injectable Contraceptives

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

1. POIC is 99.7% effective if used correctly and consistently
2. CIC is 99.95 % effective with correct and consistent use

The dosages for the different injectable contraceptives, is shown in table 15.

Table 15: DOSAGES FOR THE DIFFERENT INJECTABLE CONTRACEPTIVES

Type of injectable	Dosage
Progestin-Only Injectable Contraceptives (POICs)	
Depot-medroxyprogesterone acetate (DMPA) 150mg	Given every three months (13 weeks), but it can be given as much as two weeks (14 days) earlier or four weeks (28 days) later.
Norethisterone Enanthate (NET-EN) 200mg	Given every two months, but it can be given as much as two weeks (14 days) earlier or two weeks (14 days) later
DMPA-SC containing 104 mg of DMPA instead of the 150 mg in the IM formulation.	Injected sub-cutaneously at three-month intervals (12-14 weeks).
Combined Injectable Contraceptives (CICs)	
Medroxyprogesterone acetate 25mg plus estradiol cypionate 5mg	Given once every 30 days, but it could be given as much as three days earlier or later.
Norethisterone Enanthate 50mg plus estradiol valerate 5mg	Given once every 30 days, but it could be given as much as three days earlier or later

7.10.2.3 Advantages and Side Effects of injectable contraceptives

Advantages of injectable contraceptives

Contraceptive Benefits

- They are highly effective and safe
- A pelvic exam is not required to initiate use
- Progestin only contain no estrogen, so they do not have the cardiac and blood-clotting effects, which are associated with estrogen-containing pills and injectable
- These are long-acting methods: each injection provides protection for two or three months, depending on the type
- Do not affect breast milk production hence can be used during breastfeeding
- Confidentiality
- Does not depend on client for efficacy

Non-contraceptive Health Benefits

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

Side effects of injectable contraceptives

- | | |
|---|--|
| <ul style="list-style-type: none">• Changes in menstrual bleeding patterns such as:<ul style="list-style-type: none">• Irregular bleeding• Heavy and prolonged bleeding• Light spotting or bleeding• Amenorrhea, especially after one year of use• Weight changes | <ul style="list-style-type: none">• Headache• Dizziness• Mood swings• Abdominal bloating• Decrease in sex drive• Acne• Breast tenderness |
|---|--|

7.10.2.4 Limitations of injectable contraceptives

- a. Return of fertility may be delayed for about four months or longer after discontinuation
- b. They do not offer protection against STIs, including hepatitis B and HIV; individuals at risk for these should use condoms in addition to injectable contraceptives
- c. This method is provider based, so a woman must go to a health care facility regularly

7.10.2.5 Counselling for informed choice

Counselling for all methods should be done with reference to the current National Family Planning Guidelines and MEC for Contraceptives to establish eligibility of clients for methods and facilitate consent and informed choice by the clients.

7.10.2.6 Management of side effects in POIs use

The following table 16 outlines the possible side effects associated with POI use and their management.

Table 16: MANAGEMENT OF SIDE EFFECTS FOR INJECTABLE CONTRACEPTIVES

Side Effect	Management
Irregular spotting or light bleeding	<ul style="list-style-type: none">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 clientIf the bleeding is persistent assess for gynecological problems and treat accordingly<ul style="list-style-type: none">If there is no gynecological problem treat with non-steroidal anti-inflammatory drugs (NSAIDs) e.g. IbuprofenIf 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 menstrua period)	<ul style="list-style-type: none">Assess for underlying gynecological problems and manage accordinglyIf there are no underlying gynecological problems give any of the following<ul style="list-style-type: none">Give NSAIDs (Ibuprofen 400-800 mg TDS for 7-14 days)COCs (one active pill daily up to 1-3 cycles)If client presents when it is 8 weeks or more from the last dose, give another dose of injectable contraceptive and set a new return date based on the current injection.This schedule could speed up the development of amenorrhea, which would stop the bleedingIf bleeding persists and becomes a threat to her life, discontinue injectable and help her choose another method.

Side Effect	Management
Amenorrhea	<ul style="list-style-type: none"> By the end of the first year on injectables, amenorrhea develops in the majority of clients. Normally amenorrhea does not require any medical treatment. Counselling and reassurance are sufficient. If in doubt, assess for pregnancy, and manage accordingly. If client is bothered by lack of menses despite reassurance, discontinue injectable, and help her choose another method.
Headache or dizziness	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Assess for pregnancy <ul style="list-style-type: none"> If pregnant, discontinue injectables If not pregnant, reassure and give analgesics If physical examination shows signs of sepsis, treat with antibiotics and analgesics If she has breast lump or other suspicious lesions, refer for appropriate source for diagnosis

7.10.2.7 Method prescription and use

When to start	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Breastfeeding. Any time within 6 weeks postpartum and not amenorrhoeic treat as for regular menses. With lactation amenorrhea give between six weeks and six months postpartum, if you can establish that she is not pregnant Non breastfeeding. Start immediately or at any time within the first 21 days postpartum. After 21 days postpartum and no menses, rule out pregnancy first and initiate but emphasize on the need of a backup method for the next 7 days Post abortion- Immediately post abortion

When to Repeat the Injection

- The injection is administered regularly, 2-monthly for NST and 3-monthly for Depo, and the injection interval dates should be adhered to
- When the injection interval cannot be adhered to, the repeat injection can be given up to 7 days early but this may disrupt bleeding patterns
- If more than 7 days late the repeat injection can be given if certain that she is not pregnant but she will need a backup method

7.10.2.8 Giving the injection

Providers should follow these guidelines for giving injectable contraceptives:

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

7.10.2.9 Switching of FP methods

Table 16 describes the process of switching a woman from another method to injectable

Table 16: SWITCHING FROM ANOTHER METHOD TO INJECTABLE

Method switching from	Instructions
Switching from another hormonal method	<ul style="list-style-type: none">• Can initiate immediately if she has been using other hormonal method consistently and correctly, or if certain that she is not pregnant. There is no need to wait for next menstrual bleeding• If previous method was another injectable, start the POI when the repeat injection is due
Switching from a non-hormonal method (other than the IUCD)	<ul style="list-style-type: none">• Can have the first injection immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period if she is within 7 days of her menstrual bleeding and• If after 7 days of menstrual bleeding she will need a backup method for the next 7 days

Method switching from	Instructions
Switching from an IUCD (including a hormone-releasing IUCD)	<ul style="list-style-type: none"> Start the injection within 7 days of menstrual bleeding and the IUCD can be removed at that time. Start the injection at any time when pregnancy is ruled out After 7 days since menstrual bleeding started, keep the IUCD and have it removed on next menstrual period
Switching between DMPA and NET-EN	<ul style="list-style-type: none"> 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

7.10.3 “Come Back Any Time”: Reasons to Return before the Next Injection

Assure every client that she is welcome to come back any time, for example, if she has problems, questions, or wants another method; she has a major change in health status; or she thinks she might be pregnant. General health advice: Anyone who suddenly feels that something is seriously wrong with her health should immediately seek medical care from a nurse or doctor. Her contraceptive method is most likely not the cause of the condition, but she should tell the nurse or doctor what method she is using.

Planning the Next Injection

- Agree on a date for her next injection in 3 months (13 weeks) for DMPA IM and SC, or in 2 months (8 weeks) for NET-EN. Discuss how to remember the date, perhaps tying it to a holiday or other event
- Ask her to try to come on time. With DMPA IM or SC, she may come up to 4 weeks late and still get an injection. With NET-EN she may come up to 2 weeks late and still get an injection. With either DMPA IM/SC or NET-EN, she can come up to 2 weeks early

- She should come back no matter how late she is for her next injection. If more than 4 weeks late for DMPA or 2 weeks late for NET-EN, she should abstain from sex or use condoms, spermicides, or withdrawal until she can get an injection. Also, if she has had sex in the past 5 days without using another contraceptive method, she can consider emergency contraceptive pills (see Emergency Contraceptive Pills).

7.10.4 Sub-Cutaneous Depo Medroxy Progesterone Acetate (DMPA- SC)

The Uniject System for DMPA SC

The DMPA-SC is contained in a Uniject system - which is a small-prefilled injection system that contains with Depo Medroxy Progesterone Acetate. The Uniject system is composed of a: Reservoir, a Port, a needle and a needle shield as shown on the diagram on the below.

Uniject is:

- Single dose, which makes it easier to inject individual patients.
- Prefilled to make sure that the correct dose is given.
- Simple to use to make it easy for health workers who do not give many injections.
- Small in size for easy transport and disposal
- Not reusable to prevent diseases such as HIV and hepatitis B or C from being passed from one patient to another from needle reuse.

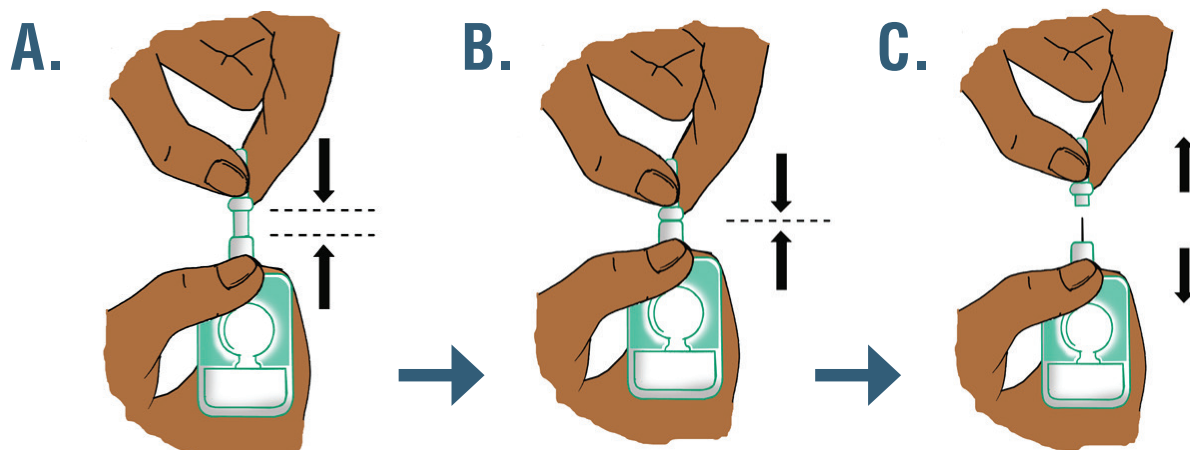
DMPA-SC is well tolerated, with similar efficacy, duration of action and side effect profile as DMPA-IM"ISBN" : "0010-7824 (Print. It has a shelf life of 3 years.

7.10.4.1 Administration of The DMPA-SC

- Prepare the supplies needed for injection
- Check the date the DMPA solution expires. If the dose has expired, do not use it.

- Open the pouch by tearing the small notch and remove the DMPA-SC.
- Be sure the DMPA is at room temperature.

7.10.4.2 Steps on How to Activate the Uniject



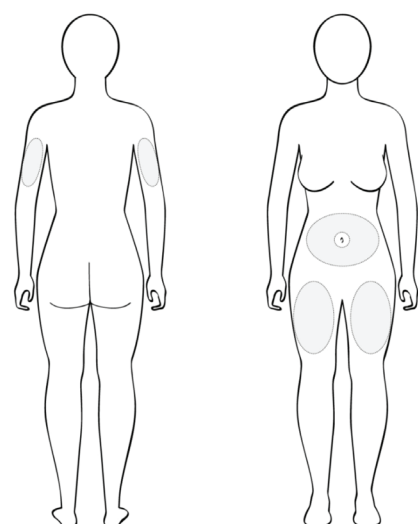
Step One	Hold the Uniject by the port.
Step Two	Shake it vigorously for 30 seconds.
Step Three	Check to make sure the solution is mixed and there is no damage or leakage
Step Four	Hold the Uniject by the port
Step Five	Keep the Uniject pointed upward during activation to prevent spilling the drug.
Step Six	Push the needle shield into the port.
Step Seven	Continue to push firmly until the gap between the needle shield and port is closed
Step Eight	Remove the needle shield.
Step Nine	Prepare the injection site (the arm, thigh or the abdomen)

7.10.4.3 How to Inject DMPA-SC

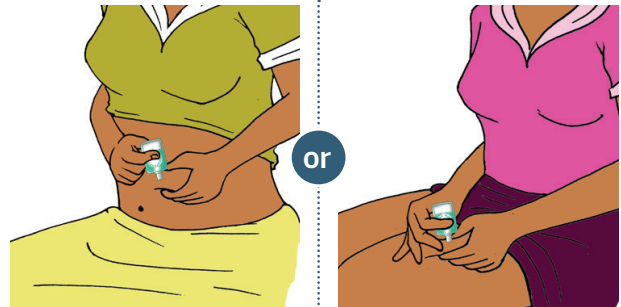
Choose the injection site: For a client who is injected by a HCP, they can choose:

- The back of the upper arm, on the abdomen (*but not the navel*)
- The front part of the thigh.

For Self Injection (S.I), its preferable to inject on the **thigh** or on the **abdomen** (*but not the navel*).



- If the skin where you will give the injection is dirty, clean it with a cotton ball soaked in clean water
- Gently pinch the skin at the injection site, “this creates a “tent” for inserting the needle”.
- If the client is very thin and it is difficult to pinch enough to pinch at the site she prefers, ask her if you can try other sites to get a better pinch
- Remember that DMPA-SC should **NOT** be injected in the buttocks, hip, or deltoid muscle like with DMPA-IM.



Step One	Insert the needle at a downward angle
Step Two	Continue to hold the Uniject by the port and insert the needle straight into the skin at a downward angle
Step Three	The port should have full contact with the skin to ensure the needle is inserted at the correct depth
Step Four	Squeeze the reservoir
Step Five	You should not aspirate
Step Six	Squeeze the reservoir slowly (5 to 7 seconds).
Step Seven	It is OK if there is a little medication left in the reservoir

7.10.4.4 Discarding The Uniject

- Do not replace/recap the needle shield.
- Immediately discard the Uniject in a puncture-proof container or a safety box.

7.10.4.5 Health Message to the client

- Tell her not to massage the injection site.
- Tell the client the name of the injection.
- Agree on a date for her next injection and give her a paper with the date written on it.
- Assure every client that she is welcome to come back any time, for example, if she has problems, questions, or wants another method; she has a major change in health status; or she thinks she might be pregnant.



7.10.4.6 Subcutaneous Self-injection

Some clients may want to inject themselves. Self-injection can be strengthened with appropriate:

- Information
- Training and demonstrations
- Referral links to a health care provider
- Monitoring and follow up.
- Safe storage of injection devices at home
- Safe disposal

NOTE:

The pharmacist/pharmaceutical technologist should share information on self-injection and train the client on Self-Injection of DMPA SC.

DMPA - SC SELF - INJECTION JOB AID

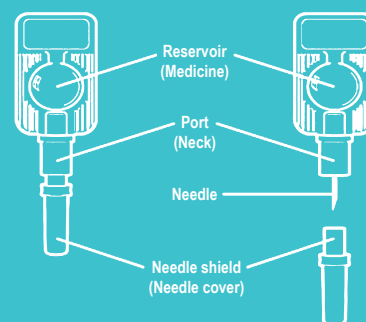


REQUIREMENTS FOR DMPA - SC SELF-INJECTION

1. DMPA - SC uniject (device)
2. Soap for hand washing
3. Cotton swabs for cleaning injection site
4. Plastic container for safe disposal of used DMPA - SC
5. Trash bin for other waste



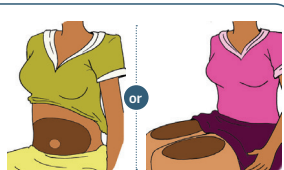
PARTS OF THE DMPA - SC UNIJECT (Device)



1.

Select the injection site:

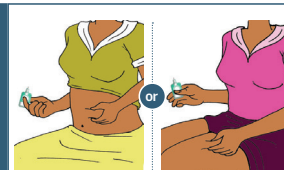
- In the abdomen (not at the navel) or
- On the front of the thigh



6.

Prepare injection site:

- Clean the injection site with cotton wool soaked in clean water
- Gently pinch the skin fold at the injection site



2.

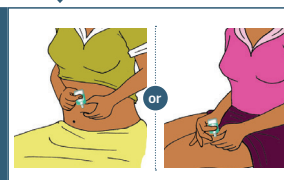
Wash your hands with soap and clean water and air dry them



7.

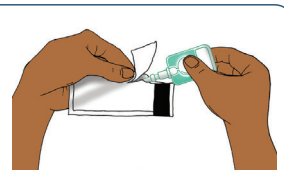
Needle insertion:

- Insert the needle at a downward angle until the port is in full contact with the skin



3.

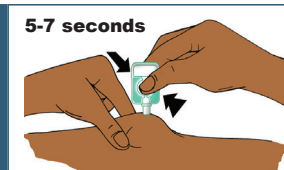
Open the foil pouch, remove the device while in a cool area (do not refrigerate) and check the expiry date



8.

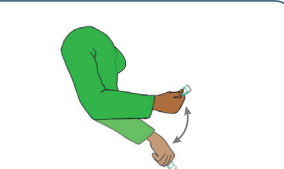
Administer the drug:

- Squeeze the medicine out slowly for 5 - 7 seconds and avoid aspiration



4.

Mix the medicine by holding the neck of the device and shake for 30 seconds. Ensure the medicine is well mixed and avoid damaging the device



9.

Discard the used device:

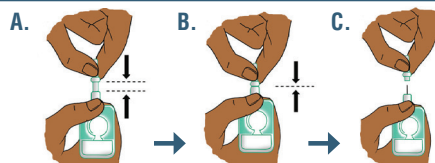
- Do not replace the needle shield.
- Immediately discard the device in a pit latrine or in a puncture-proof plastic container with a lid, label it, keep it safe and discard the container earlier or when 3/4 full



5.

Activate the device (close the gap):

- A. Hold the device by the neck while pointing the needle upwards and avoid squeezing the medicine out
- B. Push the needle cover firmly into the neck to close the gap
- C. Remove the needle cover



Supported by:



STEP 10: Plan for your next injection in 3 months

- Use a calendar to count 3 months to your next injection date.
- Write that injection date on your calendar.

What if you miss your scheduled reinjection date?

If you are within 2 weeks before or 4 weeks after your scheduled injection date:

- You can still give yourself an injection and be protected against pregnancy.
- Cross off the date you missed on your calendar and write your actual injection date.
- Count 3 months from your actual injection date to your next injection date.
- Write that new injection date on your calendar.

If you are more than 1 month after your scheduled injection date:

- Do not give yourself a Sayana Press injection.
- Contact your health worker.
- Use condoms or do not have sex until you speak with your health worker.

Example calendar

Month 1							Month 3						
Mon	Tues	Wed	Thu	Fri	Sat	Sun	Mon	Tues	Wed	Thu	Fri	Sat	Sun
		1	2	3	4	5	1	2	3	4	5	6	7
6	7	8	9	10	11	12	8	9	10	11	12	13	14
13	14	15	16	17	18	19	15	16	17	18	19	20	21
20	21	22	23	24	25	26	22	23	24	25	26	27	28
27	28	29	30	31			29	30	31				

Month 2							Month 4						
Mon	Tues	Wed	Thu	Fri	Sat	Sun	Mon	Tues	Wed	Thu	Fri	Sat	Sun
					1	2				1	2	3	4
3	4	5	6	7	8	9	5	6	7	8	9	10	11
10	11	12	13	14	15	16	12	13	14	15	16	17	18
17	18	19	20	21	22	23	19	20	21	22	23	24	25
24	25	26	27	28	29	30	26	27	28	29	30	31	

Common Sayana Press side effects

Common side effects can include the following and are not usually cause for concern:

- Lack of monthly bleeding.
- Heavy or irregular monthly bleeding.
- Headaches.
- Changes in mood or sex drive.
- Weight gain.
- Abdominal pain.



Other Important Information

Sayana Press does not protect against sexually transmitted infections such as HIV. Please use condoms in addition to Sayana Press to prevent against sexually transmitted infections.

Store Sayana Press in a safe place away from children or animals and extreme heat or cold.

If you have questions about self-injection, your health, or side effects, please contact a health worker.

7.11 Barrier Methods of Contraception

Barrier methods prevent the sperm from gaining access to the upper reproductive tract and making contact with the egg. These methods include male and female condoms. Whereas condoms, diaphragms, and cervical caps are mechanical barriers, spermicides are chemicals that interfere with the movement of the sperm and its ability to fertilize the egg. Currently in Kenya, the use of diaphragms, cervical caps, and spermicides is negligible. As a result, the main focus is on male and female condoms.

7.11.1 Mode of action

Male and female condoms help prevent both pregnancy and most STIs (including HIV), because when used correctly, the condoms keep sperm and any disease organisms in semen out of the vagina; also, they prevent any disease organisms in the vagina from entering the penis.

7.11.2 Male Condom

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

7.11.2.1 Effectiveness

Male condoms are only moderately effective in typical use (15 percent pregnancy rate), but much more effective when used consistently and correctly (2 percent pregnancy rate).

7.11.2.2 Advantages of Condoms

- Easily accessible and affordable
- Offer contraception only when needed.
- Easy to obtain and can be used without seeing a health care provider.

- With consistent and proper use, they are highly effective protection against STIs, including HIV/AIDS.
- Reduce the risk of cervical cancer.
- Help to prevent premature ejaculation.
- Almost every man is eligible to use a condom.
- Condoms are easy to use with a little practice.
- There is no health risk associated with this method.
- Condoms do not interfere with the act of intercourse, as do the foaming tablets.

7.11.2.3 Limitations of Condoms

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

NOTE:

- Male condoms should not be used with petroleum products and oils, which lead to rapid degeneration and could reduce their effectiveness in preventing pregnancy and protection against STI, including HIV/AIDS
- In-case of spillage or breakage of condom, offer emergency contraception and counsel on HIV and STIs

7.11.2.4 When to Start

Any time client is ready to use.

7.11.2.5 Disposal of Male Condoms

Clients should be advised on proper ways of using condoms (male and

female) as well as disposing of the used ones.

In the case of the male condom:

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

7.11.2.6 Management of Possible Side Effects

Table 17: **MANAGEMENT OF POSSIBLE SIDE EFFECTS OF USING CONDOMS**

Side effect	Management
Irritation	May result from allergy to latex though this is very rare <ul style="list-style-type: none">• Advice the couple to use a non-latex brand of condoms• Screen for presence of infection and treat, if present

7.11.2.7 Eligibility Criteria

Who Should Use Male Condoms?

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

- Men who wish to participate actively in FP
- Couples who need a back-up method (e.g., for missed pills)
- Couples who have sex infrequently and who do not need continual protection
- Couples who need temporary methods while awaiting another method
- Couples who want protection from STI/HIV
- Those who are not using another method, or
- Those who are using another method for pregnancy prevention, and are

at a risk of acquiring an STI or HIV/AIDS (dual method use)

- Postpartum clients or post-abortion clients before initiating more appropriate methods
- Any client who needs more time to make a decision about a contraceptive method
- Couples living with HIV/AIDS—whether discordant or concordant

7.11.2.8 Who Should Not Use Male Condoms

- Allergy to latex male condoms

7.11.3 Female Condom

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

7.11.3.1 Effectiveness

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

7.11.3.2 Advantages and Benefits

- Almost every woman is eligible to use this method.
- They are effective if used consistently and correctly.
- They offer contraception only when needed.
- Condoms can be used without seeing a health care provider.
- With consistent and proper use, condoms are highly effective protection against STIs, including HIV/AIDS.
- They protect against PID.
- The woman can control this method.
- It can be inserted eight hours before an anticipated sexual act.
- There is no need to see a health care provider before use.

- Condoms are easy to use with a little practice.
- No health risk is associated with the method.
- Unlike latex rubber, there is no known allergy to polyurethane, the material from which female condoms are made.

7.11.3.3 Limitations of Female Condoms

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

7.11.3.4 When to Start

- Any time client is ready to use

7.11.3.5 Disposal of Used Female Condoms

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

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

7.11.3.6 Correcting myths and misconceptions about barrier methods

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

- The female condom is difficult to use
- It requires some practice before one can use it with ease. It is recommended to try inserting it several times before utilizing it in a sexual situation.
- The inner ring causes pain to both male and female
- It should not cause any discomfort if inserted properly.
- Usage of both male and female condoms at the same time or wearing 2 male condoms for effectiveness

NOTE:

1. Demonstration of condom Use by the provider is critical for consistent and proper use.
2. Using both condoms simultaneously may cause friction due to inadequate lubrication resulting in either or both condoms slipping or tearing, or the outer ring of the female condom being pushed further inside the vagina.

7.11.3.7 Eligibility Criteria

Who Can Use the Female Condom?

- All women of reproductive age of any parity, including nulliparous women
- Women who need to rule out possible pregnancy before proceeding with another method.
- Women who need a back-up method.
- Women who need temporary methods of contraception.
- Post-abortion clients before initiating other methods.
- Women who need dual protection if they are using another method for pregnancy prevention, but are at a risk of acquiring an STI or HIV/AIDS

7.12.1.8 Women Who Should Not Use a Condom

A woman who has one or more conditions that make pregnancy dangerous and needs a more effective method of protection against pregnancy may want to consider other, less client-dependent, methods of contraception

7.12 Natural Family Planning Methods

Family planning methods that do not use any hormones or devices. The following are types of Natural family planning methods

- Lactational amenorrhea method (LAM)
- Fertility awareness methods (FAMs)
- Withdrawal method (Coitus Interruptus)

7.12.1 Lactational Amenorrhoea Method (LAM)

The Lactational Amenorrhea Method (LAM), a sub-set of Natural Family Planning (NFP), is a temporary, postpartum method of FP based on the natural effect of breastfeeding on fertility. LAM works primarily by preventing ovulation but for this to occur, exclusive breastfeeding is mandatory. Therefore, effectiveness depends on the user. As commonly used, the pregnancy rate is about 2 per 100 women in the first six months. With perfect use, the pregnancy rate is less than one per 100 women.

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

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

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

7.12.1.1 Mode of action

- Hormones released during continuous breastfeeding suppress ovulation which makes pregnancy impossible.

7.12.1.2 Effectiveness

- LAM is up to 98% effective, if practiced during exclusive breastfeeding period
- Effectiveness is reduced when exclusive breastfeeding is not practiced

7.12.1.3 Advantages and Benefits of LAM

Contraceptive benefits	Non contraceptive benefits
<ul style="list-style-type: none">• Effective protection against pregnancy as long as all three LAM criteria are met LAM does not interfere with sexual activity.• It has no known health risks.• Return to fertility is immediate once you stop exclusive breastfeeding.	<ul style="list-style-type: none">• Breastfeeding provides passive immunity for the child.• Counselling for LAM encourages women to start a follow-on method at the appropriate time.• LAM is affordable FP—it has no direct costs.• Women living with HIV/AIDS can use LAM.

7.12.1.4 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 might 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 might be inconvenient or difficult for some women, especially working mothers.
- LAM does not protect a woman against STIs, including hepatitis B, HIV, and AIDS.
- Fertility resumed before resumption of menses

7.12.1.5 When to start

- Start breastfeeding immediately (within one hour) or as soon as possible after the baby is born

7.12.1.6 Helping clients switch to a new Method

A woman can switch to another method any time she wants while using LAM.

- If she still meets all 3 LAM criteria, it is reasonably certain she is not pregnant. She can start a new method with no need for a pregnancy test, examinations, or evaluation.

- To continue preventing pregnancy, a woman must switch to another method as soon as any one of the 3 LAM criteria no longer applies. Help the woman choose a new method before she needs it. If she will continue to breastfeed, she can choose from several hormonal or non-hormonal methods

7.12.1.7 Managing Problems with LAM

Problems with breastfeeding or LAM affect women's satisfaction and use of the method.

- If the client reports any problems, listen to her concerns, give her advice, and, if appropriate, treat.
- Offer to help the client choose another method—now, if she wishes, or if problems cannot be overcome.

7.12.1.8 Eligibility Criteria

Women Who Can Use LAM without Restrictions	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Those who are not exclusively breastfeeding • Those who have resumed menses • The baby is more than six months of age • Women with conditions that make pregnancy an unacceptable risk pregnancy (LAM may not be appropriate for them because of its relatively higher typical-use failure rates.) • The new-born has a condition that makes it difficult to breastfeed (e.g. prematurity, deformities of the mouth, jaw, or palate)

7.13.1 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.

7.13.1.1 Effectiveness

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

To achieve this effectiveness, the woman must be able to recognize her fertile time. This is managed through several approaches, either singly or in combination, which include calendar-based methods and symptoms-based methods. These are mentioned in the following table:

Table14: CALENDAR-BASED METHODS AND SYMPTOMS-BASED METHODS

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. This can be done through mobile applications, physical calendar etc.
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. The SDM makes use of Cycle Beads®, a color-coded string of beads used with the SDM that represent the days of a woman's fertility cycle.
Symptoms-Based Methods	Symptoms-based methods depend on observation of signs of fertility, such as the presence or absence of cervical mucus, changes in the amounts and characteristics of the cervical mucus, changes in body temperature, a combination of the latter two, or use of specific ovulation detection kits.
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.
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.
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.

7.15.1 Symptom-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.

7.15.1.1 New Approaches to Fertility Awareness-Based Methods

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

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

Key Points about FAMs for Providers and Clients

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

7.15.1.2 Advantages of Fertility Awareness-Based Methods

Contraceptive benefits	Non-contraceptive benefits
<ul style="list-style-type: none">• They do not require contraceptive commodities and supplies.• Less expensive.• Limited need for professional consultation.• There are no side effects or health risks.• Return to fertility is immediate.	<ul style="list-style-type: none">• Improve knowledge of the reproductive system and understanding of menstrual cycle.• Shared responsibility by couples.• Enhances Male engagement and spousal communication /Cooperation• They can be used by both literate and illiterate women.• They allow adherence to religious and cultural norms.• Women who want to become pregnant can use them to identify fertile days.• They can be used where other methods are contra-indicated.

7.15.1.3 Limitations of Fertility Awareness-Based Methods

- Clients require intensive education and instruction before being confident to use method.
- No protection against sexually transmitted infections including HIV
- These are user-dependent methods hence need cooperation and commitment by both partners.
- May not be easy to use if menstrual cycle is irregular.
- Require accurate daily record keeping.
- Unreliable if client is breastfeeding and has amenorrhea.
- These methods have high failure rates if client is not well trained.

7.16.1 Withdrawal Method (Coitus Interruptus)

Coitus Interruptus (CI) is one of the traditional methods of birth control. 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.

7.16.1.1 Effectiveness

The failure rate of the withdrawal method ranges from 4-10 pregnancies per 100 women per year when it is used consistently, to 14-23 pregnancies per 100 women per year among actual users (i.e., when it is not used consistently).

7.16.1.2 Advantages of Coitus Interruptus

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

7.16.1.3 Limitations

- It demands consistent self-control on the part of the male partner, which could be difficult at times.
- 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;

NOTE:

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

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

7.13 Long Acting Reversible Contraceptives (LARC)

7.13.1 Introduction

Long acting and reversible contraceptives (LARCs) are mainly the implants and intrauterine devices or systems. LARCs are cost effective and have a very low failure rates compared many short acting methods. LARCs can be provided to clients who desire to limit, space for longer periods or those who do not want no more children but choose not go on permanent methods.

Long acting reversible contraceptive devices are broadly divided into two groups:

- **Session 1:** Contraceptive Implants (2 rods and 1 rod)
- **Session 2:** Intrauterine Contraceptive Devices (Copper, Hormonal)

Definitions

Intrauterine device (IUD): A small, flexible plastic frame that a trained provider inserts into a woman's uterus to provide very effective, safe, and long-term protection from pregnancy; both copper and hormonal IUDs are available

Implants: Small, flexible plastic rods or capsules that are placed just under the skin of the upper arm and release a progestin hormone into the body

7.13.2 Contraceptive Implants

7.13.2.1 Introduction

This session is designed to provide participants with information on contraceptive implants. It includes the general information about implants, what they are, types, mechanism of action, advantages and limitations, who is eligible to use the method, client assessment, how to insert and remove the implants and management of side effects and complications.

7.13.2.2 Specific Objectives

By the end of session, you will be able to:

1. Acquire knowledge for counselling and referral of implants.

7.13.2.3 Description

Contraceptive implants are small capsules or rods which when inserted under the skin of a woman's upper arm release the hormone progestin slowly to prevent pregnancy. They are also called "Sub-dermal Implants". They do not contain estrogen and are therefore free from the side effects associated with estrogen.

7.13.2.4 Effectiveness of Implants

Far less than 1 pregnancy per 100 women using implants over the first year (1 per 1,000 women). This means that 999 of every 1,000 women using implants will not become pregnant.

7.13.2.5 Mode of Action of Implant

Implants prevent pregnancy by:

- Suppressing ovulation
- Thickening cervical mucus.
- Thinning the endometrium.

7.13.2.6 Types of Implants

The table below shows the common implants used in Kenya, and their duration of effectiveness.

Table 17: TYPES OF IMPLANTS IN KENYA

HORMONE	DESIGN	BRAND	DURATION OF EFFECTIVENESS
Levonorgestrel 75mg per rod	2 rods	Jadelle®	5 years
		Sino-implant® [ZARIN®]	4 years
		Indoplant®	4 years
Etonogestrel 68mg	1 rod	Implanon-NXT®	3 years

7.13.2.7 Providing The Method

When to start using an implant

The table below summarizes situations when a woman can be provided with an implant and the suggested actions.

Table 18: SITUATIONS WHEN A WOMAN CAN HAVE A CONTRACEPTIVE IMPLANT

SITUATION	SUGGESTED ACTION
Immediate post-partum (Within 48hours)	<ul style="list-style-type: none"> No need for back up. Counsel clients during the antenatal period.
Woman is having her menstrual cycles	<ul style="list-style-type: none"> Insert implant within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed Insert implant any other time, if it is reasonably certain that she is not pregnant If it has been more than 7 days since menstrual bleeding started, she will need additional contraceptive protection for the next 7 days
Woman with amenorrhoea	<ul style="list-style-type: none"> Insert implant any time, if it is reasonably certain that she is not pregnant. She will need additional contraceptive protection for the next 7days
Woman is breastfeeding	<ul style="list-style-type: none"> Less than 6months postpartum and she has amenorrhoeic, insert implant any time. If she is fully or nearly fully breastfeeding (see LAM), no additional contraceptive protection is needed More than 6weeks postpartum and her menstrual cycles have returned, she can have the implant inserted as advised for other women having menstrual cycles

SITUATION	SUGGESTED ACTION
Woman is switching from another hormonal method	<ul style="list-style-type: none"> • Implant can be inserted immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain she is not pregnant. There is no need to wait for her next menstrual period • If her previous method was an injectable, she should have the implant inserted when the repeat injection would have been given. No need of additional contraceptive protection
Woman is switching from a non-hormonal method (not IUCD)	<ul style="list-style-type: none"> • Implant can be inserted immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her menstrual period • If she is within 7days of the start of her menstrual bleeding, no additional contraception is needed • If it has been more than 7days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7days
Woman is switching from an IUCD (including hormonal)	<ul style="list-style-type: none"> • Implant can be inserted within 7days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUCD can be removed at that time • Implant can also be inserted at any other time, if it reasonably certain she is not pregnant • If she has been sexually active in this menstrual cycle, and it has been more than 7days since the menstrual bleeding started, it is recommended that the IUCD should remain in position to be removed at the time of her next menstrual period • If she has been sexually active in this menstrual cycle and it has been more than 7days since menstrual bleeding started, she will need protection for the next 7days, if the IUCD is removed at that time. Otherwise she should retain it for removal at the time of her next menstrual period • If she has amenorrhoea or has irregular bleeding, she can have the implant inserted as advised for other amenorrhoeic women

7.13.2.8 Benefits of Implants

Contraceptive Benefits of Implants	Non-contraceptive Benefits of Implants
<ul style="list-style-type: none">• Highly effective and safe• Not associated with delays in return to fertility following discontinuation• Known to offer continuous, long-acting protection against pregnancy	<ul style="list-style-type: none">• Reduction of menstrual flow• Helping to prevent ectopic pregnancy (but do not eliminate risk altogether)• Not affecting breastfeeding• Protection against iron deficiency anaemia

7.13.2.9 Limitations of Implants

- They must only be inserted and removed by trained providers
- Insertion or removal of implants requires a minor surgical procedure with appropriate infection prevention practices
- Common side effects include menstrual changes, such as irregular light spotting or bleeding, prolonged bleeding, infrequent bleeding and amenorrhea
- Non-menstrual side effects include headache, dizziness, nausea, breast tenderness, mood changes, weight change and mild abdominal pain

NOTE:

They do not protect against sexually transmitted infections (STIs) including hepatitis B and HIV; individuals at risk should, be encouraged to use condoms.

7.14 Intrauterine Contraceptive Devices (IUCD)

7.14.1.1 Introduction

The purpose of this session is to equip HCPs with knowledge to clients seeking FP services.

7.14.1.2 Description of IUCD

An intrauterine contraceptive device (IUCD) is a small plastic device inserted into a woman's uterus through her vagina and cervix by trained health

care providers to prevent pregnancy. It provides long term and reversible prevention against pregnancy.

7.14.1.3 Types of IUCD

There are two broad categories of IUCDs:

Copper-based IUCDs	Hormone-releasing devices
Examples: Copper bearing devices include the Copper T 380A (Cu T380A), the Copper T 220C (Cu T220C), the Multi-load Copper 375 (ML Cu 375) and the Nova T	Examples: Releasing devices include Levonorgestrel-releasing IUDs (Mirena® -LNG-20IUS). However, these hormone- releasing devises are currently not widely available in the public sector but there is a plan to introduce them in the near future.

7.14.1.4 Mode of action of IUCD

The combination of mechanisms of action by which Copper based IUCD prevents fertilization include:

- Inhibition of sperm migration in the upper female genital tract by creating a local inflammatory reaction that appears to prevent sperm from reaching the fallopian tubes
- Release of copper ions in the uterus and the fallopian tubes, thereby enhancing the debilitating effect on sperm
- Inhibition of ovum motility
- The levonorgestrel-releasing IUCD causes changes in the amount and viscosity of the cervical mucus thus inhibiting sperm penetration

7.14.1.5 Effectiveness

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

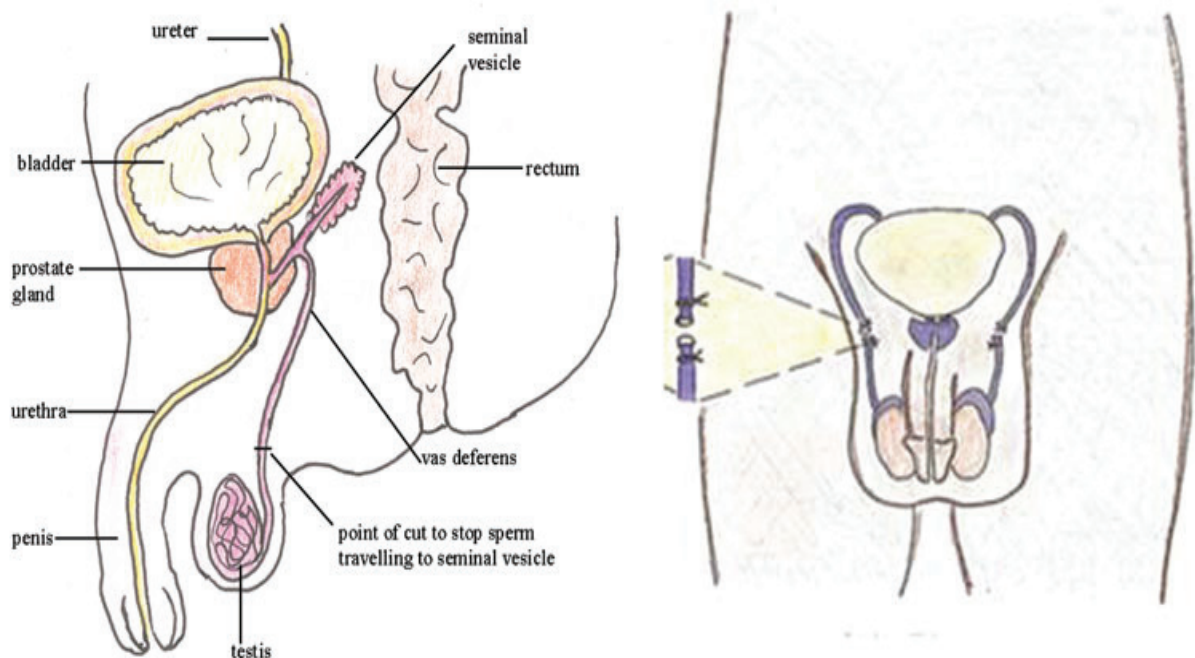
7.14.1.6 Benefits of copper based IUD Use

Contraceptive benefits

- Highly effective and safe
- Provides immediate protection after insertion
- Long acting protection – up to 12 years for Cu T 380 A
- Efficacy is less reliant on client action
- Can be used immediately after delivery, abortion or ectopic pregnancy
- No further cost to client after insertion
- Immediate return to fertility upon removal
- Copper IUCD is effective as an emergency contraceptive if inserted within 120 hours (5days) of unprotected sex
- Does not interfere with breastfeeding

Non-contraceptive benefits

- IUCD does not interfere with sexual intercourse
- IUCD help prevent ectopic pregnancy
- IUCDs help protect against endometrial cancer
- May help protect cervical cancer(ref WHO global hand book 2018)



7.14.1.7 Types of IUCDs and their duration of effectiveness

Table 19: TYPES OF IUCDS AND THEIR DURATION OF EFFECTIVENESS

Device	Duration of effectiveness	User Effectiveness	Failure Rate	
Copper based devices	Copper T 380A	Up to 12 years	97.8%	2.2 per 100 women
	TCu380S	8 years	98.9%	1.1 per 100 women
	Copper T200	8 years	98,9%	1,1 per 100 women
	Gynefix	8 years	99%	1.0 per 100 women
	NOVA T	5 years	98%	2.0 per 100 women
	Multiload- MLCu-375	5 years	98.8%	1.2 per 100 women
	Multiload- MLCu-250	3 years	99%	1.0 per 100 women
	Copper T 220	3 years	97.8%	2.2 per 100 women
Hormone-releasing IUCDs	Mirena (LNG-20IUS)	5 years	98.%	1.1 per 100 women
	Lingus (LNG-IUS)	5 years	99%	1.0 per 100 women
	Liletta - LNG-IUS)	3 years		

Source: National family planning guidelines for service providers, 2018

7.14.1.8 Timing of IUCD

The IUCD may be inserted at three distinct periods, namely: the post pregnancy, post abortion and interval. The table below shows period and timing of insertions of IUCD.

Table 20: PERIOD AND TIMING OF INSERTIONS OF IUCD

Period of insertion	Timing of insertions
Post pregnancy insertions	Post placental insertions - this can be done immediately after the delivery of the placenta (within a period of 10 minutes)
	Trans-caesarean insertions: The IUCD is inserted in the uterus immediately after the delivery of the placenta and membranes before the uterine incision is closed
	Immediate post pregnancy insertions: The IUCD is inserted within 48 hours after the delivery of the placenta. If this is not possible then it can be inserted after 4 weeks.

Period of insertion	Timing of insertions
Post abortion insertions	This insertion is done immediately or within 12 days of the evacuation of the uterus or after a complete abortion. It is critical that there is no evidence of infection
Interval	The IUCD may be inserted at any time of the menstrual cycle as long as the provider can be reasonably sure that the client is not pregnant.

It is important to note that post pregnancy IUCD insertions are to be delayed in conditions where the risk of infections is high such as in prolonged rupture of membranes, prolonged labour, puerperal sepsis etc.

7.14.1.9 Limitations of IUCD

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

7.14.1.10 Side effects of IUCD

Common side effects may include increased menstrual bleeding and cramping, more commonly during the first few months of use and they resolve afterwards.

7.15 VOLUNTARY SURGICAL CONTRACEPTION

Voluntary surgical contraception (VSC) is a permanent contraception for male and female with desired family size. VSC prevalence rate in Kenya is 3% (KDHS, 2014). VSC involves bilateral tubal ligation in female and vasectomy in male they are irreversible hence clients require effective counselling before making informed choice.

7.15.1 Vasectomy

Vasectomy is the surgical process of cutting/blocking the vas deferens in order to prevent spermatozoa from mixing with semen. Ejaculation still occurs, but without sperms. Vasectomy is not synonymous with castration, and it does not affect a man's sexual ability or desire. The operation is minor performed under a local anaesthesia as outpatient. Vasectomy does not become effective immediately. The client should be instructed to use condoms or another FP method for three months after the operation. Since it is a permanent procedure and success of reversal cannot be assured, effective counselling must be done for informed consent.

7.15.1.1 Benefits of Vasectomy

- Permanent providing a lifelong protection.
- Does not interfere with sexual intercourse.
- Cost effective
- The man takes responsibility for contraception

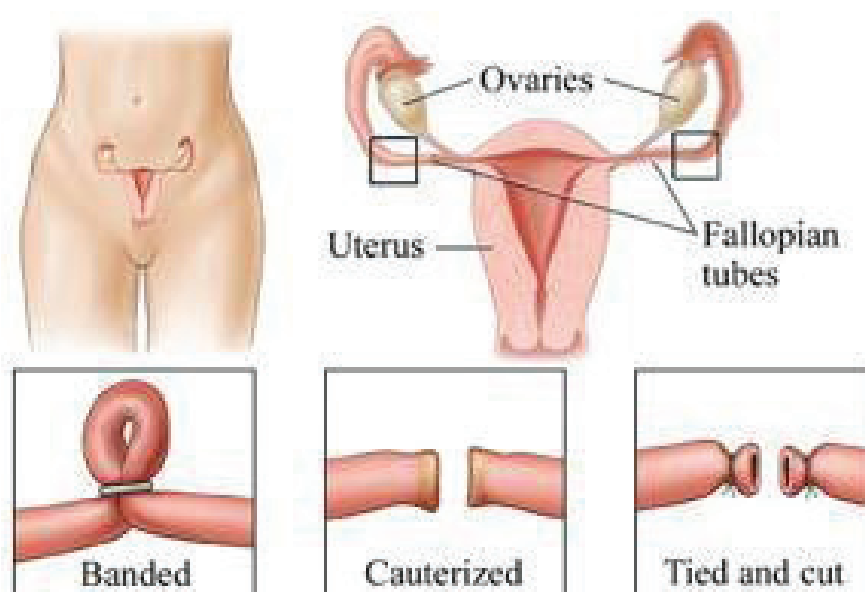
7.15.1.2 Limitations and Risks

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 including HIV.
- There are minimal risks and side effects of local anaesthesia and surgical procedure

7.15.2 Tubal Ligation

Tubal ligation is the blocking of fallopian tubes to prevent union of ova and sperms. Ovulation still occurs but ova does not reach the uterus it does not affect a woman sexual desires. The operation is performed under a local anaesthesia and or sedation in theatre.



7.15.2.1 Benefits of Bilateral Tubal Ligation

- Highly effective and safe
- It is permanent
- It has no effect on breast-feeding
- BTL does not affect a woman's sexual desire, ability and performance
- Its cost effective
- No significant long term side effects

7.15.2.2 Limitations Of BTL

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

UNIT 8: INTEGRATION AND REFERRALS



Introduction

In this section services to be offered within community pharmacy and those which will require referral will be outlined.



Objective

By the end of this session the participants will be able to:

1. Define integration of services
2. Demonstrate understanding of the services to be integrated within the scope of the practice of pharmacy
3. Understand services to be referred
4. Describe the overview of HIV Self Testing in Kenya

8.1 Definition

The organization and management of health services so that people get care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money (WHO, Amy 2008). This would entail integration of FP and STI including HIV prevention services in community pharmacies.

8.2 Role of Pharmacist In Integration

The pharmacist will have knowledge and skills to engage clients on modern FP methods and STI including HIV prevention. The Pharmacy will provide a

space to carry out family planning and HIV pre-testing counselling, offer FP services (mainly short term FP methods including injectable DMPA), expand access to HIV-self testing through dispensing/selling the HIVST kits and facilitate linkage to care through effective referrals.

8.2.1 Rationale

Inadequate uptake of FP by women of reproductive age is currently at 58% (KDHS, 2014). About 42% of women are not accessing modern FP methods. The purpose is to increase access and reduction of unmet need for FP among women of reproductive age.

On the other hand, inadequate uptake of testing for HIV remains a primary bottle neck towards universal access to treatment and care as well as an obstacle to realizing interventions for HIV prevention. HIV prevention has the potential of being a high impact low cost intervention to reach population groups that are not tested and to increase the number of people with HIV who are identified and initiated on treatment.

8.2.2 Types of Integration

On-Site: One-stop shop where Integrated FP and HIV prevention services are offered by one service provider in one room during the same consultation, or **One-stop-shop** approach (supermarket) where integrated FP services and pre-HIVST counselling offered and HIVST kits are dispensed by more than one service provider within one facility during the same visit. There could also be internal referral mechanism within the same facility

Off-Site: FP and HIV prevention services are offered completely outside the facility through a facilitated referral

The Mixed Approach: FP and HIVST services are initiated in one facility or site but the rest of the services are received in another facility or site especially in situations where the skills, equipment etc. are inadequate.

8.2.3 Services for Integration

Services	Description
Family Planning counselling & Referrals	<ul style="list-style-type: none">• Counsel on all FP methods• Counsel & refer for LARC methods• Counsel & refer for FP permanent methods• Dispel myths and misconceptions on FP
Provision of FP methods	<p>Provide short term methods to include;</p> <ul style="list-style-type: none">• DMPA IM/SC (<i>Specifically trained to do so</i>)• COCs• POPs• ECs• Female & male condoms
STI including HIV Prevention Services	<ul style="list-style-type: none">• Condom• Pre-exposure prophylaxis (PrEP)
HIVST Services	<ul style="list-style-type: none">• HIVTS, Pre/ post-test counselling, and• Dispensing HIVST kits• Referral Services
Post Rape Care (PRC)	<ul style="list-style-type: none">• Information & optional HIVST• Post-Exposure Prophylaxis (PEP)• Emergency Contraception (EC)• Referral

8.2.4 HIV Preventive Services

Table: HIV PREVENTIVE SERVICES

HIV Preventive Services	Description
Behavioural Interventions	Interventions to encourage safer sex choices/behaviours such as: <ul style="list-style-type: none">• risk reduction counselling,• sexuality education,• social marketing to promote effective condom use etc.
Structural Interventions	Interventions that promote an enabling environment <ul style="list-style-type: none">• protecting the rights of PLHIV• GBV prevention and mitigation• stigma reduction• empowerment etc.
Biomedical Interventions	Post Exposure Prophylaxis (PEP)
	Treatment of STIs
	Voluntary Medical Male Circumcision (VMMC) (One boy one blade)
	Treatment as Prevention (TasP)
	Pre-Exposure Prophylaxis (PrEP)
	Harm reduction for persons who inject drugs (PWID)

8.2.5 Pre-Exposure Prophylaxis

8.2.5.1 Definition

PrEP means Pre-Exposure Prophylaxis, which is the use of anti-HIV medication to prevent HIV negative people from becoming infected. With PrEP, you take a pill once a day, even on the days you don't have potential exposure to HIV.

8.2.5.2 Rationale

- HIV is a main concern in Kenya, despite progress made there are still many new infections.
- More than 52,000 new infections occur annually.

INDICATIONS AND CONTRAINDICATIONS FOR PREP

Indications for PrEP

Recommended for HIV uninfected persons at substantial ongoing risk of HIV acquisition

Guidelines highlight risk situations that place one at substantial ongoing risk which include:

- Sexual partner/s is/are HIV positive and: not on ART, or on ART < 6 months, or on ART with suspected poor adherence.
- Sexual partner/s are of unknown HIV status and at high-risk for HIV
- Engaging in transactional sex /work
- With history of recent or current STIs
- With recurrent use of post-exposure prophylaxis
- History of sex whilst under the influence of alcohol or recreational drugs
- Inconsistent or no condom use
- Using injection drugs where needles and syringes are shared
- In sero-discordant relationships trying to conceive

Contraindications for PrEP

- HIV infection (confirmed HIV positive)
- Renal impairment - as shown by creatinine clearance < 50 ml/min
- Lack of willingness to adherence to daily PrEP and associated follow-up schedule
- Adolescents weighing < 35kgs or age < 15 years

8.2.5.3 Eligibility for PrEP

- Establish willingness to adhere to PrEP and medical follow-up including HIV retesting
- Screen for substantial risk of HIV infection-using risk assessment tool - RAST

- Document HIV status - HIV testing using the national algorithm for HTS
- Complete a symptom checklist to exclude acute HIV infection

8.2.5.4 Information for PrEP during dispensing

- How PrEP works as part of combination prevention
- Need for follow-up tests including HIV testing
- Limitations of PrEP
- Discuss when and how PrEP may be discontinued
- PrEP use
 - Adherence
 - Tolerability
 - Adverse effects
 - Subsequently a 3-month prescription can be given, however drug refills are done monthly

NOTE:

- Pharmacists and pharmaceutical technologists will dispense PrEP as Prescription Only Medicine (POM)
- In case of Adverse Drug Reactions, Prescriber to be informed. Regular laboratory tests (liver and kidney function tests) including HIV test as per guidelines.
- Safety and side effects and what to do in case these are experienced
- What to do in case of client experiences symptoms of sero-conversion (acute HIV infection)

8.2.5.5 PrEP Monitoring and Requirements for PrEP provision

PrEP Monitoring	Requirements for PrEP provision
<ul style="list-style-type: none">• Assess adherence and provide ongoing adherence counselling and support• Monitor for and manage side effects• Assess for FP need and use (efficacy)• Provide other prevention services including risk reduction counselling, condoms, STI screening etc.• Review indication for PrEP	<ul style="list-style-type: none">• Human Resource availability and training (pharmacists and pharmaceutical technologists)• Commodity Management Procedures (ordering/handling and reporting)• Monitoring and Evaluation Systems (documentation and reporting)• Laboratory (Baseline tests and monitoring)• A Laboratory report and prescription from a health facility

8.6 Referral Services

8.6.1 Specific objective

By the end of this session the participants will be able to:

- Identify services to refer
- Effective Referrals based on clients 'need

8.6.2 Definition

A comprehensive healthcare system is used to manage clients' healthcare, needs by directing client from an initiating facility to an organization, service or community unit that better provide the level of care needed (Kenya Health Sector Referral Implementation Guidelines, 2014 1st Edition).

8.6.3 Rationale

- Management at appropriate level of care
- Continuum of care

TYPES OF REFERRALS AND REFERRAL SERVICES

Types of referrals	Referred Services
1. Community Pharmacy-Public Health Facilities and vice versa	1. Sexually Transmitted Infections (STIs)
2. Community Pharmacy-Private Health Facilities	2. Reproductive Tract Cancer Screening
3. Community Pharmacy-Community Pharmacy	3. Essential Obstetric Care service
	4. Long acting family planning
	5. HIV care and treatment
	6. Medication Therapy Management

8.7 HIV Self Testing Program in Kenya

8.7.1 Objectives

By the end of this session, the participant should be able to:

- Acquire knowledge and skills on HIV Self testing

8.7.2 Background

In 2015, about 1.5 million Kenyans were living with HIV with 268,588 being young people. About 1 million are currently on treatment while about 500,000 are yet to be initiated on treatment. HIV self-testing (HIVST) tool was introduced to reach help Kenya reach the 90:90:90 goal.

In 2017, Kenya released guidelines on HIVST in line with WHO guidance on HIVST and partner notification. The guidelines:

- Position HIVST as a strategy to achieve the UNAIDS 90 –90 –90 goals
- Outline the approaches, procedures, benefits and risks of HIVST
- Support the introduction of HIVST as a HTS intervention using quality-assured products

8.7.3 Overview of HIV Self-Testing (HIVST)

HIVST is process in which a person collects his or her own sample (oral fluid or blood), performs an HIV test and interprets the result. It is often done in private - either alone or with someone trusted. A screening test- **does not** provide a definitive HIV-positive diagnosis.

All reactive (positive) self-test results **need to be referred for confirmation** by a trained health provider using the national testing algorithm. HIVST is a complementary approach to existing HIV testing services.

8.7.4 Benefits of HIVST

HIVST is well-positioned to help address HIV diagnosis gaps.

- Promotes access to HTS
- Increases autonomy and is thus empowering
- Assures privacy
- Is convenient
- Not stigmatizing

The chart below illustrates HTS Approaches & Settings

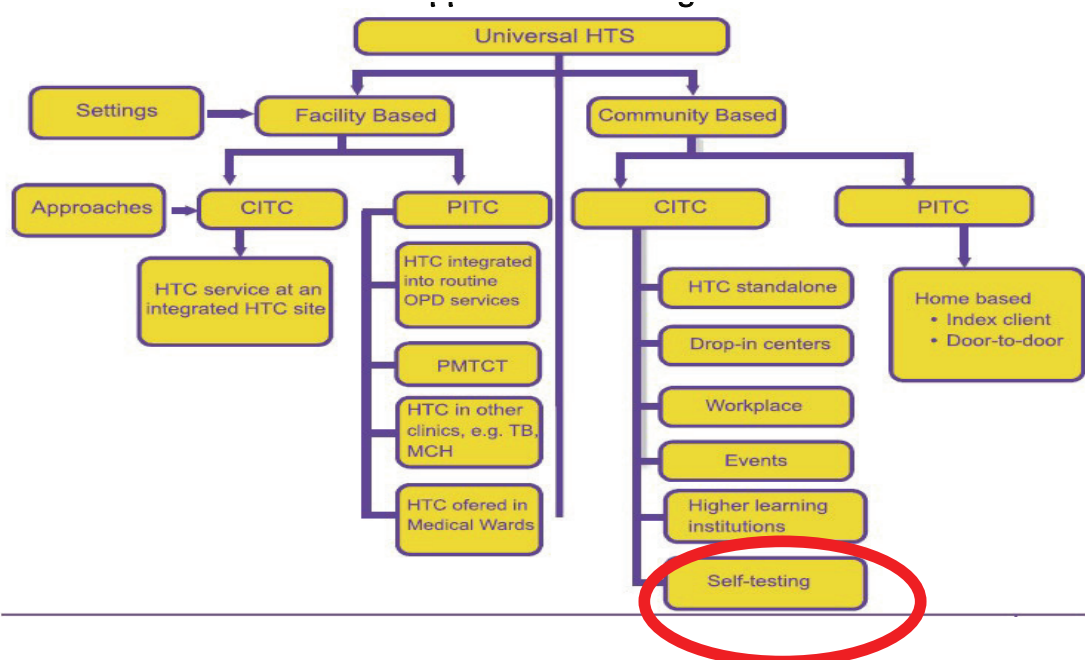


Figure 12: HTS APPROACH

8.7.5 HIVST will be implemented as per the 5Cs of HTS

Consent: People receiving HTS must give their informed consent to be tested and counselled. Verbal consent is sufficient and written consent is not a must. They should be informed of the process for HIV testing and counselling and of their right to decline.

Confidentiality: Discussions held between the HTS provider and the client should be confidential and not disclosed to a third party without the express consent of the person being tested. Although confidentiality must be respected, it should never be used to reinforce secrecy, stigma or shame.

Counselling: Pre-test information and post-test counselling can be provided in a group setting if appropriate; however, all persons should have the opportunity to ask questions in a private setting if they request it

Correct test results: Providers of HTS should strive to provide high-quality testing services and QA mechanisms that ensure people receive a correct diagnosis. QA may comprise both internal and external measures.

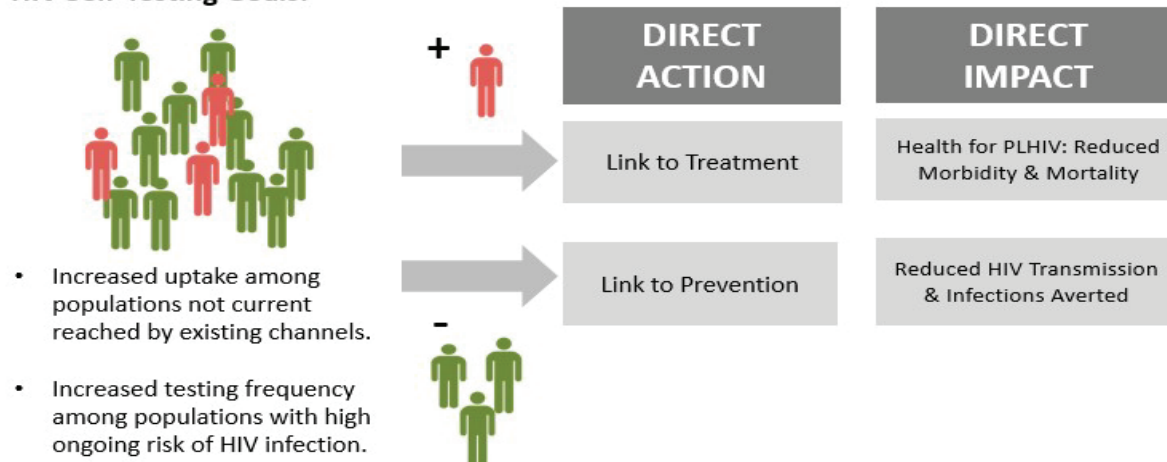
Connection: In the context of HIVST, connection also includes linkage to further HIV testing in a stigma free community or facility-based setting, where test results can be confirmed and an HIV diagnosis given by a trained provider.

8.7.6 HIV Self-Testing (HIVST)

HIVST is process in which a person collects his or her own sample (oral fluid or blood), performs an HIV test and interprets the result

- It is often done in private - either alone or with someone trusted
- A screening test- does not provide a definitive HIV-positive diagnosis.
- All reactive (positive) self-test results need to be confirmed by a trained health provider using the national testing algorithm.
- HIVST is a complementary approach to existing HIV testing services

HIV Self-Testing Goals:



Source: CHAI, Adapted from BMGF/UNITAID framework, presented at IAS 2017

Figure 13: HIV SELF-TESTING GOALS

8.7.6.1 Benefits of HIVST

- HIVST is well-positioned to help address HIV diagnosis gaps.
- Promotes access to HTS
- Increases autonomy and is thus empowering
- Assures privacy
- Is convenient
- Less stigmatizing for high risk populations

8.7.6.2 Self-Testing Approaches

Approach 1:	Approach 2:
<p>Directly Assisted</p> <ul style="list-style-type: none"> • When a trained provider, peer educator or health professional gives an in-person demonstration on how to perform and interpret the HIV self-test. • When an individual conducts his/her own self-test using the instructions provided, without the help or instruction of a health professional 	<p>Unassisted</p> <p>Health provider assistance during testing</p> <ul style="list-style-type: none"> • Telephone hotline assistance • Web based video demonstrations and testing instructions

8.7.6.2 Testing Support Tools

Both HIVST directly assisted and unassisted HIVST may include additional support tools for the tester which provide information on how to conduct the test, pre and post-test counselling, referrals to health providers and other support services.

1. Manufacturer's instructions and brochures
2. Health provider pre-test demonstration

8.7.6.3 HIVST Algorithm

- HIVST must be conducted using the nationally approved HIV self-test kits
- Clients with a **reactive (positive) self-test result should be re-tested** with a trained and qualified HTS provider using the national algorithm
- Clients with a non-reactive (negative) self-test result should be advised to re-test based on their risk

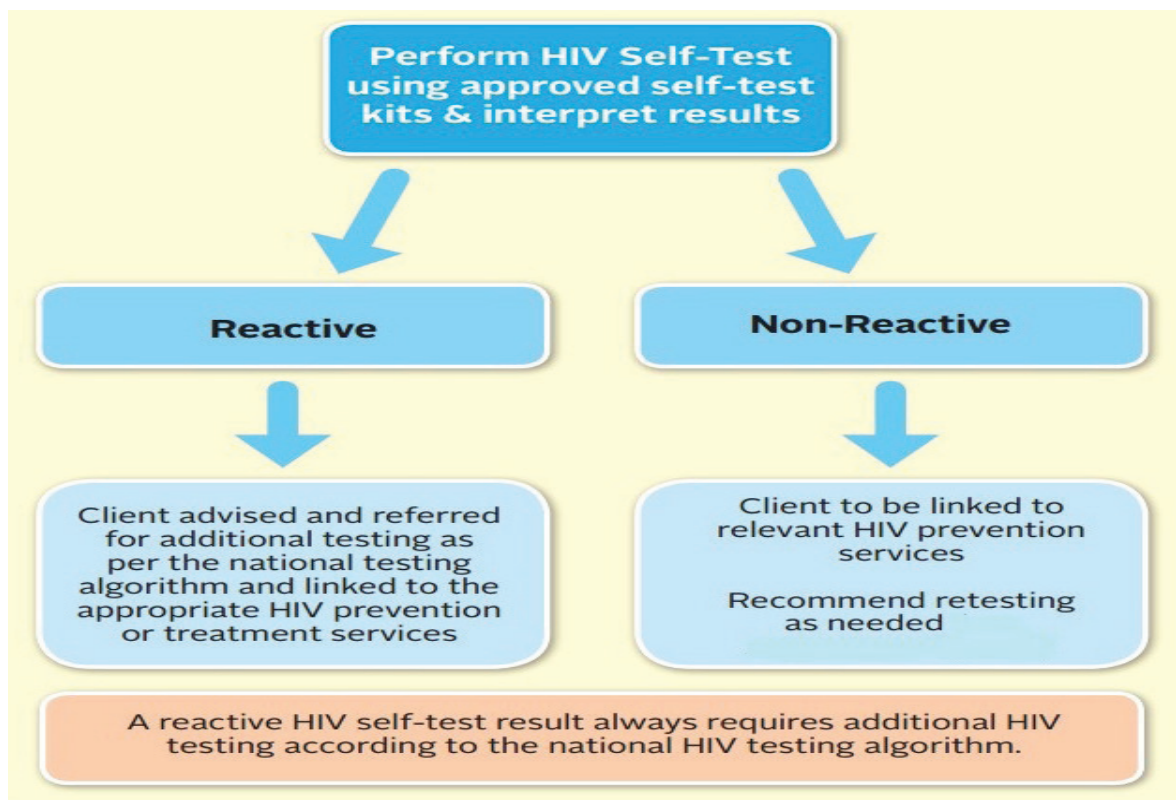


Figure 14: HIV SELF-TESTING ALGORITHM

UNIT 9

DOCUMENTATION, REPORTING, MONITORING AND EVALUATION



Introduction

This unit introduces participants to documentation, recording and reporting for family planning services. In this unit, participants are introduced to the data tools used in the program, namely; **Services delivery tools** and **Commodity management data tools**

Participants will engage in practical sessions to develop competence in the use of these tools and data for decision making.



Objectives:

- Define common terms
- Explain dimensions of data quality for FP
- Describe documentation for FP services
- Describe the reporting processes for FP
- Illustrate data flow for family planning
- Define the roles of pharmacists and pharmaceutical technologists in FP data management
- Illustrate the process of Monitoring and Evaluation in FP and HIVST
- Define FP indicators.

9.1 Definitions of Common Terminologies

Data	Factual information used as a basis for reasoning, discussion or calculation.
Data Quality	<p>Data is required for monitoring and evaluation of the FP programs and for responding to information requests from stakeholders.</p> <p>Quality data is important for</p> <ul style="list-style-type: none">• Policy development• Planning• Research• Advocacy• Resource mobilization
Record (noun)	A documentation of a specific event
Report	<p>Narrative description of happenings/events.</p> <p>Reports involve filling out, compiling specific information on data for use at a certain level.</p>
Record keeping	Involves documentation and custody of information to facilitate future planning and reference

9.2 Dimensions of Data Quality

The table below explains the dimensions of quality data.

Table 22: DIMENSIONS AND HOW TO ENSURE QUALITY OF DATA

Dimension	Definition	How to Ensure Quality
Accuracy	The data measure what they are intended to measure.	Data that has been reported matches the primary source documents at the point of collection. Example, record the number of cycles provided to a client.
Reliability	Repeated measurements using the same procedures get the same results	Data collection is aligned with protocols and procedures that do not change depending on the data collector, when or how often they are collected. All age group cut-offs are the same on all forms and reports.
Completeness	Data represents a comprehensive picture of all health events; each required data field is filled in every time	All the data elements that should have been recorded are reported for a given period. All the columns in the FP register are populated as required.

Dimension	Definition	How to Ensure Quality
Precision	Data has sufficient detail to use for decision making	The data contains adequate detail. For example, if an indicator requires “the number of clients receiving family planning methods by type and visit type,” then the tool would lack precision if one records the method type and not the visit of the individual who received the method.
Timeliness	Data is up to date/ current and available on time	Reports are submitted by the prescribed deadline at each level. All FP data is submitted by 5 th of every month.
Integrity	Data is protected from deliberate bias or manipulation for political or personal reasons	The data collection system is protected from bias or manipulation for reasons other than medical care. E.g. Reporting additional clients to account for the missing FP commodities

9.3 Documentation for FP Services

Documentation refers to a piece of written, printed, or electronic matter that provides information, evidence or that serves as an official record. Remember if it is not documented in the medical record then it did not happen. During FP service delivery data is recorded for each service provided to each patient.

Table 23: DOCUMENTATION FOR FP SERVICES

Client Category	Register	FP specific Data element
Walk in	FP register	FP services
Adolescents & youth	ASRH register	FP services
HIV positive women	FP register	FP services

NOTE:

Data element should be documented for all FP services offered in the respective service delivery point.

9.4 Reporting for FP Services

9.4.1 Why Report

- Better estimate needs for the private sector hence reduce costs of production through economies of scale which will impact the price of commodities.
- Document the private sector pharmacies contribution to family planning service provision in order to inform policy change so that other essential programs could be initiated. through the pharmacies e.g. immunization

Reporting is an important part in FP service provision. The summarized data elements are uploaded into the KHIS2 at the end of each month. Data should be uploaded into the KHIS2 by 10th of every month. Service providers play an important role in the reporting process and should therefore ensure the report submitted is of good quality.

The following steps should be followed to ensure complete and accurate reports:

- All data elements in the registers
- Monthly summaries should be computed on the last day of every month
- Conduct periodic verification of data
- Conduct periodic analysis of the data

Focus on capturing the below indicators:

- Dispensed/consumption
- Closing/Ending Balances (Stock status)

RECOMMENDATION:

Use the already existing tools for data capture used by the pharmacies. For the ones not using, we can get the difference between the opening stocks and ending stocks to determine the consumption.

Service data: we can use inference from the commodity data.

[illegible]

Figure: FP AND HIV DATA COLLECTION TOOL

9.4.2 Family Planning Data Flow

Data flow is the movement of data through a system comprised of software, hardware or a combination of both. FP data flow at the facility level is defined by the movement of data from one service delivery point to the other. In order to establish informed decision-making service providers for FP should not only accurately document and report to the next level but also routinely use these data for decision making.



Figure: DATA FLOW AND USE FROM THE PHARMACY

9.4.3 Monitoring and Evaluation

Monitoring is the collection of routine data that measure progress toward achieving program objectives. It is used to track changes in program performance over time. Monitoring is the systematic and routine collection of information for four main purposes:

- To learn from experiences to improve practices and activities in the future
- To have internal and external accountability of the resources used and the results obtained
- To take informed decisions on the future of the initiative
- To promote empowerment of beneficiaries of the initiative

Evaluation is the process of examining a program or process to determine what's working, what's not, and why. Evaluations appraise data and information that inform strategic decisions, thus improving the program in the future. Evaluations should help to draw conclusions of the following five main aspects of interventions

1. Relevance
2. Effectiveness
3. Efficiency
4. Impact
5. Sustainability

Information gathered in relation to these aspects during the monitoring process provides the basis for the evaluative analysis.

9.4.4 Role of service pharmacists & pharmaceutical technologists in Monitoring and Evaluation

Monitoring and evaluation (M&E) must be an ongoing element of any FP service delivery program. Service providers contribute in monitoring and evaluation by:

- Reporting of FP commodities and services
- Monthly submission of reports
- Routine data quality audits/assessments

9.4.5 Family Planning Indicators

Indicators are quantifiable measures which shows how close a program is to its desired path and outcomes. FP indicators are divided into two broad categories depending on the frequency of data collection.

Routine indicators: are reported on a monthly, quarterly and annual basis through the service statistics.

Periodic indicators: are collected after a predefined period through surveys.

REPRODUCTIVE HEALTH COMMODITY MANAGEMENT



Introduction

This unit is meant to help participants understand family planning health commodities and their management.



Objectives

By the end of this unit, the participants will be able to;

- Define reproductive and family planning commodities
- Outline categories of FP commodities
- Describe Logistics management

10.1 Define reproductive and family planning commodities

10.1.1 Reproductive health (RH) and family planning (FP) Commodities

RH commodities refer to those medicines, medical supplies and equipment that are used in the promotion of reproductive health, prevention, diagnosis and management of RH conditions. Family planning (FP) commodities refers to medicines, medical supplies and technologies that are used for contraception.

10.1.2 Categories of FP commodities

FP commodities can be classified as hormonal and non-hormonal (Refer to Unit 7: FP Methods for more details)

Hormonal- Short term methods	Hon-hormonal-Short Term Methods
<ul style="list-style-type: none">• DMPA IM/SC• Combine Oral Contraceptive (COCs)• Progestin Only Pills (POPs)• Emergency hormonal Contraceptives• Female & Male condoms	<ul style="list-style-type: none">• Barrier Methods (Male & Female Condom)• Fertility Awareness Based Methods• Hon-hormonal-LARC Methods• IUCDS
Long Term reversible Contraceptives	Hon-hormonal-Permanent Methods
<ul style="list-style-type: none">• Implants• Hormonal IUCDs	<ul style="list-style-type: none">• Bilateral Tubal Ligation(BTL)• Vasectomy

10.1.3 Commodity Management

Commodity management is the practice of ensuring effective selection, procurement, distribution, storage and use of medicines, medical supplies and technologies.

10.1.3.1 The Logistics Management Cycle

The cycle shows the interrelationship between activities in a logistics system. These activities are: appropriate selection of products, quantification & procurement followed by inventory management, storage, distribution and dispensing to clients. Each component of the cycle is governed by policies, laws and regulations.

10.1.3.2 The Logistics Management Cycle

Policy

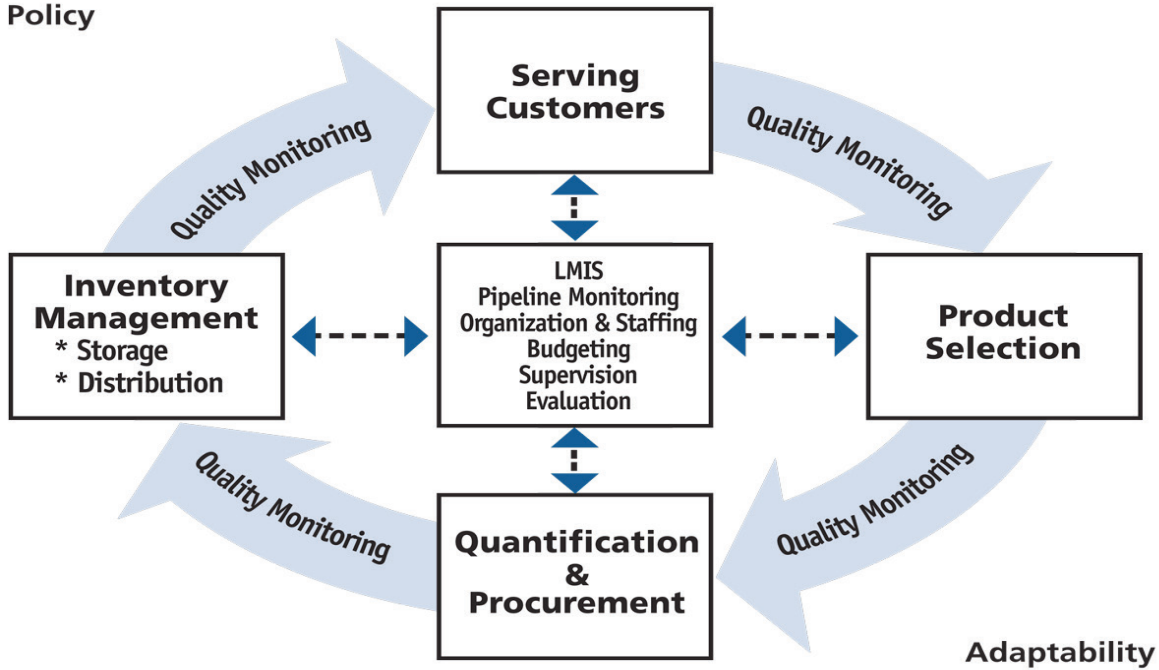


Figure 13: The Logistics Management Cycle

10.1.3.2 Serving Customers

There are eight Consumer Rights as described below:

The Right to Safety: To be protected against products, production methods and services which are hazardous to health or life.

The Right to be Informed: To be given the facts needed to make an informed choice, to be protected against dishonest or misleading, advertising and labelling.

The Right to Choose: To be able to select from a range of products and services, offered at competitive prices with an assurance of satisfactory quality.

The Right to be Heard: To have consumer interests represented in the making and execution of government policy, and in the development of products and services.

The Right to Redress: To receive a fair settlement of just claims, including compensation for faulty goods, misrepresentation or unsatisfactory services.

The Right to Consumer Education: To acquire knowledge and skills needed to make informed choices about goods and services, while being aware of basic rights and responsibilities.

The Right to a Healthy Environment: To live and work in an environment which is non-threatening to the well-being of present and future generations

The Right to Satisfaction of Basic Needs: To have access to basic and essential goods and services: adequate food, clothing, shelter, health care, education and sanitation.

10.1.4 The six rights of logistics

A logistic system ensures movement of required quantities of commodities within the least possible time and cost. Logistics management must conform to the six rights;

Right product: The client will be offered the best FP method appropriate to them based on MEC

Right quantity: The client will receive the sufficient quantity for the desired FP period

Right Condition: The client receives an efficacious and safe product

Right place: The client should be served in a convenient area that offers privacy, space and is well equipped with appropriate FP supplies.

Right time: The client should receive an FP method as and when they desire and as appropriate as per MEC

Right cost: The client should receive affordable and accessible FP products

10.1.5 Product Selection

Diligent selection is important in ensuring good quality end products. Things to consider;

- Treatment guidelines and protocols
- Registration status and approvals
- Cost effectiveness

10.1.6 Quantification & Procurement

Quantification is process of estimating quantities and costs of health commodities during a specific period and determining when the products should be delivered to ensure uninterrupted supply.

10.1.6.1 Estimating requirements of FP Commodities

Three methodologies are used based on the type of data;

- Using Consumption data (this is the preferred method when data is available)
- Using Services data
- Using Demographic/Population data

Procurement is the process is obtaining the products. This process should follow a set of specific procedures and adhere to regulations that ensure a transparent and open process that supports the six rights. Procurement is only possible after carefully estimating the quantities of commodities required (quantification)

10.1.7 Inventory Management

Good storage and distribution practices ensure that a product reaches the end user in the state it was intended to.

Management of
expiries and safe
disposal of expiries
(Refer to PPB guidelines
of management
of expiries)



FP commodities are meant to be transported;

- At controlled temperatures
- In the original packages
- While being handled in dry conditions

Factors to consider for good storage

- Adequate space, shelving and pallets
- Good ventilation
- Enough lighting while avoiding direct sunlight
- Proper inventory records
- Good pest control practices
- Stock Management
- Stock rotation

10.2 Logistics Management Information System (LMIS)

Logistics management information system (LMIS) is a system that is used to capture, analyse and report commodity data for decision making Other factors to consider in a logistics system

Organization and staffing. A logistics system can only work if well-trained, efficient staff monitor stock levels, place orders, and provide products to clients. Health programs assign the appropriate resources to staff (for example, supervision authority and technical knowledge) to complete logistics activities. Organization and staffing, therefore, are important parts of the cycle. For a logistics system to work effectively, pharmacy staff must make the six rights a top priority.

Budgeting. Allocation and management of finances directly affect all parts of the logistics cycle, including the quantities of products that can be procured, the amount of storage space that may be available, the number of vehicles that can be maintained, and the number of staffs working in logistics.

- Mobilizing resources and securing a budget line item for FP commodities and logistics activities is extremely important to ensure that products are available and that the logistics system operates effectively.
- To determine the resources needed to scale up, supply chain managers first need to assess what the expected costs are at different levels of the logistics system. When determining supply chains costs, managers should consider the cost of storage, transportation, and management; and determine what share of these costs each group will cover (i.e., Ministry of Health, donors, nongovernmental organizations [NGOs], etc.).

Supervision. Supervising the staff who work within the logistics system keeps it running smoothly and helps to anticipate needed changes.

- Routine, effective supervision, coupled with on-the-job training in logistics, helps to both prevent and resolve supply problems and human resource constraints.

Monitoring and evaluation. Routine monitoring and periodic evaluation of the pipeline and logistics system activities help demonstrate how well the system is performing, the areas that can be improved, as well as the system's impact on service provision.

Pipeline Monitoring. A commodity pipeline is the entire chain of storage facilities and transportation links through which supplies move from the manufacturers to the customer.

- Pipeline monitoring involves, tracking shipments, actual consumption figures, monitoring stock status (between max and min), losses or adjustments. When monitoring the pipe line, you will need to adjust forecasts, shipment schedules, and/or shipment quantities.
- Each of the components of the logistics cycle are governed by various policies. A logistics system should be flexible in order to serve the customers and meet the six rights. In each of the steps, the process should be carefully monitored and evaluated, a system of feedback developed to ensure continuous improvement.

PHARMACOVIGILANCE



Introduction

This session is intended to strengthen the knowledge of the learner on pharmacovigilance, identification and reporting on Adverse Drug Reactions (ADRs)



Objectives

- Define pharmacovigilance
- Importance of pharmacovigilance
- Define Adverse Drug Reactions (ADRs) and identify their sources
- Discuss the roles and responsibilities of pharmacists and pharm techs in pharmacovigilance
- Discuss the guidelines and reporting tools for the national pharmacovigilance in Kenya

11.1 Definitions of Pharmacovigilance

Pharmacovigilance (PV) is the science of collecting, monitoring, researching, assessing and evaluating information from health care providers and patients on the adverse effects of medicines with a view to identify new information about hazards and preventing harm to patients.

Post Marketing Surveillance (PMS) ensures that even after registration, drugs continue to meet the required standards whilst in the market to guarantee quality, safety and efficacy of these products.

11.1.2 Importance of Pharmacovigilance

- Early detection of unknown safety problems
- Detection in increases in frequency of reactions
- Identification of risk factors
- Quantifying risks
- Preventing patients from being affected unnecessarily

11.1.3 Adverse Drug Reactions (ADRs)

Adverse Drug Reactions (ADRs) is a response to a medicine which is noxious and unintended and occurs at doses normally used in human for the prophylaxis, diagnosis or therapy of disease, or the modification of physiological function. The key players are regulatory bodies, pharmaceutical companies and health care professional.

11.1.3.1 How to detect ADRs

Since ADRs may act through the same physiological and pathological pathways as different diseases, they are difficult and sometimes impossible to distinguish. The following step-wise approach may be helpful in assessing possible drug-related ADRs:

1. Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised;
2. Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient;
3. Determine the time interval between the beginning of drug treatment and the onset of the event;
4. Evaluate the suspected ADR after discontinuing the drugs and monitor the patient's status.
5. Analyse the alternative causes (other than the drug) that could on their own have caused the reaction;

6. Use relevant up-to-date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction. The Department of Pharmacovigilance in the Pharmacy and Poisons Board is a very important resource for obtaining information on ADR. The manufacturer of the drug can also be a resource to consult;
7. Report any suspected ADR to the person nominated for ADR reporting in the hospital or directly to the The Department of Pharmacovigilance.

11.1.3.2 Sources of information on ADRs:

- US-FDA
- Scientific literature e.g. medical journals
- WHO/UMC publications
- Pre-market clinical safety data
- Newspapers, Internet websites, chat rooms, colleagues
- Product complaints
- Unpublished manuscripts
- Post-marketing surveillance
- Cohort Event Monitoring
- Spontaneous reports
- Others

Table 24: COMMON EXAMPLES OF ADRS IN FAMILY PLANNING

Contraceptive	Examples of common Adverse Drug Reactions (ADRs)
Combined Oral Contraceptives (COCs)	Deep Venous Thrombosis (DVT) – may manifest as pain in the leg, Ischemic heart disease – may manifest as breathlessness, heavy chest or palpitations
DMPA	Osteoporosis (develops later in life especially if the injectable is started in adolescents)- may manifest as brittleness and bending of bones

NOTE:

ADRs can be life threatening or non-life threatening. Refer to Guidelines on the National Pharmacovigilance System in Kenya (2009)

Health professionals are in the best position to detect and report on suspected ADRs because of:

Their everyday interaction with patients

- All healthcare providers should report suspected ADRs as part of our professional responsibility, even if we are doubtful about the precise relationship with the given medication or even if the reaction is considered minor.

11.1.3.3 Role of the pharmacist in pharmacovigilance

- Patient education
- Detection of ADRs and appropriate clinical management
- Reporting of ADRs
- Documentation- to maintain accurate documents
- Investigation, where necessary
- Patient feedback
- Coordinate all activities of pharmacovigilance
- Training other health care staff

11.1.3.4 Reporting for PV

PPB requires pharmacists to report on:

- Any ADR
- Poor-quality medical products
- Suspected contamination, molding, colour change
- Poor packaging / poor labelling
- Therapeutic failures
- Counterfeit medicine
- Receiving expired medicines

11.1.3.5 How to detect poor quality products

Look out for


- Colour change
- Separating of components
- Powdering / crumbling
- Caking
- Moulding
- Change of odour
- Mislabeling
- Incomplete pack
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging / poor labeling
- Therapeutic failures
- Receiving expired medicine

For further information refer to the Pharmacy and Poisons Board link below
<https://pharmacyboardkenya.org/downloads>

NOTE:

Reporting should preferably be done online to PPB using the link provided below;
www.pv.pharmacyboardkenya.org

11.2.4 Reporting tools for Pharmacovigilance

	<p>MINISTRY OF HEALTH PHARMACY AND POISONS BOARD LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506 TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409</p> <p><u>ADVERSE DRUG REACTION ALERT CARD</u></p>	PV 4
PATIENT NAME:		
AGE: GENDER:		
DATE ISSUED: ADDRESS:		
SUSPECTED DRUG(S):		
DESCRIPTION OF REACTION:		
Other comments (if any):		
.....		
<p><i>Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha m hudumu wa afya kadi hii unapo pata matibabu</i></p>	<p><i>Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.</i></p>	

CRITERIA FOR ISSUE OF A PATIENT ALERT CARD

The criteria for issue of the Patient Alert Card is as follows:

The alert card is given to:

- ◆ Patients who are hypersensitive / allergic / intolerant to a particular drug
- ◆ Patients who develop a 'near-fatal' reaction to any particular drug
- ◆ Patients who had a drug- induced morbidity to any drug
- ◆ Patients who had hospital admission due to an ADR to any drug
- ◆ Patients who developed an ADR which caused increase in the health care expenditure

PV 6: FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS



PV 6

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
DEPARTMENT OF PHARMACOVIGILANCE

IN CONFIDENCE**FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS**

Name of Facility		District Name		Province Name	
Facility Address		Facility Telephone			
PRODUCT IDENTITY					
Brand Name				Generic Name	
Batch/Lot Number		Date of Manufacture		Date of Expiry	
Name of Manufacturer			Country of Origin		
Name of Distributor/Supplier		Distributor/Supplier's Address			
PRODUCT FORMULATION (Tick appropriate box)			COMPLAINT (Tick appropriate box/boxes)		
<input type="checkbox"/> Oral tablets / capsules <input type="checkbox"/> Oral suspension / syrup <input type="checkbox"/> Injection <input type="checkbox"/> Diluent <input type="checkbox"/> Powder for reconstitution of suspension <input type="checkbox"/> Powder for reconstitution of injection <input type="checkbox"/> Eye drops <input type="checkbox"/> Ear drops <input type="checkbox"/> Nebuliser solution <input type="checkbox"/> Cream / Ointment / Liniment / Paste <input type="checkbox"/> Other			<input type="checkbox"/> Colour change <input type="checkbox"/> Separating <input type="checkbox"/> Powdering / crumbling <input type="checkbox"/> Caking <input type="checkbox"/> Moulding <input type="checkbox"/> Change of odour <input type="checkbox"/> Mislabeling <input type="checkbox"/> Incomplete pack <input type="checkbox"/> Other		
Describe complaint in detail:					
Storage Conditions					
Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Other details (if necessary):		
Was product available at facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Was product dispensed and returned by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Was product stored according to manufacturer/MoH recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Comments (if any)					
.....					
Name of Reporter			Contact number		
Cadre / Job Title			Signature		
Once completed one copy of this form should be e-mailed or posted to:					
Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB	Fax: 2713431	E-mail: pv@pharmacyboardkenya.org	
<p><small>Your support in this Pharmacovigilance program is appreciated.</small></p> <p><small>Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to: The Pharmacy and Poisons Board on the above address</small></p>					

PV 1: FORM FOR REPORTING SUSPECTED ADVERSE DRUG REACTIONS



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
P.O. Box 27663-00506 NAIROBI

Tel: (020)-3562107 Ext 114, 0720 606811, 0733 864411 Fax: (020) 2713431/2713439
Email: pv@pharmacyboardkenya.org

PV 1
(rev.2.0)

IN CONFIDENCE

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Tip: Fields marked with * are mandatory

Form ID:
IMPORTANT UNIQUE FORM ID

REPORT TITLE *

e.g Nevirapine related rash

**NAME OF
INSTITUTION**

COUNTY *

ADDRESS

Sub County

INSTITUTION CODE

**INSTITUTION
CONTACT**

PATIENT'S INITIALS *

e.g A.B

WARD / CLINIC

WARD / CLINIC

IP/OP. NO.

PATIENT'S ADDRESS

e.g kayole

DATE OF BIRTH *

If selected, year is mandatory.

--OR--

AGE GROUP

clear!

SEX *

☐ Male ☐ Female

☐ Unknown

clear!

PREGNANCY STATUS

☐ Yes ☐ No

WEIGHT (kg)

Kg

HEIGHT (cm)

cm

**ANY KNOWN
ALLERGY**

☐ yes ☐ No

clear!

If yes, specify

(specify)

DIAGNOSIS

(What was the patient treated for)

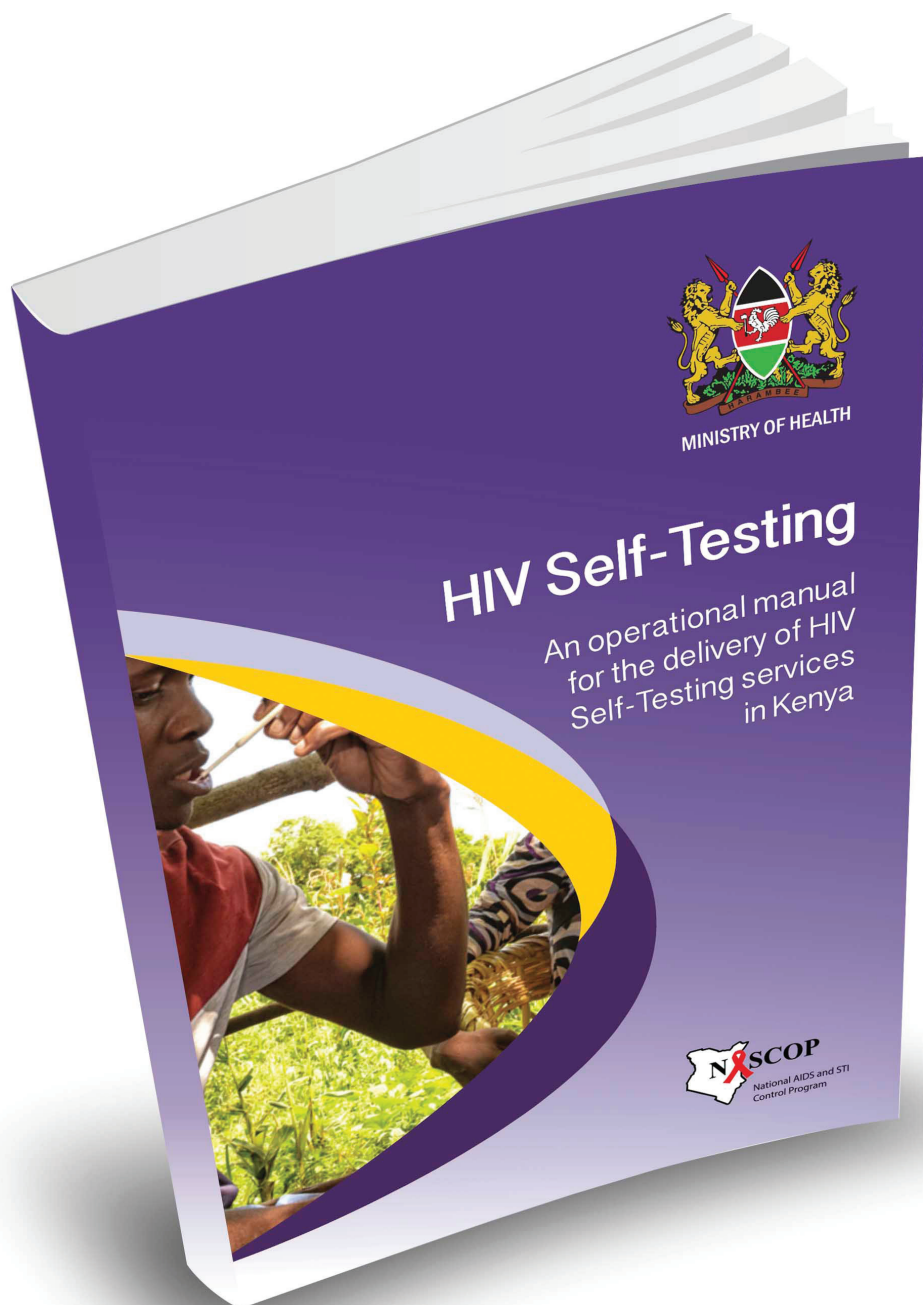
**BRIEF DESCRIPTION
OF REACTION ***

e.g accompanied by vomiting

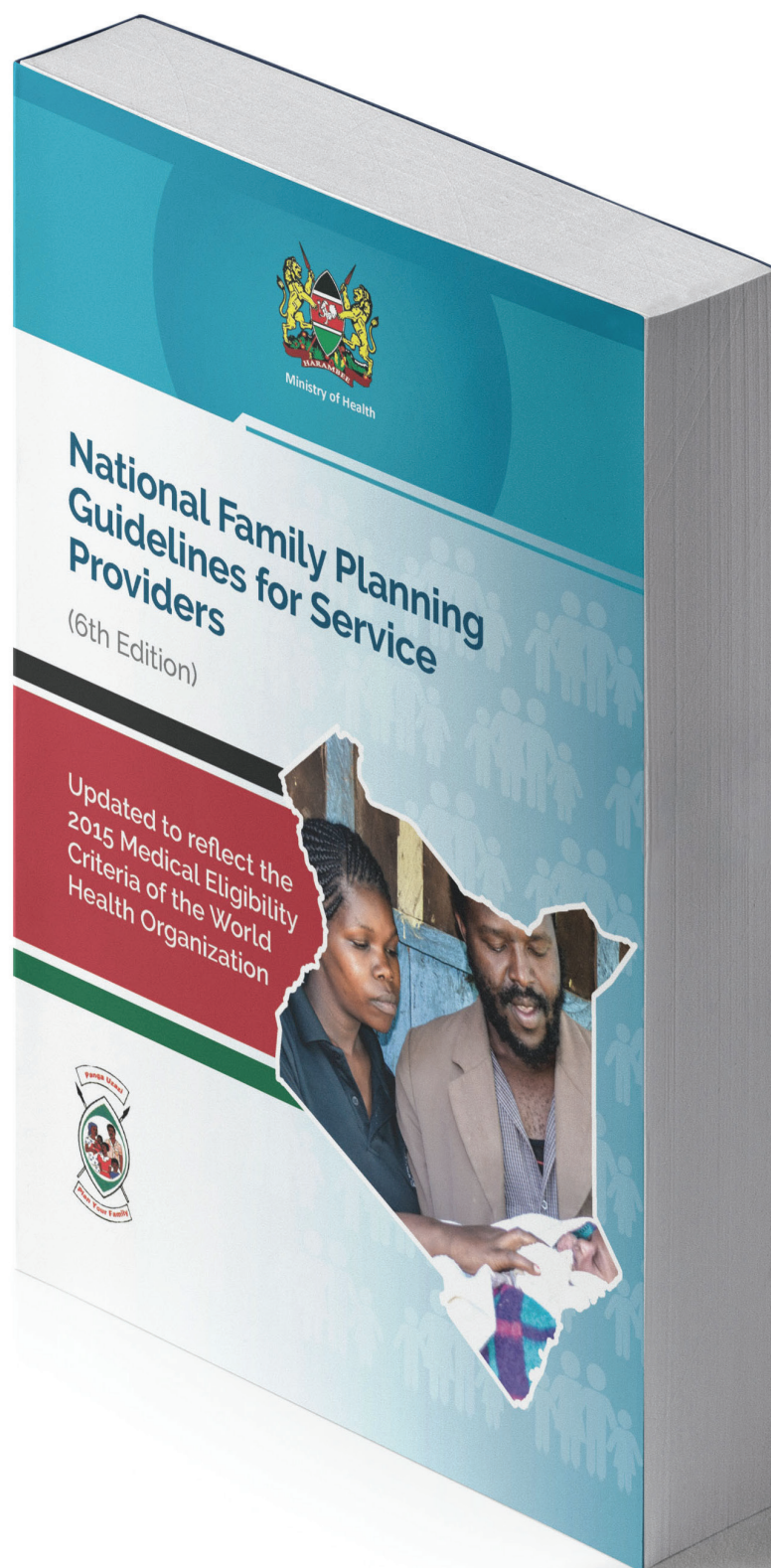
**DATE OF ONSET OF
REACTION ***

Date format dd-mm-yyyy e.g (18-05-2012)

ANNEXES







FAMILY PLANNING PROVIDER ACCREDITATION APPLICATION FORM

The Pharmaceutical Society of Kenya

FAMILY PLANNING PROVIDER ACCREDITATION APPLICATION FORM FOR PRIVATE PHARMACIES

APPLICANT'S GENERAL INFORMATION:

Note: Application form to be completed by the Pharmacist-in-charge or Pharm-tech in-charge

Name of the Pharmacy: _____

Pharmacy Physical Location: _____

Pharmacy Postal Address: _____

Premises Registration Number PPB (Attach copy): _____

Date of Registration of Premises (by PPB): _____

Pharmacy Email Address: _____

Pharmacy Telephone No: _____

PHARMACIST – IN – CHARGE: (Fill in this section if the superintendent is a pharmacist)

Full Name: _____

PSK Membership No: _____

PPB License to Practice for current year (Attach copy) _____

Kenyan ID or Foreigner Certificate No (Attach copy) _____

Pharmacist in-Charge-Mobile No: _____

Pharmacists on shift: Other PPB Registered Pharmacist(s) should attach copies of their current PPB license to practice, PSK Membership, Identification, and PIN.

Name of Pharmacist - on - Shift	Current practice license No. (Attach copy)	PSK Membership No.
1. Dr.		
2. Dr.		
3. Dr.		

Pharm-techs - on - shift: PPB enrolled pharm-techs employed at the premises should attach copies of their current PPB license to practice.

Name of Pharm-techs on Shift	Current practice license No. (Attach copy)	PPB Enrolment no. and KPA Membership No.
1.		
2.		
3.		

PHARMTECH IN- CHARGE: (Fill in this section if the superintendent is a pharm-tech)

Full Name: _____

KPA Membership No: _____

PPB Enrollment No: _____

PPB License to Practice for current year (Attach copy) _____

Kenyan ID or Foreigner Certificate No (Attach copy) _____

Pharm-tech-in-Charge-Mobile No: _____

Pharm-techs - on - shift: Other PPB enrolled pharm-techs should attach copies of their current PPB license to practice.

Name of Pharm-techs - on - Shift	Current practice license No. (Attach copy)	PPB Enrolment no. and KPA Membership No.
1.		
2.		
3.		

TERMS & CONDITIONS

- I. Accreditation of personnel shall be dependent on:
 - a. Letter of good standing from PSK or KPA
 - b. Proof of completion and passing of AFP provider course
- II. Accreditation of premises is conditional of the following;
 - a. The Registered PPB Pharmacist-in-charge and all pharmacists on shift must be up to date members of PSK.
 - b. The enrolled pharmtech in charge and all pharmtechs on shift must be members of KPA
 - c. The pharmacy must have an up-to-date license of Registration with the PPB.
 - d. Only a registered pharmacist or enrolled pharmtech can provide advanced family planning to clients and not any other employee at the premises
- III. Premises must have a private counselling and consultation area
- IV. Premises must have a mechanism and procedure for disposal of medical waste including sharps
- V. Accreditation of premises will be revoked if there ceases to be a trained and approved superintendent in charge at the pharmacy.

Name of Pharmacy: _____

Applicant's Name: _____

Applicant's Signature: _____ Date: _____

PSK OFFICE USE ONLY

Checklist of attached documents

Document	Confirmation	Remarks
Premises Registration Certificate from PPB		
Superintendent's License to Practice		
Superintendent's ID		
Pharmacists on shift licenses to Practice		
Pharmtechs on shift licenses to practice		
Private counseling and consultation area		
Mechanism for disposal of medical waste including sharps		
Letter of good standing from PSK or KPA for all pharmacists or pharmtechs at premises		
Proof of completion of provider course for all pharmacists and pharmtechs at premises		



**PHARMACEUTICAL
SOCIETY OF KENYA**



KENYA PHARMACEUTICAL ASSOCIATION
— Pharmaceutical Excellence —