NATIONAL STANDARDS FOR FAMILY PLANNING SERVICES

MALDIVES

CONTENTS

FOREWORD

Maldives has made considerable progress in the areas of Maternal and Child Health especially much effort has been made to maintain the lower rates of maternal and child mortaity post MDG. The government is committed to ensure easy access to safe, affordable and effective methods of family planning and information.

The 'National Standards for Family Planning Services' 2005 has been revised in discussion with various stakeholders and also orientation provided to the service provides on the updated manual. The standards provide in-depth technical details about the safety of different contraceptive methods in context to specific health conditions. The document is complemented with Operational Guidelines, Jon Aids/ Medical Eligibility Criteria (MEC) Wheel. These standards conform to the Medical Eligibility Criteria for Contraceptive Use 2015, by the World Health Organization.

I Would encourage all health service providers and health care providers/ programme managers to go through these documents and base practices on latest evidences provided. The National Standards and Operational Guidelines together can address barriers to quality family planning services and help improve reproductive, maternal and child health.

My appreciation goes to those organizations, institutions and individuals who have contributed, especially very appreciative of the contributions made by the Obstetricians of Indhira Gandhi Memorial Hospital, Hulhumale Hospital and ADK Hospital who kindly came onboard and shared their clinical expertise in this area. A great deal of credit must go to the rest of the stakeholders who were involved in the various meetings and workshiops while developing this document.
I wish to express my sincere thanks to partner agencies especially the WHO country officer for the support in facilitating generious technical and financial assistance during the process of developing this document.

Thasleema Usman
Commisioner of Quality Assurance
Ministry of Health

MESSAGE

In line with the commitment to Universal Health Coverage; its commendable to notice the Government of Maldives efforts to providing good quality, affordable and accessible reproductive health services across the country.

Access to high-quality, affordable sexual and reproductive health services and information, including a full range of contraceptive methods is a fundamental to realizing the rights and well-being especially of women and girls. As an integral part of the Reproductive Health Services, Family planning at times could be a life- saving intervention for women and girls.
Key global initiatives, including the Sustainable Development Goals and the Global Strategy for Women's, Children's and Adolescents' Health, call for universal access to family planning services as a right of women and girls and crucial to a healthy life.

As part of WHO support to strengthen Reproductive Health Services in Maldives, WHO worked in collaboration with Health Protection Agency, Ministry of Health and other relevant stakeholders to review and revise 'National Standards for Family Planning Services in accordance with the most updated global guidelines. These updated standards and guidelines are developed with the aim to provide basic reference and decision-making document for family planning services by health care providers at all levels of health services.

I am pleased to note that Operational Guidelines accompany these technical standards and guidelines together with behavior change communication activities and sustained advocacy will contribute to increasing the reproductive health choices and facilitate informed decisions and result in increase in the contraceptive prevalence rate for modern contraceptive methods and address the increasing unmet need for family planning in Maldives.

WHO Country Office considers it a matter of great privilege for extending technical support to the Ministry of Health for development of these FP tools and guidelines and as a responsive and reliable partner assure support in implementing and monitoring these in the coming years.

Dr Arvind Mathur
WHO Representative

ACKNOWLEDGEMENTS

Nationl Standards for Family Planning first appeared in 2005 and has been updated in 2019. Both the editions have benefited from the contributions of many people in many different organizations. We wish to thank all these contributors. Without the collaboration and commitment of all involved, this book would not have been possible.

The updated standards conform to the Medical Eligibility Criteria for contraceptive use, 2015, by the World Health Organization and the efforts that have gone into updating the National Standards for Family Planning, Maldives is duly acknowledged.

Deepest appreciation is expressed to Permanent Secretary, Ministry of Health, for providing insights around the practices and her thoughts on addressing them.

We express gratitude to WHO Maldives for providing technical and financial support and acknowledge the efforts to update the National Family Planning Guidelines. Technical inputs of UNFPA and UNICEF experts is also very much appreciated.

Our sincere appreciation goes to Dr. Loveleen Johri, Sr. Public Health Consultant, who updated the National Guidelines as per WHO's Medical Eligibility Criteria, 2015, in discussion with various stakeholders and provided orientation to providers on the updated manual.

The document would not have been possible without the kind support and help of many individuals and organizations. We appreciate the contributions of the many people especially the following people provided their expertise during expert meetings and throughout the development of the book:

Dr Aseel Jaleel, Head of the Department, Senior Consultant in Obstetrics and Gynaecology, IGMH Dr. Aminath Shaheedha, Consultant in Obstetrics and Gynaecology, IGMH
Dr. Zakiya Ahmed, Consultant in Obstetrics and Gynaecology, IGMH
Fathimath Fileeshiya, RHC Ward Manager, IGMH
Dr Ibrahim Zakaria Moosa, Maldives Islamic University
Dr Vikas Ratan Gosavi, Consultant in Obstetrics and Gynaecology, ADK Hospital
Dr Hawwa Inaya Abdul Raheem, Consultant in Obstetrics and Gynaecology, Hulhumale Hospital

Many others also contributed their expertise on specific topics and participated in the development of consensus on technical content. We would like to extend sincere thanks to all the experts mentioned below, who worked on the draft document and provided technical and programmatic inputs. Contributors are named in the annexe, who supported updating and expanding this edition of the Standards

We would like to extend sincere thanks to all of them.

REPRODUCTIVE HEALTH AND FAMILY PLANNING SCENARIO IN MALDIVES

Reproductive health (RH) is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity in all matters related to the reproductive system and to its functions and processes. Reproductive health is a crucial part of overall health and is central to human development. The Government of Maldives is a signatory to the Program of Action of the International Conference on Population and Development (ICPD), which includes the concept of RH care as the constellation of methods, techniques and services that contribute to reproductive health and wellbeing by preventing and solving reproductive and sexual health problems. Table 1 provides information on the availability of the various family planning methods at different facility levels within the country. The newly-adopted 2030 Agenda for Sustainable Development sets a global target to ensure universal access to sexual and reproductive health-care services, including family planning under Target 3.7 and Target 5.6. (Global Strategy for women's, children's and adolescent's health (2016-2030).

NATIONAL REPRODUCTIVE HEALTH POLICY

In 1986, the Republic of Maldives adopted a policy to strengthen and implement family planning programme in the country. By 1990, all the 187 inhabited islands of Maldives were covered under the family planning programme. The Government of Maldives recognises that reproductive health is a crucial component of general health and that developmental and intergenerational focus on RH services is a major facilitating service towards achieving the right of the individual and couples to protect their reproductive health and to take responsibility for their reproductive functions. Government of Maldives is committed to providing reproductive health services that are affordable, have equity in access and quality corresponding to the needs of each individual, encompasses the principles of primary health care, ensures privacy of the individual and is sensitive and responsive to the socio-cultural circumstances of the individual. Reproductive health services should ensure confidentiality and should not discriminate against any individual on account of gender or social background. The policy recognises the right of the individual to information and education and emphasises access to accurate information in order that they take full, free and informed decisions and is consistent with national policies and legal provisions.

NATIONAL REPRODUCTIVE HEALTH STRATEGY 2005-2007 and 2014-2018

The goal of the national reproductive health strategy 2005-2007 was 'reproductive health and rights for all Maldivian women, men and adolescents'.

COMPONENTS OF REPRODUCTIVE HEALTH STRATEGY

The seven thematic areas of reproductive health in the National Reproductive Health Strategy are:

1. Safe Motherhood and Newborn Care
2. Family Planning
3. Adolescent and Reproductive Health
4. Sexually Transmitted Infections and HIV/AIDS
5. Gender Based Violence
6. Partnering with Men in Sexual and Reproductive Health
7. Reproductive Morbidities (including infertility and cancers)

The specific goal for family planning according to National Reproductive Health Strategy is to ensure easy access to safe, affordable and effective methods of family planning and information.

THE FAMILY PLANNING STRATEGY FOCUSES ON TWO OBJECTIVES:

1. Increase the contraceptive prevalence rate for modern methods with particular emphasis on addressing unmet needs.
2. Strengthen contraceptive procurement and logistics system.

The strategic approaches for achieving its objectives to increase contraceptive prevalence rate for modern methods with emphasis on addressing unmet needs are as follows:

- strategies for increasing demand for family planning
- strategies for improving access and quality of family planning services

The revised National Standards for Family Planning Services contribute to achieving the first objective of the family planning strategy. The aim is also to sink in these standards with the National Adolescent and Youth Health Standards.

THE OBJECTIVES OF THE NATIONAL STANDARDS FOR FAMILY PLANNING SERVICES ARE TO:

1. Provide a basic reference document for family planning providers at all levels of health services
2. Provide guidance for policy makers, health managers and service providers
3. Develop training materials and job-aids for all health providers
4. Develop appropriate material for use in the community

While implementing the guidelines, efforts should be made to promote advocacy and behaviour change communication activities. These activities are critical for increasing utilization of FP services. It is hoped that the document will be adapted for various levels of health care. The first priority is to adapt it for the primary health care services.

Table 1: Provision of FP methods and level of health facility/level of health care in Maldives

		TERTIARY HOSPITAL	REGIONAL HOSPITAL	ATOLL HOSPITAL	HEALTH CENTRE
	COUNSELLING	■	■	■	■
	METHODS				
	CONDOMS	■	■	■	■
	COCs/CHC	■	■	■	■
	POPs	■	■	■	■
	INJECTABLES (DEPO-PROVERA)	■	■	■	■
	IUD (CU T 380A)	■	■	■	
	IMPLANON	■	■		
	FEMALE STERILIZATION (MINILAP)	■	■	■	
	FEMALE STERILIZATION (LAPAROSCOPIC)	■	■		
	MALE STERILIZATION	■	■	■	
	REFERRAL		■	■	■
	CLIENT FOLLOW-UP AS PER PROTOCOL	■	■	■	■

Note : Emergency contraceptive pills are made available at all health facility levels.

CONTRACEPTIVE SCENARIO IN MALDIVES

The population of Maldives has grown from 72,237 in 1911 (first census enumeration) to 326,000 in 2010 (almost four times increase). In 1986, The Republic of Maldives adopted a policy to strengthen and implement family planning programme in the country. By 1990, all the 187 inhabited islands of Maldives were covered under the family planning programme. The Maldives 2009, DHS data is mainly used in this document for reference. Table 2 depicts select demographic and health indicators for Maldives.

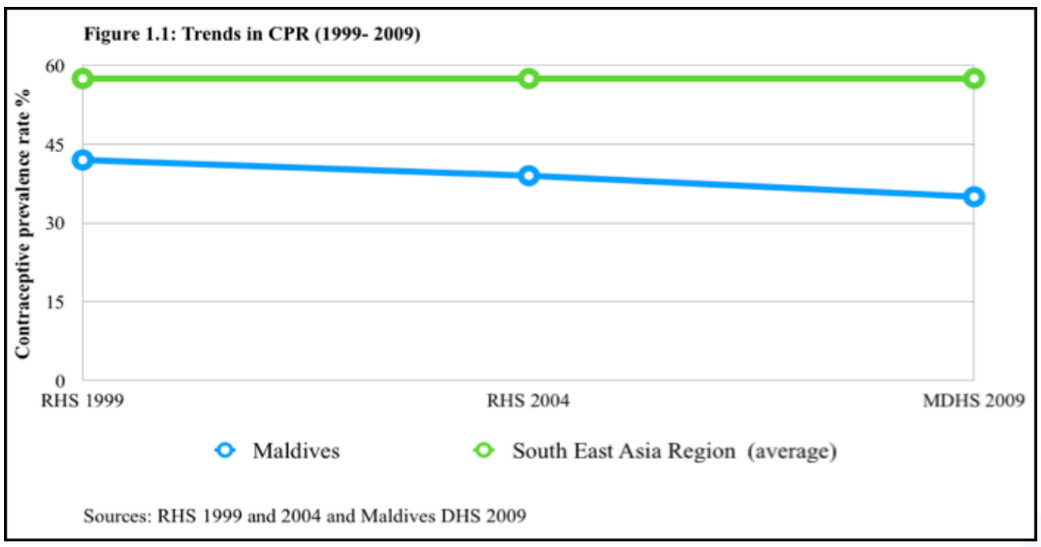
Table 2: Key health and demographic indicators in Maldives

INDICATORS	
Total Population (Census 2014)	4,07,660
Annual Population Growth Rate (Census 2014)	1.65%
Population density (persons per square km), 2006	2.59
Urban population, 2006	35.0%
Population below 15 years of age, 2006	31.4%
Total Fertility Rate (MDHS 2009)	2.5
Contraceptive prevalence rate, (MDHS 2009)	34.7%
- Pills (MDHS 2009)	4.6
- IUD (MDHS 2009)	0.8
- Female sterilization (MDHS 2009)	10.1
- Male sterilization (MDHS 2009)	0.5
- Condom (MDHS 2009)	9.3
- Injectable (MDHS 2009)	1.2
- Any modern method (MDHS 2009)	27.0
- Any traditional method (MDHS 2009)	7.8
Not currently using (MDHS 2009)	65.3
Unmet need for family planning, (MDHS 2009)	28.1%
- Unmet need for spacing (MDHS 2009)	14.9
- Unmet need for limiting (MDHS 2009)	13.2
Median age at first marriage for girls (in years) (MDHS 2009)	20.0
Median age at first birth (in years) (MDHS 2009)	22.5
Crude birth rate (per 1000 population), (MoH 2016)	19
Maternal Mortality Rate (per 100 000 live births) , (MoH 2016)	44
Infant Mortality Rate (per 1000 live births) , (MoH 2016)	8
HIV adult prevalence rate (age 15-49 years), 2002	<0.01%*

* Maldives country update: 2013; Report on Global HIV/AIDS epidemic 2002/ UNAIDS

CONTRACEPTIVE PREVALENCE RATE (CPR)

While the average contraceptive prevalence rate (CPR) remains almost plateaued across South East Asia region, over the last decade, CPR in Maldives shows a gradual decline from 42% in 1999 to 35%in DHS 2009 over the same period of time (Figure 1.1). Per MDHS 2009, only about 35% couples were using a method of family planning. Majority, 65.3 %, were not using any contraceptive method.



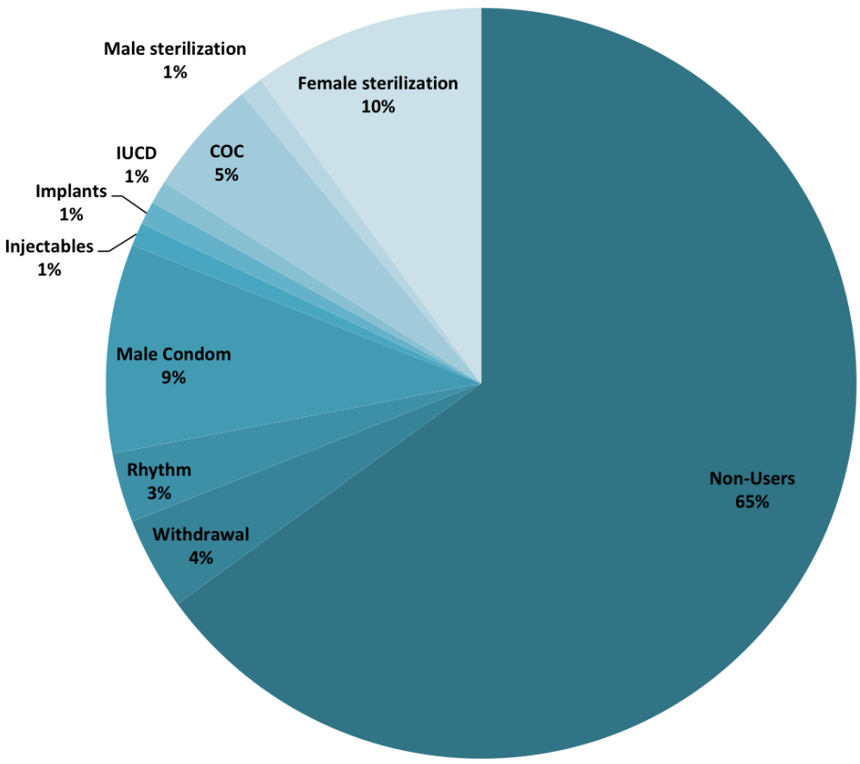
Contraceptives are an essential tool for maintaining desired birth interval for an improved maternal and child health. A wide range of reversible long and short term spacing methods and limiting/ permanent methods are available in Maldives. According to MDHS 2009 data, rural women had a slightly higher percentage (35 %) of contraceptive use as compared to urban women (34%).

Contraceptive use varied markedly by region, from 28% in South to 42% in Central region. Interestingly, the MDHS 2009 showed a general decline in CPR among educated women as compared to the uneducated.

Uneducated women showed CPR of (44%) as compared to educated women (27%), who are educated beyond secondary level.

35%
Contraceptive use
Rural women

34%
Contraceptive use
Urban women

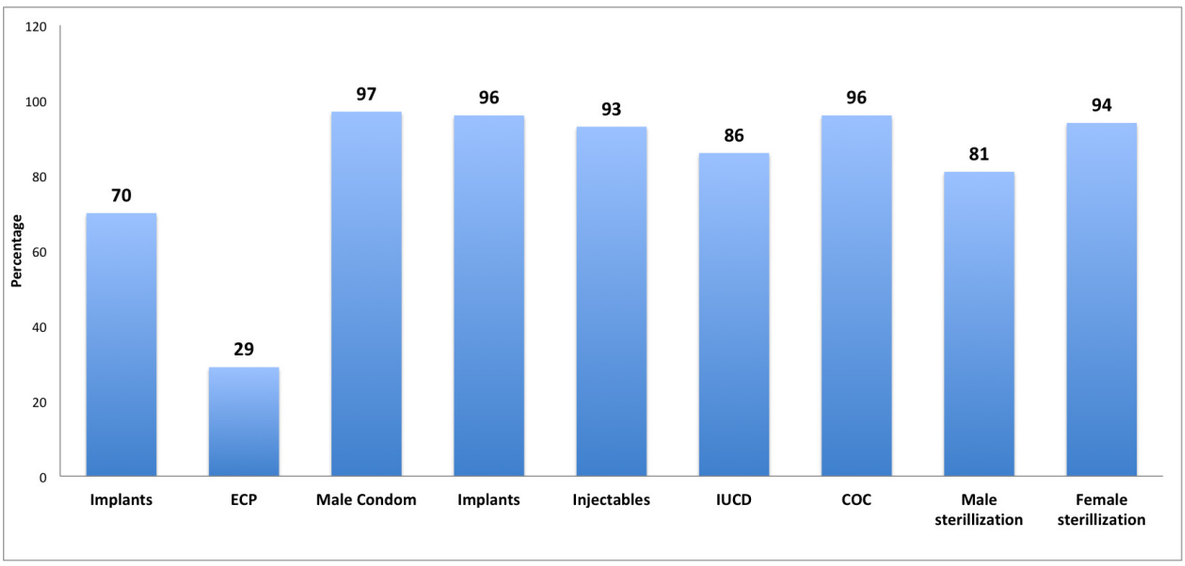


Per DHS Maldives, 2009, only 34.7% of the currently married women in the age group 15-49 years, were using a family planning method including traditional methods (Figure 1.2). Of the total users, majority, 10 % adopted female sterilization as, followed by male condoms (9%). Around 8% used traditional methods including Withdrawl, Rhythm and other Folk methods. Around 65% were not using any method. Despite availability of a range of modern FP methods, and good knowledge about different FP methods (Figure 1.3), their adoption was only 27%.

TOTAL FERTILITY RATE (TFR)

The latest TFR in Maldives is 2.5 (MDHS 2009). TFR is higher in rural areas (2.8 births per woman) as compared to urban (2.1 births per woman). The peak age for childbearing ranges from 25-29 years in urban women, where as it is 20-24 years in rural women.

Figure 1.3: Knowledge about modern contraceptives among currently married women (15-49 years) (MDHS, 2009)



The Government of Maldives adopted a policy to implement family planning programme in 1986. By 1990, the programme had reached across all the islands. Over the past 8 years, Maldives has had significant success in achieving Millennium Development Goal 5 (MDG 5). Some challenges, mainly due to unique geographic conditions in Maldives, still remain.

The revised National Standards for Family Planning Services that include updates from the Fifth Edition of the WHO, Medical Eligibility Criteria, 2015, and Standard Practice Recommendations, 2016, for different contraceptives, are aimed to provide updated technical information for family planning service providers to help address contraceptive needs of the couples and individuals. Improved family planning indicators in Maldives will further contribute in achieving the Sustainable Development Goals.

CHAPTER 1

CLIENTS' RIGHTS AND PROVIDERS' NEEDS

1.1 INTRODUCTION

"Reproductive rights embrace certain human rights that are already recognized in national laws, international human rights, and other relevant consensus documents. These rights rest on the recognition of basic rights of all couples and individuals to decide freely and responsibly the number and spacing of their children and to have the information and the means to do so and the right to attain the highest standards of sexual and reproductive health" (Para 95, Beijing Platform for Action, 1995).

Reproductive and sexual health care, including family planning, aims to improve the quality of life of an individual. A rights-based approach to the provision of contraceptives assumes a holistic view of clients, which takes into account clients' needs and considering all appropriate eligibility criteria in helping clients choose and use a family planning method.

Family planning services are a part of preventative health services. Therefore, the rights of the clients of family planning services should be seen in the context of the rights of the clients of health services. The fulfilment of the rights of FP clients should be a goal for programme managers and service providers. This goal is directly related to the availability and quality of FP information and services.

A quality focus in all areas of service provision is important as the quality of the services will influence the program outcomes. To achieve the goals of client-centered services, providers' needs should be met so they can provide quality services to the clients.

1.2 CLIENTS' RIGHTS

The following are the rights of clients:

1.2.1 RIGHT TO INFORMATION

Clients should be given adequate information in order to make an informed voluntary choice of a contraceptive method. Information given to clients to help them make this choice should include: understanding of the relative effectiveness of the method; correct use of the method; signs and symptoms that would necessitate a return to the clinic; information on return to fertility after discontinuing method use; and information on STI protection. They have the right to know where and how to obtain more information and services for planning their families.

1.2.2 RIGHT TO ACCESS

All clients have the right to receive services from FP programmes, regardless of their social status, economic situation, ethnic origin, geographical location or any other characteristics which may place individuals in certain groups. This means a right of access through various health care providers as well as other service delivery systems. FP programmes should take the necessary steps to ensure that services will reach all eligible individuals.

1.2.3 RIGHT TO CHOOSE

Eligible individuals or couples have the right to decide freely whether or not to practice family planning and the choice of contraceptive method. Family planning programmes should assist people in the practice of informed free choice by providing unbiased information, education and counselling as well as an adequate range of contraceptive methods.

A client's concept of acceptability and appropriateness changes with circumstances. Therefore, the right of choice also involves the client's decisions concerning discontinuation of a method of contraception, method switching and also where practical, a right to choose where to go for FP services and the type of service provider with whom they feel most comfortable. This choice may involve a choice of physical location of service delivery, e.g. FHO, CHO, Hospital, Health Centre or a FP clinic.

1.2.4 RIGHT TO SAFE AND QUALITY SERVICES

Family planning clients have a right to safety in the practice of family planning. This implies the following:

- Although it is well recognized that the benefits to health from family planning outweigh the risks, clients have a right to protection against any possible negative effects of a contraceptive method on their physical and mental health.
- Since all pregnancies represent a risk to health, the right of the client to safety also includes the right to effective contraception.
- When receiving family planning services, clients have a right to protection against other health risks which are not related to a method of contraception, for example, protection against the possibility of acquiring an infection through the use of contaminated instruments.

Safety relates to quality of service provision, including both the adequacy of the service delivery facility itself and the technical competence of the service providers. Ensuring the client's right to safety includes:

- Assisting the client in making an appropriate choice of contraceptive
- Screening for contraindications
- Using the appropriate techniques for providing the method if possible
- Teaching the client about the proper use of the method and ensuring proper follow- up
- Ensuring that the conditions in service delivery sites together with the equipment are adequate for the provision of safe services
- Ensuring that any complications or major side effects receive appropriate treatment, if this treatment is not available at a particular service station/site, the client should be referred to another facility.

1.2.5 RIGHT TO PRIVACY

When discussing his/her needs or concerns the client has a right to do this in an environment in which she/he feels confident. The client should be aware that her/his conversation with the counsellor or service provider will not be overheard by other people. When a client is undergoing a physical examination it should be carried out in an environment in which his/her right to bodily privacy is respected. The client's right to privacy also involves the following aspects related to quality of services:

When receiving counselling or undergoing a physical examination, the client has the right to be informed about the role of each individual inside the room, besides those providing services, e.g. training students, supervisors, instructors, researchers, etc. Where the presence of individuals undergoing training is necessary, prior permission of the client should be obtained.

A client has a right to know in advance the type of physical examination which is going to be undertaken. The client also has a right to refuse any particular type of examination if she/he does not feel comfortable with it or to request this examination to be done by another provider.

Any case-related discussion held in the presence of the clients (particularly in a training institution) should involve and acknowledge the client and not talk over the client. It is, after all, the client's sexual and reproductive organs and functions that are under discussion.

1.2.6 RIGHT TO CONFIDENTIALITY

The client should be assured that any information she/he provides or any details of the services received will not be communicated to third party without his/her consent. As such, family planning services should be performed in conformity with the local legal requirements and in accordance with ethical values.

A breach of confidentiality could cause the client to lose confidence and trust in the staff of a service delivery programme.

In accordance with the principle of confidentiality, service providers should refrain from talking about clients by name or in the presence of other clients. Clients should not be discussed outside the service site. Clients' records should be kept closed and filed immediately after use. Similarly, access to client records should be controlled.

1.2.7 RIGHT TO DIGNITY

Family planning clients have a right to be treated with courtesy, consideration, attentiveness and with full respect for their dignity regardless of their level of education, social status or any other characteristics which would single them out or make them vulnerable to maltreatment.

1.2.8 RIGHT TO COMFORT

Clients have a right to feel comfortable when receiving services. This right of the client is closely related to adequacy of service delivery sites which should have proper ventilation, lighting, seating and toilet facilities. The client should spend only a reasonable amount of time at the premises to receive the required services. The environment in which the services are provided should conform to cultural values, characteristics and demands of the community.

1.2.9 RIGHT TO CONTINUITY OF CARE

Clients have a right to receive services and supply of contraceptives for as long as they need them, as long as there are no adverse side effects. The services provided to a particular client should not be discontinued unless this is a decision made jointly between the provider and the client. In particular, a client's access to other services should not depend on whether she/he continues or discontinues the contraceptive services. The client's right to continuity of service includes referral and follow-up.

1.2.10 RIGHT TO OPINION

Clients have a right to express their views on the service they receive. Clients opinions on the quality of services, in the form of appreciation or complaint, together with their suggestions for changes in the service provision, should be viewed positively in a programme's ongoing effort to monitor, evaluate and improve its services.

1.3 PROVIDERS' NEEDS

Systems and capacity needs to be in place to support the work of the pro-viders, which include:

- Information, training and skills development
- Adequate supplies, equipment and infrastructure
- Good quality management and supervisory support at the facility and regional levels

1.3.1 NEED FOR INFORMATION, TRAINING AND SKILL DEVELOPMENT

Service providers should have access to competency-based training so they can acquire the knowledge, skills and confidence needed to perform family planning services – counselling, client assessment, ensuring eligibility to use family planning methods, techniques of providing the methods and follow-up care in a holistic way. They should also be trained and skilled in identifying side effects and complications to manage them effectively. Training and refresher training should emphasize both technical and communication skills.

1.3.2 NEED FOR ADEQUATE SUPPLIES, FUNCTIONING EQUIPMENT AND INFRASTRUCTURE

Service providers need to have the appropriate physical facilities and organization to provide quality services. Providers also need continuous and reliable supplies of family planning methods, expendable and non-expendable supplies (refer to Appendix A), counselling and educational material, and appropriate job aids to enable them to provide safe and effective services.

1.3.3 NEED FOR QUALITY MANAGEMENT AND SUPERVISORY SUPPORT, AT THE FACILITY LEVELS

To meet this need, supervisors (facility/clinical/area supervisors) should use the approach of facilitative supervision which emphasizes the supervisor's role in facilitating quality improvement among a team of staff. It also emphasizes mentoring, joint problem solving and two-way communication between a supervisor and those being supervised. In order to facilitate change and improvement and to encourage staff to solve problems, supervisors must have the solid technical knowledge and the skills needed to perform tasks, know how to access additional support as needed, and have time to meet with the staff they supervise. Supervisors should also ensure that providers have opportunities to refresh and update their knowledge and skills.

CHAPTER 2

OVERVIEW OF FAMILY PLANNING METHODS AND SERVICE PROVISION

2.1 INTRODUCTION

A range of family planning methods are available in Maldives. A method that is most suitable can be chosen. The role of the provider is to assist the client to make an informed decision and provide the chosen method.

2.2 AVAILABLE FAMILY PLANNING METHODS: NATIONAL FAMILY PLANNING PROGRAMME

Table 2.1: Available Contraceptive Choices Under the National FP Programme, Maldives

INDICATORS REVERSIBLE/ SPACING METHODS	
Long Acting Reversible Contraceptives (LARC)	IUD (380 A) for interval and post-partum insertions Progesterone Only Injectables/ Depo Medroxy Progesterone Acetate (DMPA) I/M Implanon/ Progesterone only Implants
Short Acting Reversible Contraceptives	COCs, POPs, ECPs and Condoms
Fertility Awareness Based Methods	Standard Days Method Cervical Mucus Method (Two Day Method) Sympto-thermal Method
Other Traditional methods	Coitus Interruptus (Withdrawl Method)
LIMITING METHODS	
Female Sterilization	Laparoscopic Sterilization Mini-lap Sterilization Post-Partum Sterilization
Male Sterilization	Non-Scalpel Vasectomy (NSV)

None of the contraceptive methods is perfect and side effects are seen with all methods of contraception.

A brief description of modern methods, how they work, their effectiveness in preventing pregnancy and their advantages and disadvantages are given in Table 2.2.

Table 2.2 Selected characteristics of modern family planning methods and effectiveness

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Male condom	• A sheath made of latex, which when put on the erect penis during sexual intercourse and taken off carefully after intercourse prevents the ejaculate from spilling inside the woman and thus prevents pregnancy and STIs including HIV/AIDS • A fresh condom is to be used with each act of intercourse	98	85	• Easy to use • Readily reversible birth control method for men • Protects against STIs including HIV/ AIDS (dual protection) • Dual method use refers to using a barrier method for protection against STI/HIV and another method for contraception • Fairly effective if used correctly and consistently • Can be used with other contraceptives where risk of STI / HIV is present • Dual protection refers to preventing both STI/HIV and unwanted pregnancy. This can be achieved by the correct and consistent use of condoms alone or by simultaneous use of 2 methods, one of which is a condom.	• A fresh condom is to be used with each act of intercourse • Failure rate is high if not used correctly and consistently • May interfere with sexual activity • High level of motivation required to use a condom consistently and correctly • Small risk of slipping, tearing and semen spillage, if not used correctly • Difficulty in disposing used condoms • Quality of condom can deteriorate if not stored properly • Allergy to latex (very rare)

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Combined Oral Contraceptives (COCs)	• COCs are tablets/pills that contain female sex hormones (estrogen and progestogen) similar to the ones naturally present in the body. COCs should be taken daily • COCs prevent pregnancy by suppressing the release of ovum and thickening the cervical mucus, preventing sperm from passing through	99.7	92	• Very effective when used correctly and consistently • Easy to use • Safe for most women • Non invasive • Reversible (can stop the pill on her own whenever desired by the client with no loss of fertility) • Does not interfere with sexual act • Can improve menstrual problems • Protects from cancers of the uterus and ovary and benign breast disease	• COC should be taken for 7 continuous days in order to suppress ovulation. The effect of each tablet lasts only for 48 hours • Not appropriate for mothers who are breastfeeding infants less than 6 months old as it may decrease the quantity of milk • Does not protect against STIs/ HIV • Effectiveness of the pill decreased in women who are on long term treatment for tuberculosis (rifampicin), anti-convulsants and on certain antibiotics (griseofulvin) • Minor side effects (such as headache, Amenorrhea/ Oligomenorrhea, Bleeding in between periods or spotting, Nausea, weight gain, high BP, etc.) are most common during the first 3 months of use and these usually disappear with continued use • Serious side effects (heart attack, stroke) with low-dose pill are rare • High risk for women who smoke and above 35 years • Women, who smoke, whether they use the pill or not, are at increased risk for heart attack or stroke.

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Pills (POPs)	• POPs are tablets/ pills that contain progesterone • **POPs provide protection against pregnancy by:** - Thickening cervical mucus making it difficult for sperm to pass through. - Making the endometrial lining thin and thus not suitable for pregnancy. - Ovulation is suppressed in about 50% of POPs users • POP should be used for at least 48 hours to achieve the contraceptive effect on cervical mucus.	99.7	92	• Very effective when used correctly and consistently • Easy to use • Reversible (no loss of fertility • Non-invasive • Not related to sexual activity • Can be used by breastfeeding women • Does not inhibit lactation • Can be used for women less than 6 weeks after delivery (WHO MEC 2015)	• Has to be taken daily at the same time • User's motivation is essential • Does not protect from HIV/AIDS • Effectiveness may be decreased in women on long term Tuberculosis (Rifampicin) therapy or on anti-convulsants • Irregular menstrual cycles are reported in some women • Headache, breast tenderness • Common side effects: disruption of menstrual pattern: irregular periods, spotting or bleeding between periods and amenorrhea • Less common side effects: headache and breast tenderness

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Progesterone only injectable (Depo Provera is the POI commonly available in Maldives)	• POI contains a female sex hormone (progestogen) similar to the one in the body • The injectable provides effective protection against pregnancy mainly by: -Making it difficult for the sperm to pass through -Making the endometrium thin, which is not suitable for pregnancy -Single injection of Depo Provera prevents pregnancy for 3 months	99.7	97	• Very effective when used correctly and consistently • Easy to use • Non-invasive, reversible • Does not interrupt sexual activity • Can be used by breastfeeding women • Does not inhibit lactation • Can be used from 6 weeks after delivery • Effective within 24 hours of receiving the injection • No daily pill taking • Decreases menstrual blood loss and duration, thus reduces anaemia • PID less common as compared to non-users due to cervical mucus thickening	• Disruption in menstrual bleeding patterns • Provider dependant • Does not protect against RTIs/ STIs including HIV/AIDS • Delayed return of fertility (median delay 10 months for Depo Provera) • Menstrual irregularities/ Amenorrhea / Prolonged bleeding (for more days than normal) in the first month of use • Weight gain (less common) Headaches or dizziness (less common)

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Hormonal implants (Implanon)	• Hormonal implant Implanon consisting of single non-biodegradable rod, measuring 2mm in diameter and 40 mm in length,containing 68 mg of Etonogestrel. The Implanon rod is inserted sub-dermally under local anaesthesia. • **Mechanism of action:** - Acts by thickening the cervical mucus preventing sperms to pass through - Protects within 24 hours after insertion - Also suppresses release of the ovum.	99.95	99.95	• Very effective • Does not interfere with sexual activity • Long term contraceptive (Implanon is effective for 3 years) • Reversible contraceptive • Does not require daily pill taking • Prompt return of fertility after rod is removed • Hormonal implants are effective within 24 hours after insertion • Can be started from less than 6 weeks of childbirth	• Provider dependent • Effectiveness of the implant may be decreased in women on long term treatment for tuberculosis (rifampicin), anti-convulsants • Menstrual irregularities: spotting, intermittent bleeding, amenorrhea • Prolonged bleeding – uncommon and often decreases after first few months of use • Does not protect from STIs including HIV/AIDS • Other less common side effects are: headache, dizziness, breast tenderness, nausea,weight gain • Most side effects stop spontaneously within the first few months of use

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Intrauterine contraceptive device (IUD) Cu T 380A is the commonly available Copper IUD in Maldives.	• Cu T 380 A is a T-shaped device with copper wires on the arms and a vertical stem. • CuT is placed in the uterine cavity. • Mechanism of action: - prevents pregnancy by interfering with the movement of the sperm - reducing the ability of the sperm to fertilize an egg - preventing implantation of the embryo. • IUD can be inserted in the post-partum period and during the interval period, during or within 12 days of the menstrual cycle	99.4	99.2	• Very effective for long-term reversible contraceptive • Effective for 10 years • Effective immediately after insertion • Does not interfere with sexual intercourse • One-time insertion procedure and does not require supplies regularly • Cost effective as no expenses for re-supplies • Can be used by breastfeeding women • Does not interact with any medicines that the client might be taking • Return of fertility immediately after removal • Helps protect against risks of pregnancy	• Does not protect from STIs including HIV/AIDS • In the first week: mild cramps, bleeding or spotting • In the first 3 months: longer and heavier periods, increased cramps during periods, bleeding or spotting between periods and expulsion of Copper T (partial or complete) • Dependent on provider • Perforation of uterus Lost Copper T thread • Infections of the genital tract due to poor infection prevention practices.

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Female sterilization (Tubal occlusion)	• Female sterilization is performed through a small cut in the lower part of the abdomen. The tubes that transport ovum from the ovary to the uterus are cut / occluded so that the ovum cannot reach the uterus. The procedure can be performed laparoscopically and also through the conventional surgical method • In laparoscopic procedure, a small ring is applied on each tube to occlude the tubes	99.5	99.5	• Very effective • Usually safe surgical procedure • Permanent method of family planning • No need to take pills daily, go for repeat injections or reinsertions • Effective immediately after the procedure • Does not interfere with sexual act • No effect on breast feeding • Mini-laparotomy can be performed immediately after the birth of a child	• Provider dependent • Uncommon complications of surgery: infection or bleeding at incision, internal infection or bleeding, injury to internal organs, risk of anaesthesia • Does not protect from RTI/STIs including HIV/AIDS • Irreversible method

Method	What is it and how it works	Effectiveness		Advantages	Disadvantages/ Limitations
		Perfect Use %	Typical Use%		
Male sterilization (Non Scalpel Vasectomy/ NSV)	• NSV in men is performed through a small opening on the scrotal skin, the tube that carries the sperm is cut so that sperm cannot reach the ovum and fertilization is prevented	99.9	99.85	• Very easy to perform, small, quick procedure leads to life- long, safe and effective family planning • Very effective permanent method of family • No interference with sex • Does not affect the man's ability to have sex • Safer than female sterilization procedure	• Trained provider dependent surgical procedure • NSV is effective only after 3 months of the procedure, and during this period condoms or another effective family planning method should be used until semen analysis confirms azoospermia • Does not protect from RTI/STI including HIV infections

*Source: Adapted from World Health Organization, *Medical Eligibility Criteria for Contraceptive Use*, 5th edition WHO, Geneva, Switzerland. 2015 and Selected practice recommendations, WHO 2016.

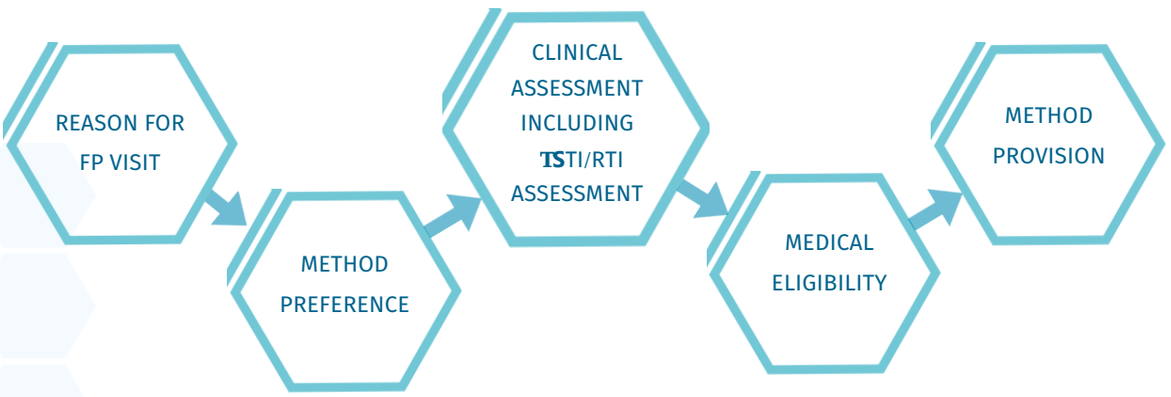
2.4 FAMILY PLANNING SERVICE PROVISION

Client attending a family planning clinic are usually interested in a method of contraception that they may have in mind and they might have other concerns as well. Often there are other issues that need to be discussed before a client can choose and be provided a contraceptive method that meets his/her needs.

2.4.1 STEPS IN DECISION MAKING AT A FAMILY PLANNING

Starting with the reason for the visit to the family planning clinic, a health care provider then goes through a sequence of steps to assist a client to reach a decision about a suitable family planning method and provides the method. Figure 2.1 illustrates the sequence of steps in decision making. These steps include determining the client's preferred method, clinical assessment including STI/RTI assessment, reviewing client's medical eligibility for that method and providing the chosen method. However, a provider might need to adapt the approach to meet an individual client's need. The steps used in decision making are described below.

FIGURE 2.1: OVERVIEW OF STEPS IN DECISION MAKING AT INITIAL FP VISIT



DETERMINE METHOD PREFERENCE BY:

- Asking if the client has any particular method in mind (Women who are given their preferred method use it longer and with greater satisfaction)
- Assessing contraceptive needs
- Assessing STI protection needs
- Describing options and helping client make a choice. (For further details refer to Chapters 6 to 14)
- Refer to Chapter 3 for discussion on client provider interaction and counselling.

CLINICAL ASSESSMENT INCLUDING STI/RTI ASSESSMENT BY:

- Taking a history and performing relevant clinical examination and laboratory tests, if indicated.

REVIEW MEDICAL ELIGIBILITY FOR PROVIDING A FP METHOD BY:

1) Using WHO's MEC Wheel as a tool to select a suitable FP method
2) Evaluating suitability of the preferred method or methods.

Refer to method-specific Chapters 6 to 14 for further details.

CHAPTER 3

COUNSELLING AND INFORMED CHOICE

3.1 INTRODUCTION

Counselling is a critical element of quality family planning services. Family planning counselling is the process of two-way face to face communication by which the counsellor assists the client to make a decision about fertility and contraceptive options. The counsellor provides accurate and complete information, addressing the client's particular reproductive health needs, concerns and goals.

Informed choice is the process by which a client makes a voluntary, well considered decision about his/her reproductive health (RH) needs. The client arrives at this decision based on accurate information in an environment of full information about available methods and resources.

3.2 OBJECTIVES OF CONTRACEPTIVE COUNSELLING

The purpose of family planning counselling is to assist individuals or couples to:

- decide whether they need and want contraception
- freely make the choice of contraception needed
- learn, understand and use the chosen method properly
- reduce anxieties, if any
- initiate the use of appropriate contraceptive method
- use the contraceptive method effectively
- switch to another method to avoid pregnancy
- prevent STIs, including HIV/ AIDS, and seek early treatment for STIs.
- confidentiality and privacy should be ensured at all counselling sessions. Encourage spouse to accompany for counselling. Wherever possible the spouse should also be counselled.

3.3 CATEGORY OF PROVIDER

Counselling can be done by any staff member with appropriate training, or a counsellor per se. General and method-specific family planning counselling can be provided by specialists (gynaecologists, surgeons) medical officers, staff nurses, community health officers (CHO) and family health officers (FHO). It is important that providers have had reproductive health counselling training prior to service provision.

3.4 PRIVACY AND CONFIDENTIALITY

Privacy and confidentiality are essential for all aspects of family planning services - counselling, client assessment and method provision and follow-up care. Clients will avoid a health care facility, sometimes travelling to a distant clinic, to preserve anonymity if they feel that their privacy and confidentiality are not respected or that service providers are critical and judgmental.

Visual and auditory privacy should be ensured and family planning services should be provided in an area separate from the waiting area, so that people in the waiting area cannot see or hear the discussion and the services being provided.

3.5 CLIENT-PROVIDER INTERACTIONS

Verbal interactions and sharing of information between the provider and client during each step of a family planning procedure help alleviate client fears and concerns. When a client feels safe and is confident in the provider's skills, the client will be more cooperative. Educating the client about potential side effects and relieving concerns correlate positively with long-term use of temporary family planning methods. The following are the behaviours to be modelled by staff when interacting with clients:

- Treat the client with respect, exhibiting friendly, calm behaviour in an unrushed manner.
- Listen attentively to assist clients to discuss their family planning.
- Treat all clients as equals when providing services.
- Speak in a language understood by the client and use simple terminology understood by the client.
- Assure confidentiality concerning the client's information.
- Use open ended questions, giving the client opportunity to give more information.
- Describe how the client can be helpful during the procedure and what to expect before, during and after the procedure.
- Provide the client an opportunity to ask questions and address concerns.
- Assure that client's modesty is maintained.
- Address doubts, fears, myths or misconceptions held by the client
- Minimize the client's anxiety.

3.6 COUNSELLING PROCESS

Family planning counselling is to be provided wherever family planning methods are available. The counselling session may be an individual session (client and service provider) or a couple counselling session (client with partner and service provider). If a client requests and desires it, a close friend or family member may be present in the counselling session.

Family planning counselling is provided using either the GATHER2 approach or the REDA3 approach. Appropriate job aids such as flip charts, samples of available FP methods etc. should be used to conduct the counselling session.

Male involvement and participation in reproductive health is important not only for preventing pregnancy, but also for prevention of STIs including HIV/AIDS. It also promotes communication between spouses.

3.6.1 CHOICE OF METHOD

Clients should make their own informed choice of method. It is the counsellor's duty to assist them to make the right choice. Often the client has a particular method in mind. The counsellor could start by asking whether the client has any particular method in mind

[2] GATHER is an acronym for Greet, Ask, Tell, Help, Explain, Return visit 3 REDA is an acronym for Rapport, Explore, Decide, Act and what their family planning needs are, i.e. birth spacing, delaying pregnancy or limiting births.

3.6.2 METHOD-SPECIFIC COUNSELLING

Once a client has chosen a FP method, method-specific counselling should be done as described below:

- Counsel every time a client visits: during the first visit and each subsequent visit.
- Ensure that privacy and confidentiality are maintained at all times.
- Establish rapport with the client.
- Ask the client what she/he knows about the specific method, assess if she has any myths and misconceptions about the method and if she/he has any past experience with the method.
- Provide information as relevant and clarify doubts. If the client is new, provide the information given below (**show the contraceptive chosen while providing information**):
    - effectiveness and return to fertility
    - mechanism of action
    - advantages, disadvantages
    - clarify myths and misconceptions
    - when to start using the contraceptive (in relation to menstrual period)
    - instructions on use (where relevant) emphasizing the importance of following instructions and what to do if the instructions are not followed
- If the client is convinced about the decision to use the method, assess the client for medical eligibility as detailed in Chapters 4, 5 and 6 to 14 on specific contraceptive methods.
- Record history and findings in the client record.
- If found eligible for using the method as described in Chapters 4, 5 and 6 to 14, demonstrate the use of the contraceptive or describe the procedure as described in specific sections in Chapters 6 to 14.
- Ask the client to repeat instructions (where relevant).
- Tell the client about:
    - Likely problems/side effects in the first three months and what to do in such situations
    - Situations when condom use is advised (risk of pregnancy due to non- compliance, conditions that affect the effectiveness of the method or exposure to STIs)
    - If condom use is advised, how to use the condoms (ask to repeat the instructions on the use of condoms)
    - Storing the contraceptive (where relevant)
    - Follow up.

3.6.3 IF CLIENT HAS NOT CONSIDERED A PARTICULAR METHOD

Assess the level of knowledge the client has about contraceptive or family planning methods that are available at the clinic.

Assess what her needs are: is it for birth spacing, delaying births or to limit births?

Explain the methods available to the client and give additional information on the method chosen by the client. The following should be included:

- effectiveness of the method
- return to fertility
- how the method works and how it should be taken
- health and contraceptive advantages
- disadvantages
- possible side-effects
- encourage questions to discover and address the client's specific concerns, worries about myths and misconceptions she has heard about methods
- focus discussion on the advantages and disadvantages of the method chosen by the client
- specify the chosen method once the client has made up her mind, by asking a direct question: "Which method would you prefer?
- if a client needs more time to think and decide, then reassure him/her that he/she can return at his/her convenience. Counsel him/her to use condoms in the meantime.

3.6.4 SPECIAL SITUATIONS

If the client chooses a method that is contraindicated to her health conditions then she should be assisted in choosing another method.

If the method chosen by the client is not available at the centre or clinic, then a referral should be made to another clinic where such facilities are available.

Offer her/him an alternative method to be used until such time that the client can get the desired method.

If the client wants a permanent method (surgical method) then it must be explained that it is permanent and reversal may be impossible or very expensive. One must not forget that informed consent should be taken.

Age and parity specifications for sterilization should be followed. Refer to Chapter 14 on voluntary surgical sterilization.

3.7 COUNSELLING DURING FOLLOW-UP VISIT

At each follow-up visit it is important to counsel the client to ensure the continuation of the method:

- Ask the client whether she and her spouse are satisfied with the method.
- Check if the client is still using the method and whether the method is being used correctly or not.
- Discuss any health changes that might have arisen since the client's last visit and confirm/rule out problems reported or identify any new conditions that are contraindications for use of the method. Record findings.
- Ask about any history of pelvic pain or discharge from the vagina or any history suggestive of STIs in the spouse.
- Check if she wishes to become pregnant and assist her to stop the method.
- Assist the client to choose another method if the client has developed conditions that are contraindications for the method.
- Ask about problems and reassure/resolve as required. (Refer to method specific Chapters 6 to 14 for further information.)
- If the client is continuing with the method, ask them to repeat the instructions and what to do if problems arise.
- Provide supplies (where relevant) and record this in the Client Card.

3.8 COUNSELLING A CLIENT WHO WANTS TO CHANGE OR STOP USING A METHOD

It is important to counsel a client who wants to change or stop using a method:

- If the client wants to stop the method because of wanting another child, tell them about return of fertility. Provide information on antenatal care and childbirth, and discuss postpartum FP.
- If the client is stopping the method because of dissatisfaction with the method, provide counselling (repeat the benefits and side effects for method of use). If still not convinced, counsel about other contraceptive methods.
- If the client is stopping the method due to side effects that have persisted in spite of management of the problem, counsel for other methods.
- If the client develops conditions that are contraindications for use of the method, counsel about other methods.
- Record findings, reasons for stopping the use of method/switching over to another method, and advice given.

3.9 CLIENT'S WRITTEN CONSENT IS MANDATORY FOR PERFORMING THE SURGICAL STERILIZATION PROCEDURE IN MALDIVES

Below are the essential elements of voluntary surgical sterilization that the client must fully understand to obtain an informed consent:

- Temporary contraceptive methods are available.
- Voluntary sterilization is a surgical procedure.
- Risks as well as benefits are associated with the procedure, both of which must be explained.
- The procedure is permanent.
- Successful procedures result in the inability to bear any more children.
- There is a small possibility of method failure.
- The client can decide against the operation at any time (without losing the right to other medical, health, or other services or benefits).

CHAPTER 4

CLIENT ASSESSMENT

4.1 INTRODUCTION

Client assessment is necessary to ensure that clients are eligible for the use of the chosen method, and to ensure continuity of the method. The Selected practice recommendations for contraceptive use, 2016, WHO, has revised medical eligibility criteria for many contraceptives and removed a number of old contraindications based on the latest evidence and Guideline Development Group (GDG) recommendations. The revised recommendations and eligibility criteria are also included in separate chapters with the methods.

4.2 CLIENT ASSESSMENT

4.2.1 HISTORY

In the case of new clients, a history should include the following:

PERSONAL HISTORY:

Name, Age of the client

REPRODUCTIVE HEALTH HISTORY:

Number of children ever born, mode of delivery, number living and their sex, age of last child, desire for more children

If the last child is less than 6 months of age, history of breastfeeding, frequency, any supplementary feeding, etc.

MENSTRUAL HISTORY:

Date of last menstrual period, duration of cycles, regularity, etc.

MEDICAL HISTORY:

History of heart disease, stroke, hypertension, diabetes, liver disease, cancer of the breast and genital tract, convulsions, migraine and mental illness, history of tuberculosis and convulsions as some of the medicines affect the effectiveness of the oral contraceptives

Box 3.1 INFORMED CONSENT

Informed consent is the client's voluntary decision to undergo a family planning procedure, in full possession and understanding of the relevant facts.

In Maldives, informed consent is taken verbally for all methods. The consent form is a legal authorization for the procedure to be performed.

The consent form becomes a legal document when signed/marked by the client. A consent is valid and binding only if the client was fully informed and knowledgeable about the content of the consent before signing.

If a client is unable to read the consent form, staff must read or explain in detail the contents of the document in a language understood by the client.

Since surgical sterilization procedures are permanent, it is important that counselling is provided to both the client and spouse.

The person executing the consent also must sign the document.

The physician is the person ultimately responsible for ensuring that the informed consent is obtained with proper client understanding. Thus, the physician's role is to see that the family planning staff have ensured that the client and spouse signed the informed consent form with full understanding

SURGICAL HISTORY

History of planned major surgery with possibilities of prolonged immobilization is important as the risk of deep vein thrombosis is high among such people. While the latest MEC recommends COCs / CHC use among women with superficial venous thrombosis and varicose veins (MEC Category 1) and women with superficial venous thrombosis (SVT) can generally use CHCs (MEC Category 2). COCs / CHCs are not recommended in Deep Vein Thrombosis. History of abdominal major surgery will also be useful to decide the type of female sterilization, type of and the level of facility where female sterilization should be performed.

CONTRACEPTIVE HISTORY:

History of contraceptive use and past experience with the method– this information is important while advising on a particular contraceptive.

Box 4.1 MEC categories for contraceptive eligibility- WHO

Category 1 A condition for which there is no restriction for the use of the contraceptive method

Category 2 A condition where the advantages of using the method generally outweigh the theoretical or proven risks

Category 3 A condition where the theoretical or proven risks usually outweigh the advantages of using the method

Category 4 A condition which represents an unacceptable health risk if the contraceptive method is used.

HISTORY OF STIs AND SEXUAL HISTORY:

Women at increased risk of STIs can get an IUD inserted (MEC 2015 Category 2). However, women with very high individual risk of STIs should not have an IUD inserted unless appropriate testing and treatment occur (MEC Category 3).

Follow-up clients: In case of revisiting clients, menstrual history, exposure to/risk of STIs, and any new medical problem/treatment and other information as relevant should be asked and recorded.

4.2.2 PHYSICAL EXAMINATION

- **General and systematic examination** (e.g., pallor, jaundice, pulse, blood pressure - if possible)
- **Abdominal and pelvic examination** to rule out liver disease, pelvic inflammatory disease, determine eligibility for use of IUDs and pre-operative assessment for female sterilization
- **Breast examination** – Though breast examination is not mandatory, all clients should be educated on how to perform breast **self-examination** and advised to consult a doctor if any abnormality is noted.

4.3 RECORD

Findings should be recorded legibly in the client card and hospital / clinic records.

4.4 RULING OUT PREGNANCY

Pregnancy should be ruled out prior to the provision of contraceptive methods combined oral contraceptive pills (COCs), progestogen-only pills (POPs), progestogen only injectable (POI), hormonal implants, IUDs, surgical sterilization and emergency contraception.

INDICATIONS FOR A PREGNANCY TEST

A pregnancy test is indicated in all clients who have one or more of the following:

- Missed period/s
- Abnormal vaginal bleeding
- Irregular cycles
- Lactating with irregular bleeding or amenorrhea
- Signs and symptoms of pregnancy such as (early morning nausea, vomiting, breast tenderness).

4.5 INTERPRETATION OF CONTRAINDICATIONS AND PRECAUTIONS

The definitions given below are more relevant for higher level facilities where specialists are available. In the case of Health Posts and Health Centers, the classification provides guidance to the health worker on conditions that need a consultation with a specialist before providing the specific method.

CONTRAINDICATIONS

A contraindication is any condition where there is unacceptable health risk if the contraceptive method is used. In such conditions, the method should not be advised. (MEC Category 4)

PRECAUTIONS

A precaution is condition where the risk outweighs the advantages of the method. However, the method can be provided after consultation with a specialist and requires follow up.
(MEC Category 3)

4.6 MEDICAL ELIGIBILITY CRITERIA - WORLD HEALTH ORGANIZATION (WHO)

The fifth edition of Medical Eligibility Criteria (MEC) 2015, the latest in the series of periodic updates by WHO, provides revised guidance on the safety of various contraceptive methods, for use in specific health conditions. The revised WHO MEC wheel can be used to identify whether the contraceptive method worsens the medical condition or whether the medical circumstance makes the contraceptive method less effective.

Depending on the individual, more than one condition will need to be reconsidered before providing contraceptives. Characteristics, such as, age, weeks / months after delivery, breastfeeding status, superficial venous thrombosis, hyperlipidemia, history of cardio-vascular disease, or liver disease etc., are to be considered for medical eligibility of a contraceptive.

Adherence to eligibility criteria helps in proper selection of clients, contributes to reducing the chances of side effects, leading to improved continuation of the method. The safety of the method should be weighed along with the benefits of preventing unintended pregnancy.

The eligibility criteria are based on evidence from studies, research and clinical experiences. They are classified by WHO into four categories:

THE MEDICAL ELIGIBILITY CRITERIA WHEEL

The MEC wheel guides family planning providers in recommending safe and effective contraception methods for women (and men) with medical conditions or medically-relevant characteristics, to find a contraceptive method that works for them. For each medical condition or medically relevant characteristic, contraceptive methods are placed into one of the four numbered categories (Box 4.1).

This simple classification enables family planning providers to provide contraception safely to clients who previously may have been excluded from methods because of a lack of clinical guidance.

MEDICAL ELIGIBILITY CRITERIA WHEEL FOR CONTRACEPTIVE USE 2015

Link to WHO MEC Wheel 2015:

https://apps.who.int/iris/bitstream/handle/10665/173585/9789241549257_eng.pdf;jsessionid=48BDB4FF431092E4C7E0E7A27C77C0B5?sequence=1

CHAPTER 5

ASSESSING SEXUALLY TRANSMITTED INFECTIONS (STIs) AND REPRODUCTIVE TRACT INFECTIONS (RTIs) DURING ROUTINE FAMILY PLANNING VISITS

5.1 INTRODUCTION

The family planning visit is an opportunity to prevent not only unwanted pregnancies but also infection (dual protection). It is also a chance to detect some silent STIs/RTIs and to offer treatment to symptomatic women who may not otherwise use health services.

Many women and men with an STI/RTI do not have symptoms or have minimal symptoms and do not realize anything is wrong. In women, silent asymptomatic infections can be more serious than symptomatic ones. Syphilis, Gonorrhoea and Chlamydia are often asymptomatic yet have serious consequences.

Clients may visit health facilities/clinics for another reason such as family planning. Identifying and treating such clients prevents the development of complications for the individual client and helps reduce transmission in the community. Thus, quality family planning services can contribute to prevention and early diagnosis of STIs/RTIs by promoting recognition of symptoms/signs and managing symptomatic clients during their routine visit for family planning.

Box 5.1 SYNDROMIC AND ETIOLOGIC MANAGEMENT

Syndromic management of STIs/RTIs refers to the approach of treating STI/RTI symptoms and signs based on the organisms most commonly responsible for each syndrome. Syndromic management guidelines are used for syndromes such as lower abdominal pain, urethral discharge, vaginal discharge, genital ulcer and inguinal bubo. In the syndromic approach treatment is provided without laboratory tests. If the client needs further tests then this can be done by referring the client to a specialist.

Etiologic management involves clinical examination followed by laboratory tests (microscopy, bacteriological examinations and serological tests) and treatment is based on the results of these tests.

The existence of a current STI/RTI is not in itself a reason to deny most contraceptive methods. Condoms, when used correctly and consistently, offer one of the most effective methods of protection against STIs and HIV.

ISSUES TO KEEP IN MIND

Most attending family planning clinics to obtain contraception and health care. Providers should bring up STIs/RTIs in a way that addresses the client's priorities. Four important points to keep in mind during client assessment are:

All sexually active individuals are potentially at risk of contracting an STI.

- Many are often not aware of their risk of STI. Providers should be sensitive to these issues in discussing risk of infection with, who may need dual protection.

- Condoms used consistently and correctly are highly effective for preventing both pregnancy and STI. These are the only methods that provide effective dual protection.

- Women with current STIs/RTIs are eligible for most contraceptive methods. However, the infection should be treated appropriately by clinician and steps taken to prevent future infection.

5.2 ASSESSING STI/RTI DURING FAMILY PLANNING VISIT

STI/RTI assessment and prevention should be mentioned at each family planning visit. The opportunities for addressing STI/RTI during the initial (choosing the method) visit and routine follow-up visits are different and should be treated separately.

5.2.1 DURING THE INITIAL FAMILY PLANNING VISIT

Women attending a family planning clinic for the first time are usually interested in contraception. The client's concern may or may not be about STI/RTI. However this is an opportunity to educate on STI/RTI.

Initiation of the discussion about STI/RTI should be timed appropriately. If STI/RTI assessment done too early, the woman might feel that her primary concern, i.e. contraception, is being overlooked.

5.2.1.1 HOW TO DO STI/RTI ASSESSMENT DURING INITIAL FP VISIT

Initiate client's STI/RTI protection during the discussion on clients preferred family planning method.
Perform STI/RTI assessment by history taking and/or by clinical examination. The key signs and symptoms of STIs/RTIs are:

- Presence of vaginal discharge
- Genital ulcer
- Lower abdominal pain
- Symptoms of STI in the partner.

CLINICAL EXAMINATION FOR WOMEN

- Pelvic examination (speculum examination and bimanual vaginal examination) is mandatory prior to the provision of IUD and female surgical sterilization, which provides the opportunity to check for associated STI/RTI.

- It is desirable that a pelvic examination be done on all women prior to initiating family planning as it is useful for evaluating STI/RTI concerns and also detecting some asymptomatic infections

CLINICAL EXAMINATION FOR MEN

- Genital examination is mandatory for all men considering vasectomy and this is an opportunity to assess for STI/RTI.

- Further evaluation and laboratory tests should be done as indicated by history and clinical examination. The extent of STI/RTI diagnostic or screening work up depends on the resources available at the facility.

MANAGEMENT OF STI/RTI

STI/RTI should be managed by etiologic management.

5.2.2 DURING FAMILY PLANNING FOLLOW-UP VISITS

There are various reasons for which a client returns to a family planning clinic. These reasons can include:

- Routine follow-up visit related to contraceptive methods
- Side-effects and concerns
- Symptoms of STIs/RTIs
- Irrespective of the reason, a follow-up visit is an opportunity to assess his/her needs and concerns especially those related to the family planning method being used, his/her STI/RTI protection needs and any current STI/RTI symptoms
- These return visits are also an opportunity to promote STI/RTI prevention through education and counselling

5.3 FAMILY PLANNING METHODS AND STI/RTI

Most family planning methods do not protect against STIs/RTIs. Some contraceptive methods might increase the risk of non-sexually transmitted RTI or their complications and clients may abandon a method and risk pregnancy if they think it is causing a problem. Yeast infection, for example, is more common in women using oral contraceptives. Providers should be aware of method-related problems and counsel clients about their management or assist clients to choose another method if the current method is unacceptable.

Dual protection refers to preventing both STI/HIV and unwanted pregnancies. This can be achieved by the correct and consistent use of condoms alone or by simultaneous use of 2 methods, one of which is a condom.
Dual method use refers to using a barrier method for protection against STIs/HIV and another method for contraception.

WHAT ARE STIs/RTIs?

Reproductive Tract Infections (RTIs) refers to infections of the genital tract. They affect both men and women. RTIs are caused in several ways. RTIs caused by overgrowth of organisms normally present in the reproductive tract are referred to as endogenous RTIs commonly seen in women. RTIs can be introduced from the outside into the reproductive tract during sexual contact – Sexually Transmitted Infections (STIs) – or by clinical procedures/interventions especially if infection prevention practices are not adhered (Iatrogenic RTIs). In men, STIs are much more common than Endogenous or Iatrogenic RTIs.

TERMINOLOGY

Reproductive tract infection is a broad term that includes infections that are sexually transmitted as well as other infections of the reproductive tract that are not transmitted through sexual intercourse. Not all Sexually Transmitted Infections (STIs) are reproductive tract infections; and not all reproductive tract infections are sexually transmitted. STI refers to the way of transmission whereas RTI refers to the site where infection develops.

Internationally the term STI/RTI is used to highlight the importance of STI within reproductive tract infections.

TYPES OF STIs/RTIs

Endogenous RTIs: Yeast Infection (Candidiasis), Bacterial Vaginosis.
STI: Gonorrhoea, Chlamydia, Syphilis, Chancroid, Trichomoniasis, Genital Herpes, Genital Warts, HIV, Hepatitis B Infection, Granuloma Inguinale, Lymphogranuloma Venereum.

5.4 KEY POINTS IN STI/RTI ASSESSMENT DURING FAMILY PLANNING VISITS

- Discuss STI/RTI prevention and concerns with all family planning clients at each visit. Promote dual protection (against pregnancy and STI/RTI) at every opportunity.
- Counsel clients that condoms can provide highly effective dual protection if used correctly, consistently and are the only method currently available for dual protection.
- While many women with risk of STIs can have an IUD inserted, some women with very high individual risk of STIs should not have an IUD inserted.
- Ask about symptoms in the partner. Women with symptomatic partners should be treated, and the treatment of partner arranged.
- Screen for STIs/RTIs whenever warranted. A blood test and a careful speculum examination can identify many silent STIs/RTIs.

CHAPTER 6

LOW DOSE COMBINED ORAL CONTRACEPTIVES (COCs)

6.1 INTRODUCTION

Combined oral contraceptive pills are preparations of synthetic Estrogens and Progestogens and this form of contraception is highly effective in preventing pregnancy. The discussion in this chapter is mainly on Monophasic low dose COC containing Ethinyl Estradiol 0.03 mg and Levonorgestrel 0.15 mg.

6.2 TYPES OF COMBINED ORAL CONTRACEPTIVE PILLS (COC)

In Maldives, the combined oral contraceptive pills that are widely and commonly available are low dose Monophasic pills (fixed concentration of Estrogen and Progesterone in each of the hormone containing pills throughout the menstrual cycle) and are available as 28 day pills. COCs are also available as 21 day pills. COCs are usually supplied in packs, each pack containing 3 cards one card for each month.

With 28 day pills, one pill containing hormones (active pill) is taken every day for 21 days, followed by the 7 placebo (inactive, non-hormonal) pills which are taken one pill each day for the last 7 days. With 21 day pills, all the pills are active (contain hormones) and one pill is taken every day for 21 days, then there is a break/interval from pill-taking for 7 days before starting a new pill card

The following 2 low dose COCs are commonly available in Maldives:

1. Microgynon ED contains Ethinyl Estradiol 0.03 mg and Levonorgestrel 0.15 mg. (28 day pills). The seven non hormonal pills contain Ferrous Fumarate 75 mg.

2. Rigevidon (28 day pills) contains Ethinyl Estradiol 0.03 mg and Levonorgestrel 0.15 mg. Each card contains 7 dummy pills i.e. pills without hormones.

Low dose COCs containing 20 microgram or less Ethinyl Estradiol might be available in Maldives. In addition, multiphasic COCs with two (biphasic [5]) or three (triphasic [6]) dose variations of estrogens and /or progestogens throughout the menstrual cycle might also be available in Maldives.

[5] Biphasic pills typically contain 2 different progesterone doses. The progesterone dose is increased about halfway through the cycle.

[6] Triphasic pills gradually increase the dose of Estrogens through the cycle (some pills also increase the dose of Progestogen). Three different increasing pill doses are contained in each cycle 0.03 mg and Levonorgestrel 0.15 mg.

6.3 EFFECTIVENESS AND RETURN TO FERTILITY

EFFECTIVENESS

Among COC perfect users (users who miss no pills and follow instructions consistently and correctly) it is highly effective (99.7%). Among COC typical users, it is only about 92% effective. Pregnancy rates during COC typical use are determined by the extent and type of imperfect use.

RETURN TO FERTILITY

When the woman stops taking the COC, her fertility returns to normal soon after stopping. Use of the pill does not alter a woman's capacity for normal fertile cycles. If a woman does not resume normal cycles after stopping the COC, a specific cause other than pill use should be sought.

6.4 CATEGORY OF PROVIDERS

COC pill can be provided by any health worker who has been trained to explain pill use, manage minor side effects and explain alternative methods of contraception. The following providers can provide COC: family health officer (FHO), community health officer (CHO), community health supervisor (CHS), staff nurse, medical officer and gynaecologist.

6.5 ELIGIBILITY CRITERIA

Combined oral contraceptive pills (COCs) should be provided to any woman who requests COC, receives appropriate counselling, makes an informed decision and who does not have any contraindications for its use.
The effectiveness data is the percentage of women without unintended pregnancy within the first year of use.

6.5.1 ELIGIBILITY CRITERIA FOR LOW DOSE COMBINED CONTRACEPTIVE PILLS (WHICH WOMEN CAN SAFELY USE COCS)

In general, most women can use low dose combined oral contraceptives safely and effectively in the following circumstances:

- If they have children or not
- Their weight
- Are of any age, including adolescents and over 40 (upto 40 years MEC cat 1 and > 40 years MEC Cat 2)
- Smoke cigarettes but are under 35 years of age
- Have just had an abortion or miscarriage (provide COCs before discharge)

Also, women with following conditions <u>can use</u> low-dose COCs (combined oral contraceptives) in any circumstances:

- Heavy, painful menstrual periods or iron deficiency anaemia (condition may improve)
- Irregular menstrual periods
- Benign breast disease
- Diabetes **without** vascular, kidney, eye or nerve disease and for less than 20 years
- Mild headaches
- Varicose veins
- Superficial venous thrombosis (MEC cat 2)
- Women who are more than 42 days postpartum can use COCs, if they are not breastfeeding. (Cat 1). If breastfeeding, follow criteria as below in section 6.5.2.
- Women with known Dyslipidemias without other cardio-vascular risk factors (MEC Cat 2)
- Thyroid disease
- Pelvic inflammatory disease
- Endometriosis
- Benign ovarian tumour
- Uterine fibroids
- Past ectopic pregnancy
- Tuberculosis, and not taking Rifampicin

Women with following conditions have an unacceptable health risks with Combined Oral Contraceptives (COCs) and such women <u>should NOT</u> use COCs

- Breastfeeding women within 6 weeks to 6 months of postpartum
- Women aged more than 35 years, who smoke more than 15 cigarettes per day
- Multiple risk factors for arterial cardiovascular disease
- Having hypertension with systolic BP 140-159 and diastolic 90-99 and more and those having vascular disease.
- Women with a clear history of Deep Vein Thrombosis (DVT), pulmonary thrombosis or current DVT
- Women having known Thrombogenic mutations.
- Current history of Ischemic heart disease or known Hyperlipidaemias (Women with known Dyslipidaemias without other known cardio vascular risk factors can generally use CHCs (MEC Category 2)
- Those suffering from complicated pulmonary hypertension, risk of atrial fibrillation,history of subacute bacterial endocarditis
- Migraine with aura
- Current breast cancer
- Diabetes with neuropathy, retinopathy, nephropathy and other vascular disease
- Acute hepatitis or severe cirrhosis of the liver or benign or malignant liver tumours

Combined low dose oral contraceptive pills (COCs) do not protect against STI/HIV.
If there is a risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method.
Male latex condoms are proven to protect against STI/HIV.

6.5.2. IMPORTANT CLARIFICATIONS AND EVIDENCES REGARDING ELIGIBILITY CRITERIA

1. COC users who smoke are at increased risk of cardiovascular diseases, especially Myocardial Infarction, compared to those who do not smoke. Risk of Myocardial Infarction increases with the increase in the number of cigarettes smoked per day.

2. It is desirable to have the blood pressure measured before initiation of COC. However, if it is not possible to measure the blood pressure, and or risks due to pregnancy morbidity / mortality are higher, women should not be denied use of COCs, just because blood pressure cannot be measured. Such women can be advised to have their blood pressure measured within three months of initiation of COCs.

3. In women with a history of high blood pressure, evaluation of the cause and level should be done as soon as possible. Women with known hypertension should NOT use COCs unless other more appropriate methods are unavailable/unacceptable.

4. Women with Thrombogenic mutations, using COCs, are known to have 2 to 20 times higher risk of Thrombosis than non-users. Therefore, COCs are not recommended for women having Thrombogenic mutations. *However, COCs can be safely given to women with Superficial Venous Thrombosis.*

5. Among women with migraine, women who had aura had a higher risk of stroke than women without aura. Therefore, in women having migraine with aura, and who are more than 35 years, should not be given COCs.

6. Women with depressive disorders can safely take COCs as the evidence suggests that COCs do not increase depressive symptoms.

7. In women with heavy and prolonged bleeding and unexpected vaginal bleeding, underlying pathological conditions (such as pelvic malignancy) should be excluded and COC use must be evaluated.

8. COCs may worsen existing gall bladder disease.

9. COCs can be safely used in women with Dysmenorrhea. In some COC users Dysmenorrhoea symptoms were reported to be reduced.

10. COCs can be safely used in women with Trophoblastic disease, benign breast disease, family history of cancer, women with pelvic inflammatory disease and STI and HIV.

11. Women with diabetes and with non-vascular disease can generally use COCs. But those women having diabetes with Neuro/Retinopathy and other vascular diseases should not use COCs.

12. Women taking Rifampicin or certain anti-convulsants (Phenytoin, Carbamazepine, Barbiturates, Rimidone, Topiramate, Oxcarbamazepine) should be prescribed COCs only if other appropriate contraceptives are either unavailable or unacceptable. Although interaction of these drugs with COCs are not harmful, these drugs are likely to reduce the effectiveness of COCs. Women on long term use of any of these drugs should be provided other contraceptive choices. Whether increasing the dose of hormones in COCs is useful in these cases is still not clear.

13. Contraceptive effectiveness of COCs is not affected by co-administration of most of the broad spectrum antibiotics.

14. Women who are breastfeeding and more than 6 months postpartum can take COCs.(MEC Cat 2/ WHO's latest 2015 Guidelines) Women who are breastfeeding and less than 6 months postpartum, should not take COCs.

6.6 COUNSELLING AND INFORMED CHOICE

All COC clients must receive appropriate counselling for selecting and using the method. Encourage clients to ask all their questions so that any uncertainties, misunderstandings and rumors can be cleared up. Counsel clients that COCs do not protect against STI or HIV/AIDS.

METHOD SPECIFIC COUNSELLING INCLUDES:

- Effectiveness, the need to use correctly and consistently, and the return to fertility (a woman who stops COC can become pregnant soon after stopping)
- Mechanism of action, disadvantages and advantages
- Alternative methods of family planning
- Rumors about oral contraceptive pills *(refer to Appendix 4)*
- How to take the pill consistently and correctly (provide written instructions as well); not to stop COC when husband is away
- How to take the pill based on the type of packaging, i.e. 28 day package or 21 day package
- What to do if she misses pills or has vomiting and Diarrhoea
- Side effects: minor side effects are most common in the first three months of use of the pill. These disappear with continued use of the pill
- The client should use condoms in addition if she thinks there is any chance that she or her partner are at risk for exposure to STI, including HIV/AIDS
- Counsel clients that breast self-examination should be done regularly and that hormonal contraceptives are contraindicated in women with breast cancer
- Where to go for repeat supplies and follow up support

6.7 CLIENT ASSESSMENT

The purpose of the health assessment is to determine the client's suitability for the use of the method. Tools 6.1 (Checklist to determine if the client is pregnant) and 6.2 (Checklist for screening clients for COCs) can be handy in assessment.

When a woman comes for family planning advice, it is also an opportunity to assess for any STIs/RTIs related concerns and if the client has any symptoms related to STI/RTI. If required, she and her partner should be offered other available sexual and reproductive health services and appropriate treatment. Refer Tool 3 ruling out STI/RTI assessment during routine FP visit.

Pregnancy should be ruled out prior to the provision of contraception.

If the woman wanting to start COC has Amenorrhoea
If the woman has Amenorrhoea, and pregnancy test is possible, get her a pregnancy test. If test is negative, offer her the contraceptive of her choice.

If pregnancy test is not possible and the provider can conduct a bimanual / per- vaginal examination, determine the size of the uterus.

Following Tool 6.1 can be used to determine/ exclude pregnancy.

Tool 6.1: Checklist to determine with reasonable accuracy that the client is not pregnant

TOOL 6.1: CHECKLIST TO DETERMINE WITH REASONABLE ACCURACY THAT THE CLIENT IS NOT PREGNANT

TOOL 6.1: CLIENT HISTORY TO DETERMINE/ EXCLUDE PREGNANCY		
NO	Have you had a miscarriage or abortion in the past 7 days?	YES
NO	Were you abstaining from sexual intercourse since your last menstrual period or delivery?	YES
NO	Have you been using a contraceptive method consistently since your last menstrual period or delivery?	YES
NO	Have you had a baby in the last 4 weeks?	YES
NO	Are you fully or partially breastfeeding your newborn baby, who is less than 6 months old? Do you have Lactational Amenorrhoea?	YES
NO	Have you had a miscarriage or abortion in the past 7 days?	YES

If the answer to all of the questions is "NO", pregnancy cannot be ruled out

Rule out pregnancy by other means such as pregnancy tests. Give her condoms until pregnancy is ruled out.

If the client answered "YES" to any of the above questions, and she is free from signs and symptoms of pregnancy, one can be reasonably sure that the client is not pregnant.

TOOL 6.2: CHECKLIST FOR SCREENING CLIENTS FOR COCs

TOOL 6.2: CHECKLIST FOR SCREENING CLIENTS FOR COCs		
NO	Are you currently breastfeeding a child less than 6 months old?	YES
NO	Do you smoke cigarettes and older than 35 years?	YES
NO	Do you have liver or gall bladder disease (yellow skin or eyes)?	YES
NO	Have you been told that you have high blood pressure?	YES
NO	Have you been told that you have diabetes (high sugar in blood) that is more than 20 years, or associated with damage to your vision, kidneys, arteries?	YES
NO	Did you ever have blood clots in your legs, lungs, heart attack or stroke?	YES
NO	Are you on long term Seizures (Fits) or Tuberculosis treatment and taking Rifampicin?	YES
NO	Have you ever been told that you have breast cancer?	YES
NO	Are you planning a major surgery that will keep you in bed for one week or more?	YES
NO	Do you have repeated severe headaches, often on one side, that are associated with aura (bright area of lost vision in eye), nausea and vomiting and worsened by movement, noise or light?	YES
NO	Do you have two or more conditions that could increase the risk of heart attack or stroke, such as, hypertension, diabetes, obesity, smoking?	YES

- If answers to all of the above questions is "NO", the client can safely use COCs.
- If the client had her last menstrual period within the past 5 days, she can star COCs immediately.
- If the client had her menstrual periods more than 5 days ago, ask her to start COCs now, and use condoms or abstain from sex for the next 7 days.

- If answer to any of the above questions is "YES", the client CAN NOT use COCs or needs further evaluation.
- Counsel her about other methods or refer to doctor for evaluation.

6.7.1 WHEN TO START COCs

A woman can be provided with COCs in advance with appropriate instructions on when to start COCs, provided she is medically eligible. Table 6.1 illustrates latest recommended guidelines on COCs.

TABLE 6.1: WHEN TO START COCs

PHASE	RECOMMENDED GUIDELINES
Woman having a menstrual cycle	Within 5 days of the start of her menstrual cycle
5 days after her menstrual cycle	She can start COCs and will need to abstain from sexual intercourse or use contraceptive protection for the next 7 days.
Breastfeeding and more than six months after giving birth	If she has Lactational Amenorrhoea: She can start COCs if it is reasonably certain that she is not pregnant. She will need to abstain from sexual intercourse or use contraceptive protection for the next 7 days If her monthly bleeding has returned: she can start COCs as above
Amenorrhoea	Any day if reasonably certain that she is not pregnant She will need to abstain from sexual intercourse or use contraceptive protection for the next 7 days
Switching from another hormonal method	If she is using a hormonal method consistently and correctly, and it is reasonably certain that she is not pregnant, she can start COCs immediately If her previous method was injectable Depo-provera, she can start COC from the time when repeat injection would have been due. No additional protection is required
Switching from non-hormonal methods	She can start COCs within 5 days of the start of her menstrual cycle. If it has been more than 5 days after the menstrual cycle and it is reasonably certain that she is not pregnant, COCs can be started with a back u[p contraceptive for the next 7 days
Switching from IUD (including hormonal IUD)	If she is switching from an IUD, she can start COCs immediately. Follow similar instructions as for post - menstrual

TABLE 6.1: WHEN TO START COCs

PHASE	RECOMMENDED GUIDELINES
After taking Emergency Contraceptive pills	She can start COCs the day after she finishes taking the ECPs. There is no need to wait for her next monthly bleeding to start her pills. Woman will need a backup contraceptive method for 7 days.

6.7.2 KEY INSTRUCTIONS / EXPLANATIONS WHILE PROVIDING COCS

1. Give enough packets of COCs. At least three packs can be given on the first visit. COCs have a long shelf life. Stocks for about 6 months can be provided safely.

2. Explain how to use the pill.

3. Provide some condoms as a backup method, in case she misses /forgets the pills or if there is a possibility of RTI/STI/HIV transmission.

4. Explain how to use condoms.

5. Plan a follow up visit and ask her to come earlier in case of a query/complication.

6.7.3 EXPLAINING HOW TO USE THE PILL

1. Show which kind of pack you are giving her, whether 21 pills or 28 pills. With 28-pill packs, point out that the last 7 pills are a different colour and do not contain hormones.

2. Show how to take the first pill from the pack and then how to follow the directions or arrows on the pack to take the rest of the pills until all pills are finished.

3. Explain linking pill-taking to a daily activity, so that chances of forgetting pills are least.

4. Taking pills at the same time each day helps to remember them. It also may help reduce some side effects.

5. For 28-pill packs: when she finishes one pack, she should take the first pill from the next pack on the very next day.

6. For 21-pill pack: after she takes the last pill from one pack, she should wait 7 days and then take the first pill from the next pack.

7. **It is very important to start the next pack on time.** Starting a pack late risks pregnancy.

8. Sometimes she may need to use a backup method, in case she misses a pill or three is risk of RTI/STI or HIV. Provide condoms if possible.

9. COC should be discontinued at least 4 weeks in advance of planned major surgery which involves immobilization as COC increases blood coagulation.

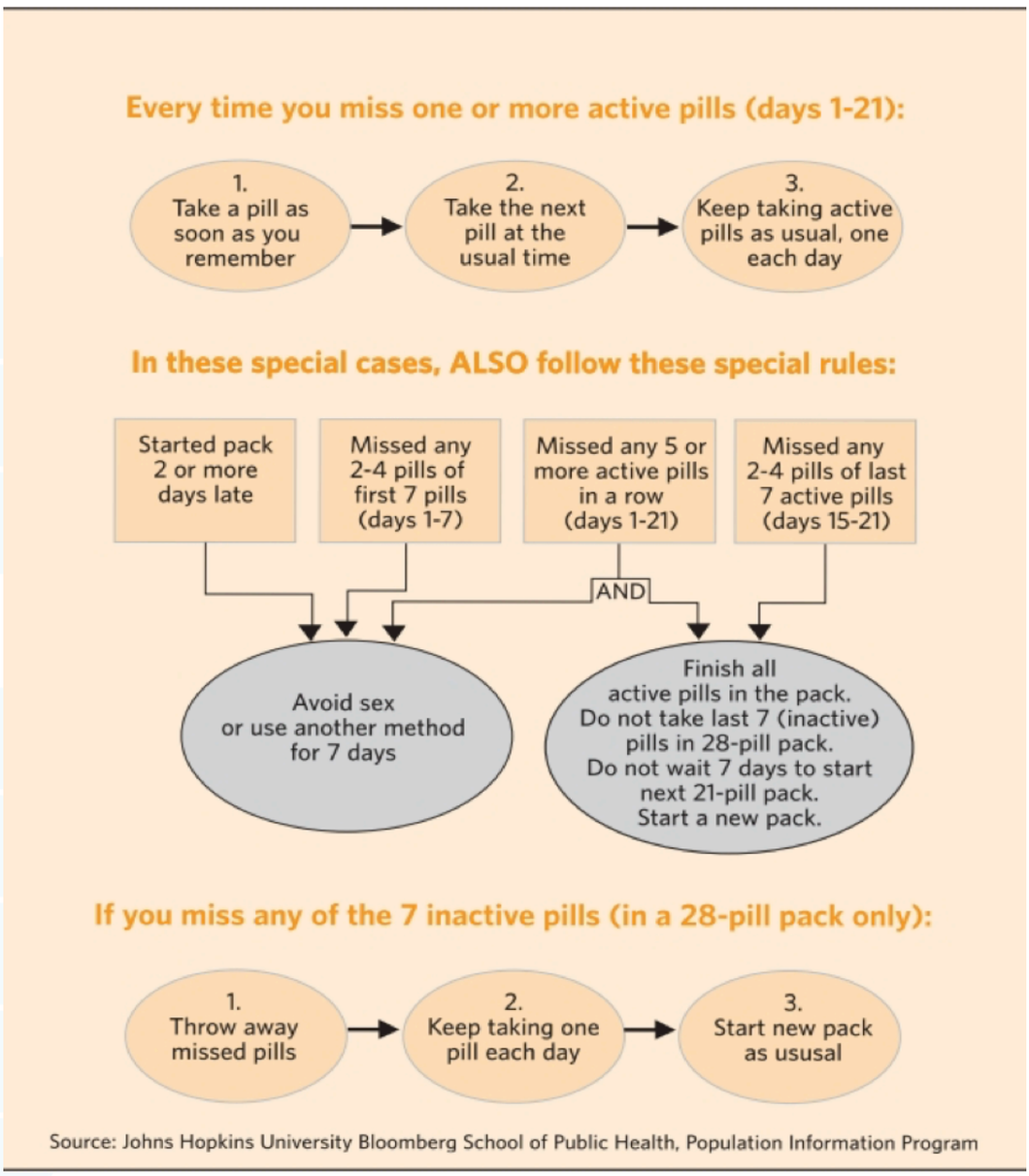
6.8 MANAGING VOMITING/SEVERE DIARRHOEA WHILE USING COCs

Vomiting within 2 hours of taking an active (hormonal) pill: The woman should take another active pill.
Severe vomiting and diarrhoea for more than 24 hours: If woman can continue taking pills, she should. If unable to take pills for 2 or more days, she should follow the missed pill procedure.

6.9 MANAGING MISSED PILLS

It is easy to forget a pill. It is important that all clients on COC should be counselled and provided with written / printed instructions on what should be done if they missed pills.
Tool 6.4 can be used as a ready reference to guide a woman if she misses one or more pills.

TOOL 6.4: MANAGING MISSED PILLS



Source: Johns Hopkins University Bloomberg School of Public Health, Population Information Program

6.10 FOLLOW UP

The client can return for more pills at her convenience any time before her supply runs out. Clients may be advised about the alternate sources of pills availability. A scheduled return visit is not always necessary.

Helping clients at any routine return visit

1. Ask if the client has any questions/doubts to discuss. Address her questions/doubts.
2. Ask about her experience with the method. In case she has problems that cannot be resolved, help her choose another method.
3. If she is comfortable with the method, provide more packs, preferably for the whole year, if possible.
4. Update client's contact information (address, telephone number etc).
5. Plan for the next visit.

6.11 MANAGING ANY PROBLEMS/ SIDE EFFECTS

Clients should be routinely counselled about common side effects and what to do if certain problems occur. Describe **the symptoms of problems that require medical attention.**

Though serious complications of the pill are rare, client should be advised to immediately see a doctor/ nurse in case of any of the following symptoms or problems:

- Severe, constant pain in belly, chest or legs
- Any very bad headaches that start or become worse after she begins to take combined oral contraceptives
- Brief loss of vision, seeing flashing lights or zigzag lines (with or without bad headache); brief trouble speaking or moving arm or leg
- Jaundice (skin and eyes look yellow)

If the client reports any common side effects of low dose COCs, do not dismiss her concerns or take them lightly.

- If the woman is worried, reassure her that the side effects are usually not dangerous. If she has just started the method, tell that these side effects usually become less or subside within 3 months.
- Urge her to keep taking the pill each day even if she has these side effects to avoid pregnancy. Skipping pills can risk pregnancy.
- If she is not satisfied after treatment and counselling, help her choose

Table 6.3: Management of side effects and health problems with COC users

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Common side-effects: such as nausea, mild headaches, tender breasts, spotting between periods, irregular bleeding, mood swings	Exclude pregnancy	Continue taking the pills. Missing pills may increase these side effects and increase risk of pregnancy. Explain that many side effects subside within 3 months of continued use.
Amenorrhoea (Absence of vaginal bleeding)	Ask how she has been taking her pills. Has she missed any pills in the cycle? Has she stopped taking pills? Rule out pregnancy. Perform pregnancy test.	If the client is taking COCs correctly, reassure her. Explain that absent menses is most likely due to lack of build-up of uterine lining; there is no menstrual blood building up within her. Advise client to return to clinic if Amenorrhoea continues to be a concern. If client is NOT taking *COCs correctly,* review instructions for use. If intrauterine pregnancy is confirmed, stop COCs and assure her that the small dose of estrogen and progestin in the COCs to which she was exposed will have no harmful effect on the foetus.
Spotting or bleeding (common during the first three months after starting the pills).	Has client recently begun COCs?	If yes, reassure. Advise that spotting and bleeding are common during the first 3 months of COCs use and decrease markedly in most women by the fourth month of use. Refer to specialist if problem persists for more than 3 months.
	Ask if she has missed one or more pills, or if she takes pills at a different time every day.	If yes, give instructions about what to do for missed pills and stress the importance of taking the pill at the same time every day. If she continues to miss pills, she may need to switch to another method to minimize risk of pregnancy.

SIDE EFFECT	ASSESSMENT	MANAGEMENT
	As appropriate: exclude gynaecological problems (e.g. uterine tumours, pregnancy, abortion, PID)	If gynaecological problems are present, refer to a doctor if possible, or manage according to clinic practice.
	Is client taking Rifampin or Epilepsy medication?	Counsel client to switch to another method until she discontinues Rifampin or Epilepsy medication.
High blood pressure	Recheck BP after 15 minutes rest. Find out if rise in BP is after starting the pill.	If blood pressure persists to be over >140/90, refer to a specialist for further evaluation. Repeat warning signs (severe headache, blurred vision, chest pain). If COCs are discontinued, help client make an informed choice of a non- hormonal method.
Headache	Assess if new headache or marked changes in headache.	Refer for evaluation if headache is new or there are marked changes.
Breast fullness or tenderness	Find out whether the pill is being taken correctly and consistently. Rule out pregnancy. Rule out breast lumps, ulcer and infection of the breast	If pregnant, advise as above. If not pregnant and no breast lumps, counsel. Refer to specialist in case of breast lumps or ulcer.
Weight gain	Check if the weight gain is after the pill. Assess food intake. If no reason found, rule out pregnancy by checking symptoms.	If pregnant, advise as above. If not pregnant, counsel. If not pregnant, counsel.

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Nausea/dizziness/nervousness (usually improves during first 3 months)	Find out if pills are taken in morning or on an empty stomach.	Take with evening meal or before bedtime.
	As appropriate: exclude pregnancy.	If pregnant, manage as above (see Amenorrhoea).
	Rule out other causes of nausea (Gall bladder disease, Hepatitis).	Evaluate for disease (Gall bladder disease, Hepatitis, Gastroenteritis). Counsel that it will probably decrease with time, or counsel client to switch to a progestogen- only method if problem is intolerable.
Vomiting (for any reasons) within 2 hours of taking an active (hormone) pill	She should take another active pill	Vomiting (for any reasons) within 2 hours of taking an active (hormone) pill
Severe diarrhoea and vomiting for more than 24 hours		She should continue taking the pills if possible. If severe diarrhoea and vomiting persists for 2 or more days, she should follow the procedure for missed pills.

6.12. RECORD KEEPING AND REPORTING

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.

The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

Note: In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 7

PROGESTOGEN-ONLY PILLS (POP)

7.1 INTRODUCTION

Progestogen-only pills (POPs) are Oestrogen-free oral contraceptives containing a low dose of Progesterone. Progestogen-only pills are also referred to as 'mini pills'. POPs are good for breastfeeding women and can also be taken by non-breastfeeding women.

7.2 TYPES OF PROGESTOGEN-ONLY PILLS (POPs)

Progestogen-only pill commonly available in Maldives. Family Planning programme is Exluton tablets containing Lynestrenol 0.5 mg. One blister strip of Exluton contains 28 white round tablets.

7.3 MECHANISM OF ACTION

Progesterone only pills, also known as 'Mini Pills' are the best hormonal contraceptives for breastfeeding women. POPs do not reduce quantity of milk and also do not have any Oestrogen related side effects.

Box 7.1 WARNING SIGNS FOR WOMEN ON POPs

See the doctor promptly in the event of:

- Extremely heavy bleeding
- Any very bad headaches, that start or get worse on taking POPs
- Yellow skin or eyes
- Possible pregnancy
- Severe leg or arm pain
- Severe lower abdominal pain, tenderness and fainting (to exclude ectopic pregnancy)

POPs ACT AS CONTRACEPTIVE BY:

- Thickening cervical mucus
- Suppressing ovulation
- Involuting endometrium

6.3 EFFECTIVENESS AND RETURN TO FERTILITY

EFFECTIVENESS

Among perfect users (users who miss no pills and follow instructions consistently and correctly), POPs is highly effective (99.7%). Among POPs typical users, it is only about 92% effective. Pregnancy rates during POPs typical use are determined by the extent and type of imperfect use. The failure rates are higher in younger women as compared to women over 40 years. POPs are most effective if taken about almost same time every day. The effectiveness rates for perfect use and typical use are similar for COCs and POPs. However, woman will be at risk of pregnancy sooner after missing a POPs than a COCs, more so if not breastfeeding.

RETURN TO FERTILITY

When the woman stops taking the POPs, her fertility returns to normal soon after stopping. Use of the pill does not alter a woman's capacity for normal fertile cycles. If a woman does not resume normal cycles after stopping the POPs, a specific cause other than pill use should be sought. The effectiveness data is the percentage of women without unintended pregnancy within the first year of use.

Progestogen-only pills (POPs) do not protect against STI/HIV. If there is a risk of STI/HIV (including the post partum period) the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

7.5 ADVANTAGES OF POPs

- Can be used by breast feeding women, immediately after birth. POPs do not change the quality and quantity of the breast milk.
- No Oestrogen related side effects, such as, stroke, heart attack. etc.
- Woman has to take one pill each day at the same time.
- Can be very effective during breastfeeding.
- Progesterone related side effects are also less as compared to those with COCs.
- May help prevent benign breast disease, ovarian and endometrial cancers and pelvis inflammatory disease.

7.6 DISADVANTAGES

- For women who are not breastfeeding, menstrual irregularities including Amenorrhoea are common.
- To be more effective, POPs need to be taken at the same time each day. For women who are not breastfeeding, even a two hour delay in taking the POP, increases the risk of pregnancy.
- Does not prevent ectopic pregnancy.

7.7 CATEGORY OF PROVIDERS

Progestogen-only pills can be provided by any health worker who has been trained to explain pill use, manage minor side effects, and explain alternative methods of contraception. The following providers can provide POPs and perform follow up care: family health officer (FHO), community health officer (CHO), community health supervisor (CHS), staff nurse, medical officer and gynaecologist.

7.8 ELIGIBILITY CRITERIA

7.8.1 INDICATIONS

POPs can be provided to any woman in the reproductive age who requests POP, after appropriate counselling and reaching an informed decision, and who does not have any contraindication for its use.

POPs are appropriate for women who:

- Cannot or will not use combined oral contraceptives
- Are breast feeding (starting as soon as after childbirth (category 2) after 6 weeks category 1)
- Weight
- Are of any age, including adolescents and those over 40 years of age
- Smoke
- Have just had an abortion or a miscarriage

Also, women with the following conditions can safely use POPs in any circumstances:

- Benign breast disease
- Dysmenorrhoea
- Diabetes, without any vascular, kidney, eye or nerve disease
- Mild headaches
- Varicose veins
- Sickle cell disease
- Thyroid disease
- Endometriosis
- Pelvic inflammatory disease
- Benign ovarian tumour
- Uterine fibroids
- Epilepsy
- Tuberculosis, unless taking Rifampicin
- Have had a miscarriage and desire contraception
- Have a history of ectopic pregnancy
- Have an STI excluding HIV and Hepatitis B
- Have adequately controlled hypertension
- Have a history of high BP during pregnancy where the current pressure is normal
- Have non-migraine
- Have other Oestrogen-related complications
- Valvular heart disease (complicated and uncomplicated), pulmonary
- hypertension, irregular heart rhythm (fibrillation) or a history of Subacute Bacterial Endocarditis (SBE) (progestins do not contribute to blood clotting)
- Have thyroid disorders (simple Goitre, Hyperthyroidism, Hypothyroidism)
- POPs have a higher absolute rate of ectopic pregnancy compared with other progestogen only contraceptives, but still less than using no method

7.8.2 Health workers should consult a doctor when women with the following conditions request POPs

- Thyroid disorders (such as Goitre, Hyperthyroidism and Hypothyroidism)
- Raised BP >140/90
- Valvular heart disease (complicated or uncomplicated)
- Superficial Thrombophlebitis
- Diabetes
- History of past ectopic pregnancy

Table 7.1: Providing Progesterone Only Pills (POPs): When to Start?

WOMAN'S SITUATION	WHEN TO START
Breastfeeding women (less than 6 months after delivery)	• If < 6 weeks postpartum, women can generally take POPs. (WHO's 2015 Guidelines,) • If her monthly bleeding has not returned, she can start POP any time between 6 weeks and 6 months. • If her monthly bleeding has returned, she can take POPs as advised for women having menstrual cycles.
Breastfeeding women (more than 6 months after delivery)	• If monthly bleeding has not returned, she can start POPs if it is reasonably certain that she is not pregnant. She will need a backup method for the first 2 days. • If monthly bleeding has returned, she can use POPs as advised for any woman having menstrual cycle.
With regular menstrual cycles	• She can start POP within 5 days after the start of the menstrual bleeding. • No backup required. • More than 5 days since start of her menstrual bleeding: POP can be started if she is reasonably sure that she is not pregnant. She will need to abstain from sex or use a backup method for the next 2 days.
Amenorrhoea	• If it has been more than 5 days since last menstrual period, she can use POP and will have to abstain from sex or use a backup contraceptive for the next 2 days.
Switching from another hormonal method	• She can start POP mediately if she has been taking previous method consistently and correctly, or if it is reasonably certain that she is not pregnant. • If she is switching from injectable DMPA, she should start POP when her next injection would be due. • She can start POPs within 5 days of the start of her menstrual period. No additional protection is required.
Switching from another non- hormonal method (other than IUD)	• She can start immediately if certain that she is not pregnant. • She can start within 5 days of the start of her menstrual bleeding. • If it has been more than 5 days when her menstrual bleeding started, she can start POP and will need to abstain from sex or use a backup method for the next 2 days

7.9 GUIDELINES FOR INSTRUCTING ON USE OF POPs

- Show the packet of POP to the client as instructions are being given.
- Explain that the first day of menstruation is the day when bleeding/spotting starts.
- Show the client where to start the pill (where it is marked START) and advise to follow the arrow to decide which pill to take next and follow the arrow till the last pill.
- Show how to take out the pill from the packet.
- **Emphasize the importance of taking 'the pill' at the same time every day, even during her periods and even when there is no sexual intercourse.**
- Ask the client to repeat the instructions.
- Provide 3 months' supply of the pill and ask the client to return after 3 months for re-supply/ follow-up or earlier if any problem develops. Ask the client to bring the used packets (even the empty ones) to make sure that the pills are being taken regularly.
- Provide a packet of condoms in case of missed pills or develop the conditions where condom use is advisable. Demonstrate how to use the condom if the client does not know how to use it.
- As soon as one card/ packet is completed, begin the next card. Start the next card even if there is bleeding or you have not started a period. Continue taking one pill at the same time each day. (Verbal and written instructions should be provided.).
- Clients should NOT stop and start pills when their partner is away for a short period of time. POPs are not effective if not taken consistently.
- Recap on side-effects: Give advice on common problems/side effects. Generally serious problems with POPs are rare. Still, women should be advised to contact the doctor immediately if she develops any of the signs and symptoms mentioned in Box 7.1.
- Incidence of pregnancy among POP users is usually low, especially if a woman is breastfeeding. In case pregnancy occurs, there are chances (1 in every 10) of ectopic pregnancy. Ectopic pregnancy is a life threatening condition and requires immediate treatment.
- If intrauterine pregnancy is confirmed, counsel client and refer for appropriate care. Discontinue POPs and assure her that the small dose of progesterone to which she was exposed will have no harmful effect on the foetus.

7.10 WHAT TO DO IF A PILL IS MISSED

- If a woman misses one or more pills, she should take one pill as soon as she remembers and then keep taking one pill every day as before.
- An exclusively breastfeeding woman on POP for extra protection, is still protected if she misses a pill.
- A woman who does not breast-feed or who breast-feeds but her menstrual cycles have begun, and if they delay taking the pill by more than 3 hours, should either abstain from sex for the next two days or take a backup protection. Such women should continue taking the pill.

7.11 IMPORTANT CLARIFICATIONS AND EVIDENCES FOR MEDICAL ELIGIBILITY OF POPS.

1. Studies have shown that POP does not affect the quality and quantity of milk among breast-feeding women less than 6 weeks postpartum.
2. When multiple risk factors for Arterial Cardiovascular Disease exist, Cardiovascular Disease may increase substantially with POPs, though this increase is substantially less than with COCs.
3. It is desirable to have blood pressure measurement taken before using POP. However, if the facility of blood pressure measurement is not available and or risks due to pregnancy morbidity/ mortality are high, women should not be denied use of POPs simply because their blood pressure cannot be measured.
4. Women with a history of Deep Vein Thrombosis/Pulmonary Embolism can use POPs, but those with current disease should use POPs only if other more appropriate contraceptives are either unavailable or unacceptable to the client.
5. Women currently suffering from breast cancer have an unacceptable health risk by using POPs.
6. HIV/ AIDS: Overall, evidence is inconsistent regarding whether there is any increased risk of HIV acquisition among POP users as compared to non-users.
7. Women taking Rifampicin or certain anticonvulsants (Phenytoin, Carbamazepine, Barbiturate, Primidone, Topiramate, Oxcarbazepine) should be prescribed POPs only if any other appropriate contraceptive is not available. Appropriate contraceptive is unavailable or unacceptable. Although the interaction of these drugs with COCs is not harmful to women, it is likely to reduce the effectiveness of POPs. Use of other contraceptives should be encouraged for the women who are long-term users of any of these drugs. Whether increasing the dose of the hormones in POPs is useful is still unclear. However, there is evidence that use of certain anti convulsants decreases the effectiveness of POPs.
8. It is important to note that Antiretroviral drugs (ARVs) have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data available suggests that the potential drug interaction between ARVs and hormonal contraceptives may alter the safety and effectiveness of both the hormonal contraceptives and ARVs. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, consistent use of condoms is recommended for preventing HIV transmission. This will also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

7.12 ROUTINE FOLLOW-UP CARE

All clients initiated on progestogen-only pills are advised:

1. First routine follow up at 3 months for assessment and supplies.
2. Return to facility earlier if she has any concerns, side-effects or if she wants to change the method.
3. Contact a doctor immediately if she has any of the symptoms listed in Box 7.1.

4. At routine follow up:

- Assess the client's satisfaction with the method.
- Determine if the client has had any problems or side effects and, if so, record them in the client clinical card/record.
- Assess for any STI/RTI-related concerns and if the client has any symptoms related to STI/RTI.
- Update the medical history, measure blood pressure and body weight, and perform any examination indicated by the history.
- Provide appropriate counselling and/or treatment as required.
- Refer client to an appropriate referral facility/specialty if any serious problems or side effects cannot be managed at the facility where the client has attended for follow up care. Provide referral slip.
- Update client's contact information (address, telephone number etc.).
- Replenish supplies for clients continuing on POP.

7.13 SIDE EFFECTS AND MANAGEMENT

Clients should be routinely counselled about common side effects and what to do if certain problems occur. When a client presents with side effects or complications they should be assessed, counselled and managed appropriately. Refer to Chapter 3 for details on counselling clients with problems using a contraceptive method.

Table 7.1 Side effects and their management for the use of progestogen-only pills

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Amenorrhoea (absence of vaginal bleeding or spotting)	Rule out pregnancy by checking symptoms; perform a pelvic exam (speculum and bimanual) and pregnancy test.	Periods of Amenorrhoea can occur among women taking POP. If pregnancy has been ruled out, there is no need for any medical treatment for the Amenorrhoea. Counselling is sufficient. Explain that if a women is breastfeeding Amenorrhoea is expected. It is not harmful. If Amenorrhoea is unacceptable to the client, discontinue POP and help her choose another method. If intrauterine pregnancy is confirmed, counsel client and refer for appropriate care. Discontinue POP and assure her that the small dose of progesterone to which she was exposed will have no harmful effect on the foetus. If ectopic pregnancy is suspected, refer promptly for complete evaluation.

Table 7.1 Side effects and their management for the use of progestogen-only pills

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Bleeding/ Spotting Prolonged spotting > 8 days Moderate bleeding: same as normal menses	Perform a pelvic exam (speculum and bimanual) to be sure bleeding is not due to another cause (e.g., genital tract lesion such as vaginitis, cervicitis, cervical polyps or uterine fibroids). If pregnancy (intrauterine or ectopic) or incomplete abortion is suspected, examine and perform a pregnancy test.	Light bleeding or spotting between periods, irregular periods, is common especially in non-breastfeeding women while using POP. Counsel that skipping pills may make bleeding side-effects worse and risks pregnancy. In women with persistent spotting or bleeding after a period of Amenorrhoea, exclude gynaecological problems when clinically warranted. If a gynaecological problem has been identified, treat the condition or refer for care. If haemoglobin less than 9 g/dl, or conjunctival pallor significant, give iron or iron folate (1 tablet daily for 1 to 3 months) and nutritional counselling. If anaemia persists, or client requests, discontinue POP and help client choose another method. If no gynaecological problems are found and she finds the bleeding unacceptable, discontinue the POP. Help her choose another method. If pregnancy is confirmed, see Amenorrhoea section in this table for management of pregnancy related conditions.
Lower abdominal pain	Rule out pregnancy by checking symptoms, perform abdominal examination and a pregnancy test.	If ectopic pregnancy is suspected, refer her for complete evaluation immediately.

Table 7.1 Side effects and their management for the use of progestogen-only pills

SIDE EFFECT	ASSESSMENT	MANAGEMENT
Weight gain	Check if the weight gain occurred while on POP. Assess food intake. If no reason is found, rule out pregnancy (as under Amenorrhoea in this table).	If pregnant, advise as discussed under Amenorrhoea in this table. If not pregnant, counsel.
Nausea	Find out whether the POP is being taken regularly every day at the same time. Rule out pregnancy (as above)	If pregnant, advise as in Amenorrhoea in this table. If not pregnant, if the POP is being taken regularly at the same time every day, counsel. Refer to specialist, if nausea continues, to rule out other causes.
Headache	Assess if the headache is new or there are marked changes in headache.	Refer for evaluation if headache is new or there are marked changes in headache.

7.13 RECORD KEEPING AND REPORTING

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.

The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

Note:In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 8

PROGESTOGEN-ONLY INJECTABLE CONTRACEPTIVES (POI)

8.1 INTRODUCTION

The progestogen-only injectable contraceptives (POI) are synthetic steroid hormones resembling the female hormone progesterone produced by the ovaries. The injectable hormone is released slowly into the bloodstream from the site of the injection.

About 12 million women are using POIs worldwide. Women prefer POIs because they are safe, effective, do not require daily action, maintain privacy and can be used by women who are breastfeeding.

The most widely used and extensively studied preparation is the 3 monthly Depo-medroxy Progesterone Acetate (DMPA). NET-EN (Norethidrone enanthate) 2 monthly injection is also available. Both these are highly effective, reversible and reliable contraceptives. Alternate, monthly injectable contraceptives, containing long acting progesterone with short acting Oestrogen Cyclofem (25 mg DMPA + 15 mg Estradiol Cypionate) and Mesigyna (50 mg NET EN + 5 mg Estradiol Valeate) are available.

8.2 TYPES OF PROGESTOGEN-ONLY INJECTABLES (POIs)

Currently Depot-Medroxy Progesterone Acetate (DMPA) known as Depo-Provera is the injectable contraceptive widely available in Maldives. Each dose of DMPA / Depo- Provera contains 150 mg of Medroxy Progesterone Acetate and is given every 3 months (12 weeks) as deep intramuscular injection.
DMPA-SC, available in some countries, containing 104 mg of DMPA is given subcutaneously.

8.3 MECHANISM OF ACTION

Progesterone only Injectables act as a contraceptive by:

- Inhibiting ovulation by preventing LH surge and lowering FSH and LH
- Thickening the cervical mucus
- Rendering endometrium less suitable for implantation
- Reducing mobility of fallopian tubes causing reduction in rate of ovum transport

8.4 EFFECTIVENESS AND RETURN TO FERTILITY

EFFECTIVENESS

Progestogen-only injectables i.e. DMPA/Depo-Provera are effective reversible contraceptive methods.

DMPA/Depo-Provera (150 mg) given every 3 months has an effectiveness of 99.7% on correct use. Typical use effectiveness of POI is 97%.

CONTINUATION RATE:

Varies between populations and centres. For DMPA, it varies from 50 - 80 % at the end of one year. Menstrual irregularities/ Amenorrhoea in about 10-15 % women is one of the major reasons for discontinuation with both DMPA and NET-EN.

RETURN TO FERTILITY

When a client stops taking progestogen-only injectables, it may take several months for fertility to return. The median delay in return to fertility with DMPA/ Depo-Provera is 10 months and for NET-EN is 6 months from the date of the last injection regardless of the duration of use.

Progestogen-only injectables (POIs) do not protect against STI/HIV. If there is a risk of STI/HIV (including the post partum period) the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

8.5 ADVANTAGES AND DISADVANTAGES OF DMPA

ADVANTAGES

- Very effective
- Confidential
- Longer -term pregnancy protection- but reversible
- No daily pill intake or other action.
- Clients can return for repeat injection 2 weeks early (though not preferred) and 4 weeks later for the repeat DMPA injection.
- Breastfeeding mothers can use the method after 6 weeks of childbirth. DMPA does not affect the quantity or quality of breast milk.
- Helps prevent ectopic pregnancies.
- Helps prevent uterine fibroids.
- May help prevent ovarian cancer.
- May help prevent iron deficiency Anaemia.

DISADVANTAGES

- Common side effects including headache, breast tenderness, moodiness, nausea, less sex drive, hair losses, etc.
- Changes in menstrual bleeding patterns, Amenorrhoea is common.
- Rarely heavy bleeding in some
- May cause weight gain.
- Does not protect against STI/RTI/HIV.

8.6 CATEGORY OF PROVIDERS

Hormonal injectables can be provided safely by a trained Family Health Officer (FHO), Community Health Officer (CHO), Community Health Supervisor (CHS), staff nurse, medical officer or a gynaecologist.

8.7 MEDICAL ELIGIBILITY CHECKLIST

Depo-Medroxy Progesterone Acetate (DMPA) / Depo-Provera should be provided to any woman who requests it after appropriate counselling and reaching an informed decision, and who does not have any contraindication for its use.

DMPA/Depo-Provera can be safely provided to most women who:

- prefer a method that does not require taking contraceptive action every day or before having intercourse, or want long-term birth spacing or have the number of children they want but do not want or cannot have a permanent method (voluntary surgical sterilization) at this time
- have or do not have children
- are **breastfeeding** and **more than 6 weeks postpartum**. For women who are less than 6 weeks postpartum and breastfeeding, DMPA is not a safe choice (WHO Cat 3).
- cannot use Estrogen containing contraception i.e. COC, or have developed Estrogen related complications taking COCs
- smoke cigarettes, regardless of the number of cigarettes smoked per day and age of the woman
- at any age including adolescents and women over 40 years of age.
- have just had an abortion or miscarriage
- are infected with HIV, whether on anti-retroviral treatment or not.
- have benign breast disease
- have mild headaches
- have mild or moderate blood pressure
- history of ectopic pregnancy
- Endometriosis
- iron deficiency Anaemia
- Varicose veins
- Valvular heart disease
- irregular menstrual periods
- sickle cell disease
- thyroid disease
- uterine fibroid
- Epilepsy
- Tuberculosis

8.8 CONTRAINDICATIONS FOR DMPA:

- pregnancy
- breastfeeding less than 6 weeks baby
- severe liver disease (Jaundice, Cirrhosis, tumour)
- history of very high blood pressure (> 160/100 mm Hg)
- history of diabetes for more than 20 years with damage to arteries, nervous system and kidneys
- history of stroke, heart attack
- history of breast cancer
- unexplained irregular vaginal bleeding (DMPA may interfere in proper diagnosis)

8.9 COUNSELLING AND INFORMED CHOICE

All clients must receive appropriate counselling for selecting and using the method. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up. Counselling and informed decision helps client in accepting and continuing a contraceptive method. It is important to address her queries and explain advantages, disadvantages and side effects of the method including menstrual irregularities.

Counsel clients that hormonal injectables do not protect against STIs or HIV/AIDS. For selecting the method, counsel about:

- effectiveness and the delay to return to fertility
- advantages and disadvantages
- alternative family planning methods
- timing of injection
- Ensure that the client has understood the importance of regular injections and how often they should be taken.
- Make sure that the woman understands about the side effects such as Amenorrhea, bleeding/ spotting and delayed return of fertility.
- The client should use condoms in addition if she thinks there is any chance that she or her partner are at risk for exposure to STIs, including HIV/AIDS.

8.10 CLINICAL ASSESSMENT

The purpose of the health assessment is to determine the client's suitability for the use of the method. In healthy women, no examination, laboratory tests are required or mandatory before initiating DMPA. However, there is special consideration for blood pressure screening. It is desirable to have blood pressure measurements taken before initiating DMPA. It is important to note that in situations where blood pressure measurement is not possible, the client should not be refused the method. They can still get the first dose of DMPA and get blood pressure checked later.
Pregnancy should be ruled out prior to the provision of contraception. A pregnancy test should be done if there is any suspicion of pregnancy. Refer to Chapter 4 for indications for performing a pregnancy test.

It is also an opportunity to assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI and to offer other available sexual and reproductive health services as appropriate.

8.11 PROVISION OF PROGESTOGEN-ONLY INJECTABLES

8.11.1 STARTING POIs

POI should be initiated only after ruling out pregnancy. A pregnancy test should be done if there is any suspicion of pregnancy. If pregnancy test is not possible, follow "Tool 6.1: Checklist to determine with reasonable accuracy that the client is not pregnant)

Box 8.1: WARNING SIGNS AND SYMPTOMS FOR WOMEN ON DMPA

- Extremely heavy bleeding
- Any very bad headaches, that start or get worse on taking POPs
- yellow skin or eyes
- possible pregnancy
- severe leg or arm pain
- severe lower abdominal pain, tenderness and fainting

Table 8.1: When to start DMPA/ POI

SITUATION	WHEN TO START DMPA / POI INJECTIONS
Having menstrual cycles	• Within 7 days of the menstrual cycle: she can take the first dose of DMPA injection. No other protection is required. • More than 7 days since the start of menstrual bleeding: She can still take the DMPA injection, if it is reasonably certain that she is not pregnant. She will need to abstain or use a backup contraceptive for the next 7 days.
Amenorrhoea	• She can take the DMPA injection, if it is reasonably certain that she is not pregnant. She will also need to abstain or use a backup contraceptive (for example condom) for the next 7 days.
Breastfeeding	• 6 weeks to 6 months after delivery, exclusive breastfeeding and having Amenorrhoea: First DMPA injection can be given. No backup required. • More than 6 weeks after delivery and menstruation has returned: First dose of DMPA can be given as for women with menstrual cycles. • Less than 6 weeks after delivery and breastfeeding: DMPA/POI is not recommended. Advise another method.
Postpartum and not breastfeeding	• Less than 21 days after delivery: DMPA/ POI can be started. No backup is required. • More than 21 days after delivery and menstrual cycles have not returned: DMPA can be started if it is reasonably certain that she is not pregnant. Backup method for 7 days will be required. • Menstrual cycles have returned: DMPA/POI to be given as advised for women with menstrual cycles
Post-abortion/miscarriage	• The first DMPA/POI injection can be given immediately after abortion. No additional backup is required.
Switching from another hormonal method	• If the woman is using another hormonal method correctly and consistently or if it is reasonably certain that she is not pregnant: DMPA/POI can be given immediately. No need to wait for her menstrual cycle. • If her previous method was another injectable contraceptive: DMPA/POI to be given when the repeat injection of the previous method would have been due.

Table 8.1: When to start DMPA/ POI

SITUATION	WHEN TO START DMPA/ POI INJECTION
Switching from a non-hormonal method (other than IUD)	- She can take the DMPA injection immediately if it is reasonably certain that she is not pregnant. No need to wait for the next menstrual cycle. - Within 7 days of start of her menstrual cycle: Can take DMPA/ POI. No need for additional contraceptive protection. - More than 7 days since start of menstruation: Can take DMPA/POI. Will need to abstain from sex or use a backup contraceptive for the next 7 days.
Switching from IUD (including LNG IUD)	- Within 7 days of start of her menstrual cycle: Can take DMPA/ POI. No need for additional contraceptive protection. The IUD can be removed at that time. - More than 7 days since start of menstruation: Can take DMPA/POI if reasonably sure that she is not pregnant. If sexually active in this cycle, IUD should be removed at her next cycle for contraceptive protection over the period. - If the woman has Amenorrhoea: Can have the DMPA/ POI injection as advised for other amenorrhoeic women.

Remark:

In the context of switching from an IUD to an injectable contraceptive, experts had some concerns about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that IUD should be left in place until the next menstrual period.

Explain how to use DMPA

- Give the injection
- Plan a return visit after 3 months for the repeat injection
- Ask the client to come back anytime if she has any questions/ problems or wants to switch to another method

8.11.2 GIVE ADVICE ON COMMON SIDE EFFECTS/ PROBLEMS:

Repeat the advice about when to return for a repeat injection and if she has any concerns (verbal and written).
Repeat the side effects and advise to return anytime to the provider. Advise her to report if she experiences any of the symptoms in the Box 8.1 below.

8.12 ROUTINE FOLLOW-UP CARE

All clients initiated on progestogen-only injectables are advised to:
Make regular follow up visits every three months (12 weeks) for clients on DMPA and every 2 months (8 weeks) for clients on NET-EN
Return to the facility earlier if she has any concerns, side-effects or if she wants to change the method.
Contact a doctor immediately if she has any of the warning signs in Box 8.1.

AT FOLLOW-UP:

- Assess the client's satisfaction with the method.
- Determine if the client has had any problems or side effects and if so, record them in the client clinical card/record.
- Check if the client is experiencing any new headaches or marked changes in headaches.
- Assess for any STI/RTI related concerns and if the client has any symptoms related to STI/ RTI.
- Update the medical history; measure blood pressure and perform any examination indicated by the history.
- Provide appropriate counselling and/or treatment as required.
- Refer the client to an appropriate referral facility/specialty if any serious problems or side effects cannot be managed at the facility where the client has attended for follow up care. Provide referral slip.
- Update client's contact information (address, telephone number etc.).
- Provide date for next follow up visits for repeat injection.

8.11.2 REPEATING PROGESTOGEN-ONLY INJECTABLES

Repeat injections of DMPA/Depo-Provera should be provided every 3 months (12 weeks). Repeat injections of NET-EN should be provided every 2 months (8 weeks). Compliance with regular injection intervals should be encouraged.

Early for an injection: The repeat injection of DMPA/Depo-Provera and NET- EN can be given up to 2 weeks early.

Late for an injection: The repeat injection for DMPA/Depo-Provera can be given up to 4 weeks late without additional contraceptive protection.
For NET- EN repeat injection can be given up to 2 weeks late without requiring additional contraceptive protection.
If she is more than 4 weeks late for DMPA/Depo-Provera or more than 2 weeks late for NET-EN repeat injection, she can be given the repeat injection if pregnancy has been ruled out. Provide additional contraception as back up for the next 7 days. If appropriate use emergency contraception.

Unknown previous injectable type and/or timing of injection: Provide available injectable if pregnancy has been ruled out. Provide backup contraception such as condoms for the next 7 days.

Switching between DMPA/Depo-Provera and NET-EN injection interchangeably is NOT recommended. If it becomes necessary to switch from one to the other, the switch should be made at the time the repeat injection would have been given

8.13 SIDE EFFECTS AND MANAGEMENT

Table 8.2 Side effects and their management for the use of DMPA/Depo-Provera

Clients should be routinely counselled about common side effects and what to do if certain problems occur. When a client presents with side effects or complications, they should be assessed, counselled and managed appropriately.

Table 8.2: Side Effects and their management for the use of DMPA/ Depo-provera

SIDE EFFECTS	ASSESSMENT	MANAGEMENT
Amenorrhoea	Rule out pregnancy. Do a per vaginal /bimanual examination, pregnancy test, etc.	• Periods of Amenorrhoea are common with DMPA users (80%) • If pregnancy is ruled out, counsel the client. • If Amenorrhoea is unacceptable to client, discontinue DMPA/ given another choice. • If intrauterine pregnancy is confirmed, counsel the client and refer for antenatal care. Discontinue DMPA and reassure the client that small progesterone hormone will have no effect on her child. • If ectopic pregnancy is expected, refer immediately for further evaluation.
Weight gain	Check if the weight gain occurred while on the injectable. Assess food intake. If no reason found, rule out pregnancy (as above)	If pregnant, advise as under Amenorrhoea in this table. If not pregnant and the injectable is being taken regularly, counsel.
Nausea	Find out if the injectable is being taken regularly as instructed. Rule out pregnancy (as under Amenorrhoea in this table).	If pregnant, advise as described under Amenorrhoea in this table. If not pregnant and the injection is being taken regularly, counsel Refer to specialist if nausea continues; to rule out other causes.

Table 8.2: Side Effects and their management for the use of DMPA/ Depo-provera

SIDE EFFECTS	ASSESSMENT	MANAGEMENT
Bleeding/Spotting prolonged spotting: >8 days Moderate bleeding: same as normal menses (prolonged spotting or moderate bleeding)	Perform a pelvic exam (Speculum and Bimanual) to be sure bleeding is not due to another cause (e.g., genital tract lesion such as vaginitis, cervicitis, cervical polyps, cervical cancer or uterine fibroids).	Light bleeding or spotting is common during POI particularly in the first injection cycle and is not harmful and usually does not require treatment. Reassure her that light inter-menstrual bleeding or spotting occurs in a large percentage of women using POI (15– 20%). NSAIDS/ Mefenamic Acid or Valdecoxib can be provided for 5-7 days. In women with persistent spotting or bleeding after a period of Amenorrhoea, exclude gynaecological problems when clinically warranted. If a gynaecological problem has been identified treat the condition or refer for care. If haemoglobin less than 9 g/dl, or conjunctival pallor significant, give iron or iron folate (1 tablet daily for 1 to 3 months) and nutritional counselling. If anaemia persists, or client requests, discontinue DMPA/Depo-Provera and help client choose another method. If a STI or PID is diagnosed, she can continue her injection while receiving treatment for STI and be counselled on condom use. If no gynaecological problems are found and she finds the bleeding unacceptable, discontinue the injectable. Help her choose another method. If not satisfied after counselling and reassurance, but wants to continue using DMPA/Depo-Provera, give: • A cycle of COCs (30 mcg estrogen) • Ibuprofen (800 mg three times daily for 5 days • other NSAIDs can also be given for 5-7 days If pregnancy is confirmed, see **Amenorrhoea** section in this table for management

Table 8.2: Side Effects and their management for the use of DMPA/ Depo-provera

SIDE EFFECTS	ASSESSMENT	MANAGEMENT
Heavy or prolonged bleeding (more than 8 days) or twice as much as her menstrual periods	Perform a pelvic exam (speculum and bimanual) to be sure bleeding is not due to another cause (e.g., genital tract lesion such as Vaginitis, Cervicitis, cervical polyps or uterine fibroids). If a pregnancy complication such as incomplete abortion is suspected, examine and perform pregnancy test.	If a pregnancy complication or gynaecological problem has been identified, refer for further management. If a pregnancy complication and gynaecological problems have been ruled out, explain to the client that heavy or prolonged bleeding is common in the first injection cycle. NSAIDs (Mefenamic Acid, Valdecoxib) may be tried for 5-7 days. If heavy or prolonged bleeding persists and if the bleeding is unacceptable to the client or is a threat to her health, discontinue the injectable and help her choose another method. In the interim, short term treatment a cycle of COCs (30 micro gm Ethinyl Estradiol) may be helpful. Provide Iron supplementation.
Lower abdominal pain	Rule out pregnancy by checking symptoms, pelvic exam (speculum and bimanual) and pregnancy test.	If ectopic pregnancy is suspected refer promptly for complete evaluation.
Headache	Assess if the headache is new or there are marked changes in the headache.	Refer for evaluation if the headache is new or there are marked changes in the headache
Breast fullness/ tenderness	Find out if the injection is being taken regularly. Rule out pregnancy as in the section under Amenorrhoea. Rule out breast lumps and infection in the breast - if breastfeeding	If pregnant, advise as under Amenorrhoea in this table. If not pregnant and no breast lumps, counsel. Refer to a specialist in case of breast lumps/ infection.

8.11 RECORD KEEPING AND REPORTING

The provider should legibly record information in the Client Clinic Card and Family Planning Register. The provider should ensure that records and registers are completed, regularly maintained and reported to the Health Protection Agency.

8.12 DEPOT-MEDROXYPROGESTERONE ACETATE (DMPA-SC)

Subcutaneously-administered depot Medroxyprogesterone Acetate (DMPA-SC) has been included as a new method in the 5th edition of WHO's 'Medical eligibility criteria for contraceptive use' (MEC) alongside DMPA for intramuscular administration (DMPA-IM). DMPA - SC contains 104 mg/0.65 mL suspension for SC injection.

Similar to DMPA - IM, Depot-medroxyprogesterone acetate (DMPA-SC), is a reversible, long-acting contraceptive. It is available as a pre-filled, single-use, non-reusable syringe/ delivery system that eliminates the need of a needle and syringe.

The pre-loaded DMPA - SC helps a woman to administer the injection herself at home or in her other private settings. Women can be very easily trained to self-administer the injection by a trained health worker.

Mechanism of action: As with DMPA- IM, DMPA- SC prevents ovulation and provides contraception for at least 14 weeks.

With the intramuscular DMPA, women need to come to a health facility once in three months, which could be a challenge for women living in remote or hard-to-reach areas. Self-administered DMPA Subcutaneous would support these clients.

Note: In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 9

TYPES OF HORMONAL IMPLANTS

9.1 INTRODUCTION

Hormonal implants are a long acting reversible low-dose progestin only implants inserted sub-dermally, preferably in the inner side of the upper arm.

9.2 TYPES OF HORMONAL IMPLANTS

The various types of progesterone only implants available are:

1. Levonorgestrel (LNG): The LNG containing implants are Norplant, Jadelle and Sino-implant(II)

    i. Norplant is a 6 -rod implant, each rod containing 36 mg of LNG (Norplant is no longer in production)

    ii. Jadelle is 2 rod implant, each rod containing 75 mg of LNG

    iii. Sino-implant (II) is a 2 rod implant, each rod containing 75 mg of LNG

2. Etonogestrel (ETG)-The ETG containing implants are Implanon and Nexplanon Implanon is available through the Maldives Family Planning programme and will be discussed in this chapter.

Implanon is a single-rod hormonal implant that contains Etonogestrel (a synthetic Progestin). It is one of the most highly effective contraceptive methods. The single non-biodegradable rod measures 2 mm in diameter and 40 mm in length and contains 68 mg of Etonogestrel with a release rate of 40 microgram per day. Implanon is effective for **3 years.**

9.3 MECHANISM OF ACTION

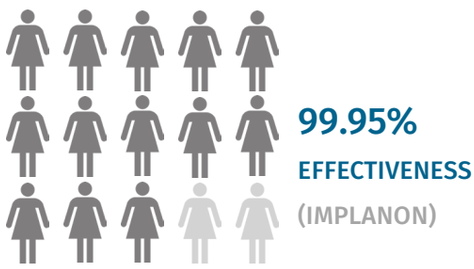
Implanon acts as a contraceptive by:

- inhibiting ovulation by preventing LH surge and lowering FSH and LH
- thickening the cervical mucus
- rendering endometrium less suitable for implantation
- reducing mobility of fallopian tubes causing reduction in rate of ovum

9.4 EFFECTIVENESS AND RETURN TO FERTILITY

EFFECTIVENESS

Implanon is one of the most effective reversible long term methods, with effectiveness of 99.95%. Contraceptive effectiveness of Implanon decreases substantially after year 3.



RETURN TO FERTILITY

When the capsules are removed, the return of fertility is immediate. If the client does not want another pregnancy and does not want to use implants any longer, she should begin using another contraceptive method right away. studies show that the blood level of progesterone hormone fall within 7 days of the Implant removal.

9.5 ADVANTAGES AND SIDE EFFECTS OF IMPLANTS

ADVANTAGES

- Very effective
- Longer -term pregnancy protection- but reversible
- No daily pill intake or other action
- Breastfeeding mothers can use the method. Implanon does not affect the quantity or quality of breast milk. Implanon can even be provided to breastfeeding women who are less than 6 weeks postpartum (MEC Cat 2). For women more than 6 weeks postpartum and breastfeeding, Implanon is allowed (MEC Cat 1)
- Helps prevent ectopic pregnancies
- Helps prevent uterine fibroids
- May help prevent ovarian cancer
- May help prevent iron deficiency anaemia

DISADVANTAGES

- common side effects including headache, breast tenderness, acne, weight change, moodiness, nausea, etc.
- changes in menstrual bleeding patterns, Amenorrhoea is common
- rarely heavy bleeding in some
- may cause weight gain.
- Uncommon: infection at insertion site, difficulty in removal
- Does not protect against STI/RTI/HIV

Hormonal implants do not protect against STI/HIV. If there is a risk of STI/HIV (including the post partum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

9.6 CATEGORY OF PROVIDER

Insertion and removal of hormonal implants can be performed by trained and competent staff nurse, medical officer or gynaecologist.

9.7 MEDICAL ELIGIBILITY CHECKLIST

Hormonal implants should be provided to any woman in the reproductive age who requests them after appropriate counselling and reaching an informed decision, and who does not have any contraindication for its use.

9.7.1 INDICATIONS FOR HORMONAL IMPLANTS

Hormonal implants are appropriate for women who:

- prefer a method that does not require taking contraceptive action every day or before having intercourse
- want long-term birth spacing or have the number of children they want but do not want or cannot have a permanent method (voluntary sterilization) at this time are breastfeeding (6 weeks postpartum) and need a contraceptive
- are postpartum and breastfeeding, even less than 6 weeks postpartum
- desire contraception after a miscarriage
- have a history of ectopic pregnancy
- smoke
- are obese
- do NOT want or can NOT use estrogen-containing contraceptives, or have developed estrogen-related complications while taking combined oral contraceptives (COCs)
- have endometriosis
- have severe Dysmenorrhoea evaluated by a gynaecologist
- have uterine fibroids
- have past or current PID
- have RTI/ STI infections including HIV
- have adequately controlled hypertension
- have Thalassaemia
- have a history of high blood pressure during pregnancy where current blood pressure is measurable and normal
- have Varicose veins and superficial Thrombophlebitis
- have thyroid disorders such as Goitre, Hyperthyroidism and Hypothyroidism
- have valvular heart disease (complicated and uncomplicated), pulmonary hypertension, irregular heart rhythm (fibrillation) or history of subacute bacterial endocarditis (SBE) (as progestins do not contribute to blood clotting and embolism).

9.8 CONTRAINDICATIONS FOR IMPLANON

- Pregnancy
- severe liver disease (jaundice, cirrhosis, tumour)
- history of very high blood pressure (> 160/100 mm Hg)
- history of diabetes for more than 20 years with damage to arteries, nervous system and kidneys
- history of stroke, heart attack
- history of breast cancer
- unexplained irregular vaginal bleeding (Implanon may interfere in proper diagnosis)

9.9 COUNSELLING AND INFORMED CHOICE

All hormonal implant clients must receive appropriate counselling for selecting and using the method. Encourage and give the client an opportunity to ask all of their questions so that any uncertainties and misunderstandings can be cleared up. Counsel the client that hormonal implants do not protect against STIs or HIV/AIDS

Clearly discuss the following points for selecting the method:

- effectiveness and return to fertility
- mechanism of action, advantages and disadvantages
- alternative family planning methods
- physical characteristic of the implants; how they are inserted and in which part of the body; how they should feel under the skin
- when implant should be removed; importance of removal or replacement at the end of 3 years; follow-up requirements
- possible changes in the menstrual bleeding pattern
- side effects and complications
- The client should use condoms in addition, if she thinks there is any chance that she or her partner are at risk of exposure to STIs, including HIV/AIDS.

9.10 CLIENT ASSESSMENT

The purpose of the health assessment is to determine the client's suitability for the use of the method. In healthy women, no examination, laboratory tests are required or mandatory before initiating progesterone only implants. However, there is special consideration for blood pressure screening: It is desirable to have blood pressure measurements taken before inserting an implant. It is important to note that in situations where blood pressure measurement is not possible, the client should not be refused the method. They can still get an implant inserted.
Pregnancy should be ruled out prior to the provision of contraception. A pregnancy test should be done if there is any suspicion of pregnancy. Refer to Chapter 4 for indications for performing a pregnancy test.

It is also an opportunity to assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI and to offer other available sexual and reproductive health services as appropriate. Refer to Chapter 5 for further details on STI/RTI assessment.

9.11 PROVISION OF HORMONAL IMPLANTS

9.11.1 TIMING OF INSERTION

Hormonal implants should be inserted only after ruling out pregnancy. A pregnancy test should be done if there is any suspicion of pregnancy.

Table 9.1: When to start Implanon/progesterone implants

SITUATION	WHEN TO INSERT IMPLANON
Having menstrual cycles	• Within 7 days of the menstrual cycle: Implant can be inserted. No additional protection is required. • More than 7 days since the start of menstrual bleeding: Implant can be inserted if it is reasonably certain that she is not pregnant. She will need to abstain or use a backup contraceptive for the *next 7* days.
Amenorrhoea	• Implanon can be inserted if it is reasonably certain that she is not pregnant. She will also need to abstain or use a backup contraceptive (e.g. condom) for the next 7 days.
Breastfeeding (Postpartum)	• 6 weeks to 6 months after delivery, exclusive breastfeeding and having Amenorrhoea: Implanon can be inserted. No backup required. • More than 6 weeks after delivery and menstruation has returned: Implanon can be inserted as for women with menstrual cycles. • Less than 6 weeks after delivery and breastfeeding: Implant can generally be given (WHO Cat 2)
Postpartum and (not breastfeeding)	• Less than 21 days after delivery: Implanon can be inserted. No backup is required. • More than 21 days after delivery and menstrual cycles have not returned: Implanon can be inserted if it is reasonably certain that she is not pregnant. Backup method or abstinence from sex for 7 days will be required. • Menstrual cycles have returned: Implanon to be given as advised for women with menstrual cycles
Postpartum and (not breastfeeding)	• The Implanon can be inserted immediately after abortion. No additional backup is required.

Table 9.1: When to start Implanon/progesterone implants

SITUATION	WHEN TO INSERT IMPLANON
Post-abortion/miscarriage	• The Implanon can be inserted immediately after abortion. No additional backup is required.
Switching from another hormonal method	• If woman is using another hormonal method correctly and consistently or if it is reasonably certain that she is not pregnant: Implanon can be given immediately. No need to wait for her menstrual cycle. • If her previous method was another injectable contraceptive: Implanon to be given when the repeat injection of the previous method would have been due.
Switching from a non-hormonal method (other than IUD)	She can have the Implanon insertion immediately if it is reasonably certain that she is not pregnant. No need to wait for the next menstrual cycle. • Within 7 days of start of her menstrual cycle: Can get Implanon inserted. No need for additional contraceptive protection. • More than 7 days since start of menstruation: Can get Implanon inserted. Will need to abstain from sex or use a backup contraceptive for the next 7 days.
Switching from IUD (including LNG IUD)	• Within 7 days of start of her menstrual cycle: Can get Implanon inserted. No need for additional contraceptive protection. The IUD can be removed at that time. • More than 7 days since start of menstruation: Can get Implanon inserted if reasonably sure that she is not pregnant. If sexually active in this cycle, IUD should be removed at her next cycle for contraceptive protection over the period. • If the woman has Amenorrhoea: Can get Implanon inserted as advised for other amenorrhoeic women.

9.11.2 PROCEDURE FOR INSERTING HORMONAL IMPLANT

Insertion of Implanon (one rod implant) is a minor surgical procedure requiring aseptic technique, as well as good surgical technique. Implanon is inserted sub-dermally on the upper inner arm or forearm, under local Anaesthesia. Implanon should not be inserted deep as this makes removal very difficult.

PRE-INSERTION TASKS

1. Prepare insertion site with antiseptic solution.
2. Inject 1 ml of 1% lidocaine applied just under the skin, raising a wheal at the insertion point and advancing up to 5 cm along the insertion track. Gently massage the area of infiltration.
3. Check for Anaesthetic effect before applying the sharp needle.

INSERTION

1. Using no-touch technique, remove the sterile disposable one-rod implant applicator from its blister pack and remove the needle shield. (Make sure not to touch the part of the needle to be introduced into the body.)

2. Visually verify the presence of the implant inside the metal part of the needle.

3. Stretch the skin around the insertion site with thumb and index finger or alternatively, stretch the insertion site skin by slightly pulling with thumb.

4. Using the needle, puncture the skin at a 20° angle and insert only up to the bevel of the needle.

5. Release the skin. Lower the applicator to a horizontal position.

6. Gently advance, while lifting the skin, forming a tent, until inserting the full length of the needle without using force. Keep the applicator parallel to the surface of the skin

7. Break the seal of applicator. Turn the obturator 90 degrees.

8. Fix the obturator with one hand against the arm and with the other hand slowly pull the needle out of the arm; never push against the obturator.

9.Remove the needle, and apply pressure to the opening site

10.Palpate to check that the rod is in place. Optionally ask the client to palpate the implant prior to dressing.

POST-INSERTION TASKS

1. Wipe the client's skin with alcohol.
2. Bring edges of incision together and close it using surgical tape, then cover it with a Band-Aid or tape on a sterile gauze (2x2).
3. Apply pressure dressing snugly.
4. Before removing gloves, dispose materials by:
    - Placing used needle (without capping) and trocar in sharps container, and
    - Placing waste materials in leak-proof container or plastic bag.
5. Remove gloves by turning inside out and place in leak-proof container or plastic bag.
6. Wash hands thoroughly and dry them.
7. Complete client record, including drawing position of rod.

POST-INSERTION COUNSELLING

1. Instruct the client regarding wound care and make return visit appointment, if necessary.
2. Discuss what to do if the client experiences any problems following insertion or side effects.
3. Assure the client that she can have implant removed at any time if she desires.
4. Ask the client to repeat instructions and answer client's questions.
5. Complete client card indicating which implant she received and by when she needs to return for removal.
6. Observe the client for at least 15–20 minutes before sending her home.

9.11.3 WOUND CARE FOLLOWING IMPLANT:

The following instructions should be given to the client regarding wound care:

- Keep the area dry and clean for at least 3 days. The incision could become infected if the area gets wet while bathing or washing clothes.
- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.
- Routine work can be done immediately, but do not put unusual pressure on the area for a few days.
- Leave the gauze pressure bandage in place for 3 to 5 days to avoid having people touch the area while it is still tender.
- If signs of infection occur, such as fever, inflammation (redness with heat) at the site, or if there is persistent pain for several days, return immediately to the clinic/hospital.
  Advise on side effects, warning signs and where to go.

9.12 ROUTINE FOLLOW-UP CARE

- Women should be advised to return at any time to discuss side-effects, queries, or if she wants to change the method.
- Advise a routine yearly follow-up
- Women should be informed that the Implant has to be removed at 3 years or earlier in case of any complications.
- Contact a doctor immediately if she has any of the warning signs in Box 9.1
- Return to the facility when it is time to have hormonal Implant removed.

Box 9.1: WARNING SIGNS

See doctor immediately in the case of:

- Severe lower abdominal pain
- possible pregnancy
- unusually heavy or prolonged bleeding
- severe headache

AT FOLLOW UP:

- Assess the client's satisfaction with the method.
- Determine if the client has had any problems or side effects and, if so, record them in the client clinical card/hospital records.
- Check if client has new or marked changes in headaches.
- Assess for any STI/RTI related concerns and if the client has any symptoms related to
- STI/RTI. If yes, advise to use condoms additionally.
- Update the medical history; measure blood pressure and perform any examination indicated by the history.
- Provide appropriate counselling and/or treatment as required.
- Refer client to an appropriate referral facility/speciality if any serious problems or side effects cannot be managed at the facility were client has attended for follow up care. Provide referral slip.
- Update client's contact information (address, telephone number etc).
- Provide a date for the next routine follow-up visit.

9.13 WHEN TO REMOVE HORMONAL IMPLANT/ IMPLANON

Implanon rod can be left in place for 3 completed years after when it should be removed. Studies are currently on to determine if Implant can be effective for 4 years.

Steps for implant/ Implanon removal

1. Prepare implant removal site with antiseptic solution.
2. Give local Anaesthesia (1 ml of 1% lidocaine).
3. Check for Anaesthetic effect before applying the sharp needle.
4. Feel for the Implanon rod and make a small incision near the site of insertion.
5. Pull out the rod with a small artery forceps.
6. The provider closes the incision with an adhesive bandage. There is no need of stitches. The adhesive bandage for 2-3 days, will keep the wound sealed and keep down swelling.

9.14 SIDE EFFECTS AND MANAGEMENT

Clients should be routinely counselled about common side effects and what to do if certain problems occur. When a client presents with side effects or complications they should be assessed, counselled and managed appropriately. Refer to Chapter 3 for details on counselling clients with problems using a contraceptive method.

Table 9.2 Management of side effects: for clients using Implanon/ progesterone implants

SIDE EFFECTS	ASSESSMENT	MANAGEMENT
Amenorrhoea	Rule out pregnancy. Do a per vaginal /bimanual examination, pregnancy test, etc.	• Amenorrhoea does not require any medical treatment. • If pregnancy is ruled out, counsel the client, which should be sufficient. • If Amenorrhoea is unacceptable to client, remove Implanon. Help her choose another method.
Nausea	Rule out pregnancy (as under Amenorrhoea in this table).	If pregnant, advise as described under Amenorrhoea in this table. Refer to specialist if nausea continues; to rule out other causes.
Headache	Assess if the headache is new or there are marked changes in the headache.	Refer for evaluation if the headache is new or there are marked changes in the headache.
Breast fullness/ tenderness	Rule out pregnancy as in the section under Amenorrhoea Rule out breast lumps and infection in the breast - if breastfeeding	If pregnant, advise as under Amenorrhoea in this table. If not pregnant and no breast lumps, counsel. Refer to a specialist in case of breast lumps/ infection.

Table 9.2 Management of side effects: for clients using Implanon/ progesterone implants

SIDE EFFECTS	ASSESSMENT	MANAGEMENT
Light bleeding/Spotting	Perform a pelvic exam (speculum and bimanual) to be sure bleeding is not due to another cause (e.g., genital tract lesion such as Vaginitis, Cervicitis, cervical Polyps, cervical cancer or uterine fibroids).	Light bleeding or spotting is common with progesterone implants, especially during the first year. It is not harmful and usually does not require treatment. Reassure her that light inter-menstrual bleeding or spotting occurs in a large percentage of women using implants (15– 20%). NSAIDS/ Mefenamic Acid or Valdecoxib can be provided for 5-7 days.
Prolonged spotting: >8 days or moderate bleeding/ **Heavy or prolonged bleeding (more than 8 days) or twice as much as her menstrual periods**		In women with persistent spotting or bleeding, exclude gynaecological problems when clinically warranted. If a gynaecological problem has been identified treat the condition or refer for care. If a STI or PID is diagnosed, woman can continue with her implant while receiving treatment for STI and be counselled on condom use. If no gynaecological problems are found and she finds the bleeding unacceptable, remove Implanon. Counsel her to adopt another method. If not satisfied after counselling and reassurance, but wants to continue using Implanon, give: • hormonal (if medically eligible): COCs or ethinyl estradiol (30 mcg estrogen) • Ibuprofen (800 mg three times daily for 5 days (after doctors consultation) • other NSAIDs can also be given for 5-7 days (after doctors consultation)

9.15. RECORD KEEPING AND REPORTING

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.

The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

Note: In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 10

INTRAUTERINE DEVICES (IUD)

10.1 INTRODUCTION

Intra Uterine Devices (IUDs), also referred to as intra uterine contraceptive devices, offer almost complete protection from pregnancy. The newer IUDs have a longer life-span and are more effective. IUDs are small flexible devices made of plastic that are placed in the uterus through the vagina. The IUD is a safe and effective long term reversible method of contraception. The IUD discussed in this chapter is Copper T 380A/TCu-380A.

10.2 DIFFERENT TYPES OF IUDs THAT ARE AVAILABLE

1. Copper bearing IUDs: made of plastic with copper sleeve and/or copper wire around the plastic. Commonly available Copper bearing IUDs are:

   - Copper T 380A/ TCu-380A: The Copper T 380A is shaped like a T and has copper on the stem and the arms, with a total exposed copper area of 380 square mm. It has a white string at its base, which extends through the cervix so that the IUD can be removed easily. Copper T 380A/TCu-380A is currently available through the Maldives FP programme.CuT-380A is effective for 10 years.

   - Multiload 375 (ML Cu 375) is another copper IUD that has a slightly different shape and is effective for 5 years.

2. Hormone -releasing IUDs: These are made of plastic and steadily release small amounts of hormone progesterone, such as Levonorgestrel, LNG-20 and Progestasert is effective for 5 years. The perfect use and typical use effectiveness for the levonorgestrel-releasing IUD is 99.9%.

These second generation IUDs such as CuT-380-A, Multiload 375, LNG-20, etc, are effective options for a longer term reversible family planning.

10.3 EFFECTIVENESS AND RETURN OF FERTILITY

EFFECTIVENESS

The TCu-380A is one of the most cost-effective reversible contraceptive methods available under the Maldives' family planning programme. With effectiveness of 99.4% with perfect use and 99.2 % with typical use. IUD is as effective an implants and injectable contraceptives. After insertion, the contraceptive action lasts 10 years. Note that an IUD inserted into a client just before the shelf life of the packaging expires is still effective for up to 10 years.

Intra Uterine Devices do not protect against STI/HIV. If there is a risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

RETURN TO FERTILITY

Fertility returns immediately after the removal of IUD.

10.4 MECHANISM OF ACTION, ADVANTAGES AND DISADVANTAGES

Copper bearing IUDs act primarily by preventing fertilisation of sperm and ovum. It reduces the motility of fallopian tubes. IUD also prevents the implantation of egg in the uterine cavity.

ADVANTAGES

- Long term, reversible contraceptive method
- Very effective
- Convenient-for client
- Does not interfere with sexual intercourse
- No hormonal side effects of copper bearing IUDs
- Immediate return of fertility
- Does not interfere with the quantity or quality of milk
- Immediate postpartum and post-abortion insertion is possible
- Risk of ectopic pregnancy is reduced

DISADVANTAGES

- Menstrual changes are initially common and generally subside in 3 months of use
- Longer and heavy menstrual bleeding in some
- More cramps and pain during menstrual bleeding
- Rare possibility of perforation if not inserted properly
- Does not protect against sexually transmitted diseases including HIV
- Trained health provider is required to insert and remove the IUD
- Can get expelled from the uterus without client's knowledge

10.5 CATEGORY OF PROVIDER: INSERTION AND REMOVAL OF IUD

IUD insertion can be performed by trained and competent gynaecologists, medical officers and staff nurses. IUD removal with visible strings can be performed by trained and competent staff nurses, medical officers and gynaecologists. IUD removal with missing strings should be done only by trained and competent gynaecologists. Provider's role including careful client selection, counselling, insertion in aseptic conditions and follow up, play a vital role in acceptance and continuation of IUD.

10.6 MEDICAL ELIGIBILITY CHECKLIST

10.6.1 INDICATIONS

IUD should be provided to any woman who requests it, after appropriate counselling and reaching an informed decision, and who does not have any contraindication to its use.

IUD is appropriate for those who:

- Prefer a method that provides highly effective, long-term contraception, but do not want a permanent method such as voluntary sterilization
- Prefer a method that does not require taking contraceptive action daily or before sexual intercourse
- Prefer not to use a hormonal contraceptive method such as combined oral contraceptive pills or have contra indications for its use
- IUD can be provided to most women including who:
    - are breastfeeding
    - have or have not had children
    - have had a miscarriage without any risk/evidence of infection
    - smoke
    - are taking antibiotics and/or anticonvulsants
    - are fat or thin
    - are postpartum
    - have benign breast disease
    - have breast cancer
    - have headaches
    - have high blood pressure
    - have varicose veins
    - have heart disease
    - have history of stroke/liver disease/ diabetes/thyroid disease
    - have anaemia
    - history of past ectopic pregnancy

10.6.2 CONTRAINDICATIONS

- Pregnancy
- Uterine fibroid- if the cavity is distorted, chances of expulsion/perforation are there
- Uterine/ Endometrial cancer
- Cervical Cancer
- Known pelvic Tuberculosis
- Post septic abortion
- Current PID
- Current STIs
- Uterine abnormalities, as insertion will be difficult

10.6.3 MAJOR EVIDENCES AND CLARIFICATIONS REGARDING MEDICAL ELIGIBILITY FOR COPPER BEARING IUDS

- **Postpartum insertion**- Evidence suggests that immediate postpartum IUD insertion has lesser expulsion rate as compared to expulsion rate with delayed postpartum insertion

- **Post-abortion insertion**- There is no difference in risk of complications for immediate verses delayed insertion after abortion.

- **Valvular heart disease**- In women with valvular heart disease, a course of antibiotics is recommended before IUD insertion

- **STI and IUD**: Many women with increased risk of STIs can generally get an IUD (MEC Cat 2). In some women with very high risk of STI, IUD insertion may further increase the risk of PID. (Medical Eligibility Criteria Fifth Edition 2015 WHO). Women with very high individual risk of STI, should generally not have an IUD inserted until appropriate testing and treatment is done. MEC 2015 also suggests that current algorithms for determining increased STI risk have poor predictive value.

- **Pelvic Inflammatory Disease (PID) and continuation of IUD** - If a woman with IUD inserted gets PID, complete treatment of PID with antibiotics is recommended. There is no need to remove the IUD. Studies have shown that there is no added advantage in removing IUD in such cases.

- **High risk of HIV:** Copper IUD use did not increase any risk of HIV acquisition or transmission (MEC 2015 Cat 2).

10.7 COUNSELLING AND INFORMED CHOICE

All IUD clients must receive appropriate counselling for selecting and using the method. Review the woman's history to determine the possibility of existing contraindications to the method, such as high individual risk of STIs, and take this into account when providing counselling. Encourage clients to ask all of their questions so that any uncertainties and misunderstandings can be cleared up. It is important to counsel clients that IUD do not protect against STI/HIV. If STI/HIV/AIDS protection is needed condoms should be used in conjunction with IUD.

The absolute risk of ectopic pregnancy is extremely low due to the high effectiveness of IUDs. However, when a woman becomes pregnant during IUD use, the relative likelihood of ectopic pregnancy is greatly increased.

10.7.1 IUD METHOD SPECIFIC COUNSELLING

Specific points to be noted while counselling for IUD:

- Show the client a sample IUD (type to be inserted) and let them feel the IUD.
- Explain that TCu-380A is effective immediately after insertion.
- Describe the mechanism of action, advantages and disadvantages.
- Talk about myths and misconceptions and clarify as needed.
- Explain the timing and procedure of insertion.
- Explain that during the insertion, the client might feel some pain.
- Describe likely problems and complications.
- Emphasise the importance of checking the threads.
- Highlight the importance of follow-up.
- Describe side effects and warning signs.
- Advise use of condom if at risk for STI, HIV/AIDS.

10.8 CLIENT ASSESSMENT

The purpose of the health assessment is to determine the client's suitability for the use of the method. It is also an opportunity to offer other available sexual and reproductive health services as appropriate. All FP clients should be educated and shown how to perform a breast self-exam and to report if there are any abnormalities noted.
Pregnancy should be ruled out prior to the provision of IUD. A pregnancy test should be done if there is any suspicion of pregnancy

MEDICAL/SOCIAL/GYNAECOLOGICAL/OBSTETRIC HISTORY:

History taking should be done as detailed in Chapter 4. It is mandatory to do STI risk assessment by medical history (history of STIs, including HIV and PID, and risk factors for STI such as multiple sexual partners) and physical examination.

MANDATORY PHYSICAL EXAMINATION:

1. Abdominal examination (especially lower abdominal tenderness, or masses)

2. Pelvic examination – speculum visualization of cervix and bimanual pelvic examination. Bimanual vaginal examination is done to identify the position of the uterus (anteverted or retroverted) and to rule out pregnancy, PID, other pathology of the uterine cavity and overt malignancies.

3. Other examination can be done as indicated by the medical history.

Laboratory tests are not routinely required for the use of an IUD except when indicated by medical history and physical examination. If possible, Haemoglobin testing is recommended prior to provision of an IUD to have a baseline result.

10.9 PROVISION OF IUD

Provision of IUD should be done using aseptic precautions, as well as good surgical technique. Infection prevention must be strictly followed for safe insertion and removal procedures. A careful pelvic examination is mandatory prior to insertion of the IUD. The uterus is sounded to determine the length of the uterus. 'No touch' technique is used to load the IUD into the inserter. After introducing the loaded IUD into the uterine cavity, the final placement of the TCu-380A is done using the withdrawal technique.

10.9.1 Timing of insertion of the IUD

SITUATION	WHEN TO START
Having menstrual cycles	**Within 12 days after the start of menstrual cycle:** IUD can be inserted at woman's convenience. No additional contraception is required (there are certain advantages to insert IUD during menstruation: a) it is confirmed that she is not pregnant and b) insertion may be easy) **More than 12 days since the start of the menstrual cycle:** IUD can be inserted if it is reasonably certain that the woman is not pregnant.
Amenorrhoeic (not postpartum)	IUD can be inserted if it is reasonably certain that the woman is not pregnant.
Postpartum (Breastfeeding and non-breastfeeding including post-caesarean section)	**Within 48 hours of delivery and immediately after removal of the placenta:** Cu IUD can be inserted If delivery is by cesarean section, IUD can be placed in the uterine cavity, before closing the uterus **48 hours to less than 4 weeks postpartum**: Use of IUD is not recommended **4 or more weeks postpartum and amenorrhoeic:** - Breastfeeding: Cu IUD can be inserted if reasonably certain that she is not pregnant. - Non-breastfeeding: Cu IUD can be inserted if certain that she is not pregnant. **4 or more weeks postpartum and menstrual cycles have returned:** Cu IUD can be inserted as for other women having menstrual cycles Women having puerperal sepsis should not get IUD inserted

10.9.1 Timing of insertion of the IUD

SITUATION	WHEN TO START
Post-abortion	Cu IUD can be inserted immediately after a first-trimester abortion and after a second trimester abortion Cu IUD should not be inserted after a septic abortion
Switching from another method	Cu IUD can be inserted if it is reasonably certain that woman is not pregnant: there is no need to wait for her next menstrual period.
For emergency contraception	Cu IUD can be inserted within 5 days of unprotected intercourse as an emergency contraceptive. Women who take Cu IUD as an emergency contraceptive should be medically eligible for it

10.9.2 TECHNIQUE OF IUD INSERTION

KEY STEPS IN THE INSERTION PROCEDURE:

- Follow proper infection prevention procedures.
- Use sterile instruments, prepared either by boiling, steaming or soaking them in disinfectant chemicals.
- Use a new sterile IUD that is sealed with its inserter.
- The "no touch" technique is the best. This includes:
  - loading the IUD into the inserter while the IUD is still in the sterile package
  - cleaning the cervix with antiseptic solution
  - not letting the loaded IUD or uterine sound touch any unsterile area (for example hands, vagina, table top, etc.)
  - passing uterine sound and inserter only once each through the cervical canal
- Explain the steps to the woman as you are proceeding.
- Tell her that she will experience some pain and discomfort during the procedure, so that she understands what to expect.
- Ibuprofen (200-400 mg), Paracetamol (325-1000mg) or other pain reliever may be given 30 minutes before procedure to reduce cramping and pain. Avoid Aspirin.
- The provider conducts pelvic examination including visualisation of cervix to assess the eligibility of the client for IUD.
- Provider cleans the cervix and vagina with an aseptic solution and holds the anterior lip of the cervix gently.
- The length of the uterine cavity is measured next with a uterine sound.
- The provider loads the IUD into the inserter while both are in the unopened sterile package.
- The provider slowly and gently inserts the IUD and removes the inserter.
- The provider cuts the strings on the IUD, leaving about 3 centimetres hanging from the cervix.
- After the insertion, the provider ensures that the woman is comfortable and can get up from the table.

Important: For postpartum insertion, only providers who have special training should insert IUDs after childbirth. Proper insertion technique is important to reduce the risk of expulsion.

FOLLOW UP FOR IUD ACCEPTORS:

1. Plan with the client for a return visit in 3 to 6 weeks or immediately after the next menstrual period to ensure that her IUD is still in place and that no infection is developed.

2. Make sure she knows:

    - Exactly what kind of IUD she has
    - When to come for checkup/ removal, etc.
    - When to have IUD removed or replaced (for TCu-380A IUD, 10 years after insertion).
    - Discuss how to remember the year to return. If she wants a new IUD, can be inserted as soon as the old IUD is removed.

It is important to provide the client with a written record of the month year of IUD insertion and the month and year of when it should be removed.

Checking the IUD: Sometimes IUDs come out, especially in the first month or so after insertion or during a menstrual period. An IUD can come out without the woman knowing about it.

A woman who got IUD inserted should check that her IUD is in place:

- after a menstrual period.
- after noticing any serious problems, such as: heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

How to check for the strings?

- The woman should wash her hands
- Sit in a squatting position.
- Insert one-two fingers in the vagina and go as far as she can, to feel for the strings. In case she is not able to feel the strings, she should report to the health provider.
- Wash her hands again.

IMPORTANT:

- She should not pull the strings, as the IUD may be dislodged.
- After postpartum insertion, the woman should be informed that the strings do not always come down through the cervix.

10.9.3 ROLE OF PROPHYLACTIC ANTIBIOTICS FOR IUD INSERTION

Routine prophylactic antibiotics are not required for insertion of IUD in healthy women.
Health workers can advise clients to visit a facility and see a doctor or nurse for a breast and pelvic exam.

Note: Women with health conditions e.g. cardiac valve disorders that warrant antibiotic prophylaxis for invasive procedures will need antibiotic prophylaxis for Cu bearing IUD insertion.

10.10 IUD AND PREGNANCY

Suspected pregnancy or confirmed pregnancy
IUD should NOT be inserted if pregnancy is suspected or confirmed.

If a woman using Copper IUD is found to be pregnant Exclude ectopic pregnancy.

- Explain that she is at an increased risk of first and second trimester miscarriages (including septic miscarriage that may be life threatening) and of pre-term delivery if the IUD is left in place.
- The removal of the copper bearing IUD reduces this risk, although the procedure itself entails a small risk of miscarriage.
- Advise the client to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

If client wants to remove Cu IUD and continue pregnancy, and if Cu IUD strings are visible or can be retrieved safely from the cervical canal:

- Advise the client it is best to remove the IUD.
- If the Cu IUD is to be removed, then remove by gently pulling on the strings.
- Explain that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

If she chooses to keep the Cu IUD, advise her to seek care promptly if she has: heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

Copper IUD strings are NOT visible or cannot be safely retrieved
If ultrasound is available, it may be useful in determining the location of the Copper IUD. If the Copper IUD is not located, this may suggest that it might have been expelled.

If ultrasound is not available or if the Copper IUD is determined by ultrasound to be inside the uterus, make clear the risks and advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

Note:
In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

10.11. REMOVAL OF IUD

Removal of IUD is a simple procedure. A speculum examination is done, IUD thread is grasped close to the cervix with sponge holding forceps/artery forceps and gently pulled out using steady gentle traction. If the removal requires more than a gentle traction, the client should be referred to a specialist.

10.11.1 INDICATIONS FOR REMOVAL AND/OR RE-INSERTION OF IUD

An IUD may be removed:

- for medical or personal reasons
- 10 years after of insertion of TCu-380A – this should be done preferably during menstrual period. A new IUD can be re-inserted at the same time if the client desires. Use a new TCu-380A for re-insertion.
- Wants another child
- Desires removal
- Severe bleeding
- Severe abdominal Pelvic infection not responding to treatment
- Pregnancy
- Menopause (cessation of periods for one year)
- Evidence of IUD displacement

10.12 CLIENT INSTRUCTIONS POST IUD INSERTION

INSTRUCT CLIENTS ON FOLLOWING POINTS:

CHECKING STRINGS

The client will need to check for the strings of the IUD to be sure it is in place. It is a good idea to check for strings after each menstrual period. Provide verbal and written instructions. Steps for checking IUD strings: as explained in previous paras.

CHANGES IN THE CLIENT'S MENSTRUAL PERIODS

For most women the first few periods will be heavier, last longer and may have more cramping. There might also be inter-menstrual bleeding or spotting. This is not harmful. However, if the bleeding lasts twice as long as usual or if she uses twice as many pads, cloths or tampons, she should see a health care provider.

SPECIAL CONCERNS FOR RETURN VISITS

A woman should get medical help as soon as possible if she has any of the warning signs. Provide verbal and written instructions on warning signs and where to go. (Refer to Box 10.1)

In addition, if either the women or her husband begins having sexual relations with other partners without using condoms, this increases her risk of getting a sexually transmitted disease because IUDs do not protect against them.

MANAGEMENT OF POSSIBLE PROBLEMS DURING INSERTION AND REMOVAL OF IUD.

TABLE 10.1 POSSIBLE PROBLEMS, ASSESSMENT AND MANAGEMENT INSERTION OR REMOVAL OF IUD

PROBLEM	ASSESSMENT	MANAGEMENT
Fainting (Syncope); slow heart rate (Bradycardia) or Vasovagal episode during IUD insertion or removal	• Is woman extremely anxious? • Does she have a small uterus or cervical Stenosis? (These characteristics increase risk for fainting and/or Vasovagal reaction.)	Every step of IUD insertion and removal should be done slowly and very gently, with an explanation of each step to the client. At the earliest sign of fainting, stop the insertion. Resume the procedure once the episode has passed and client desires.
Suspected uterine perforation (during uterine sounding or IUD insertion)	Client complains of suddenly significant pain during procedure. There is feeling of giving way Sound measures more than 9 centi meters	If the pulse and blood pressure are normal, make the client lie down and check the pulse and blood pressure every 15 minutes for an hour. Stop the procedure (and remove IUD if inserted) If BP is low or the pain is severe around the uterus, hospitalise, start IV fluids and refer the client to a specialist.
Missing strings	Ask the client whether she knows if the IUD has come out/been expelled. If client does not know if IUD was expelled, check if she is pregnant by history, abdominal/ pelvic examination and a pregnancy test. If she returns while menstruating and strings are not visible, rule out lost IUD or perforation. If she returns with delayed (more than 4 weeks) menses, check for pregnancy (pelvic exam, Pregnancy test).	If examination/test reveals intra uterine pregnancy, refer to Box 10.1 IUD and pregnancy.

Box 10.1 WARNING SIGNS

See doctor promptly in the case of:
- **Severe lower abdominal pain**
- **Missed period, possible pregnancy**
- **Severe vaginal bleeding**
- **Infection exposure (such as Gonorrhea), abnormal discharge**
- **Fever and/or chills, especially if accompanied by lower abdominal pain**
- **Strings missing, shorter or longer then usual, or the tip of the IUD can be felt when she is checking for the strings.**

10.13 ROUTINE FOLLOW-UP CARE

- Routine follow-up after the first menses to check if IUD is in place and to rule out any infection.
- Routine subsequent follow up every 6 months.
- Advise the client to return to the facility earlier if she has any concerns
- Advise the client to contact doctor immediately if she has any of the warning signs in Box 10.1.
- She should return to the facility for IUD removal. TCu-380A lasts for 10 years.

AT FOLLOW UP:

Assess the client's satisfaction with the method.
Determine if the client has had any problems or side effects and, if so, record them in the client clinical card/record.
Assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI.
Perform pelvic examination (speculum examination and bimanual vaginal examination) is mandatory to check for IUD strings or any signs of STI/RTI.

10.14 SIDE EFFECTS AND MANAGEMENT

Box 10.2 IUD AND PELVIC INFLAMMATORY DISEASE (PID)

Women using IUD diagnosed with PID

Treat PID using appropriate antibiotics.
There is no need to remove IUD if she wishes to continue its use.
If she does not want to keep IUD, remove it AFTER antibiotic treatment has been started.
If the infection does not improve, remove IUD and continue antibiotics.
Provide comprehensive management for STI, including partner management and counselling about condom use.

Clients should be counselled about common side effects and what to do in case of a problem.
When a client presents with side effects/ complications they should be assessed, counselled and managed appropriately.

TABLE 10.2 MANAGEMENT OF SIDE EFFECTS OF IUD

Side Effect	ASSESSMENT	MANAGEMENT
Amenorrhoea		
(Absence of vaginal bleeding or spotting)	Ask client: when she had her last menstrual period when she last felt the IUD strings If she has symptoms of pregnancy Rule out pregnancy (Intrauterine or ectopic) by checking symptoms, and performing a pelvic exam (speculum and bimanual) and a pregnancy test	If pregnancy is ruled out, no treatment is required except counselling and reassurance. Explain that blood does not build up in the uterus. Advise the client to return to the IUD provider for further evaluation if Amenorrhoea remains a concern. If the client is elderly, exclude possible menopause. Refer to section: management of a client who is pregnant with IUD
Irregular bleeding with or without symptoms of pregnancy	Perform abdominal and pelvic (speculum and bimanual vaginal) examination to check for infection, pelvic pain or tenderness, palpable adnexal mass or enlarged uterus (consistent with pregnancy).	If less than 3 months and no evidence of pregnancy or pathology, counsel client that spotting or bleeding is common during the first 3 to 6 months after insertion of Copper IUD and decreases over time. If she desires treatment, a short course of NSAID may be given during the days of the bleeding. If there are no other gynaecological problems and if the client finds bleeding unacceptable, remove the IUD and assist her to choose another method. If PID suspected, manage as explained in previous paras

TABLE 10.2 MANAGEMENT OF SIDE EFFECTS OF IUD

Side Effect	ASSESSMENT	MANAGEMENT
Ectopic pregnancy	Must be suspected in clients with irregular bleeding and/or abdominal pain.	Refer promptly to an appropriate facility for complete evaluation if ectopic suspected. If other gynaecological problems are identified, refer for further management.
Bleeding (heavy/prolong ed) Amount: more than normal period Duration: more than 8 days vaginal, cervical or pelvic infection Check for clinical signs of anaemia: Check Hb	Perform pelvic examination (speculum and bimanual) to be sure that client does not have: • Intrauterine or ectopic pregnancy • Incomplete abortion	If client has had IUD less than 3 months: If exam is normal, reassure and give iron tablets (1 tablet daily for 1–3 months). Ask client to return in 3 months for another check. Use NSIAD, such as ibuprofen, during bleeding episodes, if available, to decrease bleeding (800 mg 3 times daily for 1 week). NOTE : ASPIRIN SHOULD NOT BE USED AS TREATMENT FOR BLEEDING
If strings are missing **Partner complains about strings**	Do per speculum examination Check to be sure that IUD is in place (i.e., not partially expelled).	Refer to specialist for further evaluation If strings are seen, reassure client that strings are present and help her feel them. Counsel client and cut strings shorter

10.11 RECORD KEEPING AND REPORTING

The provider should legibly record information in the Client Clinic Card and Family Planning Register. The provider should ensure that records and registers are completed, regularly maintained and reported to the Health Protection Agency.

CHAPTER 10A

LEVONORGESTREL - 20 IUD (LNG-20)

10A.1 INTRODUCTION

Levonorgestrel Intra-Uterine Device (LNG-20) is T shaped plastic device that steadily releases small amounts of Levonorgestrel each day. LNG is similar to hormone progesterone that is widely used in oral contraceptive pills and implants. It has been used widely in some parts of the world over the past 10 years and is considered to be an ideal IUD. Besides preventing pregnancy, it reduces the pain and bleeding during menstrual periods.

10.A.2 EFFECTIVENESS

The failure rate with LNG 20 is as low as that with sterilization. It has an added advantage of reducing the bleeding and pain during menstruation.

10.A.3 MECHANISM OF ACTION

LNG releases approximately 20 micrograms of Levonorgestrel every 24 hours for 5 years. LNG makes the cervical mucus thicker, preventing sperm to move up the uterine cavity. It also thins the endometrial lining to prevent implantation. It also prevents ovulation.

10.A.4 ADVANTAGES

- More effective than Cu IUDs.
- Much less pain, bleeding and discomfort during menstrual periods as compared to that with Cu IUD.
- Pelvic infection is much less as compared to Cu IUDs
- Studies have shown that LNG 20 has lower ectopic pregnancy rate as compared to that with other Cu IUDs.

10. A.5 DISADVANTAGES

- It is costlier than other Cu IUDs
- Can cause irregular bleeding or spotting in the initial 6 months of use.
- Not suitable for women at risk of STIs or ectopic pregnancy

10.A.6 MAJOR EVIDENCES AND CLARIFICATIONS

Most medical eligibility criteria for Cu IUDs and LNG-20 are similar. Since LNG - 20 is a hormonal IUD, following additional criteria and major clarifications are to be noted:

- Cu IUD is safer than LNG 20 in cases of cardiac ailments and high blood pressure.
- In women with current deep vein thrombosis/ pulmonary embolism, current history of Ischaemic heart disease and migraine, LNG-20 should only be given if other choices are unavailable or unacceptable.
- LNG-20 is not suitable for women with breast cancer as it has hormones.
- LNG-20 is also not the first method of choice for women with liver disease.
- LNG-20 decreases endometriosis and dysmenorrhea symptoms.
- For women with heavy and prolonged menstrual bleeding, LNG-20 is beneficial as it reduces the symptoms.
- In women with fibroids, LNG-20 was reported to reduce the symptoms and also reduces the size of the fibroid.

10.A.7 TIMING OF INSERTION OF LNG-20

LNG IUD is inserted within a week of the beginning of a menstrual period. This helps in easy insertion and reduced chances of expulsion.

It can be inserted immediately after abortion that is not infective.

In postpartum women, LNG-20 can be inserted within 48 hours after delivery and immediately after the delivery of the placenta. If delivery is by cesarean section, LNG-20 can be placed in the uterine cavity before closing the uterus. From 48 hours to 4 weeks of delivery, LNG-20 is generally not recommended, unless other reliable methods of contraception are not available or unacceptable. 4 or more weeks postpartum, LNG-20 can be inserted.
If a woman wants to shift from another contraceptive method to LNG, it can be easily inserted if it is reasonably certain that the woman is not pregnant. there is no need to wait for the menstrual cycle to return.

Note:
In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 11

BARRIER METHODS

11.1 INTRODUCTION

Barrier contraceptive methods act in one or more ways to prevent pregnancy. Mechanical barriers such as male condoms, female condoms and diaphragms, prevent the sperm from entering the vagina and uterine cavity.

11.2 TYPES OF BARRIER METHODS

Male condoms are widely available in Maldives. Other barrier contraceptive methods are various kinds of spermicides, female condoms and diaphragms.

A condom is a sheath made of thin latex (synthetic rubber) that is put on a man's erect penis before intercourse. Some condoms are covered with a lubricant or a spermicide. Condoms may be available in different sizes, colour or texture. Male condom is a very effective method of contraception, if used correctly and consistently. Condoms provide dual protection from unwanted pregnancy and also from sexually transmitted infections. It prevents pregnancy by creating a barrier, which prevents the sperms from entering the vagina and thereby preventing fertilization of the ovum.

11.3 EFFECTIVENESS OF MALE CONDOMS

If used correctly and consistently, condoms are 98% effective in preventing pregnancy.
However, the typical use effectiveness is only 86%.

11.4 CATEGORY OF PROVIDERS

Condoms are available free of charge from NGO clinics and public facilities. Male condoms can be purchased from pharmacies. It is important that personnel who provide condoms both in health facilities as well as pharmacies should be trained in providing correct information regarding condom effectiveness and the correct use of

Dual protection refers to preventing both STI/HIV and unwanted pregnancy. This can be achieved by the correct and consistent use of condoms alone or by simultaneous use of 2 methods, one of which is a condom. Dual method use refers to using a barrier method for protection against STI/HIV and another method for contraception.

If there is risk of STI/HIV (including during pregnancy or postpartum) condoms should be used correctly and consistently. Male latex condoms also protect against STI/HIV.
Condoms used correctly and consistently are the only method currently available for DUAL PROTECTION, i.e. they prevent unwanted pregnancy as well as STIs including HIV/AIDS

11.5 ELIGIBILITY

Barrier methods should be provided to any client who requests them, who has received appropriate counselling and made an informed decision. Condoms can be used by most couples except when either man or the woman has severe allergy to latex.

11.6.1 ADVANATAGES

- Can be used immediately after childbirth
- Prevent STI/ HIV infections and pregnancy
- Safe - no hormonal side -effects
- Improves male participation
- Can be stopped any time
- Easy to carry in case sex happens unexpectedly
- Can be used by men of all ages
- Prevents premature ejaculation

11.6.2 DISADVANTAGES

- Latex may cause allergy to some
- Sex act to be interrupted to wear the condom on an erect penis
- Rare chances of rupture of condom
- Rare chances of slippage
- If not stored properly, can tear/ break

11.7 COUNSELLING AND INFORMED CHOICE

In the process of assisting clients (male or female) to decide a barrier method, they should be counselled on the use of contraception in general, including other methods, and their advantages and disadvantages. Confidentiality is important and should be ensured even when condoms are provided through pharmacies and public outlets.

Counselling helps to ensure informed choice and proper condom use. However, counselling should not be a prerequisite for providing condoms. As for other methods the following should be included in counselling:

- effectiveness and the importance of correct and consistent use
- advantages and disadvantages
- alternative methods of contraception

Clarify myths and misconceptions related to condoms. Counsel regarding fears about breakage of condoms. While instructing a male or female client, show them the condom. Demonstrate using anatomical models/illustrations (if possible).

11.8 CLIENT ASSESSMENT

The purpose of the assessment is to determine the client's suitability of the method and to assess for any STI/RTI related risks and if required, offer other STI/RTI related services.

11.9 PROVISION OF CONDOMS

11.9.1 CLIENT INSTRUCTIONS FOR CONDOM USE

When should you use a condom:

- Use a condom every time with every act of intercourse.
- Be sure you have a condom before you need it.
- Each condom should be used only once and discarded.
- How to check the expiry date on the packet

HOW TO USE THE CONDOM CORRECTLY:

- Put the condom on the penis when it is erect and before the penis is in contact with the woman's genitals.
- Remove the condom carefully from the packet taking care not to tear it.
- Do not unroll the condom before it is put on the penis.
- Place the condom on the erect penis ensuring that the rolled rim remains on the outside of the condom.
- **Squeeze the tip of the condom** to ensure that half an inch air free space is left to collect the ejaculate. In case of condoms with a readymade tip, squeeze the tip first to expel air. Care should be taken not to tear the condom with fingernails.
- Continue to squeeze the tip while unrolling it all the way to the base of the penis.
- Cover the penis fully to preventing slip of condoms as well as preventing contact with ulcers (if present) on the penis or in the vagina.
- After intercourse, hold the rim of the penis before coming out of the vagina to prevent slippage of the condom and spilling of contents in the vagina. Pull the penis out before it goes limp so that the condom does not slip and get left in the vagina which will result in the ejaculate spilling and causing a pregnancy or transmitting STIs / HIV.
- Slide the condom off slowly without spilling the contents **only after** the penis is pulled out and is not in contact with the woman.
- Tie a knot over the mouth of the used condom so that the contents do not spill and dispose of the used condom in trash or by burying /burning it.
- Use a new condom if the condom has not been properly put on or there is a breakage.

IF THE CONDOM SLIPS OR BREAKS:

- Immediately wash the genitalia with soap and water to minimize risk of pregnancy and STIs/HIV.
- Contact a health worker for emergency contraception.

INSTRUCT ON THE FOLLOWING:

- Do not use the condom if it is discoloured or brittle.
- Do not test the condoms for holes as it is already electronically tested.
- Do not lubricate the condom as it is already lubricated.

STORAGE OF CONDOMS

- Make sure supplies are adequate. (Keep an extra supply of condoms on hand.)
- Store condoms in a cool and dry place and not exposed to sunlight as heat and sunlight cause breakage of condoms.
- The date on the condom package is the date that the condom was manufactured, not the expiration date. Under proper storage conditions the condom should be safe for 5 years.

Ask the client to demonstrate proper use of condom on a model

INSTRUCTIONS FOR RETURN VISIT

- Return to the provider if your spouse or you are not satisfied with the method.
- In case of allergy, return to the provider for advice.
- Return after one month or earlier for supplies. Provide information on other sources of supplies (if any).

11.10 ROUTINE FOLLOW-UP CARE

No routine follow up visit is required. The client can return for further supplies as required. Advise the client to return at any time if he/she has any concerns or if he/she wants to change the method.

AT FOLLOW-UP:

- Assess the client's satisfaction with the method.
- Determine if the client has had any problems or side effects and, if so, record them in the client clinical card/record.
- Assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI.
- Update the medical history and perform any examination indicated by the history.
- Replenish supplies.

11.11 SIDE EFFECTS AND MANAGEMENT

Clients should be routinely counselled about common side effects and what to do if certain problems occur. When a client presents with side effects or complications they should be assessed, counselled and managed appropriately. Refer to Chapter 3 for details on counselling clients with problems using a contraceptive method.

TABLE 11.1 MANAGEMENT OF PROBLEMS/ SIDE EFFECTS OF THE CONDOM

PROBLEM	ASSESSMENT	MANAGEMENT
Condom broken before or after use	Check for holes	Before use: advise to use a new condom. After use: advise to wash the genitalia with soap and water immediately. Provide emergency contraception as discussed in Chapter 15.
Local irritation to penis or vagina	Rule out allergy Rule out infection in both partners	If allergic to latex, counsel for another method. If either partner has an infection, manage both partners accordingly.
Diminished sexual pleasure		Counsel and if not satisfied suggest another method.
Man is not able to maintain an erection while putting on or using the condom	Often due to embarrassment	Counsel on how to make condom use more enjoyable. Recommend a dry condom, without spermicide. (water can be used as a lubricant). If problem continues, help the client to choose another method. If client is at risk of STI, advise using the condom despite discomfort.

11.12 QUALITY CONTROL

Any programme offering barrier methods must have a system to ensure that the products offered are of acceptable quality and size. This requires:

- Proper transport and storage.
- A 'check' system to make sure that the products are not used after their expiry dates or after their recommended shelf life.
- A procedure put in place to ensure that samples of the products are checked or tested

- Purchase of the condoms from a government approved supplier.

11.13 RECORD KEEPING AND REPORTING

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.

The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

Note:
In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

11.14 OTHER BARRIER METHODS

11.14.1 FEMALE CONDOMS

The female condom is a loose plastic sheath, made of poly-urethane that is inserted into the vagina before sexual contact and helps to protect against both pregnancy and STIs/HIV. However it may be less effective than the male condom in preventing pregnancy, HIV and other STIs. Female condoms may be more effective against pregnancy when used consistently i.e. at each act of sexual intercourse and when combined with another method, such as spermicide. However female condoms cannot be used at the same time as the male condom. The female condom may also be more expensive than male condoms.

CLIENT INSTRUCTIONS FOR FEMALE CONDOMS

ADVISE THE CLIENT:

- Use a new condom for each act of intercourse.
- Do not use if unopened package is torn or leaking, or the condom is dried out.
- Insert before penis touches vagina.
- Can be inserted up to 8 hours ahead of time.
- Condoms are lubricated but may need extra lubricant inside so that they are not moved out of place during sex. More lubricant can be added either inside the condom or onto the penis.
- Removing the female condom: when finished, the woman must move away from partner and take care not to spill semen on the vaginal opening. Gently twist the outer ring and pull the female condom out of the vagina.
- Disposing of a used condom: throw away the used female condom in trash or bury/ burn it.

THE FOLLOWING THREE ESSENTIAL CRITERIA MUST BE MET FOR EFFECTIVE USE OF LAM AS A METHOD OF CONTRACEPTION.

1. Exclusive/exclusive breastfeeding including at least one breastfeed at night
2. Mother's menstrual bleeding has not returned yet, and
3. Baby is less than 6 months old

11.15 SPERMICIDES

Spermicides are available in the form of jellies, creams, foams, foaming tablets and suppositories. Spermicides act by killing the sperm or by making the sperm unable to move towards the egg. The effectiveness of spermicides ranges from 71-85% and is highly dependent upon correct use and greatly increased when used together with condoms.
Women at high risk of HIV infection or those already HIV infected should not use spermicides. Repeated and high-dose use of spermicide nonoxynol-9 is associated with an increased risk of genital lesions, which may increase the risk of acquiring HIV infection.

CLIENT INSTRUCTIONS FOR SPERMICIDES

Advise the client about the importance of:

- using spermicide before each act of intercourse
- following the recommendations of the manufacturer for use and storage of each individual product
- another application if intercourse takes place more than 1 hour after initial application.

CHAPTER 12

LACTATIONAL AMENORRHOEA METHOD AND POST PARTUM CONTRACEPTION

12.1 INTRODUCTION

Lactational Amenorrhoea Method (LAM) uses breastfeeding, with specific criteria, as a temporary method of family planning. It is an effective, method that enables both mother and infant to take full advantage of the numerous other benefits of breastfeeding, including longer birth intervals and the healthiest source of nutrition for infants. It provides natural protection against pregnancy and forms the basis of initiating another method at an appropriate time.

12.2 EFFECTIVENESS OF LAM

LAM leads to changes in the natural hormones in body so that ovulation does not occur. When used correctly and consistently, the effectiveness is almost 99% in the first 6 months. If used typically (commonly), effectiveness is almost 98% in the first six months.

Note:

- Baby should be fed on demand, more than 6-8 times per day/night without supplementation (baby's diet is 90% breast milk). Interval between two feeds should not be more than 4 hours during the day and 6 hours during the night.
- Spotting that occurs during the first 56 days is not considered as menses.
- If any of the above criteria is not met, the woman should be advised to adopt another method of contraception that does not interfere with breastfeeding.

The Lactational Amenorrhoea Method (LAM) does not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or post partum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

12.3 CATEGORY OF PROVIDERS

Counselling for LAM can be provided by any health worker who has been trained and is competent to explain the criteria for LAM and instruct on the use of LAM as well as to explain alternative methods of contraception and their use. The following providers can counsel on LAM: Family Health Officer (FHW), Community Health Officer (CHO), staff nurse, medical officers and gynaecologist.

12.4 ELIGIBILITY

For mothers who wish to use LAM as a contraceptive, a central consideration must be that she should fully/exclusively breastfeed her baby. This means that the principal source of nutrition for an infant comes from breast milk:

12.4.1 CONTRA INDICATIONS FOR LAM

- Client has resumed her menses.
- Baby suckles infrequently (i.e. less than 6 to 10 times a day on both breasts) or baby sleeps through the night.
- Client has added regular supplemental foods or liquids to her baby's diet.
- Baby is 6 months old or older.

If any one of the above conditions is true, LAM is contra-indicated. Clients should be counselled about the need for another method for contraception and to continue breastfeeding.

12.4.2 BREASTFEEDING AND HIV INFECTION

Breast feeding should be promoted, protected and supported in all populations, for all women who are HIV negative or of unknown HIV status.

FOR WOMEN WHO ARE HIV POSITIVE:

- If replacement formula milk/ top feeding is acceptable, feasible, affordable, sustainable and safe, the woman can take a decision to avoid breastfeeding.

- If it is not possible to provide sufficient and regular supplies of formula milk/ top feed, exclusive breastfeeding is recommended to ensure sufficient nourishment for the baby, especially during the first month of life and should then be discontinued as soon as it is feasible.

- Women who are HIV positive should receive counselling that includes information about both the risks and benefits of various infant feeding options based on local assessments, and guidance in selecting the most suitable option.

- Women who are HIV positive and can receive appropriate Anti-Retroviral (ARV) therapy, should exclusively breastfeed their infants for the first 6 months. There is now strong evidence that giving (ARVs) to either the HIV positive mother or to the HIV exposed infant or both, can reduce the risk of transmitting HIV through breastfeeding.

12.5 COUNSELLING FOR LAM

Lactational Amenorrhoea Method (LAM) is understood by the mother if the time is taken to explain it in a language she understands, and her concerns and questions are addressed. The desired outcome is a woman who:

- clearly understands the three major conditions which make LAM effective
- knows what optimal breastfeeding practices are and when to stop using LAM and adopt another contraceptive method
- knows what contraceptive method she wants to use that is compatible with breastfeeding
- knows that condoms should be used if there is a risk of STI/HIV.

Counselling should include the following:

- Begin immediately to obtain the benefit of Colostrum.
- Feed on demand, at least every 4 hours in day, and every 6 hours at night.
- Fully breastfeed for 6 months (baby's diet is more than 90% breast milk).
- Encourage nutritious diet for the breastfeeding mother.
- Continue to breastfeed as long as possible.
- Discuss/ initiate an alternative contraceptive method before 6 months postpartum in women who want continued contraception.

When to stop using LAM as the sole contraceptive

- Baby reaches 6 months
- Menses start
- Baby receiving supplemental feedings

Discuss complementary family planning methods for the lactating mother:

Refer to Table 12.1 and Figure 12.1 in this chapter for description of other methods for lactating women.

- Offer client a back-up method before she no longer meets the LAM criteria, so she can be fully protected before she is at risk for pregnancy.
- Counsel the client that lubricated condoms can help with vaginal dryness associated with breastfeeding. The client will then be protected until she can visit the family planning clinic for help in choosing a different method if desired.

12.6 ROUTINE FOLLOW-UP CARE

- Women who choose LAM for contraception should be seen again 5 months postpartum to help them choose another method if desired.
- The client should also be advised to return to facility earlier if she has any concerns or if she wants to change the method.
- Clients who have decided on the method to use after stopping LAM should be given:
  - instructions on how to use the chosen method or when to return to initiate the method
  - the selected method, when appropriate, prior to leaving the facility rather than referring the client to an outpatient department or other clinic to obtain services.

It is important that providers who perform outreach services to women who have had home births carry with them a supply of family planning methods in order to provide these methods to women who choose them.

12.7 POST PARTUM CONTRACEPTION

All postpartum women should be counselled and provided with the family planning method they choose prior to their discharge from the birthing facility. All methods of contraception are appropriate for postpartum women. However, the time for starting each method depends on a woman's breastfeeding status.

12.7.1 RETURN TO FERTILITY POSTPARTUM

Following delivery every woman experiences a period of infertility. The period of infertility following delivery in **non-breastfeeding** women may be less than 6 weeks post-delivery (on average, the first ovulation occurs around 45 days postpartum). The period of infertility for **breastfeeding** mothers is longer than for non-breastfeeding mothers. The return of fertility, however, is not predictable (conception can occur before the woman has signs or symptoms of the first menses). This period of temporary infertility is due to the effect of suckling which causes a surge in the hormone Prolactin thereby inhibiting ovulation. Ovulation remains disrupted or suppressed, as long as the frequency, duration and intensity of suckling are high. Ovulation in a lactating woman often naturally resumes around 6 months postpartum.

12.7.2 COUNSELLING POSTPARTUM WOMEN

Contraceptive counselling and service provision should be part of:

- immediate postpartum care for hospital-based birthing services
- initial and follow-up visits to postpartum women during outreach services
- routine postpartum services offered to women in the first 6 weeks following childbirth.

It is best if counselling for postpartum contraception begins in the antenatal period:

12.7.3 WHEN TO START CONTRACEPTION

While most methods of contraception are appropriate for postpartum women, the time for starting each method depends on a woman's breastfeeding status. Methods that can be used whenever a couple resumes sexual intercourse, even in the immediate postpartum period, include:

Spermicides
Condoms (lubricated condoms may help overcome vaginal dryness)
Withdrawal (both condoms and withdrawal prevent seminal fluid from being deposited in the vagina)

Figure 12.1 and **Table 12.1** shows the recommended time of starting contraception for breastfeeding and non-breastfeeding women

12.7.4 CONTRACEPTION FOR NON-BREASTFEEDING WOMEN

Although most non-breastfeeding women will resume menstrual cycles within 4 to 6 weeks after delivery, only about one-third of first cycles will be ovulatory and even fewer will result in pregnancy. In order to avoid all risk of pregnancy, however, contraception should be started at the appropriate time:

- barriers, spermicides or withdrawal with the resumption of sexual intercourse following delivery
- hormonal contraceptives, IUDs or voluntary female sterilization BEFORE the resumption of sexual intercourse following the delivery.

Figure 12.1 shows the recommended time of starting contraception for postpartum women.

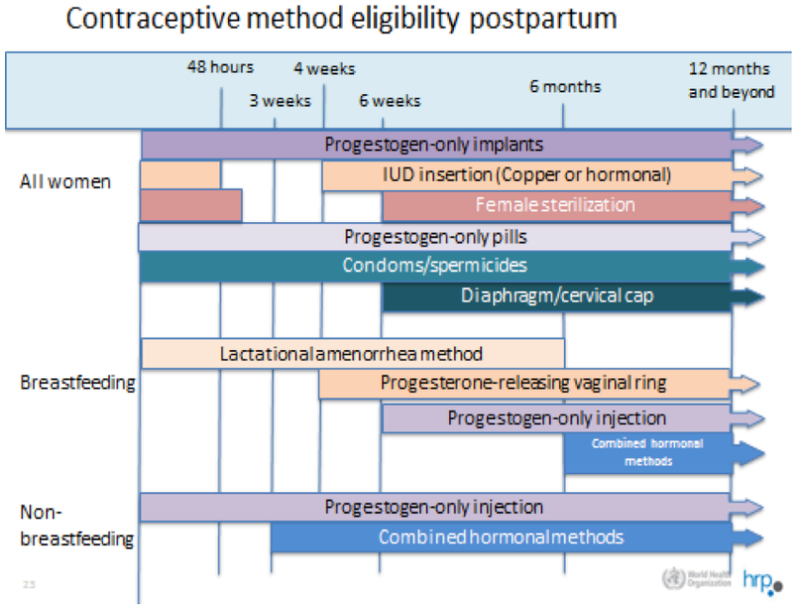


Table 12.1 Recommended Times That a Woman Can Start a Family Planning Method After Childbirth

Family Planning Method	FULLY OR NEARLY EXCLUSIVE BREASTFEEDING	PARTIALLY BREASTFEEDING OR NOT BREASTFEEDING
Lactational Amenorrhea Method	Immediately	(Not applicable)
Vasectomy	Immediately or during partner's pregnancy	
Male or female condoms	Immediately	
Spermicides		
Copper-bearing IUD	Within 48 hours, otherwise wait for 4 weeks	
Female sterilization	Within 7 days, otherwise wait for 6 weeks	
Levonorgestrel IUD	4 weeks after childbirth (also < 48 hours of childbirth*) 48 hours to 4 weeks- LNG IUD not recommended	
Fertility awareness methods	Start when normal secretions have returned (for symptoms-based methods) or she has had 3 regular menstrual cycles (for calendar-based methods). This will be later for breastfeeding women than for women who are not breastfeeding	
Progestin-only pills	< 6 weeks of childbirth*	
Implants		
Progestin-only injectables	6 weeks after childbirth*	Immediately
Combined oral contraceptives	6 months after childbirth	21 days after childbirth if not breastfeeding 6 weeks after childbirth if partially breastfeeding

Source: Adapted from Family Planning Global Handbook for Providers including WHO's 2017 recommendations*

CHAPTER 13

TRADITIONAL FAMILY PLANNING METHODS

13.1 INTRODUCTION

The two commonly used traditional methods of family planning are:

- Fertility awareness-based methods
- Coitus interruptus (withdrawal method)

Traditional family planning methods, both fertility awareness-based methods (FAB) and coitus interruptus, do not protect against STI/HIV. If there is a risk of STI/HIV (including the postpartum period), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV. Women with conditions which make pregnancy an unacceptable risk should be advised that traditional methods of family planning may not be appropriate for them because of their relatively higher failure rates with typical use.

13.2 CATEGORY OF PROVIDER

Health professionals including family health worker (FHW), community health worker (CHW), community health supervisor (CHS), staff nurse, medical officers, gynaecologists and experienced couples can teach the method, provided they have had appropriate training.

13.3 TYPES OF FERTILITY AWARENESS-BASED METHODS

There are a variety of fertility awareness-based methods (FAB) used for contraception. FABs are based on the practice of voluntarily avoiding sexual intercourse during the fertile period of a woman's cycle (i.e. when the ovum is released) to avoid pregnancy. FABs including Standard Days Method, Ovulation Method, Two Day Method, and the Symptom Thermal Method- can be used in combination with abstinence or barrier methods during the fertile period.
For this method to be effective the following are essential:

- Good communication and understanding should be present between couples.
- The sexual behaviour of couples will have to be modified.

Fertility-awareness based methods can also be used to achieve pregnancy by planning intercourse during the fertile phase.

13.3.1 STANDARD DAYS METHOD (SDM) -NEW FERTILITY-AWARENESS BASED METHOD

Standard Days Method (SDM) relies on a 'standard rule' or a fixed window of fertility that makes it easy for women to know when they are likely to become pregnant. For a woman with a regular cycle of 26 to 32 days in length, the fertile period will be from day 8 to day 19. The woman should abstain or avoid unprotected intercourse on cycle days 8-19. SDM can be safely used for most women.

SDM does not involve calculation or observation and hence it is easy for providers to teach and for women to learn and use. It is easy to incorporate this method into the existing family planning menu as the method has minimal logistical burden and can be offered either in clinics or community based programs.

A colour coded string of beads (Figure 13.1) called **CycleBeads™** can be used by women using SDM as it facilitates tracking a woman's menstrual cycle and the fertile days.

HOW TO USE CYCLEBEADS™

CycleBeads™ represent each day of a woman's cycle. They include 32 beads: a red bead represents the first day of the menstrual bleeding, followed by 6 brown beads representing days when pregnancy is very unlikely and 12 white glow in the dark beads representing days when pregnancy is likely. The remaining brown beads represent days when pregnancy is unlikely. A client can track her cycle days by moving a small rubber ring from one bead to the next each day starting with the first day of her period.

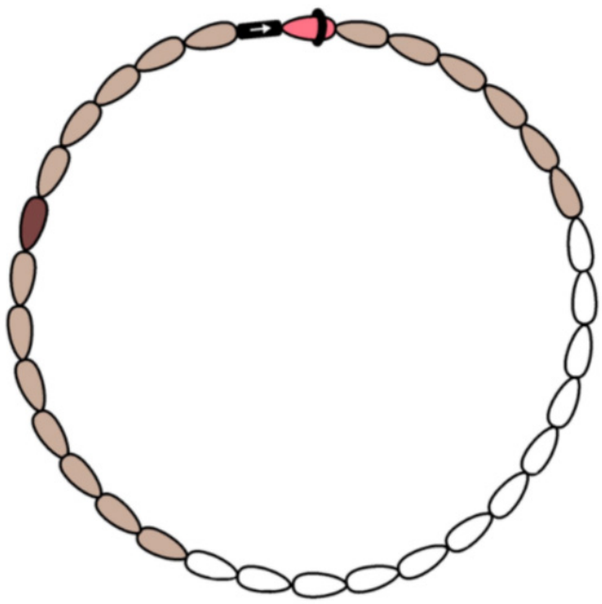
Figure 13.1: CycleBeads

Arrow shows the direction in which to move the ring. Each bead represents a day of the menstrual cycle

RED bead marks the first day of the cycle.

All white beads mark the days when one is likely to get pregnant.

All BROWN beads mark the days when woman is not likely to get pregnant



13.3.2 Other fertility-awareness based methods used are calendar method, basal body temperature method, two day method, cervical mucus method and sympto- thermal method.

13.4 EFFECTIVENESS OF FERTILITY AWARENESS-BASED METHODS

EFFECTIVENESS

The effectiveness (in preventing pregnancy) ranges from 91-98% when the **method is used correctly and consistently.** The typical effectiveness rate ranges from 80-88%. The effectiveness of these methods depends on the accuracy of the method to identify the fertile days, a couple's ability to correctly identify the fertile period and their ability to follow the rules of the method they are using. SDM has been shown to have an effectiveness of 95% for perfect use and 88% for typical use.

RETURN TO FERTILITY

Fertility awareness-based methods can also be used to achieve pregnancy by having intercourse during the fertile phase.

13.5 ELIGIBILITY FOR FERTILITY AWARENESS-BASED METHODS

The following couples are eligible to use the method:

- Couples who can abstain from sexual intercourse during fertile periods.
- Women with regular menstrual cycles (SDM users should have regular cycles ranging between 26 to 32 days). About 80 % of women have their cycles in this range.
- Women who want to practice contraception using non-mechanical or chemical methods.
- Women who have contraindications for other methods.
- For religious or cultural reasons.
- Couples with the need to delay the use of other family planning methods.

13.6 COUNSELLING FOR FERTILITY AWARENESS-BASED METHODS

In the process of assisting clients (male or female) to decide on FAB methods, they should be counselled on the effectiveness of the method, how it works, advantages and disadvantages, alternative methods of contraception and how to use the method correctly and consistently.

Counselling is critical for couples who want to practice fertility awareness method:

- Ensure the spouse is present.
- Ensure the client/couple understands the fertile period.
- Provide condoms as a back-up method and demonstrate the use of condoms.
- Clients should be counselled that SDM is not appropriate for clients with menstrual cycles outside the 26-32 days range because of a higher risk of pregnancy. Help them to consider another method.
- The client should use condoms in addition if she thinks there is any chance that she or her partner are at risk for exposure to STIs, including HIV/AIDS.

13.7 CLIENT ASSESSMENT FOR FAB

The purpose of the health assessment is to determine the client's suitability for the use of the method. It is also an opportunity to assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI and offer other available sexual and reproductive health services as appropriate. Refer to Chapter 5 for further details on STI/RTI assessment.

13.8 INSTRUCTIONS ON THE USE OF FERTILITY AWARENESS-BASED METHODS (STANDARD DAYS METHOD)

13.8.1 PROVIDER INSTRUCTIONS

- Find out the menstrual cycle pattern of the client and advise on the period of fertility, based on the menstrual cycle pattern.
- Ensure that the client understands the period of fertility.
- Use colored illustrations (if possible) to explain the menstrual cycle and fertile period.
- Provide condoms as a back-up method and demonstrate the use of condoms.
- Ensure that the client has understood the use of condoms.
- SDM is not appropriate for clients with menstrual cycles outside the 26-32 days range because of a higher risk of pregnancy. Help her consider another method.

13.8.2 CLIENT INSTRUCTIONS

Count the 8th day of the menstrual cycle (counting the first day of onset of bleeding/spotting as day 1).
Avoid sexual intercourse from the 8th to the 19th day. This is the time when the ovum is released and the risk of pregnancy is high.
From the 20th day it is safe to have sex.
If cycle beads are to be used then demonstrate how to use them.
If sex cannot be avoided, use a condom.
Tell her to seek advice from health care provider if she has changes in the days of menstrual cycle.

13.9 ROUTINE FOLLOW UP CARE FOR FAB METHOD

No routine follow-up visit is required.
Advise client to return at any time if he/she has any concerns or if he/she wants to change the method.

AT FOLLOW-UP:

Assess the client's satisfaction with the method.
Determine if the client has had any problems such as changes in her menstrual pattern and, if so, record them in the client clinical card/record.
Assess for any STI/RTI related concerns and if the client has any symptoms related to STI/RTI.
Ensure/provide supply of condoms as a back-up method and demonstrate the use of condoms.
Ensure that the client has understood the use of condoms.

13.10 COITUS INTERRUPTUS (WITHDRAWAL METHOD)

Coitus interruptus is a traditional method of FP in which the man completely withdraws his penis from the woman's vagina before he ejaculates. This method prevents pregnancy by preventing the deposition of sperm in the vagina. For this method to be effective it is essential that there is good communication and understanding between the couple and that they can modify their sexual behaviour.

13.10.1 EFFECTIVENESS OF COITUS INTERRRUPTUS

The effectiveness (in preventing pregnancy) is 96% when the method is used correctly and consistently.

13.10.2 ELIGIBILITY FOR COITUS INTERRRUPTUS

The following are eligible to use the method:

- couples who have control over their sexual act and can withdraw fully before ejaculation
- women who want to practice contraception using non-mechanical or chemical methods
- women who have contra-indications for other methods
- for religious or cultural reasons

13.10.3 COUNSELLING FOR COITUS INTERRUPTUS

Counselling is critical for couples who want to practice fertility awareness method.
Ensure the spouse is present.
Ensure the client/couple understands the importance of full withdrawal.
Explain to the client/couple the fertile period to enable them to avoid sex during that period.
Provide condoms as a back-up method and demonstrate the use of condoms.
Ensure that the client has understood the use of condoms.

13.10.4 ADVICE IN SITUATIONS WHERE THE METHOD IS NOT USED CORRECTLY

Counsel and provide emergency contraception in case the penis is not withdrawn before ejaculation.

13.11 ROUTINE FOLLOW-UP CARE

No routine follow up visit is required.
Advise the client to return at any time if he/she has any concerns or if he/she wants to change the method.

13.12 RECORD KEEPING AND REPORTING FOR TRADITIONAL METHODS

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.
The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

Note:

In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. A client needs counselling should an unplanned or unwanted pregnancy occur. Unplanned pregnancy may be followed by many conflicting emotions such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner.

CHAPTER 14

VOLUNTARY SURGICAL STERILIZATION FEMALE AND MALE

14.1 INTRODUCTION

Surgical contraceptive methods (male and female sterilization) are effective permanent methods of contraception available to men and women who desire not to have any more children.
Essential elements of quality sterilization services include counselling and client assessment, informed consent, infection prevention, selection of appropriate procedures, safe anaesthesia regimens, and post-operative care and instructions. Strict adherence to infection prevention practices at all times (before, during and after surgery) is crucial to the safety of the procedure.

14.2 TYPES OF VOLUNTARY SURGICAL STERILIZATION

The various types of male and female sterilization are listed below

Female surgical sterilization – Tubal Occlusion

- Interval Sterilization
  - Mini-laparotomy
  - Laparoscopic sterilization

- Postpartum Sterilization
  - Mini-laparotomy
  - Tubal occlusion at the time of Caesarean section

Male surgical sterilization – Vasectomy

-No-scalpel Vasectomy (NSV)

Male and female surgical sterilization does not protect against STI/HIV. If there is a risk of STI/HIV (including pregnancy or post partum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

14.3 EFFECTIVENESS OF FEMALE AND MALE SURGICAL STERILIZATION

Tubal occlusion and vasectomy both have effectiveness of over 99% and complication rates of < 2%. Failure usually is due to one of the following:

- vas deferens or fallopian tube spontaneously re-canalise
- inability to complete procedure
- incorrect surgical technique

PERMANENCY

Voluntary sterilization procedures should be considered permanent (irreversible). It is possible in some cases to reverse the procedure, that is, rejoin the cut fallopian tubes (females) or the vas deferens (males). The microsurgical services required to reverse female and male surgical sterilization are rare. Even when such services are available, the client may not be a proper surgical candidate or a reversal attempt may not be successful. Therefore,client's considering voluntary surgical sterilization should be certain that they do not wish to have any more children.

14.4 FEMALE SURGICAL Sterilization

Female surgical sterilization is a relatively simple procedure that involves permanently blocking/ occluding both the fallopian tubes to prevent fertilisation. This is the most commonly adopted method of contraception across the world with more than 180 million couples using it.

14.5 CATEGORIES OF PROVIDERS FOR FEMALE SURGICAL Sterilization

Female sterilization should be performed only by trained and competent gynaecologists or surgeons.

14.6 ADVANTAGES AND DISADVANTAGES OF FEMALE Sterilization

ADVANTAGES

- Very effective method of contraception
- Permanent method. A single procedure gives a lifelong, safe and effective protection against unwanted pregnancies
- Failure rate is very low (0.5 % in first year)
- No interference with sex act
- No effect on breast feeding
- No known side effects or health risks
- Can be performed immediately after childbirth, during cesarean section and at interval period
- Helps protect against ovarian cancer

DISADVANTAGES

- Requires a trained provider to perform the surgery
- Uncommon complications of surgery (wound infection, bleeding at the incision, injury to internal organs, anaesthesia risk)
- Compared to male sterilization, female sterilization is more risky and complicated
- Reversal of surgery is very difficult/ with poor results
- No protection against STI/RTIs

14.7 MEDICAL ELIGIBILITY FOR FEMALE SURGICAL STERILIZATION

14.7.1 INDICATIONS

Female sterilization can be done for clients seeking a permanent contraceptive method and wanting no more children. It can be performed on most women. With proper counselling and informed consent, the procedure can be performed on following women:

- who just gave birth (within 7 days) or after 42 days of childbirth provided there is no infection

Also, women with following conditions can have the female sterilization procedure under any circumstances

- mild pre-eclampsia
- past ectopic pregnancy
- benign ovarian tumors
- irregular or heavy bleeding patterns, dysmenorrhoea
- vaginitis without purulent cervicitis
- varicose veins
- HIV positive, high risk for HIV women or with other STIs
- non-pelvic tuberculosis
- along with cesarean delivery

Gynaecological and Medical conditions when sterilization should be DELAYED:

- pregnancy
- postpartum or second trimester abortion (>7 to 42 days)
- serious postpartum or post abortion complications
- severe pre-eclampsia/ eclampsia
- pelvic inflammatory disease
- current STIs
- pelvic cancers
- malignant trophoblastic disease
- deep-vein thrombosis
- acute heart disease
- gall bladder disease
- acute viral hepatitis
- severe iron deficiency anaemia (Hb below 7 g%)
- acute lung disease/pneumonia
- systemic infections/ gastroenteritis
- abdominal skin infections
- complicated abdominal surgeries/ infected emergency surgeries, where prolonged immobilisation is required

Gynaecological and Medical conditions when the client for sterilization should be REFERRED to a higher facility with experienced staff:

- fixed uterus due to previous surgery or infection
- hernia (umbilical or abdominal wall)
- endometriosis
- postpartum uterine rupture or post abortion perforation
- moderate or severe high blood pressure (160/100 or higher)
- diabetes / vascular disease
- complicated valvular disease
- severe liver cirrhosis
- hyperthyroid
- coagulation disorders
- chronic lung diseases
- pelvic tuberculosis

Gynaecological and Medical conditions when the surgeon/ gynaecologist has to be ALERT performing sterilization:

- past PID
- current breast cancer
- uterine fibroid
- mild hypertension (140/90; 155/99)
- past heart disease or stroke
- epilepsy or taking medicines for seizures
- diabetes with vascular disease
- hypothyroid
- mild liver disease
- obesity

DOCUMENTING DENIAL OF VOLUNTARY STERILIZATION

When a client is judged unsuitable for voluntary sterilization, the reason(s) and the action taken should be stated on the client card/record/case sheet.
Procedure is delayed until the condition is evaluated or corrected. Appropriate alternate temporary methods of contraception should be provided in the interim.

14.7 COUNSELLING AND INFORMED CHOICE FOR FEMALE SURGICAL

STERILIZATION

A client's decisions about fertility and contraception are made for a variety of reasons. Decisions are influenced by personal circumstances such as family size, economic situations and the health status of one or both partners. The decision may also be affected by cultural expectations and information available about family planning. The person counselling should only explain the procedures, not coerce the client into making the decision to undergo sterilization. The decision remains with the client.
Tubal occlusion is intended to be a permanent method and involves surgery with its associated risks. Voluntary sterilization has consequences, risks and concerns that need to be discussed with each client. It is therefore essential that service providers provide clients with necessary information and counselling about the procedure so that the client can reach an independent and informed decision. Counsel both partners if possible.

Pre-operative counselling should focus on:

- preparing her for the operation
- giving her instructions on how to prepare for surgery and what to expect during and after the operation
- ensuring that she has made the decision voluntarily, without any coercion and incentives
- documenting her informed consent and signature
- discussing other temporary and permanent family planning methods that are available

The client or spouse must be counselled in a language and terminology they understand. Privacy must be maintained during counselling. The following information should be understood by the client:

- effectiveness, permanency of the procedure, small failure rate
- advantages/disadvantages of the method
- side effects.

INFORMED CONSENT

Informed consent is the client's voluntary decision to undergo or not to undergo a surgical sterilization procedure, in full possession and understanding of the relevant facts. In Maldives, the informed consent should be signed by the client and is the legal authorisation for performing the procedure. Therefore service providers should ensure that client have signed the informed consent form with full understanding. In special cases where the client is mentally disabled the guardian can give consent. A sample of the informed consent form is provided in the appendices.

Box 14.1 FEMALE SURGICAL STERILIZATION IS NOT APPROPRIATE IF THERE IS ANY SUGGESTION THAT THE CLIENT:

- shows excessive interest in reversal
- disagrees with/does not want to sign informed consent
- is under pressure from another person.

Informed consent for surgical sterilization is an agreement by an individual (male or female), after appropriate counselling has been given. The consent is an exercise of free choice with a full understanding of the nature and consequences of the procedure to be performed. The consent must be obtained BEFORE performing the procedure.

The following are primary and ethical obligations and responsibilities of the service provider:
- Ensure that the individual gives free and informed voluntary consent for the operation.
- Ensure she is legally competent to give consent.
- Informed consent the client must be obtained for all clients requesting surgical contraception.

This serves as legal authorisation for surgery and documents informed and voluntary choice. Make sure that the client has been informed about the following:

- alternatives to the procedure
- availability of reversible methods of contraception
- specific surgical procedures to be followed
- risks of surgical procedures and of anaesthesia
- risk of failure
- permanency of the method
- free choice of the client.

14.8 CLIENT ASSESSMENT FOR FEMALE SURGICAL Sterilization

Client assessment prior to surgical sterilization is necessary to:

- ascertain the client's fitness for the surgical sterilization procedure
- exclude possible risks associated with the procedure
- exclude pregnancy (Pregnancy should be ruled out prior to performing female surgical sterilization. A pregnancy test should be done if there is any suspicion of pregnancy.

The following should be taken/assessed and recorded in client case sheet/record:

DEMOGRAPHIC INFORMATION

Includes client's name, address, age, spouse's name, occupation, education, number of living children and age of the youngest child.

MEDICAL AND OBSTETRIC HISTORY

History of chronic/acute conditions: active tuberculosis, heart disease, hypertension, anaemia, diabetes, bleeding disorders, psychiatric conditions, pelvic or abdominal surgery, pelvic inflammatory disease, vaginal discharge, urinary tract infections, recent injuries or infections, history of pregnancies (live births, miscarriages, abortions, deliveries and any complications) date of last menstrual period and description of menses breastfeeding, family planning method use, STI risk assessment, allergies to medication, etc.

PHYSICAL EXAMINATION AND TESTS

The following physical examination and tests should be done:

- pulse, temperature and blood pressure
- auscultation of heart and lungs
- pelvic examination: speculum visualization of cervix and bimanual vaginal examination to rule out pregnancy, PID, other pathology of the uterine cavity and overt malignancies.
- pregnancy test if LMP, history and pelvic exam is suggestive of pregnancy
- urine analysis for sugar and protein
- haemoglobin test.

14.9 PROCEDURE: FEMALE SURGICAL STERILIZATION

14.9.1 TIMING OF PROCEDURE

Interval female surgical sterilization should be performed within the first five days of the menstrual cycle. Pregnancy should be ruled out in all women undergoing female surgical sterilization.

Postpartum female surgical sterilization should be performed within the first 7 days after vaginal delivery or 6 weeks after delivery just as interval female surgical sterilization. Postpartum surgical sterilization can also be performed in conjunction with a Caesarean section performed for obstetric indications if the client has been appropriately counselled well in advance.

Post miscarriage sterilization in the absence of sepsis can be done within the first 7 days after miscarriage if client desires female sterilization.

14.9.2 TYPE OF ANAESTHESIA FOR FEMALE SURGICAL sterilization

The goal of anaesthesia is to minimise psychological and emotional distress and trauma in the client and keep her free from pain and discomfort. The following factors should be considered in the choice of anaesthesia: type of surgical technique, the skill of the surgeon and anaesthetist, the availability of appropriate drugs, the safety and comfort of the client, the ability of the surgeon to manage complications should they occur.

Interval female sterilization using mini-laparotomy can be performed either under spinal anaesthesia or general anaesthesia. Postpartum female surgical sterilization can be performed under local anaesthesia with sedation or under general anaesthesia.

LOCAL ANAESTHESIA

Local anaesthesia used, with or without sedation is the best option for performing female sterilization procedures. It is safer than spinal or general anaesthesia, recovery is faster, and the procedure can be performed at more facilities.

PREOPERATIVE MEDICATION

Premedication serves to reduce fear and anxiety. It can provide analgesia, prevent postoperative nausea and vomiting, and induce amnesia.
The following regimen (Box 14.2) is recommended when performing female sterilization procedure under local anaesthesia with conscious sedation:

Box 14.2 REGIMEN FOR LOCAL ANAESTHESIA WITH CONSCIOUS SEDATION

Tablet Diazepam 10 mg orally (for a woman weighing >35 Kg) 45 minutes before the procedure with one sip of water.

Pethidine 25 mg WITH Phenergen 12.5 mg WITH Atropine 0.6 mg IV is to be administered together intravenously in operating theatre just before procedure with monitoring of vital signs every 5 minutes.

Xylocaine 1% 10–20 ml Local infiltration to the skin and wait 1–2 minutes after infiltration to begin the procedure.

GENERAL AND SPINAL ANAESTHESIA

The provision of general and spinal anaesthesia including preoperative medication should be provided as per protocols.

14.9.3 TECHNIQUE OF FEMALE SURGICAL sterilization

Learning to perform female serialisation requires training and practice under direct supervision. The description below is a summary and not a detailed explanation of steps.

INTERVAL STERILIZATION

Interval sterilization is done by **mini-laparotomy procedure or through laparoscopy**

THE MINI-LAPAROTOMY PROCEDURE

Explained here is for an interval sterilization. The postpartum sterilization procedure is slightly different.

1. The provider uses all infection prevention procedures.
2. After sedation and local anaesthesia, 2-5 cm incision is given in the supra-pubic region (immediately above the pubic hair line) and abdomen is opened in layers.
3. The uterus is raised with uterine elevator, and each fallopian tube is brought forward through the incision. This may cause a little discomfort.
4. Each tube is tied and cut securely.
5. The incision is closed with stitches and covered with adhesive bandage.
6. The woman receives instructions on what to do after she leaves the hospital. She can be discharged same day or the next day.

THE LAPAROSCOPIC STERILIZATION PROCEDURE

This method is used **ONLY** for interval sterilisation.

1. The provider follows all aseptic precautions.
2. After sedation and local anaesthesia, the surgeon places a special needle (Verees' Needle) into the woman's abdomen. Through the needle gas (Carbon Dioxide) or air is put into the abdominal cavity. This procedure moves abdominal wall away from the internal organs and uterus and tubes.
3. A small incision (1 cm) is made just under the navel, and a tracer and laparoscope is inserted. Laparoscope is a special long thin tube that has fiberoptic light system and lenses along with operating forceps/ prongs.
4. Rings are placed on both the tubes.
5. After the rings are put, the laparoscope is removed and the gas/ air is let out.
6. The incision is closed with 1 or 2 stitches and covered with adhesive tape.
7. The woman is instructed about follow up care and can be discharged from the hospital in a few hours after surgery.

Explaining self-care for mini-laparotomy or laparoscopy procedure (Client instructions Box 14.3)

Before the procedure, the woman should:

- Should not eat or drink anything for 8 hours before surgery.
- Bathe thoroughly before the procedure.
- Wear clean loose fitting clothes.

AFTER THE PROCEDURE:

- Rest for 2-3 days.
- Keep the incision clean and dry for 2-3 days.
- Take prescribed medicines as advised
- **Follow up after 7 days for stitch removal.** If necessary, follow up can also be done at client's home or another nearby facility.
- Return to the facility immediately if-
    - she has fever
    - pus from the wound
    - pain, heat swelling, or redness in the wound
    - abdominal pain, cramping, or tenderness
    - fainting/ dizziness
    - she thinks that she is pregnant (missed periods, nausea and breast tenderness)

PREVENTING FAILURE OF FEMALE STERILIZATION

Five common causes of failure are:

- Undetected pregnancy (in the luteal phase that got missed)
- Surgical occlusion of another structure and not the fallopian tube (round ligament is commonly mistaken for tubes).
- Incomplete occlusion of the tubes.
- Slippage of rings.
- Development of fistulas.

FOLLOWING TWO PRECAUTIONS CAN BE TAKEN TO REDUCE FAILURES:

- Perform the procedure within 7 days of menstrual cycle.
- To confirm identification of fallopian tubes, they can be traced upto the fimbrial end.

POSTPARTUM STERILIZATION (PPS)

A procedure conducted within 7 days of childbirth is slightly different. Since the uterus at this time is raised upto the umbilicus, a sub- umbilical incision is given to perform the mini laparotomy. The fallopian tubes at this time are enlarged and need to be tied carefully. Abdomen and skin are closed in the same way as in mini-laparotomy for other method.

14.9.4 MONITORING CLIENT DURING FEMALE STERILIZATION PROCEDURE (PER OPERATIVE)

Monitoring and recording of vital signs must take place before, during and after the operation until the client has fully recovered.

Pre-operative: Blood pressure, pulse and respiration should be monitored and recorded before and after the preoperative dose of sedative is given. This provides the baseline data for the client.

Intra-operative: During surgery, the medical team should monitor and record blood pressure, pulse and respiration at least every 5 minutes.

Post-operative: Blood pressure, pulse and respiration must be monitored and recorded at least every 15 minutes until stable. Once the client is stable, vital signs should be monitored once every hour until she is fully awake.

14.9.5 DISCHARGE AFTER FEMALE SURGICAL STERILIZATION

Discharge

Following female sterilization done under local, spinal or general anaesthesia, clients can be routinely discharged on the same or the next post-operative day. Prior to discharge ensure client:

- can stand or walk steadily
- can talk or converse clearly and coherently
- has eaten and has passed urine
- can dress herself and is ambulatory
- is afebrile and the wound is clean

Box 14.4 DANGER SIGNS POST FEMALE Sterilization

See doctor promptly in the case of:

- fever (greater than 38 C or 100.4 F)
- dizziness with fainting
- persistent or increasing abdominal pain and/or swelling
- bleeding or fluid coming from the incision.

Box 14.3 CLIENT INSTRUCTIONS FOR FEMALE STERILIZATION: PREOPERATIVE, POSTOPERATIVE AND DISCHARGE

PREOPERATIVE CLIENT INFORMATION

- Bathing, wearing clean and loose clothes
- Fasting for 8 hours before surgery and taking no medications for 24 hours prior to surgery unless prescribed by a physician
- Being accompanied to the facility and home after the procedure
- The steps of the operation, including information on sedation/anaesthesia, screening, lab tests, what to expect in operating theatre, expectations about pain/discomfort, emptying bladder before surgery
- Removal of jewellery, nail polish, hairpins, eye glasses and dentures before surgery

POST-OPERATIVE CLIENT INFORMATION

- She should rest at home for 1-2 days after discharge in order to decrease complications.She may resume light activities 2-3 days after discharge and normal activities after 1 week.
- She may resume intercourse after 1 week.
- Keep the incision clean and dry. She may bathe or wash after 2 days.
- Explain how to use post op medications that are given.
- The following are the routine post op medications:
    - analgesics tablets for 3 days post surgery
    - antibiotics: Amoxycillin 500 mg 8 hourly for 5 days
    - multivitamin tablets for 5 days.

- Explain what problems to look out for (for danger signs refer to Box 14.4), what to do about each of the problems such as fever, pain and bleeding, and where to go and whom to contact in case of emergency and for any other problems and questions she may have.

- Any other relevant information such as:
    - Once the operation is completed she is sterile.
    - Her menstrual periods will continue until she reaches menopause.
    - If she misses a menstrual period and has any other signs of pregnancy, abdominal or pelvic mass/ pains she should contact the clinic.
    - Give the client a chance to ask questions and express any other concerns.

- Give the exact date and time for a follow-up visit (within 7 days post surgery).

- Written/printed postoperative and discharge instructions should be given to the client.

14.10 ROUTINE FOLLOW-UP CARE

ALL CLIENTS WHO HAVE HAD FEMALE STERILIZATION SHOULD BE ADVISED THE FOLLOWING:

- First follow-up should be done within 7 days of surgery.
- Return to facility earlier if she has any concerns.
- Contact doctor immediately if she has any of the warning signs as in Box 14.4.

AT FOLLOW-UP:

The following should be done at the follow up visit

- Inspect the wound site.
- Remove sutures if any.
- Address client concerns.
- Perform any other client evaluation/referral as indicated.

A second follow- up visit should be scheduled if continued care is required.

14.11 MANAGEMENT OF COMPLICATIONS OF FEMALE SURGICAL Sterilization

Serious complications are rare and occur in fewer than 1% of all female sterilization procedures. Clients should be routinely counselled about common side effects and possible complications and what to do if certain problems occur. When a client presents with side effects or complications they should be assessed, counselled and managed appropriately.

ANAESTHESIA COMPLICATIONS

Major complications may occur with general and local anaesthesia for both mini-laparotomy and laparoscopy. Serious complications are likely to occur as a result of overdose or improper administration of anaesthesia. However, toxic reactions may manifest as convulsions requiring assisted ventilation and anticonvulsants (e.g., diazepam). Adequate monitoring and early recognition of complications is the key to minimising adverse outcomes.

SURGICAL EMERGENCIES

The surgical team should manage surgical emergencies at the operative site.

14.12 RECORD KEEPING AND REPORTING FOR FEMALE SURGICAL STERILIZATION

The provider should record information in the Client Clinic Card/Case Sheet/Record and Family Planning Register legibly. The provider should ensure that records and registers are completed, regularly maintained and reported to the Health Protection Agency.

Box 14.5 FAILURE OF SURGICAL STERILIZATION

In Maldives abortion is allowed only under the 5 conditions stated under the 'Fatwa' of Ministry of Islamic Affairs. However, a client needs counselling if an unplanned or unwanted pregnancy occurs. Unplanned pregnancy may be followed by many conflicting emotions' such as fear, anger, excitement and despair following the discovery. The conflicting emotions are influenced by her social circumstances and her relationship with her partner. It is important to resolve the conflict over the unplanned pregnancy as quickly as possible in order to limit the psychological and physical damage to the client. Counselling is extremely helpful in assisting the client to come to terms with the pregnancy.

TABLE 14.3: MANAGEMENT OF COMPLICATIONS OF FEMALE STERILIZATION

COMPLICATIONS	ASSESSMENT	MANAGEMENT
Intraoperative haemorrhage (injury to mesosalphinx)	Determine presence of injury to mesosalphinx.	Identify the source of bleeding and ensure hemostsis
Bladder, intestinal injuries (rare)	Determine presence of hematuria and other signs of internal injury.	Identify and repair. The procedure should be performed by a trained and competent surgeon.
Shock or acute distress (very rare)	Check for increased respiration and pulse, decreased blood pressure, evidence of hemodynamic instability.	Cardio pulmonary resuscitation
Wound infection	Confirm presence of infection or abscess	If skin infection is present, treat with antibiotics. If abscess is present, drain and treat as indicated.
Postoperative fever	Determine source of infection.	Treat infection based on findings.
Haematoma (subcutaneous)	Determine presence of infection or abscess.	Apply warm, moist packs to site. Observe – usually will resolve over time but may require drainage if extensive.
Superficial Bleeding (skin edges or subcutaneously)	Determine presence of infection or abscess.	Treat based on findings.
Failure of tubal occlusion/ tubal ligation	Confirm with pregnancy test.	Explain how failure happened. If **intrauterine pregnancy** is confirmed, counsel client and refer for appropriate care. If e**ctopic pregnancy i**s suspected, refer immediately for complete evaluation.

14.13 MALE STERILIZATION (VASECTOMY)

Vasectomy is a simple minor surgical procedure performed as an outpatient/ambulatory procedure. Both the conventional vasectomy procedure and the Non-Scalpel Vasectomy (NSV) are one of the safest procedures. The vas deferens on each side of the scrotum are identified by palpation before entering the scrotum. The vas deferens on each side is occluded so that the sperm are not released into ejaculation.

14.14 CATEGORY OF PROVIDERS FOR VASECTOMY

Male sterilization should be performed only by trained and competent medical officers and surgeons.

14.15 ELIGIBILITY FOR VASECTOMY

14.15.1 INDICATIONS

Vasectomy can be done for a client who seeks permanent contraceptive method and wants no more children. There is no medical condition that would be an absolute contraindication for male sterilization, although there could be some conditions that may require extra care.

14.15.2 ABSOLUTE CONTRAINDICATIONS FOR VASECTOMY

Box 14.6: MALE SURGICAL STERILIZATION IS NOT APPROPRIATE IF THERE IS ANY SUGGESTION THAT THE CLIENT:

- shows excessive interest in reversal
- disagrees with/ does not want to sign informed consent
- is under pressure from another person.

Generally there are no absolute medical contra indications to voluntary male sterilization

14.15.3 DELAY VASECTOMY

For the conditions below, vasectomy should be delayed until specific conditions resolve. Help the client choose another method for the interim.

- acute systemic infection or gastroenteritis
- depression: help client choose another method and refer for treatment of depression
- STI: chlamydial and gonococcal infection
- uncontrolled diabetes
- local skin or scrotal infections
- large varicocele*
- large hydrocele*
- intrascrotal mass

Procedure is delayed until the condition is evaluated or corrected. Alternative temporary methods of contraception should be provided in the interim.

14.15.4 CONDITIONS WITH ANTICIPATED DIFFICULTIES

In the following conditions surgery should be undertaken in a setting with an experienced surgeon and staff, equipment required to provide general and other back-up medical support. Alternate temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.

- Cryptorchidism
- Filariasis involving the scrotum can lead to difficulties to palpate the spermatic cord.
- Coagulation disorders (risk of hematoma, risk of infection)

***Large hydrocele or large varicocele:** Vas may be difficult or impossible to locate in the presence of a large hydrocele or large varicocele. A single procedure to repair hydrocele/varicocele and vasectomy can decrease the risk of complication. Alternative methods of contraception should be provided if referral is required or there is any delay in performing the procedure.

†Inguinal hernia: clients with inguinal hernia requesting vasectomy:

- Vasectomy can be done concurrent with hernia repair.
- The procedure should be done in a setting with experienced surgeon and staff under GA and other back up medical support.
- Alternative temporary methods of contraception should be provided if referral is required or there is any delay in performing the procedure.

DOCUMENTING DENIAL OF VOLUNTARY STERILIZATION

When a client is judged unsuitable for voluntary sterilization, the reason(s) and the action taken should be stated on the client card/record/case sheet

14.16 COUNSELLING AND INFORMED CHOICE FOR VASECTOMY

The client's decisions about fertility and contraception are made for a variety of reasons. Decisions are influenced by personal circumstances such as family size, economic situations and the health status of one or both partners. The decision may also be affected by cultural expectations and information available about family planning. The person counselling should only explain the procedures not coerce the client into making the decision to undergo sterilization. The decision remains with the client.

Vasectomy is intended to be a permanent method and involves surgery with its associated risks. Voluntary sterilization has consequences, risks and concerns that need to be discussed with each client. It is therefore essential that service providers provide clients with necessary information and counselling about the procedure, clarify myths and misconceptions and emphasize that vasectomy is not castration. Counsel both partners if possible.

PRE OPERATIVE COUNSELLING SHOULD FOCUS ON:

- preparing him for the operation
- giving him instructions on how to prepare for surgery and what to expect during and after the operation
- ensuring that he has made the decision voluntarily
- documenting client informed consent
- discussing other temporary and permanent family planning methods that are available

The client must be counselled in a language and terminology he understands. Privacy must be maintained during counselling. The following information should be understood by clients:

- side effects of the method
- advantages/disadvantages
- the need to use contraception such as condoms or for the partner to use temporary methods for 3 months post vasectomy and the need for confirmatory semen analysis 3 months post vasectomy.

INFORMED CONSENT FOR VASECTOMY

Informed consent is the client's voluntary decision to undergo or not to undergo a surgical sterilization procedure, in full possession and understanding of the relevant facts. In Maldives, the informed consent should be signed by the client and is the legal authorisation for performing the procedure. Therefore service providers should ensure that client have signed the informed consent form with full understanding. In special cases where the client is mentally disabled, the guardian can give consent. A sample of the informed consent form is provided in the appendices.
The consent is an exercise of free choice with a full understanding of the nature and consequences of the procedure to be performed. The consent must be obtained BEFORE performing the procedure.

The following are primary and ethical obligations and responsibilities of the service provider:

- Informed consent by the client must be obtained for all clients requesting surgical contraception.
- This serves as legal authorization for surgery and documents informed and voluntary choice.
- Make sure that the client has been informed about the following:
    - alternatives to the procedure
    - availability of reversible methods of contraception
    - specific surgical procedures to be followed
    - health risks of surgical procedures and of anesthetic
    - risk of failure
    - benefits to be expected
    - permanency of the method o free choice of the client.

14.17 CLIENT ASSESSMENT FOR VASECTOMY

The purpose of client assessment prior to surgical sterilization is necessary to:

- ascertain clients' fitness for the surgical sterilization procedure
- exclude possible risks associated with the procedure

Preoperative Assessment

The recommended information to include in a preoperative medical evaluation of a male client are:

Demographic information

Includes client's name, address, age, occupation, education, number of living children, and age of the youngest child

Medical history to include the following

- Respiratory problems (e.g. asthma), Heart disease or Diabetes
- Bleeding disorders
- Scrotal or inguinal surgery
- Genitourinary infections/STI risk assessment
- Sexual impairment and scrotal abnormalities
- Current medications
- Allergies to medications

PHYSICAL AND LABORATORY EXAMINATION

Genital examination is mandatory prior to performing vasectomy. Other examinations should be done as indicated by the medical history. It is important that providers review history and perform the clinical examination and ensure the client's voluntary consent for the procedure. There are no mandatory laboratory tests to be done prior to vasectomy.

The following tests are recommended as a good preventative health measures:

- pulse and BP
- urine sugar and protein

14.18 VASECTOMY PROCEDURE

14.18.1 Timing of procedure

Vasectomy can be performed for male clients as requested as long as there are no reasons to delay the procedure. Procedure should be delayed till after successful treatment if the client has infection of the operative area, acute systemic infections or if there are associated inguino-scrotal problems.

14.18.2 Anaesthesia

Vasectomy can be performed under local using 1% Xylocaine. Occasionally general can be used when vasectomy is performed using the Modified Standard Vasectomy technique. When GA is used client requires admission day prior to the surgery and is discharged on the first post-operative day.

14.18.3 Vasectomy techniques

The two techniques of vasectomy are

1. Modified standard vasectomy
2. Non-scalpel vasectomy

Modified standard vasectomy

Currently in Maldives **modified standard vasectomy** is the commonly used technique. This technique involves making a small midline incision on the scrotum followed by blunt and sharp surgical dissection to deliver the vas deferens. The vas deferens is then tied with suture material, cutting and removing a section of the vas on both sides.

No-scalpel vasectomy technique (NSV)

This method is also done in Maldives. It requires two specially designed but simple instruments to puncture the scrotal skin to access the vas deferens. The instruments are:

1. NSV ringed forceps (3.0 to 4.0 mm diameter ring)
2. NSV dissecting forceps

Compared with traditional vasectomy, NSV results in fewer complications, produces less pain during the procedure and early follow-up period, and permits couples to resume sexual activity earlier after surgery. Also, there is a reduction in the time required for the vasectomy when skilled providers use the no-scalpel approach.

In NSV, the vas deferens is palpated and then isolated using the ringed NSV forceps. The dissecting forceps are then used to puncture the scrotal skin (as opposed to an incision) to access and deliver the vas. The NSV technique does not require skin suture as the scrotal skin puncture is very small.

Vaso-occlusion by fascial interposition

The preferred method to occlude the vas is to divide the vas, remove a small segment followed by fascial interposition and ligation of both ends with non-absorbable sutures. In fascial interposition, the fascial sheath (the thin layer of tissue that surrounds the vas) is sutured over one end of the cut vas. Fascial interposition thus places a tissue barrier between the cut ends of the vas.

14.18.4 MONITORING THE CLIENT DURING VASECTOMY PROCEDURE

The client should be monitored by observing his general condition and state of consciousness during and after surgery. Vital signs should be monitored continuously if general anaesthesia is used.

14.18.5 POST-OPERATIVE CARE AND DISCHARGE

14.18.5.1 Vasectomy under local anaesthesia: Clients who have had their vasectomy performed under local can be discharged after 30 minutes if they are stable and do not have abnormal findings. Before the client is discharged, a trained staff member should repeat and verify his understanding of the discharge instructions. Routine antibiotic prophylaxis is NOT given for vasectomy. Clients are provided analgesics such as paracetamol for 3 days.

14.18.5.2 Vasectomy under general anaesthesia: If vasectomy was performed under general, the client's vital signs and state of consciousness should be closely monitored post operatively in the recovery room. The client must be ambulatory, alert and oriented with normal vital signs before being sent to the ward. Clients are then discharged on the first post-operative day (considering day of surgery as day of operation). Before the client is discharged, a trained staff member should repeat and verify the client's understanding of the discharge instructions.

14.18.5.3 Post vasectomy contraception

All clients should be counselled on the importance of using post vasectomy contraception till semen analysis confirms the effectiveness of vasectomy. A client who has undergone vasectomy should wait **3 months** before relying on his vasectomy for contraception. Current evidence shows that 20 ejaculations after vasectomy (in the absence of a 3 month waiting period) is not a reliable determinant of vasectomy effectiveness. The client should however resume sexual activity (while using contraceptive protection) during the 3 month waiting period after his vasectomy in order to clear any remaining sperm from his semen.

14.19 ROUTINE FOLLOW-UP CARE AFTER VASECTOMY

All clients who have had a vasectomy are advised the following:

- First follow up 3rd day post vasectomy to check wound.
- Second follow up 3 months post vasectomy to do mandatory semen analysis to confirm effectiveness of vasectomy.
- Return to facility earlier if he has any concerns.
- Contact doctor immediately if he has any of the warning signs in Box 14.8.

At follow-up

The operating surgeon if possible, should conduct the follow up assessment:

During the first follow up visit:

- Inspect the wound site.
- Remove sutures if any.
- Perform any other client evaluation that should be done.
- Address client concerns if any.

At second follow up visit at 3 months post vasectomy:

- Do semen analysis to confirm effectiveness of vasectomy.
- Address client concerns if any.

Further follow-up can be scheduled if continued care is required

POST-OPERATIVE INFORMATION FOR ALL CLIENT:

- Resume normal activities in 3 days.
- Resume sexual activity whenever comfortable but with an additional contraceptive method for 3 months post vasectomy. A client who has undergone vasectomy should wait 3 months before relying on his vasectomy for contraception. During this period, he should resume sexual activity, but he or his partner will need to use additional contraceptive protection. Provide the client with supply of condoms, and explain how to use them. Effectiveness of vasectomy is confirmed by a semen analysis done 3 months post vasectomy.
- Wound care: Keep incision clean and dry. Avoid getting the wound wet while bathing. Soap and water can be used to wash the wound after 3 days.
- Wear close fitting scrotal support for at least 48 hours and then as long as it is needed.
- Describe the warning signs (refer to Box 14.7 – signs of infection, bleeding, pain) and where to go if needed.
- Explain how to use medications that are given.
- Clients are provided with analgesics such as paracetamol for 2 days. (Antibiotics are not used routinely for vasectomy.)
- Reiterate that sexual performance is unchanged after vasectomy and that vasectomy does not affect a man's ability to have sex.
- Written or printed post-operative care and discharge information should be given to the client before he is discharged.

Box 14.7 POSTOPERATIVE DANGER SIGNS POST VASECTOMY
See doctor in the event of:

- fever (greater than 38 C or 100.4 F)
- dizziness with fainting
- persistent or increasing scrotal pain and/or swelling bleeding or pus coming from the incision

14.20 MANAGEMENT OF COMPLICATIONS OF VASECTOMY

Serious complications are extremely rare and occur in less than 1% of all male sterilization procedures. Clients should be routinely counselled about common side effects and possible complications and what to do if certain problems occur (Table 14.5).

14.20.1 ANAESTHESIA COMPLICATIONS

Use of general anaesthesia significantly and unnecessarily increases the risks of major complications associated with vasectomy and is not recommended except in certain complicated procedures. For local anaesthesia, when intravascular injections are avoided and the recommended doses of xylocaine are not exceeded, toxic reactions are rare. However, toxic reactions may be manifested as convulsions requiring assisted ventilation and anticonvulsants (e.g. diazepam).

14.20.2 SURGICAL COMPLAINTS

The most common complaints following vasectomy are swelling of scrotal tissue, bruising and pain. While these symptoms generally disappear without treatment, ice packs, scrotal support and simple analgesics provide relief. The incidence of these symptoms can be reduced by using gentle operating technique and checking for bleeding.

Complications, such as haematomas and infections, are uncommon. Haematomas can be minimized by ensuring meticulous haemostasis. Also, clients must be careful not to strain the scrotal sac for several days after surgery. Infections can be minimized through the use of meticulous aseptic technique and good postoperative care. There is no evidence that routine prophylactic use of antibiotics is beneficial if asepsis is adequate.

Table 14.5 Management of complications of vasectomy

COMPLICATION	ASSESSMENT	MANAGEMENT
Superficial bleeding	(skin edges or subcutaneously)	Apply secure pressure over wound. Then check if bleeding persists.
Bleeding post-operatively		Place secure pressure dressing on wound. If bleeding persists, reopen wound under local anaesthesia, identify the bleeders and ligate them with sterile suture.
Vasovagal reaction	Check vital signs.	Reassure client. Elevate client's lower extremities. Provide additional local anaesthesia if needed
Wound infection	Confirm presence of infection or abscess.	If skin infection is present, provide antibiotics. If abscess is present, drain and treat as indicated.
Haematoma	Confirm presence of infection or abscess.	Apply warm, moist packs to site. Observe; if extensive may require drainage. If infected, treat as indicated.
Sperm granuloma	Confirm presence of nodule.	If Asymptomatic: no treatment, if painful: analgesic if persistent pain: Evacuate cyst.
Pregnancy of the partner / Vasectomy failure	Confirm pregnancy and age of gestation. Assess for azoospermia by semen analysis.	If more than 3 months since vasectomy and semen analysis is positive for sperm, discuss repeat vasectomy for man, if necessary, or possibly tubal ligation for partner. Refer for appropriate care.

14.21 RECORD KEEPING AND REPORTING FOR VASECTOMY

The provider should record information in the Client Clinic Card/Case Sheet/Case Record and Family Planning Register legibly. The provider should ensure that registers are completed, regularly maintained and reported to the Health Protection Agency.

CHAPTER 15

EMERGENCY CONTRACEPTION (EC)

15.1 INTRODUCTION

Emergency contraception or post-coital contraception refers to methods of contraception that can be used to prevent pregnancy in the first few days after intercourse. It is also intended for emergency use following unprotected intercourse, contraceptive failure (for example torn condom, forgotten pills), rape or coerced sex.

The four Emergency contraception methods described here are (three types of hormonal pills and Copper bearing Intra Uterine Contraceptive Device/ IUD):

1. UPA (Ulipristal acetate)-ECP - single dose - 30 mg tablet- included in WHO's guidelines in 2016. It may not be available in some countries yet.

2. LNG (Levonorgestrel)- ECP:

    i. Single dose (preferred) 1.50 mg (Two 0.75 mg tablets)
    ii. Split dose- one dose of 0.75 mg followed by a second dose of 0.75 mg 12 hours later

3. Combined ECPs- (100 micro gram ethinyl estradiol plus 0.5 mg LNG)

    i. Split dose: one dose of 100 micro gram ethinyl estradiol plus 0.5 mg LNG, followed by the second dose after 12 hours

4. Copper IUD for EC

15.2 MECHANISM OF ACTION OF ECPS

The mechanism of action of emergency contraceptive pills depends on the time during the menstrual cycle that they are taken. Emergency contraceptive pills may:

- inhibit or delay ovulation
- thicken cervical mucus
- inhibit tubal transport of the egg or sperm
- interfere with fertilization
- alter the endometrium, thereby inhibiting implantation of a fertilized egg.

They <u>do not work</u> if a woman is already pregnant.

15.3 EFFECTIVENESS OF EMERGENCY CONTRACEPTIVE PILLS

Overall, only 1–3% of women using emergency contraceptive pills initiated within 72 hours after unprotected intercourse become pregnant during that cycle (the chances of pregnancy are approximately four times greater when no emergency contraceptive is used). ECPs are not as effective as regular use of most of the modern contraceptives.

If the woman has used hormonal emergency contraception and pregnancy does occur, the small doses of hormones are not harmful to the developing foetus and will not terminate a pregnancy.

15.4 CATEGORY OF PROVIDER

Emergency contraceptive pills should be provided by doctors (gynaecologists or medical officers) or Health Officer who have been properly trained to counsel and provide emergency contraceptive pills. All providers must adhere to service standards.

15.5 HOW TO PRESCRIBE ECP

Timing of prescribing ECPs

Ideally UPA ECPs, LNG ECPs and Combined ECPs should be taken as early as possible after unprotected intercourse, within 120 hours (5 days). However the woman should be advised that the effectiveness of ECPs is reduced longer the interval between unprotected intercourse and ECP intake.

UPA ECPs may be more effective between 72- 120 hours than other ECPs.
Copper IUD can be inserted up to 120 hours after unprotected intercourse.

Remarks

- Evidence suggests that single dose LNG-ECP regimen is as effective as split dose LNG-ECP.
- WHO expert group considers single - dose option to be preferable to split -dose option for better compliance.
- Evidence also suggests that LNG-ECPs and UPA-ECPs are preferable to combined ECPs because they cause less nausea and vomiting.

15.6 ELIGIBILITY FOR EMERGENCY CONTRACEPTIVE PILLS

15.6.1 INDICATIONS

Emergency contraception is meant to be used only following an unprotected act of sexual intercourse to prevent pregnancy. The following are a number of situations when a woman can use or may need to use emergency contraception:

- When a woman has been a victim of sexual assault.
- After incorrect or inconsistent use of regular contraceptive methods:
    - failed coitus interruptus,
    - when ejaculation has occurred in the vagina or on the external genitalia;
- Miscalculation of the infertile period when using periodic abstinence, or failure to abstain from sexual intercourse during the fertile days
- Woman is more than 2 weeks late for the Net En contraceptive injection and more than 4 weeks late for the DMPA contraceptive injection and had unprotected intercourse
- Missed 3 or more active (hormonal) combined oral contraceptive pills in the first week and had unprotected intercourse
- Missed one or more progesterone only pills by more than 3 hours and had unprotected intercourse
- Unprotected intercourse prior to the effective time of vasectomy (3 months).
- Accidental failure of other contraceptive methods such as:
    - condom breakage or
    - slippage
    - IUD expulsion.

Emergency contraceptive pills are for emergency use only and not recommended for routine use because of the higher possibility of failure compared to regular contraceptives and the increase in side effects such as nausea and vomiting.

15.6.2 MEDICAL ELIGIBILITY FOR ECPS

Medical conditions in which other hormonal contraceptives are restricted/ not indicated, do not apply to ECP. There is no evidence that ECPs increase the risk of cardiac, metabolic and other complications. Therefore practically all women can take ECPs.

Note: if a woman is already pregnant, ECPs are contra-indicated

15.7 COUNSELLING

All clients should be counselled prior to providing emergency contraception. Let the client tell her story if she so wishes. Offer support without judging the client. If she decides to take emergency contraceptive pills, inform her that:

- Emergency contraceptive pills prevent pregnancy.
- ECP do not cause abortion.
- ECP should not be used as regular contraception – counsel on regular contraception.
- ECPs do not protect against STIs or HIV/AIDS.
- Explain the effectiveness of emergency contraceptive pills if used correctly and their mechanism of action depending on when in the menstrual cycle the ECPs are taken.

15.8 CLIENT ASSESSMENT

Prior to providing emergency contraceptive pills, it is mandatory to ensure the client is NOT already pregnant (i.e. she might have become pregnant in the previous month) and a pregnancy test should be done to confirm client is not already pregnant.

15.9 PROVISION OF EMERGENCY CONTRACEPTIVE PILLS

15.8.1 Regimen

Preferred regimen for emergency contraceptive pills (ECP)

1. **SINGLE DOSE LEVONORGESTREL 1.5 MG ORALLY** to be taken as early as possible after unprotected intercourse, within 120 hours (5 days).

2. **Alternative regimens of emergency contraceptive pills**
   Two doses Levonorgestrel 0.75 mg orally at an interval of 12 hours. First dose should be taken as early as possible after unprotected intercourse, within 120 hours, and the second dose 12 hours after the first dose.

3. **Ulipristal Acetate (UPA)- ECP (if available)- Single dose**, one 30 mg tablet to be taken as early as possible up to 120 hours (5 days) after unprotected intercourse.

4. **Two doses of combined ethinyl estradiol 100 micrograms and levonorgestrel 0.5 mg orally** at an interval of 12 hours. First dose should be taken as early as possible after unprotected intercourse, within 72 hours and the second dose 12 hours after the first dose.

Ideally emergency contraceptive pills should be taken as early as possible after unprotected intercourse, that is within 120 hours (5 days). *However, it must be explained to the woman that longer the delay in taking the ECPs and intercourse, the lower is the effectiveness of the pills.*

15.8.2 Nausea and vomiting associated with emergency contraceptive pills / Preventing emergency contraceptive pills associated nausea and vomiting

Many women will not experience nausea and vomiting when taking emergency contraceptive pills. However, it is difficult to predict which women will experience nausea and vomiting. Women taking levonorgestrel-only emergency contraceptive pills are less likely to experience nausea and vomiting compared to women taking combined estrogen progesterone emergency contraceptive pills.
Routine anti-emetics before taking emergency contraceptive pills is not recommended.
Pre-treatment with anti-emetics can be considered depending on availability and clinical judgement.

Management of vomiting after taking emergency contraceptive pills

- If a woman vomits within 2 hours after taking a dose of emergency contraceptive pills: she should take another dose as soon as possible.

- If vomiting occurs 2 hours after taking LNG ECP and Combined ECP: no need to take repeat dose of emergency contraceptive pills.

- However, if vomiting occurs within 3 hours of taking UPA ECP: dose has to be repeated as UPA takes about 3 hours for absorption.

If she is taking combined estrogen progesterone emergency contraceptive pills she can use an anti-emetic before taking the combined estrogen progesterone emergency contraceptive pills. If vomiting continues, a repeat ECP dose can be given vaginally.

15.9 INSTRUCTIONS FOR CLIENTS TAKING EMERGENCY CONTRACEPTIVE PILLS

- How to take the emergency contraceptive pills.
- What to do if she has nausea and vomiting.
- May have spotting or bleeding a few days after taking pills.
- Expect a menses within 3-4 weeks.
- Return for follow up check after 4 weeks. Provide date for next visit.
- Return to clinic/facility earlier if she has any concerns.
- Emphasize that emergency contraception SHOULD NOT be used on a regular basis (from month to month) because it is much less effective than other methods.
- If already chosen a method for future contraception counsel on how and when to start her chosen future contraceptive method.

15.10 ROUTINE FOLLOW-UP CARE AND RESUMPTION OR INITIATION OF REGULAR CONTRACEPTION AFTER USING EC.

- All clients provided with emergency contraception should be followed up after 4 weeks, for a check-up.
- If a client has not had a menses within 4 weeks, check for pregnancy. If positive, she should receive counselling and referral to antenatal care.
- If not pregnant, counsel regarding regular contraception and assist client to choose a method.
- If the woman used copper bearing IUD for emergency contraception: the same can be continued and no further contraception is needed.
- If the woman used LNG or combined ECPs: the woman can immediately resume her contraceptive method, or start any contraceptive method immediately, including IUD, if it is reasonably certain that she is not pregnant.
- If the woman used UPA - ECP, she can start any hormonal contraceptive (CHC. POI or POP) from the 6th day after taking UPA. If she wants to come later for a contraceptive, she can adopt any of the methods once reasonably sure that she is not pregnant. Counsel client to use condoms if she thinks there is any chance that she or her partner are at risk for exposure to STIs, including HIV/AIDS.

15.11 RECORD KEEPING AND REPORTING

The provider should legibly record information. The provider should ensure that records and registers are completed, regularly maintained.
The compiled monthly report of "Family Planning Monthly Summary Report" should be sent before 10th of every month to the Reproductive Health Program of Health Protection Agency.

APPENDIX A

A1 EQUIPMENT AND SUPPLIES FOR IMPLANON, IUD AND MALE AND FEMALE SURGICAL STERILIZATION

All equipment, instruments and supplies must be in optimum working order, available and accessible to the provider. A functioning laparoscope and all its attachments are mandatory for laparoscopic sterilization. The following table is a list of equipment and supplies needed for Implanon insertion and removal, IUD insertion and for male and female sterilization.

EQUIPMENT AND SUPPLIES FOR HORMONAL IMPLANTS (IMPLANON) INSERTION AND REMOVAL

NON EXPENDABLE EQUIPMENT & SUPPLIES

Implanon Insertion Tray
Implanon set
Sponge holding forceps
Small bowl
Cheatle forces
Jar
Spot light Torch/flashlight
Syringe 5 ml
Forceps, circle, curved 5.5”
Needle 20 Gauge x 4” Mosquito forceps, curved 5” Dissecting forceps

Implanon Removal Tray
Mosquito forceps 2
Sponge holding forceps
bowl

EXPENDABLE SUPPLIES

Instruments wrapping cloth 18” sq.
Arm drapes with centre hole (Eye-towel)
12” sq Small hand towel
Steri-strips, butterfly or plain band-aid
Sterile gloves various sizes
Gauze 4” X 4”
Implanon
Local anaesthetic with adrenaline 30 ml
Soap for hand wash
Betadine antiseptic solution/Hibiscrub
Light Sources
Batteries (if torch is used for light)

A2 SUPPLIES FOR HORMONAL INJECTABLES (POI)

Disposable syringes and needles
Gauze sponges or cotton swabs
Antiseptic solution
Soap
DMPA injection (preferable single dose vial)

A3 EQUIPMENT AND SUPPLIES FOR IUD INSERTION AND REMOVAL

NON-EXPENDABLE EQUIPMENT

Vaginal speculum, medium (Sims/ Cuscos)
Sponge holding forceps
Small bowl for antiseptic solution
Cervical tenaculum/Vulsellum (small toothed)
Uterine sound
Scissors, long handled
Instrument pan and cover
Long curved artery forceps
Cheatle forceps
Cheatle jar
Kidney tray (big size) for keeping used instruments
Torch/ lashlight

EXPENDABLE SUPPLIES

Copper-T 380A in a pre-sterilized pack.
Disinfectant
Torch with batteries,
Gloves various sizes
Antiseptic solution/Betadine (povidone iodine) solution/Hibiscrub
Instrument wrapping cloth 18"sq
Small hand towel (inside set)
Light sources
Ensure IUD packet is not open or damaged and that date of expiry is not over. Tarnishing on the surface of CuT may be seen occasionally due to moisture. Tarnishing does not affect the safety or effectiveness of the CuT, provided the packet is NOT open or damaged.

A4 EXPENDABLE SUPPLIES FOR FEMALE STERILIZATION

FEMALE STERILIZATION: LAPAROSCOPIC

Gauze cloth
Adhesive tape 4"x 5m roll
Sterile gloves various sizes
Disposable syringes 5 cc
Surgical blade # 11
Fallope rings/bands
Thread for skin stitches
Liq. Betadine
Liq. Cidex
Antibiotics

Paracetamol

FEMALE STERILIZATION: MINILAPAROTOMY

Gauze cloth
Adhesive tape 4"x 5 m roll
Sterile gloves various sizes
Disposable syringes 5 cc and 10 cc
Surgical blade # 10
Surgical blade handle #3
Forceps tissue delicate 5.5"
Forceps artery straight 5.5"
Forceps artery/ mosquito, delicate curved 5"
Forceps Allis, delicate 6", 5x6 teeth
Forceps Babcock 7.5"
Forceps sponge straight 9.5"
Retractor abdominal wall (small size – interval sterilization)
Retractor abdominal wall double ended for post-partum sterilization
Scissors 7" curved
Scissors operating Mayo 6.75" curved
Needle holder Mayo Hegar 7"
Round body needle # 10/11
vicryl 2/0
Silk sutures for tying fallopian tubes
Vicryl for rectus sheath
Vicryl for skin
Vaginal speculum Sims/Cusco
Foleys Catheter
Xylocaine Inj. 1% vials
Liq. Betadine, 500 ml
Inj. Pethidine 50 mg
Inj. Phenargan 50 mg.
Inj. Atropine 0.6 mg
Hypochlorite for decontamination
Antibiotics Amoxcillin
Paracetamol tablets

A5 INSTRUMENTS FOR VASECTOMY INCLUDING SPECIAL INSTRUMENTS REQUIRED FOR NO SCALPEL VASECTOMY

Iodine cup, 4 oz 1.5" high
Addison forceps, 5"
Forceps, artery, straight, 51/2"
Forceps, artery, curved
Scalpel handle
Surgical blade, size 10
Iris scissors, curved
Sponge holding forceps
Ringed forceps, 4.0 mm ring (NSV)
Ringed forceps, 3.0 mm ring (NSV)

A6 EXPENDABLE SUPPLIES FOR VASECTOMY

Gauze cloth 18 m x 1 m
Sterile gloves various sizes
Liq. Betadine
Xylocaine Inj. 1% 30 ml vial
Disposable Syringe 5 ml with 1.5", gauge 23-24 needle
Black silk
Paracetamol tablets
Hypochlorite solution for decontamination
Dressing
Adhesive tape 4" x 5" roll
Further reading
Department of Public Health, Maldives, Logistics Management Guidelines for Family Planning, Male', Maldives, (in press).

APPENDIX B

INFECTION PREVENTION

B1 INTRODUCTION

Infection prevention practices are crucial to minimize the transmission of infections to clients and service providers, including clinic helpers who handle contaminated instruments and wastes.

B2 PROTECTIVE BARRIERS

Protective barriers are physical, mechanical or chemical processes which help prevent the spread of infectious microorganisms from client to client, clinic staff to client, or vice versa. Protective barriers include:
- hand-washing
- wearing gloves and surgical attire
- antisepsis
- processing equipment, instrument and other items
- managing clinical waste.

B3 HAND-WASHING

Hand washing may be the single most important procedure in preventing infection. To encourage handwashing, a continuous supply of fresh water, either from the tap or a bucket, and soap should be provided. Microorganisms grow and multiply in moisture and in standing water. Therefore, avoid basins containing standing water, even with the addition of an antiseptic agent such as Dettol or Savlon , because microorganisms may survive and multiply in these solutions.

B3.1 INDICATIONS FOR HAND WASHING

- Before and after examining a client especially when touching mucous membranes
- Provision of injectables
- Before putting on sterile or high-level disinfected (HLD) gloves
- After removing gloves, as they may have invisible holes or tears
- After handling contaminated objects, such as used (soiled) instruments
- When accidentally touching blood or other body fluids (e.g. when collecting laboratory specimens).

TECHNIQUE OF HAND WASHING

It is the best practice for providers to wash their hands between each client contact.

For clinical examination, pelvic examination (bimanual and speculum examination and insertion/removal of IUD):
Wash hands with plain soap for about 15–30 seconds; then rinse in a stream of water. Dry hands with a clean towel or air dry.

For surgical procedures (e.g., laparoscopy, minilaparotomy, vasectomy, insertion and removal of Implanon implants):
- Remove all items of jewellery, including wristwatch
- Wash hands with an antiseptic soap for 3 to 5 minutes
- Scrub hands with a soft brush or sponge. Begin at the fingertips; wash between all fingers and move toward the elbow
- Repeat for the second hand
- Rinse each arm separately, fingertips first, holding hands above the level of the elbows to prevent water from runing down from the elbow to the hand
- Dry hands with a sterile towel
- After handwashing has been completed, hold hands above the level of the waist.

- Repeat handwashing if hands touch any unsterile object before gloves are put on. However, if this happens while wearing gloves, just change gloves.

B3.2 WEARING GLOVES AND SURGICAL ATTIRE

WEARING GLOVES

Gloves should be worn by all staff prior to contact with blood and body fluids, either when serving a client or when handling contaminated equipment and materials. Change gloves between each client to avoid cross contamination. Using new, single- use (disposable) gloves is preferable. However, re-usable gloves can be washed and sterilized by autoclaving, or washed and high-level disinfected by boiling before reuse. Table A3.1

B3.3 ANTISEPSIS

Antisepsis involves cleaning of the client's skin or mucous membrane with an antiseptic substance to remove or eliminate as many microorganisms as possible, prior to any invasive procedure. Care should be taken not to irritate or damage skin or mucous membrane.

- No touch technique' is used to insert an IUD aimed to minimize chances of uterine infection following insertion. The method involves loading sterile packaged IUD into their inserters while both IUD and inserter are still in the sterile packaging.

INDICATIONS TO USE ANTISEPTICS

- Surgical handscrub
- Skin, cervical and vaginal preparation before a clinical procedure
- Handwashing in high-risk situations, such as before invasive procedures (e.g., insertions of central venous catheters or tubes) or before contact with clients at high risk of infections (e.g., newborns or immunosuppressed clients)

Note: While preparing skin for surgical procedure, do not shave hair at the operative site. Shaving increases the risk of infection as the tiny nicks in the skin provide an ideal setting for microorganisms to grow and multiply. If the hair must be cut, trim the hair close to the skin surface immediately before surgery.

SELECTION OF ANTISEPTICS

The following antiseptic solutions are approved for use:

- Idophors, various concentrations 0.5% to 10% (e.g. Betadine)
- Alcohols (60 to 90%), ethyl, isopropyl, 'methylated spirits
- Chlorhexidine gluconate 4% (e.g. Hibitane, Hibiscrub) Centrimide and chloro hexidine gluconate (CHG), various concentrations (e.g., Savlon)
- Iodines (2 to 3%), tincture and aqueous (e.g., Lugol's) (not for use on mucous membranes such as vagina)

Remember: antiseptics do not have the same killing power as the chemicals used for HLD. Therefore, antiseptic solutions should never be used to:

- disinfect inanimate objects, such as instruments and reusable gloves
- clean surfaces, such as floors or countertops.
  Instruments and items such as pickups (lifters, cheatle forceps), scissors, scalpel blades and suture needles should never be left soaking in an antiseptic solution; they should always be stored dry.

  Microorganisms can live and multiply in antiseptic solutions and contaminate the instruments and other items, leading to infections.

STORAGE AND DISPENSING OF ANTISEPTICS

Contamination of every antiseptic has been documented. Microorganisms contaminating antiseptic solutions include gram-negative bacilli and endospores and, rarely, staphylococcus. These organisms can cause subsequent infection when used for handwashing or on a client's skin or mucous membrane.

TO PREVENT CONTAMINATION OF ANTISEPTIC SOLUTIONS:

Pour the antiseptic, unless supplied commercially in small quantities, into small, clean, reusable containers for daily use. This prevents evaporation and contamination, which could occur if the large container is opened too often. Do not store gauze or cotton wool in aqueous antiseptics as this promotes contamination.

Establish a routine schedule (e.g., each week) for preparing new solutions.

Store antiseptics in a cool, dark area. Never store chemicals in direct sunlight or in excessive heat (e.g., upper shelves in a tin-roofed building).

When using antiseptic solutions, always pour the solution out of the container. Touching the rim or contents of the container with gauze, a cotton swab or hand contaminates the entire bottle of antiseptic.

B3.4 PROCESSING OF EQUIPMENT AND OTHER ITEMS

The purpose of processing of instrument is to reduce the spread of microorganisms by equipment, instrument and other items while reusing these materials for providing services. It is not only for clients/patients but also for service providers and clinic support staff.

STEPS IN PROCESSING EQUIPMENT AND OTHER ITEMS:

1.Decontamination
2. Cleaning
3. Sterilization [Rarely High level disinfection (HLD)]
4.Storage

DECONTAMINATION

Decontamination is important for pre-treating instruments and objects that may have come in contact with body fluids, to make them safer to handle by personnel who clean them. Proper decontamination will inactivate Human Immunodeficiency Virus (HIV) and hepatitis B virus (HBV), hepatitis C virus (HCV) and hepatitis D, making instruments safer for staff to handle. Using 0.5% chlorine solution is an inexpensive and effective way for decontamination.

PREPARATION OF 0.5% CHLORINE SOLUTION

Chlorine solution can be made from liquid household bleach (sodium hypochlorite) or from other chlorine compounds available in powder (calcium hypochlorite or chlorinated lime) or tablet form (sodium dichloroisocyanate). Refer to Table A3.3 for required items for decontamination.

PROCESS OF DECONTAMINATION

- Keep a fresh plastic bucket containing 0.5% chlorine solution near the procedure site
- Immediately after each procedure, place the used items in 0.5% chlorine solution for 10 minutes. Do not wait too long before starting decontamination, to prevent organic materials from drying and becoming hard to remove
- After 10 minutes, rinse with water and remove gross organic material before being cleaned

Soaking instruments for excessive periods of time in the chlorine solution can damages them.

- Decontaminate large surfaces (e.g., pelvic examination tabletop) by wiping them with 0.5% chlorine solution.

PRECAUTIONS

Use only plastic containers for chlorine solution. Chlorine damages metal containers
Use utility gloves while working with chlorine solution
Submerge all the instruments in 0.5% chlorine solution so that the chlorine solution level is above the instruments. Open jointed items such as clamps and scissors
To prevent damage to the instruments do not keep them in chlorine solution for more than 10 minutes.

Chlorine solutions should be replaced DAILY or MORE OFTEN if necessary, because they lose potency rapidly over time or after exposure to light.

Rinse the instruments with cold water immediately after decontamination.

Store the chlorine powder where there is good ventilation. Do not keep it in a general storage area where there are other metal instruments and equipment.

CLEANING

Cleaning is a crucial step in instrument processing. Cleaning greatly reduces the number of organisms and endospores on instruments and other equipment. Refer to Table A3.3 for list of required items for cleaning.

PROCESS

Hold items under soapy water (warm, if available) and vigorously scrub with a brush to completely remove all blood, tissue and other residue. Use a liquid or powdered detergent, which can easily dissolve in water. Avoid the use of soap or detergents that contain soap, because fatty acids contained in soap react with the minerals in hard water and form residue, which is difficult to remove. Do not use abrasives because they may damage instruments.

Be sure to remove all materials caught in the small spaces (e.g., between the teeth of clamps or hemostat) and around the joints.

Rinse thoroughly with water, as soap may interfere with chemical disinfection or sterilization.

Dry by air or with a clean towel. (Water from wet instruments will dilute chemicals used for sterilization or disinfection.) Drying is not necessary for instruments which are to be boiled.

HIGH-LEVEL DISINFECTION (HLD)

High-level disinfection is effective in destroying all microorganisms but does not always kill endospores. High-level disinfection is appropriate for items that do not come into contact with the bloodstream or tissues under the skin. Also, when sterilization is not possible, high-level disinfection is the only acceptable alternative for processing instruments and other items for reuse. Table A3.3 gives the list of required items for HLD.
HLD can be achieved by two techniques: boiling and chemical disinfection.

PROCESS

Decontaminate, clean and rinse items thoroughly. Completely immerse items in water. Open instrument with joints such as clamps and scissors. Disassemble items composed of more than one part. Make sure that any bowls and containers to be disinfected are full of water.

Cover and bring water to a rolling boil. **Boil items for 20 minutes.** Begin timing after water reaches a rolling boil. **Do not add or remove any item once timing begins.**

Lower heat to keep water at a rolling boil because too vigorous boiling wastes fuel, evaporates the water and may damage equipment.

After 20 minutes, remove items from water using high-level disinfected forceps/pickups.

Allow items to air dry. Use immediately or store in a high-level disinfected container for up to 1 week.

Use the same water throughout the day, adding only enough to keep the surfaces at least 2 cm above the equipment to be disinfected. Frequent draining and replacement of water increases the risk of mineral deposit.

HIGH-LEVEL DISINFECTION WITH CHEMICALS PROCESS

Decontaminate, clean and rinse items thoroughly.
Completely immerse items in a high-level disinfectant solution so that the solution touches all surfaces. Open instrument with joints such as clamps and scissors. Disassemble items composed of more than one part. Make sure that any bowls and containers to be disinfected are full of chemical solution.

Soak for 20 minutes. Do not add or remove any items once timing has begun. Remove, using disinfected forceps or gloves.

Thoroughly rinse items with boiled water.
Allow to air dry. Use immediately or store in a high-level disinfected container for up to 1 week.

PRECAUTIONS

The vapours of glutaraldehyde are toxic and irritating to the skin, eyes and respiratory tract. Always wear gloves and use it in a well-ventilated area.

Chemical disinfection of needles and syringes should be avoided because they are difficult to rinse effectively, and chemical residues may interfere with the action of medications being injected.

STERILIZATION

Sterilization kills all microorganisms including endospores and should be used for all objects entering body cavities or the vascular system. Sterilization can be achieved by using steam (autoclaving) or soaking in a chemical sterilization liquid. Refer to Table A3.3 for list of items required for sterilization.
Steam sterilization
High-pressure saturated steam is generally the method of choice for sterilizing instrument and other items used in family planning and other healthcare facilities.

Process

Decontaminate, clean, rinse and air dry items thoroughly.
Wrap items with desired wrapping materials.

Arrange items/packs in autoclave to allow free circulation of steam.

Sterilize wrapped items for 30 minutes, unwrapped items for 20 minutes at 121°C (250°F) and 106 kPa pressure (915 lbs./in). If using a mixed load, sterilize for 30 minutes. Start timing when required temperature and pressure have been reached.

When time is complete, turn off heater and release the pressure valve. Wait until pressure gauge reads zero (approximately 20 to 30 minutes) to prevent steam from escaping abruptly when opening the door and hurting the person performing the procedure.

Wrapped items can be stored for up to 7 days. Unwrapped items should be used immediately or stored in a covered sterile container for up to 7 days.

CHEMICAL STERILIZATION

Chemical sterilization may be used for items which are sensitive to heat such as endoscopes.

Process

Decontaminate, clean, rinse and dry items thoroughly.
Completely immerse items in chemical sterilant solution. Open instrument with joints such as clamps and scissors. Disassemble items composed of more than one part. Make sure that any bowls and containers to be disinfected are full of chemical solution.

Allow to soak for at least 8–10 hours in 2% glutaraldehyde solution. Do not add or remove any items once timing has begun.

Remove items with sterile forceps/pickups, rinse well with sterile water and allow to air dry. Store in a covered sterile container for up to 7 days.

STORAGE OF STERILE OR DISINFECTED EQUIPMENT

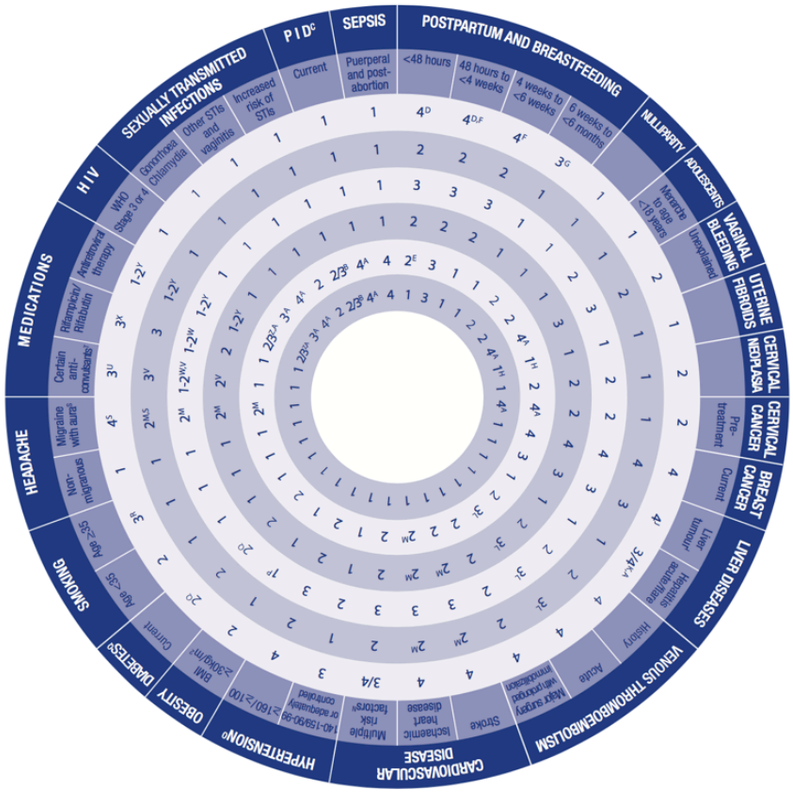
Proper storage of high-level disinfected and sterilized equipment is just as important as the high-level disinfection or sterilization process itself.
Sterilized/disinfected equipment should be stored in enclosed shelves or in covered containers to protect it from moisture, dust and debris. The storage area should be easily accessible, but away from circulation of contaminated material and individuals not related to the preparation or handling of equipment and materials. It should also be separated from the area where contaminated material is cleaned and prepared for sterilization or disinfection.

STORAGE OF STERILE OR DISINFECTED EQUIPMENT: KEY

Store the packs when they reach room temperature.
Do not place warm packages in plastic dust covers. Moisture will be trapped and remain there until opened.
If the pack is dropped, torn or gets wet, consider it contaminated. Mark packs and containers used for storing sterile or disinfected items with expiration date and list of items.
Store packs and containers (drums) containing sterile items off the floor.
Items should be stored in an enclosed cabinet.
Re-process objects which have not been used within 1 week.

APPENDIX C

WHO MEC WHEEL 2015



REFERENCES

1. Contraceptive Updates, Reference Manual for Doctors, Ministry of Health and Family Welfare, Government of India, 2005
2. Decision making tool for family planning clients and providers, Geneva, World Health Organisation 2005
3. EngenderHealth, COPE® Handbook: A Process for Improving Quality in Health Services, Revised Edition, EngenderHealth 2003
4. EngenderHealth. Facilitative Supervision Handbook. New York, 2001.
5. Family Planning: A Global Handbook for Providers, Johns Hopkins Bloomberg School of Public Health USAID and World Health Organisation, 2007
6. Family Planning in South East Asia: Fact Sheets, World Health Organisation
7. International Planned Parenthood Federation in collaboration with the World Health Organisation and AVSC International: Medical and Service Delivery Guidelines for Family Planning: Second Edition, 1997
8. Logistics Management Manual, Department of Public Health, Maldives,
9. Medical Eligibility for Contraceptive Use, Fifth Edition, 2015, World Health Organization
10. National Standards for Family Planning Services, Department of Public Health, Maldives, 2005
11. Service Delivery Tools and Job Aides for Family Planning Providers, FHI 360
12. Selected Practice Recommendations for Contraceptive Use, Third edition, 2016
13. Sexually Transmitted and other Reproductive Tract Infections: A Guide to Essential Practice, WHO, Geneva, Switzerland. 2005

ANNEXE:

Dr. Aseel Jaleel, Senior Consultant in Obstetrics and Gynaecology, IGMH

Dr. Zakiya Ahmed, Consultant in Obstetrics and Gynaecology, IGMH

Dr. Aminath Shaheedha, Consultant in Obstetrics and Gynaecology, IGMH

Dr Hawwa Inaya, Consultant in Gynecology, Hulhumale'

Dr Vikas Ratan Gosavi, Senior Consultant Gynaeologist, ADK

Dr Sasi Seerappan, Consultant in Obstetrics & Gynecology, ADK

Dr. Fathimath Shamaa Shareef, Medical Officer,IMGH

Dr Shaistha Zubair, Medical Officer, Dhamanaveshi

Ms. Husna Mohamed,Director, IGMH

Ms. Fathimath Fileeshiya, Ward Manager, IGMH

Ms. Humaira Jamal, Deputy Ward Manager, IGMH

Ms. Aminath Fazeela, Ward Manager, IGMH

Vahudha Ahmed, Registered Nurse, Dhamanaveshi

Lubna Nizam, Clincal Nurse, Dhamanaveshi

Asiya Ibrahim, Senior Lecturer, School of Nursing

Ms Sheeza Abdul Wahid, Head, Maternal and Clinical Care Nursing, ADK

Ms Fathmath Aasthana, Senior Staff Nurse Grade 111, In-Charge of Labour room, ADK

Aminath Nabaaha, Community Health Officer, Villingili

Afrah AbduRahman, Registered Nurse, Villingili

Shihama Nasheed Aboobakuru, Registered Nurse, Villingili

Fathimath Naaila, Member, SHE

Aminath Azlifa, Director SRH, SHE

Thaima Jaadhullah, Program Coordinator, SHE

Fathimath Abdul Gayoom, Clinical Nurse, Hulhumale'

Fathimath Mohamed, Clinical Nurse, Hulhumale'

Midhath Ahmed, Senior Registered Nurse, Hulhumale'

Sinva Abdul Latheef, Public Health Program Officer, Dhamanaveshi

Aminath Shiuna, Lecturer, School of Nursing

Shifaza Adam Shareef, lecturer, FHS

NATIONAL STANDARDS FOR FAMILY PLANNING SERVICES

Reviewed in 2021

Document No: MoH-QA/S/21/106-0