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Reference Manual for

Oral Contraceptive Pills

March 2016

राष्ट्रीय स्वास्थ्य मिशन

Family Planning Division
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Ministry of Health & Family Welfare

Government of India, Nirman Bhawan, New Delhi-110101

भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

MESSAGE

The Family Planning agenda has been revitalized and is widely regarded as one of the key national and international development priorities. Acknowledgement of reproductive rights of women, including the ability to make informed choices and adopt effect contraceptive methods, forms the cornerstone of the National Family Planning Programme of the Government.

Oral contraceptive methods, both hormonal and non-hormonal ones, offer women and couples a wide range of options for delaying, spacing, and limiting births. Oral contraceptives are safe, effective and reversible methods to prevent pregnancy, and are an important part of the National Family Planning progam's contraceptive method mix. The current environment is conducive to the provision of contraceptives and involves improved access, expanded choice, quality care, training and ensuring a continuous and efficient commodity supply.

The reference manual has been developed keeping these factors in mind. I congratulate the Family Planning Division on this initiative. I am confident that the States, service providers and programme officers will make optimum use of this valuable resource.

(B.P. Sharma)

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FOREWORD

Family Planning promotion is unique among medical interventions in the scope of its potential benefits which range from reduction of poverty, maternal and child mortality to empowerment of women. Socioeconomic development is intrinsically linked to investments in family planning resulting in an accelerated pace of change. Strategies that are cost effective are ably supported through good public health infrastructure, high mass media exposure leading to a strong demand for services. With the maturing of programmes, phasing in new methods along with constant improvements in service quality becomes a priority.

Improved access to and use of contraception will help beneficiaries implement their preferences and avoid unwanted pregnancies. Oral Contraceptives are one of the oldest and most popular temporary family planning methods. The safety and efficacy of the methods are well established.

This Manual seeks to ensure that all service providers and programme managers have the latest and correct information on oral contraceptive methods - Combined Oral Contraceptives, Progestin Only Pills, Centchroman Pills and Emergency Contraceptive Pills - for providing safe, effective as well as maintaining the quality of client centric services.

The efforts of the Family Planning Division in developing this manual are laudable. I am certain that this manual will serve as an important reference for increasing the usage of oral contraceptives all over the country.

(C.K. Mishra)

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PREFACE

Ensuring healthy timing and spacing of pregnancies is one of the key interventions for reproductive, maternal, neonatal, child and adolescent health (RMNCH+A) strategy. Encouraging women and couples to plan for healthy pregnancies, including timing and spacing, will help to improve health outcomes for both mothers and children. There is renewed emphasis on the use of reversible or spacing methods of contraceptives which are safe and effective for women.

The desire for smaller families and motivation for healthy spacing of births has steadily increased. To achieve their childbearing preferences and to prevent unintended pregnancies, women and their partners need effective contraception. In order to address the unmet need for modern contraceptives, we need to expand the choices, improve access to contraceptive services, supplies and provide high-quality services.

Contraceptive effectiveness depends on both the mechanism of action of a method and on the extent to which the method relies on adherence by the user. Combined Oral Contraceptive pills inhibit ovulation and their failure rates, when used perfectly, are very low.

This comprehensive Manual is meant for all stakeholders including programme managers, trainers and service providers (medical officers, nursing personnel and midwives). It will not only help in developing the knowledge and skill of service providers in providing quality services, but will also empower programme managers in expanding the use of oral contraceptives in districts and states. It has been developed with the aim to improve the acceptance, continuous use of oral contraceptives and user satisfaction.

The endeavours of the Family Planning Division in putting together this Manual is appreciated. I am certain that the Manual will be a guiding document for all levels of health care providers.

(Dr. Rakesh Kumar)

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ACKNOWLEDGEMENT

The Government has initiated efforts to expand oral contraceptive options by inclusion of Progestin-Only Pills and Centchroman in the national programme and provide them through the public health delivery system.

Considering the programmatic thrust on postpartum family planning, as many women come to health facilities for childbirth, oral contraception, which are safe for breastfeeding women, have great potential to improve use of family planning methods by postpartum women.

I am extremely grateful to Shri B. P. Sharma, Secretary (H&FW) and Shri C. K. Mishra, Additional Secretary & Mission Director (NHM), Ministry of Health and Family Welfare for their guidance and unstinting support. The development of the manual on oral contraceptives has been made possible with constant support and encouragement received from Dr. Rakesh Kumar, Joint Secretary RCH.

I extend my heartfelt thanks to all the members of the Family Planning Technical Resource Group, especially the core group comprising of Dr. Alok Banerjee, Dr. B. P. Singh, Dr. Sunita Singhal, Dr. Ravi Anand and Dr. Saswati Das who played a pivotal role in providing critical information and technical assistance to guide the development of this manual.

I am thankful to all the members of the Family Planning Division namely Dr. Teja Ram, Deputy Commissioner, Dr. Pragati Singh, Ms. Shilpa John, Ms. Renuka Patnaik and Mr. Jay Prakash. Appreciation is extended to all the members of the National TSU team especially Dr. Nidhi Bhatt who was instrumental in refining and developing this guideline.

I am confident that the techno-managerial manual will serve as an important guide to ensure effective implementation and strengthen service delivery of oral contraceptives across all the States/UTs.

(Dr. S. K. Sikdar)

CONTENTS

ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ANM	Auxillary Nurse Midwife
ASHA	Accredited Social Health Activist
BCC	Behaviour Change Communication
CDC	Centre for Disease Control
CDRI	Central Drug Research Institute
CHC	Community Health Centre
CPR	Contraceptive Prevelance Rate
DFWO	District Family Welfare Officer
DH	District Hospital
DLHS	District Level Household Survey
DQAC	District Quality Assurance Committee
ECP	Emergency Contraceptive Pills
ELA	Expected Level of Achievement
GMSD	Government Medical Store Depot
Hb	Haemoglobin
HIV	Human Immunodeficiency Virus
HTSP	Healthy Timing and Spacing of Pregnancy
IEC	Information Education Communication
IIPS	International Institute for Population Sciences
IUCD	Intra Uterine Contraceptive Device
LHV	Lady Health Visitor
LMP	Last Menstrual Period
LNG	Levonorgestrol
MEC	Medical Eligibility Criteria
MO	Medical Officer
MTP	Medical Termination of Pregnancy
NCHS	National Centre for Health Statistics

NHM	National Health Mission
NSAID	Non Steroidal Anti-Inflammatory Drug
OCP	Oral Contraceptive Pills
PHC	Primary Health Centre
POC	Progestin Only Contraceptive
POP	Progestin Only Pills
QA	Quality Assurance
RCH	Reproductive and Child Health
RTI	Reproductive Tract Infections
SC	SubCentre
SDH	Sub District Hospital
SN	Staff Nurse
SQAC	State Quality Assurance Committee
STI	Sexually Transmitted Infections
UNFPA	United Nation Population Funds
UNpop	United Nations Population Division
WHO	World Health Organization

Chapter 1 Introduction

1.1 Background

India's population of over 1.25 billion is slated to overtake that of China in the next decade. The population size is more than the population of USA, Brazil, Bangladesh, Pakistan, Indonesia and Japan put together. It is well known now that Family Planning is important not only for achieving population stabilization but is also central to improve the maternal and new born health and survival. Even though India has made considerable progress in reducing maternal mortality ratio, it still contributes to 20% of maternal deaths worldwide, according to the 2012 report of World bank, UNFPA, WHO. Family Planning can avert more than 30% of maternal deaths and 10% child mortality if couples spaced their pregnancies more than 2 years apart (Cleland J et al, 2006. Lancet).

In 1951, India was the world's first nation to launch the Family Planning Programme. Over the years India's Family Planning Programme has evolved with the shift in focus from merely population control to more critical issues of saving the lives and improving the health of mothers and newborns. However, the unmet need for contraception at national level has been 20.5 percent (DLHS 3, 2007-08).

Ensuring healthy timing and spacing of pregnancies is now one of the key interventions for reproductive, maternal, neonatal, child and adolescent health (RMNCH+A) strategy. At the 2012 London Summit, the Government of India (GoI) made a commitment to increase access to family planning services to 48 million additional users by the year 2020.

The renewed emphasis on use of reversible or spacing methods of contraceptives, which are safe and effective for women, has brought the spotlight on improving women's access to oral contraceptive methods.

Oral contraception is a known and popular method of contraception and refers to birth control methods taken orally, to prevent or delay pregnancy. The combined oral contraceptive pill was the first oral contraceptive method and was marketed in 1960. In the following decades newer methods of oral contraception such as, progestin-only pills and Centchroman (Ormeloxifene) and emergency contraceptive pills have been popularised. Oral contraceptive methods are highly effective when taken correctly and consistently

Combined Oral Contraceptives (COCs) contain low doses of the hormones progestin and estrogen while Progestin-Only Pills (POPs), also called minipills, contain low dose of the progestin hormone only, allowing breastfeeding women to use them. The first non-steroidal once a week pill 'Centchroman (Ormeloxifene)' was developed indigenously by the Central Drug Research Institute (CDRI), Lucknow.

Emergency Contraceptive Pills (ECPs) can reduce the risk of unintended pregnancy when taken after unprotected sexual intercourse and offer women an important second chance to prevent pregnancy when a regular method fails, no method was used or sex was forced. ECPs contain either progesterone alone or progestin and estrogen combined together to prevent ovulation.

Documented evidence shows that expansion of the contraceptive method mix in low and middle-income countries has a positive relationship with contraceptive use. Use of contraception may be increased by extending the availability of current methods and by introducing new methods in the existing basket of choices.

1.2 The Global Evidence for Use of Oral Contraceptives

According to the United Nations population data, 63% of partnered, reproductive-age women worldwide, representing about 740 million couples practice some form of contraception. Almost 90 percent of them employ modern methods, which include oral contraceptives ("the pill"), condoms, injections, intrauterine devices (IUDs) and sterilization. Worldwide, an estimated 8% of all married women currently use the oral contraceptive pill. It is the number one contraceptive method in Africa, Europe and Oceania (Australia, New Zealand and the South Pacific islands). Oral Contraceptives (OCs) are an effective family planning method being used by over 100 million women worldwide. Many more have used OCs at some time in their lives (Population Reports, Oral Contraceptives: An Update, Series A, No. 9, Spring 2000). It is also the most prevalent form of reversible contraception in the Americas. However, in India, the use of the Oral contraceptive pill is relatively low (Source: EPI from UN Pop, Earth Policy Institute, 2012, Fig. 1).

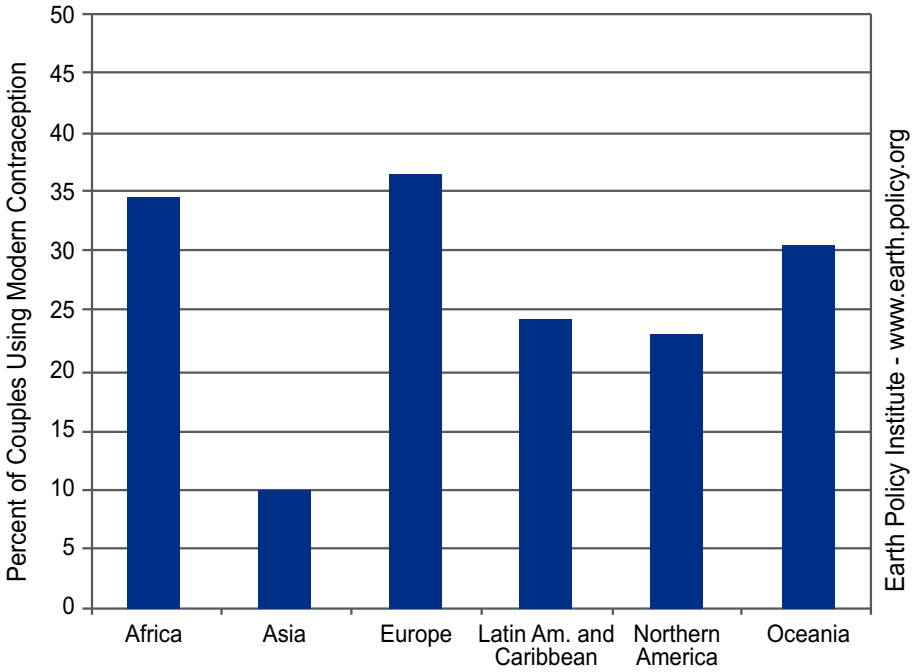


Fig. 1: Contraceptive Pill Prevalence by Region, Latest Year

Source: EPI from UNPoP

1.3 Global Evidences for Use of Emergency Contraceptive Pills

The use of ECPs is increasing worldwide. In United States, 2006–2010, among sexually experienced women aged 15–44, roughly one in nine (11% or 5.8 million) women had ever used emergency contraception, up from 4.2% in 2002. Most women who had ever used emergency contraception had done so once (59%) or twice (24%). According to Euromonitor International's report, India's market for emergency contraceptives jumped by 88% between 2009 and 2014, ranking the country third in the world after the US and China. Young adult women aged 20–24 were most likely to have ever used emergency contraception; about one in four had done so (23%) (Source: CDC, NCHS Data Brief No. 112, February 2013).

1.4 Oral Contraceptive usage in the National Family Planning Program of India

Despite the fact that oral contraception being safe and effective options for many women worldwide, its use in India is very low, it is only 4% (Fig. 2).

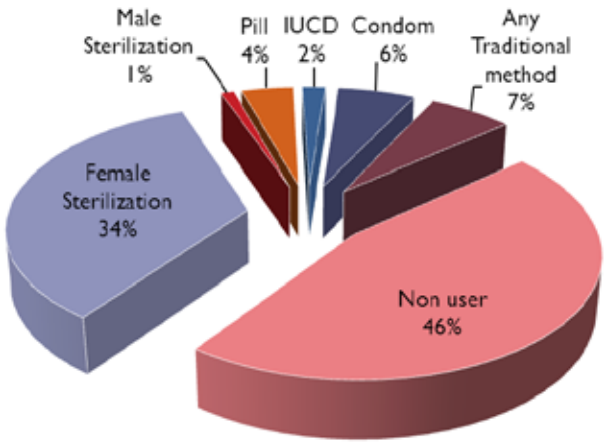


Fig. 2: Oral Pill Usage Versus Other Methods in India

Source: DLHS -3 (2007-2008), IIPS, Mumbai

1.5 Introduction of other Oral Pills in the National Family Planning Program

Considering the resurgence of interest and experience in postpartum family planning, as many women come to health facilities for childbirth, oral contraceptives which are safe for breastfeeding women, have good potential to improve use of family planning methods by postpartum women. In addition to postpartum sterilization and postpartum IUCD currently available under the National Programme, other postpartum family planning options can be – (i) Progestin only Pills (POPs) which is a well-recognized non- invasive option for spacing births in the postpartum period particularly for breastfeeding women and (ii) Centchroman (Ormeloxifene) as once-a-week contraceptive, a promising non-hormonal option for spacing, as it is safe for lactating women. Government has initiated efforts to expand oral contraceptive options by inclusion of Progestin-Only Pills and Centchroman (Ormeloxifene) in the national programme and provide them through the public health delivery system. Strategies to increase pill use include making various oral contraceptive pills accessible to women at various stages of reproductive cycle, giving women complete and easily understandable information, providing individual counseling and giving follow-up messages to remind women about effective pill use. Making pills more accessible by elimination of unnecessary restrictions to their safe use can also help women use the pill more effectively.

1.6 Purpose of the Manual

This manual seeks to ensure that all providers have the latest and correct information on oral contraceptive methods (Combined Oral Contraceptives (COCs), Progestin Only Pills (POPs), Centchroman (Ormeloxifene) Pills and Emergency Contraceptive Pills (ECPs)) for providing high quality services that are safe and client centred. It aims to revitalize the training aspects of oral contraceptive methods and firmly establish it in the National Family Planning Program.

1.7 Target Audience

This comprehensive manual is meant to be used all over the country by all stakeholders, including programme managers at the national, state, district and block level, trainers and service providers at all level (medical doctors, nursing personnel and other paramedicals), faculty of medical colleges as well as clients, who want to get acquainted with the program and be aware of their rights and responsibilities. It will not only help in enhancing the knowledge and skills of service providers in providing quality services, but also empower the programme managers in scaling up the services in their states or districts which will in turn help to improve the acceptance and continuation rates leading to user satisfaction.

Section I

Technical Aspects of Oral Contraceptive Pills

Chapter 2

Overview of Oral Contraceptives

An Oral Contraceptive method, both hormonal and non-hormonal ones, offer women and couples a wide range of options for delaying, spacing and limiting births. Oral contraceptives are safe, effective, reversible methods to prevent pregnancy and need to be taken regularly. They are an important part of the National Family Planning Program's contraceptive method mix.

They do not disrupt an existing pregnancy and do not interfere with sexual intercourse. However, they do not protect a woman from HIV or other Sexually Transmitted Infections (STIs). Women using oral contraceptives must use condoms to prevent HIV and other STIs.

2.1 Types of Oral Contraception

A. Hormonal

B. Non-hormonal

A. Hormonal: There are two main categories of hormonal contraceptives:

1. Combined hormonal contraceptives contain both an estrogen (usually ethinyl estradiol) and a progestin
2. Progestin-only contraceptives contain only progesterone a synthetic analogue (progestin).

Combined Oral Contraceptive (COC)	Taken daily, irrespective of intercourse. Releases a low dose of both estrogen and progestin into the bloodstream. Effectiveness depends on regular intake.
Progestin-Only Pill (POP)	Taken daily, irrespective of intercourse. Releases a low dose progestin into the bloodstream. Effectiveness depends on regular intake at the same time every day (within a window of 3 hours). Safe for breastfeeding women.
Levonorgestrel Emergency Contraceptive Pill (ECP)	A progestin-only method. Prevents pregnancy in emergency situation (unprotected /accidental intercourse) to be taken within 72 hours as a single dose (1.5 mg). Emergency contraceptive pills do not provide ongoing protection against pregnancy.

B. Non-Hormonal: Centchroman (Ormeloxifene)

Centchroman (Ormeloxifene)	A non-steroidal, non-hormonal method, taken twice a week on fixed days for the first three months, followed by once a week thereafter. Safe for breastfeeding women.

2.2 Contraceptive Effectiveness of Oral Contraceptives

Contraceptive effectiveness is described in two ways:

- **Perfect use**: Pregnancy rates (failure rates) during perfect use show how effective a method is when it is used perfectly, consistently and exactly according to directions.
- **Common (or typical) use**: Pregnancy rates (failure rates) during common (or typical) use show how effective a method is during actual use by the average person who does not always use the method consistently and correctly.

The contraceptive effectiveness of various pills is detailed below.

Table 1 : Effectiveness of Oral Contraceptive Pills

Method	Contraceptive Effectiveness	
	With Perfect Use	**With Typical Use**
Combined Oral Contraceptive Pills (COCs)	• 0.3 pregnancy per 100 women	• 8 pregnancy per 100 women
Progestin-only Pills (POPs)	• **Breastfeeding women:** 0.3 pregnancy per 100 women • **Non-breastfeeding:** 0.9 pregnancy per 100 women	• **Breastfeeding women:** 1 pregnancy per 100 women • **Non-breastfeeding:** 3-10 pregnancy per 100 women
Centchroman (Ormeloxifene)	• 1-2 pregnancy per 100 women	• No documented failure rate with typical use available

Emergency Contraceptive Pills (ECPs)	• ECPs are not a continuous form of birth control, hence annualized pregnancy rate is not calculated.
	• If all 100 women used ECPs containing
	  • Only progestin, 1 pregnancy per 100 women
	  • Both estrogen and progestin, 2 pregnancy per 100 women
	• The sooner after unprotected sex that EC pills are taken, the more effective they are.	

Chapter 3

Counselling

3.1 Counselling

Counselling is defined as a helping process where a (skilled service provider) explicitly and purposefully gives his/her time, attention and skills to assist a client to explore their situation, identify and act upon solutions within the limitations of their given environment.

Counselling is a very essential component of Family Planning Services. Counselling is a client centered approach that involves communication between a service provider/counsellor and client. It enables the service provider/counsellor to understand clients' perceptions, attitudes, values, beliefs, family planning needs and preferences and accordingly can guide him/her towards decision making. The provider/counsellor should be non-judgmental. Privacy (auditory and visual) and confidentiality should be maintained during the process of counselling.

3.2 Benefits of Family Planning Counselling

- Increases acceptance
- Enhances continuation of methods
- Dispels rumours and corrects misunderstandings about contraceptive methods
- Promotes effective use
- Increases client's satisfaction

3.3 Decision-Making

Counselling helps the client to make voluntary decision regarding:

- Whether to use contraception to delay, space or limit childbearing.
- Which method to use.
- Whether to continue using contraception if side effects occur.
- Whether to switch methods when the current method is unsatisfactory.
- Whether to involve one's partner in reaching a decision.

3.4 Principles of FP Counselling

- Privacy.
- Confidentiality.
- Respectful, non-judgmental, accepting and caring attitude.
- Simple culturally appropriate language easy for client to understand.
- Good verbal and non-verbal interpersonal communication skills.
- Brief, simple and specific information with key messages.
- Opportunity for client to ask questions and express any concerns.
- Effective use of audio-visual aids, anatomic models and contraceptive samples.
- Repeat key information shared by the client, show and confirm that you have understood correctly what they are saying.
- Voluntary Informed Decision making by client.

3.5 Stages of Family Planning Counselling

3.5.1 Stage I: General Counselling

During this stage, the provider creates the conditions that help a client select a family planning method.

- Establish and maintain a warm, cordial relationship and listen to the client's contraceptive needs.
- Rule out pregnancy using the Pregnancy Checklist (Annexure 2).
- Display all the methods using flip charts, photographs, illustrations or posters. Arrange by method type: Spacing (temporary/reversible methods) methods, Limiting (Permanent) methods.
- Set aside methods that are not appropriate for the client.

Keeping aside the methods helps to avoid taking time to provide information on methods that are not relevant to the client's needs.

Tip: Use visual materials such as brochures, photos and actual samples of different choices during counselling.

3.5.2 Stage II: Method Specific Counselling

- Give information about the methods that have not been set aside, including their effectiveness. Remove myths/misconceptions and address the queries (Please refer Annexure 6).
- Ask the client to choose the method that is most convenient for her/him.
- Determine client's medical eligibility for the chosen method.
- Give the client complete information about the method that she/he has chosen.
- Check the client understands and reinforce key information.
- Make sure the client has made a definite decision. Give client the selected method or a referral and back-up method depending on the method selected.
- Encourage the client to involve her/his partner(s) in decisions about contraception, either through discussion or a visit to the clinic.
- Assess STI/HIV risk. If the client has STI symptoms, refer or treat her/him with syndromic approach (if needed HIV counselling). Discuss dual protection. Offer condoms and instruct the client in correct and consistent use.
- Provide follow-up instructions for the method chosen.
- Invite the client to return at any time. Thank client for the visit and complete the session.

3.5.3 Follow up Counselling

- Elicit client experience and satisfaction with the method
- Discuss problems, side effects and manage, if any.
- Encourage continuation unless major problems exist.
- Repeat key instructions.
- Answer questions and address clients' concerns.
- Encourage satisfied clients to talk to other couples to adopt this method.

3.6 Counselling for Special Groups

- **Young people (15- 24 years of age):** Young people need youth-friendly services and service providers/counsellor should address the specific needs and concerns of this group.
- **Men:** Involving men in family planning is particularly important. Addressing men's interests and concerns helps couples reach healthy decisions jointly and removes a common barrier to women's use of family planning.
- **Clients affected by gender based violence:** women who are affected by violence and rape victims are at risk of unintended pregnancy. Emergency contraception is particularly important in these groups.

For general and method specific counselling on COCs, POPs or Centchroman (Ormeloxifene), please refer Annexure 4.1, 4.2, 4.3, 4.4

Combined Oral Contraceptive Pills (COCs)

4.1 What are COCs?

Combined Oral Contraceptives pills (COCs) contain low doses of two synthetic hormones- progestin and an oestrogen which are similar to the natural hormones in woman's body.

4.2 Key Points

- COCs are safe and effective.
- COCs have several non-contraceptive benefits, like protection against endometrial and ovarian cancer, iron deficiency anaemia, polycystic ovarian syndrome and endometriosis.
- COCs should not be given to breast feeding women till 6 months postpartum.
- One pill is to be taken every day. For greatest effectiveness, a woman must take pills daily without any break (28 pills packet).
- Missing pills increases the risk of unwanted pregnancy.

Fig. 3: COCs in the Public Sector - (a) ASHA Supply (b) Free Supply

The available COC pills in the public sector is Mala-N (Fig. 3)

- Mala N contains Levonorgestrel (0.15mg) + Ethinyl estradiol (30 micrograms). Mala-N is supplied free of cost through government health centres and hospitals.
- Each strip of Mala-N contains 21 hormonal tablets and 7 non hormonal (iron) tablets.

4.3 When to Start COCs?

A woman can start using COCs, any time she wants, if it is reasonably certain that she is not pregnant. Use the Pregnancy Checklist (Annexure 2).

Woman's situation	When to start
Having menstrual cycles	• Any time, within 5 days after the start of her monthly bleeding. No need for a backup method. • Any time, after 5 days of start of her monthly bleeding, if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 7 days of taking pills (if pregnancy cannot be ascertained give her COCs now and tell her to start taking them during her next monthly bleeding and use condoms till then).
Breast Feeding	
Less than 6 months after giving birth	• Not recommended in less than 6 months after giving birth. Prescribe the alternative methods like POPs, Centchroman (Ormeloxifene) and Injectable Contraceptives.
More than 6 months after giving birth	• Any time, if her monthly bleeding has not returned and if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 7 days of taking pills (if pregnancy cannot be ascertained give her COCs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • If her monthly bleeding has returned, COCs can be started as advised for women having menstrual cycles.
Not breastfeeding	
Less than 4 weeks after giving birth	• Any time on days 21–28 after giving birth. • Give her pills any time to start during these 7 days. No need for a backup method. (If additional risk for venous thromboembolism exists, wait until 6 weeks).
More than 4 weeks after giving birth	• Any time, if her monthly bleeding has not returned and if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 7 days of taking pills (if pregnancy cannot be ascertained give her COCs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • If her monthly bleeding has returned, COCs can be started as advised for women having menstrual cycles.
After miscarriage or abortion	• Immediately, within 7 days after first- or second-trimester miscarriage or abortion, no need for a backup method. • Any time, if it is more than 7 days after first or second trimester miscarriage or abortion and it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 7 days of taking pills (if pregnancy cannot be ascertained give her COCs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • In case of medical abortion, COCs can be started on the day of misoprostol use or within five days after taking it.
No monthly bleeding (not related to childbirth or breastfeeding)	• Any time, if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 7 days of taking pills.

Switching from a non-hormonal method	• If she is switching from Cu-IUCD:
	  • Immediately, within 5 days of her monthly bleeding. No need of backup method.
	  • If it is more than 5 days after start of monthly bleeding-start COCs along with a backup method (e.g. Condom).

Woman's situation	When to start
Switching from a hormonal method	• Immediately, if she has been using the hormonal method consistently and correctly or if it is otherwise reasonably certain that she is not pregnant. No need to wait for her next monthly bleeding and no need for a backup method. • At the time of repeat Injection, if switching from injectable contraceptive. No need for a backup method.
After taking Emergency Contraceptive Pills (ECPs)	• Same day, there is no need to wait for her next monthly bleeding to start her pills. • A new COC user should begin a new pill pack. • A continuing user who needed ECPs due to pill-taking errors can continue where she left off with her current pack. • A backup method (e.g. Condom) is needed for the first 7 days of taking pills.

4.4 How to Use COC Pills?

- One pill should be taken every day, even if there is no intercourse, until the pack is empty.
- Linking pill intake to a daily activity such as after dinner may help her remember and reduce some side effects.
- 28-pill packs: When she finishes one pack, first pill from the next pack should be taken on the very next day. Bleeding occurs when woman is on the tablets given in the last row of the pack (iron tablets). However, pills should be continued, irrespective of bleeding.
- It is very important to start the next pack on time. There is risk of pregnancy, if pack is started late.
- If she vomits within 2 hours of taking a pill, another pill from the pack should be taken as soon as possible and rest of the pills should be continued as scheduled.

4.5 How to Increase Compliance of COC Use?

- Assure every client that she is welcome to come back or ask question any time to the provider, if she has problems, wants another method, has any major change in health status or thinks that she might be pregnant.
- Encourage her to come back for more pills before her supply is finished.
- Whenever client comes back to the provider, ask:
    - How she is doing with the method, whether she is satisfied and has any questions or anything to discuss.
    - Especially if she is concerned about bleeding changes. Give her any information or help that she needs (see Management of Side Effects, Missing of Pills and Problems Requiring Switching Methods in Section 4.6).
    - If she often has problems remembering to take a pill every day. If so, discuss ways to remember making up for missed pills, ECPs or choosing another method.
    - If there are major life changes that may affect her needs particularly plans for having children and STI/HIV risk. Follow-up as needed.
    - If possible, get her blood pressure checked every year.

4.6 How to Manage Side Effects, Missing of Pills and Problems Requiring Switching Methods?

Problems with side effects affect woman's satisfaction and use of COCs. They deserve providers' attention. If she reports side effects or problems, listen to her concerns, give advice and if appropriate, provide treatment. Encourage her to keep taking a pill every day even if she has side effects as missing pills can risk pregnancy. Explain that many side effects will subside after a few months of use. Offer help to choose another method if she wishes or cannot overcome the problems.

4.6.1 Problems Reported as Side Effects

Side Effects	How to Manage

Irregular and unexpected bleeding	• Reassure her that many women using COCs experience irregular bleeding. It is not harmful and usually becomes less or stops after the first few months of use.
	• Other possible causes of irregular bleeding: Missed pills, taking pills at different times every day; vomiting or diarrhoea, taking anticonvulsants or Rifampicin.
	• To reduce irregular bleeding:
	  • Take a pill each day and at the same time.
	  • Make up for missed pills properly, including after vomiting or diarrhoea.
	  • For modest short-term relief, take 800 mg Ibuprofen/ Mefenamic acid/Tranexamic acid 3 times daily after meals for 5 days or another nonsteroidal anti-inflammatory drug (NSAID), when irregular bleeding starts.
	  • If taking pills for more than a few months and NSAIDs do not help, give a different COC formulation, if available. Ask to try the new pills for at least 3 months.
	  • If irregular bleeding continues or starts after several months of normal or no monthly bleeding or some other conditions unrelated to method use is suspected, consider further evaluation.

No monthly bleeding	• Ask her any spotting (which she may not recognise as a monthly bleeding) or no bleeding at all. Reassure and tell her that some women using COCs stop having monthly bleeding and this is not harmful. It is similar to not having monthly bleeding during pregnancy. She is not infertile. Blood is not building up inside her. • Ask if she has been taking a pill every day. If so, reassure that she is not likely to be pregnant and can continue taking COCs as before. • If she skipped the 7 non-hormonal pills (28-day pack), reassure that she is not pregnant and can continue using COCs. • If she has missed hormonal pills or started a new pack late, COCs can be continued. • Ask her to return for checkup if she has signs and symptoms of early pregnancy after missing 3 or more pills or starting a new pack 3 or more days late.

Side Effects	How to Manage
Ordinary headaches (non-migrainous)	• Try the following (one at a time): • Suggest Ibuprofen (200–400 mg), Paracetamol (500–1000 mg) or other pain relievers. • Some women get headache during the hormone-free week (those 7 days when a woman does not take hormonal pills). • Any headaches that gets worse or occurs more often during COC use should be evaluated.
Nausea or Dizziness	• For nausea, suggest taking COCs at bedtime or with food. • If symptoms continue consider locally available remedies.
Breast tenderness	• Recommend to wear a supportive bra (including during strenuous activity and sleep). • Try hot or cold compresses. • Suggest Ibuprofen (200–400 mg), Paracetamol (500–1000 mg) or other pain reliever.
Weight change	• Review diet and counsel as needed.
Mood changes or changes in sex drive	• Some women have changes in mood during the hormone-free week (those 7 days when a woman does not take hormonal pills). • Ask about changes in her life that could affect her mood or sex drive (including changes in relationship with her partner). Give her support as appropriate.
Acne	• Acne usually improves with COC use. It may worsen for a few women. If she has been taking pills for more than a few months and acne persists give a different COC formulation, if available. Ask her to try the new pills for at least 3 months. • Women who have serious mood changes such as major depression should be referred for care.

4.6.2 Problems Associated with Missing of Pills

Missed Pills	How to Manage
Missed 1 or 2 pills/ started new pack 1 or 2 days late?	• Take one hormonal pill as soon as possible or two pills at scheduled time. • There is little or no risk of pregnancy.
Missed 3 or more pills in the first or second week/started new pack 3 or more days late?	• Take one hormonal pill as soon as possible and continue the scheduled pill. • Use a backup method for the next 7 days. • Also can consider taking ECPs, if she had sex in the past 72 hours.
Missed 3 or more pills in the third week?	• Take one hormonal pill as soon as possible and finish all hormonal pills in the pack as scheduled. Throw away the 7 non-hormonal pills in a 28-pill pack. • Start a new pack the next day.

Missed Pills	How to Manage
	• Use a backup method for the next 7 days. • Also can consider taking ECPs, if she had sex in the past 72 hours.
Missed any non-hormonal pills? (last 7 pills in 28-pill pack)	• Discard the missed non-hormonal pill(s). • Keep taking COCs, one each day. Start the new pack as usual.
Severe vomiting or diarrhoea	• If she vomits within 2 hours after taking a pill, she should take another pill from pack as soon as possible and continue taking the scheduled pills. • If she has vomiting or diarrhoea for more than 2 days, follow instructions for 1 or 2 missed pills above.

4.6.3 Problems Requiring Switching Methods

Problems reported by the client may or may not be due to the method.

Problems	How to Manage
Unexplained vaginal bleeding (that suggests a medical condition not related to the method) or heavy or prolonged bleeding	• Refer or evaluate by history and pelvic examination. Diagnose and treat, as appropriate. She can continue using COCs while her condition is being evaluated. • If bleeding is caused by sexually transmitted infection or pelvic inflammatory disease she can continue using COCs during treatment.
Starting treatment with anticonvulsants or rifampicin	• Barbiturates, Carbamazepine, Oxcarbazepine, Phenytoin, Primidone, Topiramate and Rifampicin may make COCs less effective. If using these medications long-term, she may want a different method, such as progestogen-only injectables or a copper-bearing IUCD. • If using these medications short-term, she can use a backup method (e.g. Condom) along with COCs.
Migraine headaches	• Regardless of her age, a woman who develops migraine headaches, with or without aura or whose migraine headaches become worse while using COCs should stop using COCs. Help her choose a method without oestrogen.

In non-ambulatory condition (one week or more)	• If she is having major surgery or her leg is in a cast or for other reasons she will be unable to move about for several weeks, tell her to:
	  • Stop taking COCs and use a backup method (e.g. Condom) during this period.
	  • Restart COCs 2 weeks after she can move about again

Problems	How to Manage
Certain serious health conditions (suspected heart or liver disease, high blood pressure, blood clots in deep veins of legs or lungs, stroke, breast cancer, damage to arteries, vision, kidneys or nervous system due to diabetes or gall bladder disease)	• Tell her to stop taking COCs. • Give her a backup method (e.g. Condom) to use until the condition is evaluated. • Refer for diagnosis and care, if not already under care.
Suspected pregnancy	• Assess for pregnancy. • Tell her to stop taking COCs if pregnancy is confirmed. • Assure her there are no known risks to a foetus conceived while taking COCs.

Progestin-Only Pills (POPs)

5.1 What are POPs?

Progestin-only pills contain very low doses of a synthetic hormone known as progestin which is like the natural hormone progesterone in a woman's body. POPs are also called "Minipills". The available product is Levonorgestrol (LNG) and Desogestrel.

5.2 Key Points

- POPs are safe and effective.
- POPs are safe for breastfeeding women as they do not affect quality and quantity of milk.
- POPs can be started in breast feeding women earlier than 6 weeks.
- Bleeding changes are common but not harmful.
- One pill to be taken every day at the same time without any break.

5.3 When to Start POPs?

A woman can start using POPs any time if it is reasonably certain that she is not pregnant. Use the Pregnancy Checklist (Annexure 2).

Woman's situation	When to start
Having regular menstrual cycles or switching from a non-hormonal method (Condoms, Centchroman (Ormeloxifene), IUCDs)	• Any day within 5 days of menstrual cycle with no need for a backup method. • Any time after 5 days of menstrual cycle if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 2 days of taking pills (if pregnancy cannot be ascertained give her POPs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • Immediately, if switching from an IUCD.
Switching from a hormonal method (COCs, DMPA)	• Immediately, if she has been using the hormonal method consistently and correctly or if it is otherwise reasonably certain that she is not pregnant. No need to wait for her next monthly bleeding and also no need for a backup method. • At the time of repeat injection, if switching from injectables. No need for a backup method.
Breast Feeding	
Less than 6 months after giving birth	• Any time, if her monthly bleeding has not returned. No need for a backup method. • If the monthly bleeding has returned, POPs can be started as advised for women having menstrual cycles.

Woman's situation	When to start
More than 6 months after giving birth	• Any time, if her monthly bleeding has not returned and if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 2 days of taking pills (if pregnancy cannot be ascertained give her POPs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • If her monthly bleeding has returned, POPs can be started as advised for women having menstrual cycles.
Not breastfeeding	
Less than 4 weeks after giving birth	• Any time, no need for a backup method.
More than 4 weeks after giving birth	• Any time, if her monthly bleeding has not returned and if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 2 days of taking pills (if pregnancy cannot be ascertained give her POPs now and tell her to start taking them during her next monthly bleeding and use condoms till then). • If her monthly bleeding has returned, POPs can be started as advised for women having menstrual cycles.
No monthly bleeding (not related to childbirth or breastfeeding)	• Any time if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 2 days of taking pills.
After miscarriage or abortion	• Immediately, if she is starting within 7 days after first or second trimester miscarriage or abortion. No need for a backup method. • Any time, if it is more than 7 days after first or second trimester miscarriage or abortion and if it is reasonably certain that she is not pregnant. A backup method (e.g. Condom) is needed for the first 2 days of taking pills (if pregnancy cannot be ascertained give her POPs now and tell her to start taking them during her next monthly bleeding and use condoms till then).
After taking Emergency Contraceptive Pills (ECPs)	• Same day, there is no need to wait for her next monthly bleeding to start her pills. • A new POP user should begin a new pill pack. • A continuing user who needed ECPs due to pill-taking errors can continue where she left off with current pack. • A backup method (e.g. Condom) is needed for the first 2 days of taking pills.

5.4 How to Use POPs?

- Explain that all pills in POP packs are of same color and are active pills containing a hormone that prevents pregnancy.
- One pill should be taken every day and at the same time until the pack is empty. Delayed intake of the pill may increase failure/risk of pregnancy.
- Linking pill intake to a daily activity such as after dinner may help her remember and reduce some side effects.
- It is very important to start the new pack on the next day at the same time as starting a pack late risks pregnancy.
- When breastfeeding is stopped continue taking POPs but its effectivity reduces **marginally**.

5.5 How to Increase Compliance of POP Use?

Assure every client that she is welcome to come back or ask question anytime to the provider, if she has problems, wants another method, has any major change in health status or thinks that she might be pregnant.

- Encourage her to come back for more pills before supply is finished.
- Whenever client comes back to the provider ask:
  - How she is doing with the method, whether she is satisfied and ask if she has any questions or anything to discuss.
  - Especially if she is concerned about bleeding changes. Give her any information or help that she needs (see Management of Side Effects, Missing of Pills and Problems Requiring Switching Methods in Section 5.6).
  - If she often has problems remembering to take a pill every day. If so, discuss ways to remember making up for missed pills, ECPs or choosing another method.
  - If there are major life changes that may affect her needs particularly plans for having children and STI/HIV risk, follow-up as needed.

5.6 How to Manage Side Effects, Missing of Pills and Problems Requiring Switching Methods?

Problems with side effects affect women's satisfaction and use of POPs. They deserve providers' attention. If the client reports side effects or problems, listen to her concerns, give advice and if appropriate, provide treatment. Encourage her to keep taking a pill every day even if she has side effects as missing pills can risk pregnancy. Explain that many side effects will subside after a few months of use. Offer help to choose another method if she wishes or cannot overcome the problems.

5.6.1 Problems Reported as Side Effects

Side Effects	How to Manage
No monthly bleeding	• **Breastfeeding:** Reassure her that this is normal during breastfeeding and is not harmful. • **Non breastfeeding:** Reassure her that some women using POPs stop having monthly bleeding and is not harmful. It is similar to not having monthly bleeding during pregnancy. She is not infertile.

Irregular and Unexpected bleeding	• Reassure her that many women using POPs experience irregular bleeding whether breastfeeding or not. Breastfeeding itself can also cause irregular bleeding and is not harmful and usually becomes less or stops after the first few months of use. Some women have irregular bleeding the entire time they are taking POPs, however, other possible causes of irregular bleeding may be due to vomiting or diarrhoea or taking anticonvulsants or Rifampicin etc.
	• To reduce irregular bleeding:
	  • Teach her to make up for missed pills properly, including after vomiting or diarrhoea.
	  • If irregular bleeding continues or starts after several months of normal or no monthly bleeding or if some other conditions, unrelated to method use is suscepted, consider further evaluation.

Side Effects	How to Manage
Heavy or prolonged bleeding (Twice as much as usual or longer than 8 days)	• Reassure her that some women using POPs experience heavy or prolonged bleeding. It is generally not harmful and usually becomes less or stops after a few months. • Additionally when heavy bleeding starts Tranexamic acid 500 mg 8 hourly can be given. • To help prevent anaemia, suggest taking iron tablets and taking foods containing iron such as meat, egg, fish, green leafy vegetables and legumes (beans, bean curd, lentils and peas). • If heavy or prolonged bleeding continues or starts after several months of normal or no monthly bleeding or if some other conditions, unrelated to method use is suscepted, consider further evaluation.
Ordinary headaches (Non-migrainous)	• Suggest Ibuprofen (200–400 mg), Paracetamol (500 mg) or other pain relievers. • Any headache that gets worse or occurs more often during POP use should be evaluated.
Mood changes or changes in sex drive	• Ask about changes in her life that could affect her mood or sex drive (including changes in her relationship with her partner). Give her support as appropriate. • Some women experience depression in the year after giving birth. This is not related to POPs. Women who have serious mood changes such as major depression should be referred for care.
Breast Tenderness (Women not breastfeeding)	• Recommend to wear a supportive bra (including during strenuous activity and sleep). • Try hot or cold compresses. • Suggest Ibuprofen (200–400 mg), Paracetamol (500 mg) or other pain reliever.

Severe pain in lower abdomen (Suspected ectopic pregnancy or enlarged ovarian follicles or cysts)	• Many conditions can cause severe abdominal pain. Be particularly alert for additional signs or symptoms of ectopic pregnancy (rare but can be life-threatening).
	• In the early stages of ectopic pregnancy, symptoms may be absent or mild but eventually they will become severe. A combination of following signs or symptoms should increase suspicion of ectopic pregnancy:
	  • Unusual abdominal pain or tenderness
	  • Abnormal vaginal bleeding or no monthly bleeding especially if this is a change from her usual bleeding pattern
	  • Light-headedness or dizziness
	  • Fainting
	• A woman can continue to use POPs during evaluation and treatment.

Side Effects	How to Manage
	• Abdominal pain may be due to other problems such as enlarged ovarian follicles or cysts. There is no need to treat enlarged ovarian follicles or cysts unless they grow abnormally large, twist or burst. Reassure that they usually disappear on their own. Advice followup in 6 weeks to ascertain that the problem is resolving. • If ectopic pregnancy or another serious health condition is suspected, refer at once for immediate diagnosis and care.
Nausea or dizziness	• Suggest her to take POPs at bedtime or with food.

5.6.2 Problems Associated with Missing of Pills

Missed Pills	How to Manage
3 or more hours late taking a pill or misses one completely	• Take a pill as soon as possible. • Keep taking pills as usual, one each day. (She may take 2 pills at the same time or on the same day). For breastfeeding women, missing a pill puts her at risk of pregnancy depending on whether or not her monthly bleeding has returned.
If she has monthly bleeding	• A backup method should be used for the next 2 days. • Also, can consider taking ECPs, if she had sex in the past 72 hours.
If she has severe vomiting or diarrhoea	• If she vomits within 2 hours after taking a pill, she should take another pill from the pack as soon as possible and continue with the schedule pill as usual. • If her vomiting or diarrhoea continues, follow the instructions for making up for missed pills above.

5.6.3 Problems Requiring Switching Methods

Problems reported by the client may or may not be due to the method.

Problems	How to Manage
Unexplained vaginal bleeding or heavy or prolonged bleeding	• Refer or evaluate by history and pelvic examination. Diagnose and treat as appropriate. She can continue using POPs while her condition is being evaluated. • If bleeding is caused by sexually transmitted infection or pelvic inflammatory disease, she can continue using POPs during treatment.
Starting treatment with anticonvulsants or rifampicin	• Barbiturates, Carbamazepine, Oxcarbazepine, Phenytoin, Primidone, Topiramate and Rifampicin may make POPs less effective. If using these medications long-term, she may want a different method such as progestogen-only injectables or a copper-bearing IUCD. • If using these medications short-term, she can use a backup method (e.g. Condom) along with POPs.

Problems	How to Manage
Migraine headaches	• If she has migraine headaches without aura, she can continue to use POPs if she wishes • If she has migraine with aura, stop POPs. Help her choose a method without hormones.
Certain serious health conditions (suspected blood clots in deep veins of legs or lungs, liver disease or breast cancer)	• Tell her to stop taking POPs. • Give her a backup method (e.g. Condom) to use until the condition is evaluated. • Refer for diagnosis and care if not already under care.
Heart disease due to blocked or narrowed arteries (ischemic heart disease) or stroke	• A woman who has one of these conditions can start POPs. If however the condition develops after she starts using POPs then it should be stopped. Help her choose a method without hormones. • Refer for diagnosis and care if not already under care.
Suspected pregnancy	• Assess for pregnancy, including ectopic pregnancy. • Tell her to stop taking POPs if pregnancy is confirmed. • Assure her that there are no known risks to a foetus conceived while taking POPs and pregnancy can be continued.

Centchroman (Ormeloxifene) Pills

6.1 What are Centchroman (Ormeloxifene) Pills?

Centchroman (Ormeloxifene) is a non steroidal, non- hormonal once a week oral contraceptive pill. It acts as selective estrogen receptor modulator (SERM). In some tissues/organs of the body, it has weak oestrogenic action (e.g, bones) while in others it has strong anti-estrogenic action (e.g, uterus, breasts etc).

6.2 Key Points

- Centchroman (Ormeloxifene) is safe and effective.
- Centchroman (Ormeloxifene) is safe for breast feeding women.
- Apart from prolongation of menstruation cycle in some women, it is not known to cause any side effects.
- One pill is taken twice a week for first three months, followed by once a week thereafter.

Fig. 3: Centchroman (Ormeloxifene) in the Public Sector - (a) ASHA Supply (b) Free Supply

6.3 When to Start and How to Use Centchroman (Ormeloxifene)?

- For initiation of the Centchroman (Ormeloxifene), the first pill is to be taken on the first day of period (as indicated by the first day of bleeding) and the second pill three days later. This pattern of days is repeated through the first three months.
- Starting from fourth month, the pill is to be taken once a week on the first pill day and should be continued on the weekly schedule regardless of her menstrual cycle. Refer table below to decide for fixed day(s).

Table 2: Schedule of Centchroman (Ormeloxifene)

If the First Day of Pill is taken on	First 3 Months	After 3 Months
	Pill to be taken on	to be taken on
Sunday	Sunday and Wednesday	Sunday
Monday	Monday and Thursday	Monday
Tuesday	Tuesday and Friday	Tuesday
Wednesday	Wednesday and Saturday	Wednesday

If the First Day of Pill is taken on	First 3 Months	After 3 Months
	Pill to be taken on	to be taken on
Thursday	Thursday and Sunday	Thursday
Friday	Friday and Monday	Friday
Saturday	Saturday and Tuesday	Saturday

6.4 How to Increase Compliance of Centchroman (Ormeloxifene) Use?

- Assure every client that she is welcome to come back or ask question any time to the provider, if she has problems, wants another method, has any major change in health status or thinks that she might be pregnant.
- Encourage her to come back for more pills before her supply is finished.
- Whenever client comes back to the provider ask:
  - How she is doing with the method, whether she is satisfied and has any questions or anything to discuss.
  - Especially if she is concerned about bleeding changes. Give any information or help that she needs (See Management of Side Effects, Missing of Pills in Section 6.5) . Assure her that these changes get normalized with continuing usage.
  - If she often has problems remembering to take pills. If so, discuss ways to remember, making up for missed pills, ECP or choosing another method.
  - If there are major life changes that may affect her needs particularly plans for having children and STI/HIV risk, follow-up as needed.

6.5 How to Manage Side Effects, Missing of Pills?

- Centchroman (Ormeloxifene) causes delayed periods in few women. But this occurs in around 8% of users and usually in the first three months. The periods tend to settle down to a rhythm once the body gets used to the drug.
- Periods can get scanty over time in some women.

Counsel and reassure her that some women using Centchroman (Ormeloxifene) have such problem. This is not harmful and will subside on its own.

6.5.1 How to Manage Missed Pills?

- Take a pill as soon as possible after it is missed.
- If pill is missed by 1 or 2 days but lesser than 7 days, the normal schedule should be continued and client needs to use a back-up method (e.g. Condoms) till the next period starts.
- If pill is missed by more than 7 days, client needs to start taking it all over again like a new user that is twice a week for 3 months and then once a week.

6.5.2 If Period is Missed with Centchroman (Ormeloxifene)

With Centchroman (Ormeloxifene), occasionally the menstrual cycle may get prolonged in some users. The contraceptive makes the periods lighter and the interval longer, which is not harmful and can actually be helpful for anaemic women, as user loses lesser amount of blood. However, if periods are delayed by more than 15 days, pregnancy needs to be ruled out.

Chapter 7

Emergency Contraceptive Pills (ECPs)

7.1 What is Emergency Contraceptive Pill?

- Emergency contraceptive pill is used to prevent pregnancy after unprotected sexual intercourse, sex was coerced or contraceptive accidents like condom rupture or missed pills.
- In the National Program, EC pills contains only progestin - Levonorgestrel (1.5 mg per tablet). However, combined oral contraceptive pills containing an oestrogen and a progestin can also be used as EC pills.
- ECPs are also called "morning-after pills" or post coital contraceptives.

7.2 Key Points

- ECPs are safe for all women even women who cannot use combined hormonal contraceptive methods.
- ECPs do not disrupt an existing pregnancy.
- ECPs provide an opportunity for women to start using a regular contraceptive method
- ECPs help to prevent pregnancy when taken up to 3 days (72 hours) after unprotected sex. The sooner they are taken the better.

Fig. 4: ECPs in the Public Sector - (a) ASHA Supply (b) Free Supply

Emergency contraceptive pills are meant to be used for emergency only. These are not appropriate for regular use as a contraceptive method because of the higher possibility of failure compared to other contraceptive method. In addition, frequent use of emergency contraception can result in side-effects such as menstrual irregularities. The repeated use poses no known health risks but is less effective than a regular method in preventing pregnancy.

7.3 How to Use?

- Take the pill immediately after unprotected/accidental intercourse or as soon as possible within next 3 days (72 hours).
- If 2 pills of Levonorgestrol or COCs are used as an emergency contraceptive, second dose to be taken after 12 hours of first dose.

7.4 How to Manage Side Effects?

Side effects are minor and they are not signs of illness. The common ones are:

- **Nausea:** Routine use of anti-nausea medication is not recommended. If user have had nausea with previous ECP use or with the first dose of a 2-dose regimen, can take anti-emetic 1½ to 1 hour before taking ECP.
- **Vomiting**: If woman vomits within 2 hours after taking ECP, she should take another dose (she can take an anti-emetic with the repeat dose). If vomiting occurs more than 2 hours after taking ECPs, she does not need to take extra pills. If vomiting continues, she can take the repeat dose by placing the pills high in her vagina.
- Slight **bleeding** or change in timing of monthly bleeding, which gradually subsides.

- **Explain that ECPs can at the most avert pregnancy resulting from the episode of unprotected/accidental sex after which pill was taken. It cannot protect her from future pregnancy, if unprotected sex occurs again any time. Therefore, it should not be used as a regular contraceptive method.**
  - Counsel the client to choose a family planning method to start using after the emergency contraception, if she does not plan for pregnancy immediately.
  - Advise the client to start a contraceptive after ECP use as most contraceptive methods can be started on the same day of ECP use.
  - If she does not want to start a contraceptive method now, give her condoms or COCs and ask her to use them if she changes her mind. Give instructions on use. Invite her to come back any time, if she wants another method or has any questions or problems.
  - Tell her that ECP does not protect from STIs/HIV.
  - Explain that ECP will not harm an existing pregnancy.
  - Advise the client to return if her next monthly bleeding:
    - Is unusually light (possible pregnancy)
    - Period is delayed beyond one week of expected date of cycle.
    - Is unusually painful (possible ectopic pregnancy)

> Copper IUCD can also be used as an emergency contraceptive method if inserted within 5 days of unprotected intercourse/contraceptive accident.

Chapter 8

Medical Eligibility Criteria (MEC) and Client's Assessment

8.1 Medical Eligibility Criteria (MEC) Categories

The Medical Eligibility Criteria (MEC) forms the scientific foundation for client assessment regarding family planning methods. It gives a detailed guidance regarding whether a family planning method can safely be given to a woman with a certain medical condition.

The criteria has been adapted and modified according to the Indian situation, based on the skills, knowledge and availability of resources in the health delivery system.

The MEC has four categories.

Category	With Clinical Judgement	With Limited Clinical Judgement
1. A condition for which there is no restriction for the use of the contraceptive method.	Use method in any circumstances	Yes (Use the Method)
2. A condition where the advantages of using the method generally outweigh the theoretical or proven risks.	Generally use the method	
3. A condition where the theoretical or proven risks usually outweigh the advantages of using the method.	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	No (Do not use the method)
4. A condition which represents an unacceptable health risk if the contraceptive method is used.	Method not to be used	

8.2 MEC Wheel for Contraceptive Use (2015)

MEC Wheel for Contraceptive Use – India (2015) is available. This is a very useful job-aid, which tells family planning providers if a woman presenting with a known medical or physical condition can use various contraceptive methods safely and effectively or not. This wheel is based on medical eligibility criteria for starting use of selected contraceptive methods. Ministry of Health and Family Welfare, Government of India, has adapted the wheel from WHO MEC wheel for contraceptive use (2015 update). The wheel should be used by family planning providers to decide if COCs and POPs can be given to women with specific medical and physical conditions or not. MEC for Oral Contraceptives is given in the Annexure 3.

8.3 Client Assessment

This section describes client assessment prior to provision of oral contraceptive methods. The primary objectives of this assessment or screening are to determine whether the family planning client

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

These objectives usually can be accomplished by asking a few key questions. Unless specific problems are identified, the safe provision of oral contraceptive methods does not require physical or pelvic examinations or any laboratory test.

8.3.1 How to Be Reasonably Sure a Client is Not Pregnant

Provider can be reasonably sure a client is not pregnant if she has no signs or symptoms of pregnancy (e.g. breast tenderness or nausea) and she answers "Yes" to at least one of the questions on the Pregnancy Checklist. This checklist, "How to be reasonably sure a client is not pregnant," is highly effective and has been validated in Kenya, Guatemala, Senegal, Mali and Egypt. When used correctly, it is more than 99% effective in ruling out pregnancy.

Before starting any method Pregnancy checklist should be used (Annexure 2). It is also given in Medical Eligibility Criteria (MEC) Wheel for Contraceptive Use – India (2015).

8.3.2 Client Assessment for Combined Oral Contraceptives (COCs):

After ruling out pregnancy (Annexure 2), ask the client the questions below about known medical conditions. Examinations and tests are not necessary.

NO		YES
	1. Are you breastfeeding a baby less than 6 months old? • If fully or nearly fully breastfeeding: Give her COCs and tell her to start taking them 6 months after giving birth or when breast milk is no longer the baby's main food—whichever comes first • If partially breastfeeding: She can start COCs as soon as 6 weeks after childbirth	
	2. Have you had a baby in the last 3 weeks and you are not breastfeeding? • Give her COCs now and tell her to start taking them 3 weeks after childbirth. (If there is an additional risk that she might develop a blood clot in a deep vein (deep vein thrombosis or VTE), then she should not start COCs at 3 weeks after childbirth, but start at 6 weeks instead.	
	3. Do you smoke cigarettes? • If she is 35 years of age or older and smokes, do not provide COCs. Urge her to stop smoking and help her choose another method.	

NO		YES
	4. Do you have cirrhosis of the liver, a liver infection or liver tumor? (Are her eyes or skin unusually yellow? [signs of jaundice]) Have you ever had jaundice when using COCs? • If she reports serious active liver disease (jaundice, active hepatitis, severe cirrhosis, liver tumor) or ever had jaundice while using COCs, do not provide COCs. Help her choose a method without hormones.	
	5. Do you have high blood pressure? Check blood pressure if possible: • If her blood pressure is below 140/90 mm Hg, provide COCs. • If her systolic blood pressure is 140 mm Hg or higher or diastolic blood pressure is 90 or higher, do not provide COCs. Help her choose a oral method without estrogen. (One blood pressure reading in the range of 140–159/90–99 mm Hg is not enough to diagnose high blood pressure. Give her a backup method (e.g.condom) to use until she can return for another blood pressure check or help her choose another method now if she prefers. If her blood pressure at next check is below 140/90, she can use COCs).	
	6. Have you had diabetes for more than 20 years or damage to your arteries, vision, kidneys or nervous system caused by diabetes? • Do not provide COCs. Help her choose a method without estrogen but not progestin-only injectables.	
	7. Do you have gallbladder disease now or take medication for gallbladder disease? • Do not provide COCs.	
	8. Have you ever had a stroke, blood clot in your legs or lungs, heart attack or other serious heart problems? • Do not provide COCs, help her choose an oral method without estrogen or help her choose a method without hormones.	
	9. Do you have or have you ever had breast cancer? • Do not provide COCs, help her choose a method without hormones.	
	10. Do you sometimes see a bright area of lost vision in the eye before a very bad headache (migraine aura)? Do you get throbbing, severe head pain, often on one side of the head that can last from a few hours to several days and can cause nausea or vomiting (migraine headaches)? Such headaches are often made worse by light, noise or moving about. • If she has migraine aura at any age, do not provide COCs. If she has migraine headaches without aura and is age 35 or older, do not provide COCs. Help these women choose a method without estrogen. If she is under 35 and has migraine headaches without aura, she can use COCs.	

NO		YES
	11. Are you taking medications for seizures? Are you taking rifampicin or rifabutin for tuberculosis or other illness? • If she is taking barbiturates, carbamazepine, lamotrigine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin or rifabutin do not provide COCs. They can make COCs less effective. Help her choose another method but not progestin-only pills. If she is taking lamotrigine, help her choose a method without estrogen.	
	12. Are you planning major surgery that will keep you from walking for one week or more? • If so, she can start COCs 2 weeks after the surgery. Until she can start COCs, she should use a backup method.	
	13. Do you have several conditions that could increase your chances of heart disease (coronary artery disease) or stroke, such as older age, smoking, high blood pressure or diabetes? • Do not provide COCs. Help her choose a method without estrogen but not progestogen-only injectables.	

If she answers "no" to all of the questions, then she can start COCs if she wants.

If she answers "yes" to a question, follow the instructions.

8.3.3 Client Assessment for Progestin-Only Pills

After ruling out pregnancy (Annexure 2), ask the client the questions below about known medical conditions. Examinations and tests are not necessary.

NO		YES
	1. Are you breastfeeding a baby less than 6 months old? • She can start taking POPs earlier than six weeks	
	2. Do you have cirrhosis of the liver, a liver infection or liver tumor? (Are her eyes or skin unusually yellow? [signs of jaundice]) • If she reports serious active liver disease (jaundice, active hepatitis, severe cirrhosis, liver tumor), do not provide POPs. Help her choose a method without hormones.	
	3. Do you have a serious problem now with a blood clot in your legs or lungs? • Help her choose a method without hormones.	

NO		YES
	4. Are you taking medication for seizures? Are you taking rifampicin or rifabutin for tuberculosis or other illness? • If she is taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin or rifabutin do not provide POPs. They can make POPs less effective. Help her choose another method but not COCs.	
	5. Do you have or have you ever had breast cancer? • Do not provide POPs, help her choose a method without hormones.	

If she answers "no" to all of the questions, then she can start POPs if she wants.

If she answers "yes" to a question, follow the instructions.

8.3.4 Client Assessment for Centchroman (Ormeloxifene)

After ruling out pregnancy (Annexure 2), if the client is identified with a medical condition in which hormonal contraceptive cannot be started, she can start Centchroman (Ormeloxifene), if she wants. Centchroman (Ormeloxifene) should not be given if client has any of the following condition:

- Polycystic ovarian disease
- Cervical hyperplasia
- Recent history of jaundice or liver disease
- Severe allergic state
- Chronic illness, like tuberculosis or renal disease

8.3.5 Client Assessment for EC Pills

All women can use ECPs safely and effectively, including women who cannot use hormonal contraceptive methods. Due to the short-term nature of their use, there are no medical conditions that make ECPs unsafe for any woman.

ECPs can be used any time a woman is exposed to unprotected sex

For example, if unprotected sex has occurred because:

- Sex was coerced
- No contraceptive was used during sex
- Contraceptive accident occurred, such as:
  - Condom was used incorrectly, slipped or broke
  - Missed more than two hormonal pills
  - Couple incorrectly used fertility awareness method
  - Man failed to withdraw, as intended, before ejaculation
  - IUCD was expelled
  - Client comes more than 4 weeks late for her repeat injection of DMPA

Section II

Managerial Aspects for Oral Contraceptive Services

Program Determinants for Quality services

9.1 Determinants of Services

The provision of adequate, appropriate and sustainable services determines the client satisfaction. It is thus imperative that the service providers are skilled on various technical aspects. Also the program managers need to understand all the managerial aspects to deliver quality services to the clients.

9.1.1 Service Delivery Points

Oral Contraceptive Pills should be available as a contraceptive choice in all public health facilities. Oral pills available under the National Family Planning Program are - Combined Oral Contraceptives, Progestin Only Pills, Centchroman (Ormeloxifene) and Emergency Contraceptive Pills.

In addition to public health facilities ASHAs also serve as a service delivery point for oral pills. Under the scheme for 'Home Delivery of Contraceptives', ASHAs distribute the Oral pills and condoms at the doorstep of the beneficiary.

9.1.2 Eligibility of Providers

Doctors (MBBS and above, AYUSH), SN/LHV/ANM are eligible to prescribe oral contraceptive pills to the client after obtaining proper history and examination.

For 'Home Delivery of Contraceptives' through ASHA it is mandatory that the first dose will be prescribed by doctors (MBBS and above, AYUSH), SN/ LHV/ANM after proper screening of the client.

9.1.3 Capacity Building of Service Providers

Skill building of provider is an essential component for quality service delivery. A situational analysis of the current status of service providers at different levels of health facilities in the district will help in identifying training needs. The training needs assessment along with the training process and schedule has been detailed in Chapter 10.

ASHAs should also be oriented from time to time during the monthly meetings on the important aspects of contraceptive service delivery.

9.1.4 Ensuring Regular Supply

Good quality reproductive health care requires a continuous supply of contraceptives and other commodities. Contraceptive logistics management requires accurate and timely reports.

Clinic staff members do their part when they properly manage contraceptive inventory, accurately record and report what commodities are used and promptly order new supplies.

Family planning staff members need to be familiar with and work within whatever systems are in place at their worksites to make certain that they have the supplies that are needed.

9.1.4.1 Logistics Responsibilities for Family Planning Providers

Workers at all levels of the health system, including those at the central, state, district, block and community levels play a role in ensuring that the contraceptives logistics system functions effectively. While specific supply chain procedures can vary across settings, medical officers, store in-charges, nurses, lady heath visitors, ANMs and ASHAs are specifically responsible for the following common activities:

1. Receive and store contraceptives in the health center according to recommended storage guidelines.
2. Record all issues and receipts of health commodities on the stock register.
3. Issue products to service providers according to FEFO (First-to-Expire, First-Out) system of distribution.
4. Conduct a physical inventory of commodities monthly and update the stock register.
5. Consolidate data on usage of commodities by all user units affiliated to the health centre.
6. Complete monthly report and send to the designated District/State authority by the scheduled date of every month.
7. Send requisition of each item based on scientific calculation timely (before the stock gets exhausted).

9.1.4.2 Demand Estimation

The quantity of various oral contraceptives required for a specific period of time at a health facility or with community health worker can be calculated based on estimated users.

The table below shows the method of demand estimation for various oral pills:

S.No.	Oral Contraceptive pills	Method for calculation
1	Combined Oral Contraceptives (In Cycles)	Estimated COC Users x 15 cycles + 10% Buffer Stock
2	Emergency Contraceptive Pill (in tablet)	Estimated ECP users (average of last 3 years) + 10% Buffer Stock
3	Centchroman (Ormeloxifene) (weekly pills) (In strips)	Estimated Centchroman (Ormeloxifene) users x 9 strips + 10% Buffer Stock
4	Progestin Only Pills (POPs) (In Cycles)	For Post-partum women - Estimated Users x 7 cycles + 10% Buffer Stock

9.1.4.3 Distribution

Supplies reach from manufacturer/supplier to the state warehouse based on the consignee list provided by the Family Planning Division, MoHFW, GoI. State has to ensure further distribution to the district level stores, block level stores and further to the service delivery points.

The replenishment/further supply of the oral contraceptive pills should be on consumption basis only. Demand estimation at state has to be an outcome of an indent submitted by district/block based on the consumption and stock in hand at facility.

9.1.4.4 Storing Procedure

Proper storage of health commodities helps ensure that products are always available, accessible and in good condition. It protects the quality of the contraceptives and other supplies and preserves the integrity of the packaging to make supplies available for use.

- The storage area should be dry, away from water, direct sunlight and fire.
- The storage area should be cleaned regularly to prevent harmful insects and rodents from entering it.
- The cartons should be stacked at least 10 cm off the floor, 30 cm away from the walls and other stacks and no more than 2.5m high.
- The cartons should be arranged with arrows pointing up with identification labels, expiry dates and manufacturing dates clearly visible.
- To make sure that the commodities do not expire before they are dispensed, First-to-Expire, First-Out (FEFO) system should be followed. With this system, the commodities with the shortest remaining shelf life are used first.
- The commodities should be stored away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies and equipment.

9.1.5 Records and Reporting System

Timely and accurate reporting is essential for smooth implementation of program. The progress of oral contraceptive acceptors should be documented in a standardized manner for program effectiveness. The documented information should be reported in time and regularly by the concerned provider and facilities.

The purpose is to collect relevant information to:

1. Document and know relevant details of acceptors by contraceptive methods.
2. Follow-up with acceptors of the methods.
3. Collect and report information to other levels of the system in order to make decisions regarding the quantity and time to distribute contraceptives and related supplies.

Relevant records of contraceptive distribution should be maintained at different service delivery points and reported on monthly basis by ASHAs to the respective ANMs for incorporation in the Subcenter level HMIS. ASHAs will maintain a beneficiary list for the distribution of contraceptives under 'Home Delivery of Contraceptives' scheme. The information to be captured by ASHAs is placed at Annexure 11.

At facility level the relevant socio-demographic information need to be recorded from all the clients who have chosen to receive oral pills as per details given in Annexure 11a.

Apart from service delivery reports, stock information contraceptive wise should be regularly updated at the facility level and submitted to the district and state who in turn would communicate the same to GoI on a quarterly basis.

Section III

Capacity Building of Service Providers on Oral Contraceptives

10.1 Assessment of Training Need

A situational analysis of the current status of service providers at the different level of health facilities in the district will help in identifying training needs. This will help to determine and plan the most appropriate interventions such as 'Training of Trainers' to develop a core group of 'trainers' and competent service providers at various levels.

The State Program Managers need to coordinate with the District Chief Medical Officer to identify the availability of service providers required for providing regular oral contraceptive pills. Based upon the need of the districts the Doctors/ Staff Nurses/ LHV/ANM can be trained. The training load can be calculated using the following RAG analysis.

Calculation of the Training Load - for various categories of providers
(Doctors, Nurses, LHVs, ANMs etc.)

Oral Contraception	DH / SDH			CHC			PHC		
	R	A	G	R	A	G	R	A	G

R- Required; A- Available; G – Gap

10.2 General Aspects of Training

10.2.1 Training Site Selection

- The facility for training should have a comfortable clean training hall to accommodate about 35 persons.
- Availability of chairs, tables, light source, fans/AC, audio-visual facility and alternate source of power.
- Space for providing refreshments and also toilet facilities.
- Availability of at least two trainers for the respective training site.

Identification and designation of these training centres at State and District level will be the responsibility of SQAC/Director Family Welfare and DQAC/CMO whichever is applicable.

10.2.2 Criteria for Designation of 'Trainers'

- Trained service providers (MBBS and above, AYUSH, Staff Nurses) with some training experience, good communication skills, well-versed with training skills and technique of adult learning principles. They should have competency/ proficiency in the skills of counselling.
- Can spare time and willing to conduct training and follow-up monitoring visits for on-site support/hand-holding, if required,
- Can be designated as a trainer by SQAC/Director Family Welfare at State level and by DQAC/CMO at District level.

10.2.3 Selection of 'Trainees'

The intended trainees for this course are - Medical Officer (MBBS/AYUSH), Staff Nurse (SN), Lady Health Visitor (LHV), Auxiliary Nurse Midwife (ANM) committed to provide the above methods after completion of the training.

When selecting trainees, priority should be given to service providers from institutions that are committed to provide FP Services. Facilities nominating trainees should be able to include new oral pills in basket of FP Services.

10.2.4 Equipment and Supplies for Training Sites

- Reference Manual for Oral Contraceptive Pills.
- Samples of all contraceptive methods including injectable contraceptive.
- Summary of Key characteristics of OCPs (Annexure 5.1,5.2,5.3,5.4)
- Formats with role plays and case studies (Annexure 7)
- Pre/Post-Test Questionnaire (Annexure 8, 8a), Training evaluation formats (Annexure 9)
- LCD Projector and screen for Power point Presentation, extension board, power back up, flip chart, flip stands, coloured markers.

10.3 Training Goal and Learning Objectives

The goal of training is to assist service providers in learning to provide safe quality oral contraceptives through improved service delivery. At the end of the training participants should be able to fulfill following objectives:

- Demonstrate appropriate counselling skills for oral contraceptive methods.
- Assess the eligibility and provide oral contraceptive methods as per standard procedure and guidelines.
- Describe the follow-up care of clients using oral contraceptive methods.
- Describe management of side effects/ other issues related to oral contraceptive methods.
- Demonstrate correct record keeping and reporting of clients using oral contraceptive methods.

10.4 Number of Trainees per Batch

Approximately 25 to 30

10.5 Training Duration

One full working day

10.6 Training Approach and Methodology

All training activities in this course should be conducted in an interactive, participatory manner as suggested in the course outline. To accomplish this, the trainer should change roles throughout the course. For example, the trainer is an instructor when presenting a classroom session, a facilitator when conducting small group discussions or role plays. Finally, when objectively assessing performance, the trainer serves as an evaluator.

Following training methodology will be used in this training course:

- Interactive presentations and group discussion
- Demonstration
- Individual and group exercises

- Role plays and case studies
- Counselling practice with real clients

A suggestive course outline (session plan) of training has been provided in Annexure 12.

10.6.1 Important Tips for the Trainers

- Familiarize with the content of all Sections and Annexures in the 'Reference Manual for Oral Contraceptive Pills, Pre/Post Test Questionnaires, Checklist on Family Planning and Method Specific Counselling for Oral Contraceptives, role plays and case studies etc.
- Make necessary preparations in advance, as per the facilitator guide.
- Plan meeting with co-facilitators before each workshop for assigning responsibilities and to clarify any doubts, concerns or reservations.
- Work together as a team subtly supporting each other in every session.
- Conduct wrap-up session at the end of each training day and start the next day with a re-cap session to provide continuity in the training.
- Arrange a seating arrangement which is informal, preferably in a semi-circle, without any podium for the trainers.
- Adopt a warm and friendly attitude towards the participants to make the training very effective and take care not to ridicule any trainee.
- Explain, demonstrate, answer questions, talk with participants about their answers to exercises, get role plays conducted and analyse them, lead group discussions, organize and supervise clinical practice in outpatient facility and generally give participants any help they need to successfully complete the course.
- Using leading questions draw the relevant information related to the session from participants and fill in the gaps, where necessary. This will help trainees to assimilate the knowledge and experiences.

10.6.2 Adapt the Curriculum to Reflect the Participants' Expectations

Use the results of the small group exercise about participants' expectations. Although trainers may not always be able to meet all of the participants' needs, knowing expectations helps in tailoring the training and add relevant information and examples to the training sessions.

Language: Use non-technical simple language during the sessions so that participants can understand and gain practice with simple terminology that can be used during their work.

10.7 Evaluation of Knowledge and Skills

Evaluation is a fundamental part of training. Proper evaluation helps ensure that the training is not merely a one-time intervention but part of a broader strategy to develop participants' skills and to help them apply those skills upon return to their work-sites. Evaluation can also help to improve future training activities. Evaluation of training includes:

- A pre and post-test of participants' knowledge: this pre-test and post-test is designed to be given at the beginning and end of the training course. The trainer can use the results to customize the training to best suit the trainees.
- Continuous assessment of the training.
- An assessment of the trainees by the trainer (Checklist on Family Planning and Method Specific Counselling ; Annexure 4.1,4.2,4.3,4.4).
- An assessment of the training by the participants (Evaluation of Training; Annexure 9)

10.7.1 Training Follow-up

For training to be truly successful, trainees must be able to use their new skills and knowledge and apply them when they return to their jobs. Practice on job helps in gaining competency and gradually proficiency in the skills. The follow up should be conducted within 2 to 3 months by District Training Coordinator/CMO (Annexure 10).

10.7.2 Certification

Certificate of attendance may be given to participants who have attended training.

10.8 Roadmap for Training

The training strategy is to start with orientation of Trainers and Program managers at the national level and state level followed by facility level training of service providers at district/sub district level. This process would ultimately build a sustainable self-renewing system of DH/CHC based Trainers responsible for developing the capacity of competent service providers for FP services

10.9 Curriculum and Schedule of Training on Oral Contraceptives

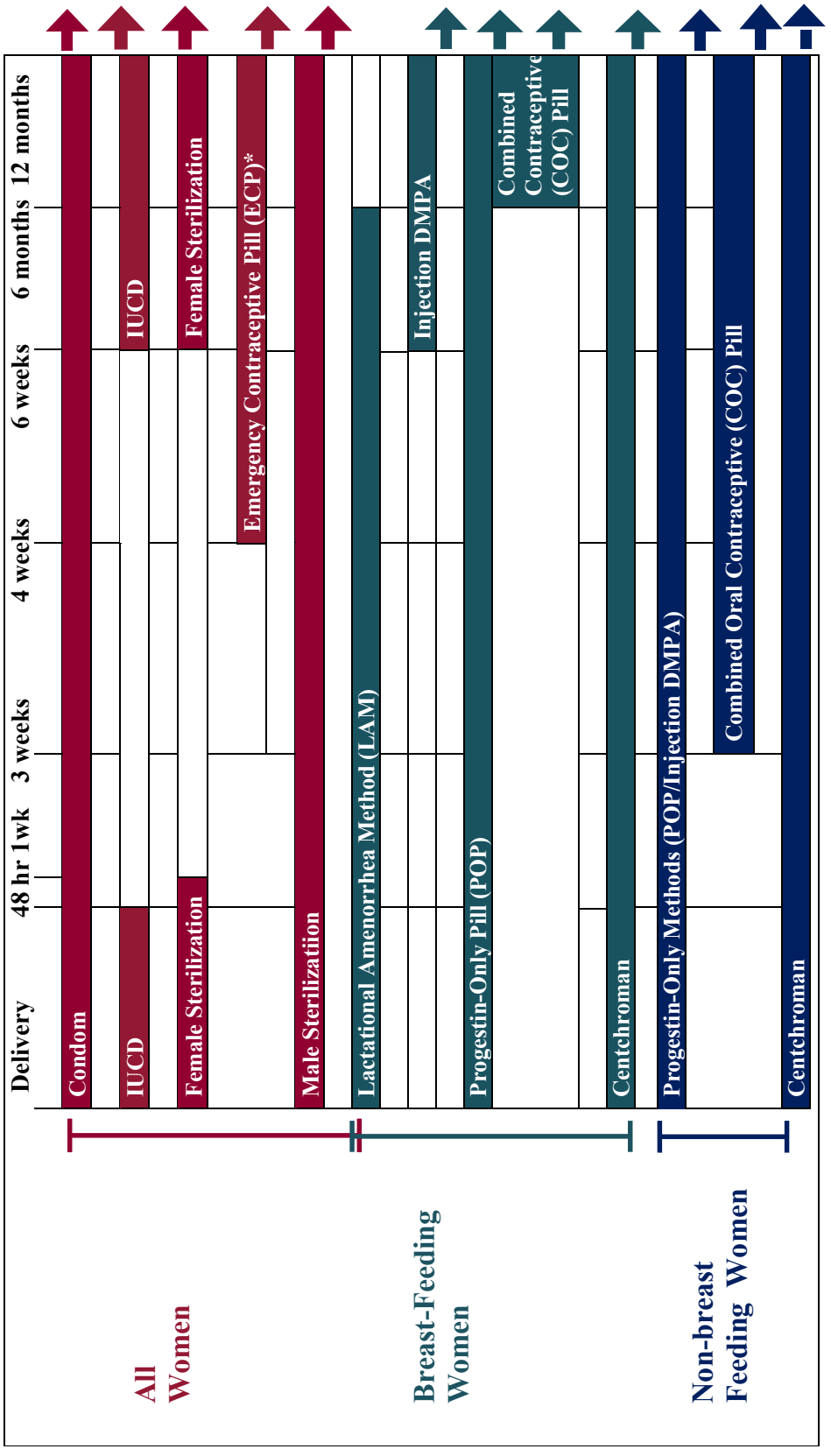
Time	Duration	Topics / Activities
9:30-10:00	30 Min	• Introductions of Participants • Participants' Expectations, Group Norms
10:00-10:20	20 Min	• Course Goal and Objectives • Review the Course Agenda, Components of the Training Package and Course Materials Given to Participants.
10:20-10:40	20 Min	• Pre Course Knowledge Assessment
10:40-11:00	20 Min	• National Family Planning Program and Need for Expanding Contraceptive Choice, Global Use of Oral Contraceptives and in the National Family Planning Program
Working Tea		
11:00-12:00	60 min	• Technical Update on Combined Oral Pills, POPs & ECPills
12:00-12:30	30 Min	• Technical Update on Centchroman (Ormeloxifene)
12:30-1:15	45 Min	• Medical Eligibility Criteria and Client Assessment for Oral Contraceptives(OCPs, POPs, Centchroman (Ormeloxifene), ECPs)
1:15-2:00	45 Min	**Lunch**
2:00-3:00	60 Min	• Counselling for OCPs • Role-Play
3:00-3:30	30 Min	• Helping Continuing Users and Managing Side Effects and Problems of Oral Contraceptives
3:30-4:00	30 Min	• Addressing Misconceptions on Oral Contraceptives
Working Tea		
4:00-4:45	45 Min	• Skill Practice Using Checklist on Counselling Skills
4:45-5:15	30 Min	• Contraceptive Logistics and Record Keeping for Oral Contraceptives
5:15-5:35	20 Min	• Post Course Knowledge Assessment Questionnaire , Course Evaluation formats and Course Closure

Section IV

Annexures

Annexure 1

Time of Initiation of Postpartum Family Planning Method



* This is to be used only in emergency. For a regular contraceptive use, take advice from ANM/Doctor at government health centre.

Annexure 2

Pregnancy Checklist

Before starting any method, ask the client, questions 1-6. As soon as the client answers "yes" to any question, stop and follow the instruction given below.

NO		YES
	1. Ask for the following 3 criteria for LAM **(All 3 must be met)** • The baby is less than 6 months old • Menstrual period has not returned after last childbirth • The baby is fully or nearly fully breastfed, fed often, day and night at least 8-10 times a day, at least once in 4 hours and at least once at night (at least 85% of feeding should be breast milk).	
	2. Have you abstained from sexual intercourse since your last monthly bleeding or delivery?	
	3. Have you had a baby in the last 4 weeks?	
	4. Did the first day of your monthly bleeding start within the past 7 days (or within the past 12 days if the client is planning to use an IUCD)?	
	5. Have you had a miscarriage or abortion in the last 7 days (or within the past 12 days if the client is planning to use an IUCD)?	
	6. Have you been using a reliable contraceptive method consistently and correctly?	

If the client answered "no" to all questions, pregnancy cannot be ruled out. The client should wait for her next monthly bleeding or do a Urine Pregnancy Test for Confirmation.

If the client answered "yes" to at least one of the questions and she has no signs or symptoms of pregnancy, you can give her the method she has chosen.

Annexure 3 Medical Eligibility Criteria for Oral Contraceptives

The table below is the quick reference chart of MEC for Oral Contraceptives adapted from the latest recommendations of WHO MEC 2015:

- Women with conditions listed under WHO Category 1 and 2 can use hormonal contraceptives
- Women with conditions listed under WHO category 3 and 4 should not use hormonal contraceptives.
- ***All women can use ECPs safely and effectively, including women who cannot use ongoing hormonal contraceptive methods. Because of the short-term nature of their use, there are no medical conditions that make ECPs unsafe for any woman.***

Condition	Combined Oral Contraceptives (COCs)	Progestin Only Pills (POPs)
Age and parity		
a) Women from menarche to 40 years of age	1	1
b) Nulliparous or parous	1	1
Smoke cigarettes/bidi		
a) Age < 35 Years	2	1
b) Age ≥ 35 Years	3 or 4	1
Anemia now or had in the past	1	1
Breastfeeding		
a) < 6 weeks postpartum	4	2
b) ≥ 6 weeks to < 6 months (primarily breastfeeding)	3	1
c) ≥ 6 months postpartum	2	1
Postpartum (non-breastfeeding women)		
a) < 21 days		
(i) without other risk factors for VTE	3	1 (For all conditions given)
(ii) with other risk factors for VTE	4	
b) ≥ 21 days to 42 days		
(i) without other risk factors for VTE	2	
(ii) with other risk factors for VTE	3	
c) ≥ 42 days	1	
Post-abortion		
Immediate post-septic	1	1
Superficial venous disorders		
a) Varicose veins	1	1
b) Superficial venous thrombosis	2	1
Known dyslipidaemias without other known cardiovascular risk factors	2	2

**I= Initiation; C= Continuation*

Condition	Combined Oral Contraceptives (COCs)	Progestin Only Pills (POPs)
Hypertension a) History of (where BP can't be evaluated) b) BP is controlled and can be evaluated c) Elevated BP (Systolic 140-159 or diastolic 90-99) d) Elevated BP (Systolic ≥ 160 or diastolic ≥ 100) e) Vascular disease	 3 3 3 4 4	 2 1 1 2 2
Deep venous thrombosis a) History of DVT/PE b) Acute DVT/PE c) DVT/PE, established on anticoagulant therapy d) Major surgery with prolonged immobilization	 4 (in all conditions given)	 2 3 2 2
Ischemic heart disease (current or history of) or stroke (history of CVA)	 4	 I* 2; C 3
Complicated valvular heart disease	4	1
Headaches a) Non-migranous (mild or severe) b) Migraine without aura (age <35 years) c) Migraine without aura (age ≥35 years) d) Migraines with aura (at any age)	 *I 1; C 2 *I 2; C 3 *I 3; C 4 *I 4; C 4	 *I 1: C 1 *I 1; C 2 *I 1; C 2 *I 2; C 3
PID/STIs a) Current purulent cervicitis or chlamydial infection or gonorrhoea b) Other STIs (excluding HIV and hepatitis) c) Vaginitis (including Trichomonas vaginalis and bacterial vaginosis) d) Increased risk of STIs	 1 (in all conditions given)	 1 (in all conditions given)
HIV/AIDS a) High risk of HIV b) Asymptomatic or mild HIV clinical disease (WHO stage 1 or 2) c) Severe or advanced HIV clinical disease (WHO stage 3 or 4)	1 (in all conditions given)	1 (in all conditions given)
Antiretroviral Therapy a) Nucleoside reverse transcriptase inhibitors (NRTIs): Abacavir/Tenofovir/Zidovudine/Lamivudine/ Didanosine/Emtricitabine/Stavudine b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs) Etravirine (ETR) Rilpivirine (RPV) Efavirenz (EFV) Nevirapine (NVP) c) Protease inhibitors (PIs) Ritonavir-boosted atazanavir (ATV/r) Ritonavir-boosted lopinavir (LPV/r) Ritonavir-boosted darunavir (DRV/r) Ritonavir (RTV)	**1** 1 for ETR and RPV 2 for EFV and NVP **2**	**1** 1 for ETR and RPV 2 for EFV and NVP 2

**I= Initiation; C= Continuation*

Condition	Combined Oral Contraceptives (COCs)	Progestin Only Pills (POPs)
d) Integrase inhibitors Raltegravir (RAL)	1	1
Unexplained vaginal bleeding	2	2
Cancers b) Cervical c) Endometrial d) Ovarian	 2 1 1	 1 1 1
Breast disease a) Undiagnosed mass b) Current cancer c) Past, no evidence of current disease for last 5 years	 2 4 3	 2 4 3
Tuberculosis (pelvic and non-pelvic)	1	1
Diabetes a) H/o gestational diabetes b) Nephropathy/retinopathy/neuropathy c) Diabetes for >20 years	 1 3/4 3/4	 1 2 2
Symptomatic gall bladder disease (current or medically treated)	3	2
Hepatitis a) Acute or flare b) Chronic or client is carrier	 4 1	 1 1
Cirrhosis a) Mild b) Severe	 1 4	 1 3
Drug interactions a) Rifampicin or rifabutin b) Anticonvulsant therapy	 3 3	 3 3

* I = Initiation, C = Continuation

The table below shows the MEC for EC Pills

Condition	COC	Progestin only	Ulipristal acetate
Pregnancy	ECP use is not applicable		
Breastfeeding	1	1	2
Past ectopic pregnancy	1	1	1
Obesity	1	1	1
H/O severe cardiovascular disease	2	2	2
Migraine	2	2	2
Severe liver disease (including jaundice)	2	2	2

Condition	COC	Progestin only	Ulipristal acetate
CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, primidone, rifabutin, St John's wort/Hypericum perforatum)	1	1	1
Repeated ECP use	1	1	1
Rape	1	1	1

Medical Eligibility Criteria for Centchroman (Ormeloxifene):

- Women with following conditions **should not use** Centchroman (Ormeloxifene):
  - Polycystic ovarian disease
  - Cervical hyperplasia
  - Recent history of clinical evidence of jaundice or liver disease
  - Severe allergic states, chronic illnesses such as tuberculosis, renal disease
- Centchroman (Ormeloxifene) possesses no effect on platelet aggregation, lipid profile and HDL cholesterol.
- Centchroman (Ormeloxifene) can be safely used by lactating mothers.

Annexure (4.1)

Checklist: Family Planning Counselling

(To be used for practicing and assessment of the FP counselling skill)

This checklist is for counselling woman/couple at any time on various methods of family planning.

Place a "✓" in case box if step/task is performed **satisfactorily,** an **"X"** if it is not performed satisfactorily or N/O if not observed.

Satisfactory: Performs the step or task according to the standard procedure or guidelines

Unsatisfactory: Unable to perform the step or task according to the standard procedure or guidelines

Not Observed: Step or task not performed by participant during evaluation by trainer

Participant _____ **Date of Observation** _____

(Some of the following steps/tasks should be performed simultaneously)						
STEP/TASK	**CASES**					
Preparation for Counselling	1	2	3	4	5	Comments
1. Ensures room/counselling corner is well lit and there is availability of chairs and table.						
2. Prepares equipment and supplies.						
3. Ensures availability of writing materials and job-aids (eg. client file, daily activity register, FP job-aids, client education material, flip book).						
4. Ensures privacy.						
SKILL/ACTIVITY PERFORMED SATISFACTORILY						
General Counselling Skills						
5. Greets the woman with respect and kindness. Introduces self.						
6. Uses body language to show interest in and concern for the woman.						
7. Asks the woman the purpose of her visit. Reassures the woman that the information in the counselling session will be confidential.						
8. Tells the woman that this session is going to help client to take decision on her own as per her needs and for ensuring good health for woman and her children (if any). Responds to the woman's questions/concerns.						
9. Uses language that the woman can understand.						
10. Discusses the health benefits to mother and baby of waiting at least two years after the birth of her last baby before she tries to conceive again.						

STEP/TASK	CASES					
General Counselling Skills	1	2	3	4	5	Comments
11. Rules out pregnancy by asking the 6 questions to be reasonably sure that the woman is not pregnant • Have you had a baby in last 4 weeks • Did you have a baby less than 6 months ago? If so, are you fully or nearly fully breastfeeding? Have you had no monthly menstrual bleeding since giving birth? • Have you abstained from sexual intercourse since your last menstrual period or delivery? • Did your last menstrual period start within past 7 days (or 12 days if you plan to use IUCD)? • Have you had a miscarriage or abortion in the last 7 days? • Have you been using a reliable contraceptive method consistently and correctly? (If client's response to any of the above question is "Yes" and she is free of signs and symptoms of pregnancy, pregnancy is unlikely.)						
12. Displays the counselling kit/flip book page/samples of contraceptives showing all the FP methods and • If client has a method in mind, provides method specific counselling on that method. • If client does not have any specific method in mind, asks the following 4 questions and eliminates methods according to client's response: i. Do you want more children in the future? (If yes, does not discuss male and female sterilization) ii. Are you breastfeeding an infant of less than 6 months old? (If yes, does not discuss combined oral contraceptive pills) iii. Will your partner use condoms? (If yes, discusses about condoms. Also, irrespective of client's response, assesses woman's risk for STIs and HIV and explains that condoms are the only method that can protect from STI and HIV) iv. Have you not tolerated an FP method in the past? (If yes, asks which method. Does not discuss the method used if the problem experienced was really related to the method)						

STEP/TASK	CASES					
General Counselling Skills	1	2	3	4	5	Comments
13. Briefly provides general information about those contraceptive methods that are appropriate for woman based on her facts to questions asked in step 12. • How to use the method • Effectiveness • Common side effects • Need for protection against STIs including HIV/AIDS						
14. Clarifies any misconception the woman may have about family planning methods.						
15. Asks which method interests the woman. Helps the woman choose a method.						
Method-Specific Counselling – once the woman has chosen a method, please provide method specific counselling for the method chosen (Please refer to checklists for method specific counselling of oral contraceptives 4.2, 4.3, 4.4)						

Annexure (4.2)

Checklist: Method Specific Counselling on Combined Oral Contraceptives (COCs)

(To be used for practicing and assessment of the method specific contraceptive counselling skill on COCs)

This checklist is for counselling woman/couple at any time on combined oral contraceptives.

Place a "✓" in case box if step/task is performed **satisfactorily**, an **"X"** if it is **not** performed **satisfactorily** or **N/O** if not observed.

Satisfactory: Performs the step or task according to the standard procedure or guidelines

Unsatisfactory: Unable to perform the step or task according to the standard procedure or guidelines

Not Observed: Step or task not performed by participant during evaluation by trainer

Participant_____**Date of Observation**_____

(Some of the following steps/tasks should be performed simultaneously)						
STEP/TASK	**CASES**					
Information on the Method	1	2	3	4	5	Comments
1. Ensures that client has chosen COC voluntarily after getting information on various contraceptive options						
2. Ensure that the client is not pregnant (Annexure 2)						
3. For assessing the medical eligibility of clients for COC, provider asks questions to ensure that the following conditions are not present, in which COC cannot be used by the woman: • Breastfeeding her baby less than 6 months of age. • Smoking cigarettes and more than 35 years of age. • Breast cancer. • Stroke, blood clot in legs or lungs or heart attack. • Repeated severe headaches, often on one side and/or pulsating, causing nausea and which are made worse by light, noise or movement • Taking any pills for tuberculosis (TB) or seizures (Fits) regularly • Gall bladder disease or serious liver disease or jaundice • High blood pressure • Diabetes • Two or more conditions that could increase the chances of a heart attack or stroke, such as smoking, obesity or diabetes						

STEP/TASK	CASES					
Information on the Method	1	2	3	4	5	Comments
4. If client is eligible for COC, tells the woman following points about the COC: • How to take pills and what to do if she misses the pills • How does it work • Effectiveness • Advantages • Disadvantages including side effects • When to come for follow up- (The client can come back any time-……..)						
5. Provides the packets of COC						
6. Asks to repeat the instructions: • How to use the method • Side effects • When to get the next supply of the pills (before her pills are finished)						
7. Asks and responds, if the she has any questions or concerns.						
8. Records the relevant information.						
Information on Other Services						
9. Educates the woman about prevention of STIs and HIV/AIDS. Informs her that COC does not protect from STIs including HIV/AIDS.						
10. Using information collected in earlier steps, determines client's needs for postpartum, newborn and infant care services. • If client reported giving birth recently, discuss or refer for postpartum care, newborn care • For clients with children less than 5 years of age, discuss and arrange or refer for immunizations and growth monitoring services						
SKILL/ACTIVITY PERFORMED SATISFACTORILY						
Follow-up Counselling						
1. Greets the woman and asks her the purpose of visit						
2. Checks whether the woman is satisfied with the method and is still using it.						
3. Asks if she has any questions, concerns or problems with COC.						
4. Explores changes in the woman's health status or lifestyle that may mean she needs a different family planning method.						

STEP/TASK	CASES								
Follow-up Counselling	1	2	3	4	5	Comments			
5. Reassures about side effects.									
6. Refers to the doctor for any physical examination, if needed.									
7. Schedules return visit for providing more pills before supply finishes									

Annexure (4.3)

Checklist: Method Specific Counselling on Progestin-Only-Pills (POPs)

(To be used for practicing and assessment of the method specific contraceptive counselling skill on POPs)

This checklist is for counselling woman/couple at any time on POPs.

Place a "✓" in case box if step/task is performed **satisfactorily**, an **"X"** if it is **not** performed satisfactorily or **N/O** if not observed.

Satisfactory: Performs the step or task according to the standard procedure or guidelines

Unsatisfactory: Unable to perform the step or task according to the standard procedure or guidelines

Not Observed: Step or task not performed by participant during evaluation by trainer

Participant_____**DateofObservation**_____

(Some of the following steps/tasks should be performed simultaneously)						
STEP/TASK	**CASES**					
Information on the Method	1	2	3	4	5	Comments
1. Ensures that client has chosen POPs voluntarily after getting information on various contraceptive options						
2. For assessing the medical eligibility of clients for POPs, provider asks questions to ensure that the following conditions are not present, in which POPs cannot be used by the woman: • Jaundice/Cirrhosis of liver/liver infection/ liver tumour • Blood clot in her legs or lungs • Client taking medication for seizures • Client taking Rifampicin/Rifabutin for tuberculosis • Breast cancer or history of breast cancer						
3. If the client is eligible for POPs, tells the woman following points about the POPs: • How to take pills and what to do if she misses pills? • How does it work? • Effectiveness (Explains the woman that the breastfeeding increases the effectiveness of POPs) • Advantages • Disadvantages including side effects especially unscheduled bleeding.						
4. Provides the packets of POPs						

STEP/TASK	CASES					
Information on the Method	1	2	3	4	5	Comments
6. Asks and responds if she has any questions or concerns						
7. Records the relevant information						
Information on Other Services						
8. Educates the woman about prevention of STIs and HIV/AIDS Informs her that POPs do not protect from STIs including HIV/AIDS						
9. Using information collected in earlier steps, determines client's needs for postpartum, newborn and infant care services • If client reported giving birth recently, discuss or refer for postpartum care, newborn care • For clients with children less than 5 years of age, discuss and arrange or refer for immunizations and growth monitoring services						
SKILL/ACTIVITY PERFORMED SATISFACTORILY						
Follow-up Counselling						
1. Greets the woman and asks her the purpose of visit						
2. Checks whether the woman is satisfied with the method and is still using it. Asks if she has any questions, concerns or problems with the method.						
3. Explores changes in the woman's health status or lifestyle that may mean she needs a different family planning method						
4. Reassures the woman about side effects especially menstrual changes						
5. Refers to the doctor for any physical examination, if needed						
6. Schedules return visit for providing more pills before supply finishes						

Annexure 4 (4.4)

Checklist: Method Specific Counselling on Centchroman (Ormeloxifene)

(To be used for practicing and assessment of the method specific contraceptive counselling skill on Centchroman (Ormeloxifene))

This checklist is for counselling woman/couple at any time on Centchroman (Ormeloxifene).

Place a "✓" in case box if step/task is performed **satisfactorily**, an **"X"** if it is **not** performed **satisfactorily** or **N/O** if not observed.

Satisfactory: Performs the step or task according to the standard procedure or guidelines

Unsatisfactory: Unable to perform the step or task according to the standard procedure or guidelines

Not Observed: Step or task not performed by participant during evaluation by trainer

Participant_____**DateofObservation**_____

(Some of the following steps/tasks should be performed simultaneously)						
STEP/TASK	**CASES**					
Information on the Method	1	2	3	4	5	Comments
1. Ensures that client has chosen Centchroman (Ormeloxifene) voluntarily after getting information on various contraceptive options. If the client is identified with a medical condition in which hormonal contraceptives cannot be started, she can start Centchroman (Ormeloxifene), if she wants						
2. For assessing the medical eligibility of clients for Centchroman (Ormeloxifene), provider asks questions to ensure that the following conditions are not present, in which Centchroman cannot be used by the woman: • Polycystic ovarian disease • Cervical hyperplasia • Recent history of clinical evidence of jaundice or liver disease • Severe allergic states • Chronic illness such as tuberculosis or renal disease						
3. If client is eligible for Centchroman (Ormeloxifene), tells the woman following points about the Centchroman (Ormeloxifene): • How to take the pills and what to do if she misses the pills • How does it work • Effectiveness • Advantages • Disadvantages including side effects						

STEP/TASK	CASES					
Information on the Method	1	2	3	4	5	Comments
5. Asks the woman to repeat the instructions about Centchroman (Ormeloxifene): • How to use the method • Side effects • When to get the next supply (before her pills are finished)						
6. Asks and responds if the woman has any questions or concerns						
7. Record the relevant information						
Information on Other Services						
8. Educates the woman about prevention of STIs and HIV/AIDS. Informs her that Centchroman (Ormeloxifene) does not protect from STIs including HIV/AIDS						
9. Using information collected in earlier steps, determines client's needs for postpartum, newborn and infant care services. • If client reported giving birth recently, discuss or refer for postpartum care, newborn care • For clients with children less than 5 years of age, discuss and arrange or refer for immunizations and growth monitoring services						
SKILL/ACTIVITY PERFORMED SATISFACTORILY						
Follow-up Counselling						
1. Greets the woman and asks her the purpose of visit						
2. Checks whether the woman is satisfied with Centchroman (Ormeloxifene) and is still using it						
3. Check whether the woman has missed any pill (Biweekly schedule in first three months and once a week pill schedule thereafter) 4. If yes show her the way of taking pill with help of an example and discuss the way to remember.						
5. Asks if she has any questions, concerns or problems with the method						
6. Explores changes in the woman's health status or lifestyle and offer her other methods if she has issues with current method (compliance and bleeding)						
7. Reassures and counsel about side effects						
8. Refers to the doctor for any physical examination, if needed						
9. Schedules return visit for providing more pills before supply finishes						

HOW DOES IT WORK	HOW TO USE THE METHOD	WHO CAN USE THE METHOD	WHO SHOULD NOT USE THE METHOD	EFFECTIVENESS AND BENEFITS	LIMITATIONS/ SIDE EFFECTS	FAILURE RATE

• Works by
• Preventing the release of eggs from the ovaries (ovulation) by suppressing follicle stimulating hormone (FSH) and luteinizing hormone (LH).
• Preventing implantation.
• Causing thickening of cervical mucus, which makes it difficult for sperm to pass through.
	• One pill to be taken every day, irrespective of intercourse.
	• After a pack of 28 pills pills is over, the next pack needs to be started from next day itself, without any break.
		• Women and couples who want an effective, reversible method.
		• Women of any age including adolescents and women over 40 years of age.
		• Women having anaemia due to heavy menstrual bleeding and menstrual cramps.
		• Women with an irregular. menstrual cycle
		• HIV positive women, whether or not on ARV
			• Breastfeeding women < 6 months postpartum.
			• Non-breastfeeding women < 3 weeks postpartum.
			• Women who smoke >15 cigarettes/day and ≥35 years old.
			• Women with the following conditions:
			  • Deep vein thrombosis (DVT)
			  • Heart disease
			  • Bleeding disorders
			  • Liver disease or tumours
			  • Recurrent migraine headaches with focal neurological symptoms
			  • Unexplained vaginal bleeding
			  • Breast cancer
			  • Currently taking anticonvulsants for epilepsy or Rifampicin for tuberculosis
			However can also be used under following conditions with expert advice:
			• Women with hypertension (BP 140/90 or more)
			• Diabetes (advanced or long standing) with vascular problems or central nervous system (CNS), kidney or visual disease.
				• Highly effective, reversible, easy to use and safe for most women.
				• Regulate the menstrual cycle and reduces menstrual flow (which is useful to anaemic women)
				• Decrease the risk of ovarian and uterine cancer, benign breast disease and incidence of acne.
				• Do not interfere with sexual intercourse.
				• Pelvic exam not mandatory before use.
				• Immediate return of fertility on discontinuation.
					• Must be taken every day.
					• Require regular/ dependable supply.
					• May cause side effects in some women, such as nausea, headache, bleeding between menses or weight gain.
					• Do not protect against STIs and HIV.
					• Risk of developing cardiovascular disease in women over 35 years of age and who smoke.
						(Expressed in no. of pregnancies per 100 women using the method over the first year)
						• **Perfect Use*: 0.3**
						• **Typical Use*: 8**

*Perfect use – when use is consistent and exact according to directions.

**Typical use – when use is not always consistent and correct.

HOW DOES IT WORK	HOW TO USE THE METHOD	WHO CAN USE THE METHOD	WHO SHOULD NOT USE THE METHOD	EFFECTIVENESS AND BENEFITS	LIMITATIONS/ SIDE EFFECTS	FAILURE RATE
• Works by • Thickening cervical mucus (this blocks sperm from meeting an egg) • Preventing the release of eggs from the ovaries (ovulation) • Thinning of endometrial lining	• One pill to be taken every day and at the same time.	• Who want an effective, reversible method • Breastfeeding women (can start as soon as after childbirth). • Women of any age including adolescents and women over 40 years of age. • Women just after abortion, miscarriage or ectopic pregnancy. • Women having anaemia. • Women, who have varicose veins. • HIV positive women, whether or not on ARV.	• History of breast cancer • Acute blood clot in deep veins of legs. • Severe liver disease, infection or tumor. • Taking medicines for seizures.	• Highly effective in breastfeeding women (99%), reversible, easy to use • Can be started soon after childbirth • Can be used while breastfeeding • Safe for most women • Do not interfere with sexual intercourse • Can be provided by trained non-medical staff • Immediate return of fertility on discontinuation	• Effectiveness decreases when breastfeeding stops • Require regular/ dependable supply • May cause side effects in some women, such as changes in bleeding patterns including: • Irregular/Prolonged bleeding/ No bleeding • Postpartum Amenorrhoea may be prolonged in breastfeeding women • Some may have side effects like headaches, dizziness, mood changes, breast tenderness, abdominal pain, nausea • Other possible change- In non-breast feeding women, ovarian follicle may be enlarged. • Do not protect against STIs, HIV	**(Expressed in no. of pregnancies per 100 women using the method over the first year)** **Breastfeeding women:** • Perfect Use*: 0.3 • Typical Use**: 1 • **Not breastfeeding women:** • Perfect Use*: 0.9 • Typical Use**: 3-10

*Perfect use – when use is consistent and exact according to directions.

**Typical use – when use is not always consistent and correct.

HOW DOES IT WORK	HOW TO USE THE METHOD	WHO CAN USE THE METHOD	WHO SHOULD NOT USE THE METHOD	EFFECTIVENESS AND BENEFITS	LIMITATIONS/ SIDE EFFECTS	FAILURE RATE
• Works by creating asynchrony between developing zygote and endometrial maturation leading to prevention of implantation (Asynchrony in the form of slight increase in transport of zygote through oviducts, acceleration of Blastocyst formation and suppression of endometrial proliferation and decidualization) It does not alter basal or peak FSH/LH levels and also no effect on the production of estrogen or progesterone.	• One tablet (30 mg) twice a week on fixed days for 3 months (for instance, if one takes the first pill on a Sunday, she should take the second one on Wednesday). From the 4th month onwards, only one tablet once a week.(first day of week i.e. Sunday in the given example)	• Women who want an effective, reversible method. • Women who want oral contraception but not hormonal pills. • Women who are breastfeeding. • Women of any age including adolescents and women over 40 years of age. • Women having anemia. • Women just after abortion, miscarriage or ectopic pregnancy. • HIV positive women, whether or not on ARV.	Women with • Polycystic ovarian disease. • Cervical hyperplasia. • Recent history of clinical evidence of jaundice or liver disease. • Severe allergic states, chronic illnesses such as tuberculosis, renal disease etc.	• Highly Safe and effective, non-steroidal non-hormonal reversible method • Easy to use orally twice a week for first three months and once a week thereafter • Can be used safely by lactating mothers • Safe for most women. Free from side effects commonly associated with hormonal oral contraceptives (such as nausea, dizziness, weight gain, etc.) • Does not interfere with sexual intercourse • Can be started without a pelvic examination. it can be provided by trained health provider • Immediate return of fertility on discontinuation • Has no effect on platelet aggregation, lipid profile and HDL cholesterol. • No teratogenic effect. • Effective in managing dysfunctional uterine bleeding • Can prevent breast cancers, uterine cancers and protection against demineralisation of bone.	• Require regular/ dependable supply • Prolongation of menstruation cycle in some women • Do not protect against STIs and HIV	**(Expressed in no. of pregnancies per 100 women using the method over the first year)** • PerfectUse*: 1.63

*Perfect use – when use is consistent and exact according to directions.

HOW DOES IT WORK	HOW TO USE THE METHOD	WHO CAN USE THE METHOD	WHO SHOULD NOT USE THE METHOD	EFFECTIVENESS AND BENEFITS	LIMITATIONS/ SIDE EFFECTS	FAILURE RATE
• Action of ECP depends on the time in the menstrual cycle when the intercourse has occurred and when ECP is taken. • ECP causes inhibition or delay of ovulation when used prior to ovulation. • It also acts by thickening of cervical mucus resulting in trapping of sperms, direct inhibition of fertilization, histological and biochemical alterations in the dometrium, alteration in the transport of egg, sperm or embryo, interference with corpus luteum function and luteolysis. • EC is not effective once the process of implantation has begun.	• To be taken as soon as possible or within 3 days) of unprotected intercourse Taking it sooner is more effective.	• All women who have had unprotected intercourse/ accidental act for any reason. • Women who are contraindicated for hormonal contraceptive can take ECP	• There are no medical conditions that make ECPs unsafe for any woman. • Pregnant women should not use ECP, however if accidentally taken it will not cause abortion.	• Moderately effective, if taken within 3 days of unprotected sex/ accidental act • 1-3% women may still conceive despite taking ECP	• Possibility of side effects like nausea, vomiting, headache, dizziness, fatigue and breast tenderness. These side effects generally do not last more than few hours • Next menstrual bleeding may be earlier or later than expected in some women • It does not provide contraception from subsequent unprotected intercourse • Does not protect against STIs and HIV	**(Expressed in no. of pregnancies per 100 women using the method over the first year)** • If 100 women each had unprotected sex once in menstrual cycle, • With no ECPs, eight can become pregnant • With Progestin-only ECP, one can become pregnant • With Combined estrogen-progestin ECPs, two can become pregnant

Annexure 6

Frequently Asked Questions (FAQs) and Clarifying Misconceptions

Responding to common queries asked about oral contraceptives by clients and clarification of misconceptions are essential in improving acceptability of these important family planning methods for many women. Providers should try to respond to clients' queries and correct misconceptions through counselling.

A. Questions and Answers (Correcting Common Misconceptions) about COCs

Question 1: Should I take "rest" from COCs after taking them for some time?

Answer: **No,** taking rest is not needed. In fact, taking a "rest" from COCs can lead to unintended pregnancy. COCs can be used for many years without having to stop them periodically.

Question 2: Will the COCs make me infertile, after I stop taking them? Or, How long will I take to become pregnant, after stopping COCs?

Answer: A woman is protected from pregnancy as long as she takes the pill regularly. Women who stop using COCs can become pregnant quickly. It only takes 1 to 3 months for woman's fertility to come back to normal after stopping the pill.

Question 3: Do COCs cause abortion?

Answer: **No,** COCs do not disrupt an existing pregnancy. They should not be used to try to cause an abortion. They will not do so.

Question 4: Getting pregnant while on the pill will lead to birth defects?

Answer: A baby will not have birth defects if a woman becomes pregnant while on pills or accidentally starts to take COCs, when she is already pregnant.

Question 5: Will the pill make me gain weight?

Answer: Most women do not gain or lose weight due to COCs. Weight changes naturally as life circumstances change and as people age. A few women experience sudden changes in weight when using COCs. These changes reverse after they stop taking COCs. It is not known why these women respond in this way.

Question 6: Will the pill change my mood or sex drive?

Answer: Although some women often blame the pill for mood swings, depression-like symptoms and irritability, studies have found no evidence that COCs affect woman's sexual behavior. Majority of COC users do not report any such change, however, some women report that both mood and sex drive improve.

Question 7: Will COCs increase the chances of cancer?

Answer: COCs actually reduces the risks of ovarian cancer and endometrial cancer. In addition, there is a greater decrease in ovarian cancer risk in people who use the pill longer. Although some studies show breast cancer slightly more common in women using COCs and those who had used COCs in the past 10 years than among other women. It is possible that the breast cancers were already there before COC use but were found sooner in COC users.

B. Questions and Answers (Correcting Common Misconceptions) about POPs

Question 1: Are POPs safe for me, as I am breastfeeding my child?

Answer: **Yes,** this is a good choice for a breastfeeding mother who wants to use pills. POPs are safe for both the mother and the baby, starting as early as possible after giving birth. They do not affect milk production. They do not cause diarrhea in baby.

Question 2: Can I continue taking POPs, when I stop breastfeeding my baby?

Answer: A woman who is satisfied with using POPs can continue using them when she has stopped breastfeeding. However, she can switch to another method if she wishes.

Question 3: Do POPs cause birth defects? Will the fetus be harmed if a woman accidentally takes POPs while she is pregnant?

Answer: **No,** good evidence shows that POPs will not cause birth defects and will not otherwise harm the fetus if a woman becomes pregnant while taking POPs or accidentally takes POPs when she is already pregnant.

Question 4: How long does it take to become pregnant after stopping POPs?

Answer: POPs do not delay the return of a woman's fertility after she stops taking them. The bleeding pattern a woman had before she used POPs generally returns after she stops taking them. Some women may have to wait a few months before their usual bleeding pattern returns.

Question 5: I did not have my monthly bleeding and I am on POPs, does this mean that I am pregnant?

Answer: Probably not, especially if a woman is breastfeeding. If she has been taking her pills every day, she is probably not pregnant and can keep taking her pills. If she is still worried after being reassured, she can be offered a pregnancy test

Question 6: Do POPs cause cancer?

Answer: **No,** only a few studies are available on POPs and cancer. Studies of Injectable (used in other countries), which contain similar hormones, have not shown any increased risk of cancer. (Refer Reference Manual for Injectable Contraceptive (DMPA))

Question 7: Will the pill change my mood or sex drive?

Answer: **Generally, no.** some women using POPs report these complaints. The great majority of POP users do not report any such changes, It is difficult to tell whether such changes are due to the POPs or to other reasons. There is no evidence that POPs affect women's sexual behavior.

Question 8: Do POPs increase the risk of ectopic pregnancy?

Answer: **No,** still, ectopic pregnancy can be life-threatening, so a provider should be aware that ectopic pregnancy is possible if POPs fail.

C. Questions and Answers (Correcting Common Misconceptions) about Centchroman (Ormeloxifene)

Question 1: Is Centchroman (Ormeloxifene) safe for me, as I am breastfeeding my baby?

Answer: **Yes,** this is a good choice for a breastfeeding mother who wants to use pills. It is a non-hormonal, non-steroidal pill and safe for breastfeeding mothers.

Question 2: Does Centchroman (Ormeloxifene) cause birth defects? Will the foetus be harmed if a woman becomes pregnant (method failure), while on Centchroman (Ormeloxifene)?

Answer: Centchroman (Ormeloxifene) does not cause congenital anomalies and babies born to user failures present normal milestones.

Question 4: Will Centchroman (Ormeloxifene) cause any serious side effect?

Answer: Apart from prolongation of menstruation cycle in some women, intake of this non-hormonal contraceptive pill, is not known to cause any side-effect, such as nausea, weight gain, fluid retention, hypertension etc commonly seen with other combined Oral Contraceptives

Question 5: Does Centchroman (Ormeloxifene) cause vaginal discharge, spotting, breakthrough bleeding or menorrhagia?

Answer: **No.** Centchroman (Ormeloxifene) does not cause vaginal discharge, spotting, breakthrough bleeding or menorrhagia.

Question 6: Does Centchroman (Ormeloxifene) cause any abnormal change in my genital tract?

Answer: **No.** Centchroman (Ormeloxifene) does not cause any abnormal change of female genital tract (vagina, cervix, uterus and ovaries).

D. Questions and Answers (Correcting Common Misconceptions) about EC pills

Question 1: Do ECPs cause abortion?

Answer: **No.** ECPs do not work if implantation has occurred or a woman is already pregnant. . ECPs do not cause abortion.

Question 2: Do ECPs cause birth defects? Will the fetus be harmed if a woman accidentally takes ECPs while she is pregnant??

Answer: **No.** evidence shows that ECPs will not cause birth defects and will not in anyway harm the fetus if a woman is already pregnant when she takes ECPs or if ECPs fail to prevent pregnancy.

Question 4: How long do ECPs protect a woman from pregnancy?

Answer: ECPs only protect the women from current unprotected sex.

Question 5: Are ECPs safe for adolescents?

Answer: **Yes.** A study of ECP use among girls 13 to 16 years old found it safe. Furthermore, all of the study participants were able to use ECPs correctly.

Question 6: Can a woman who cannot use combined (estrogen-progestin) oral contraceptives or progestin-only pills as an ongoing method still safely use ECPs?

Answer: **Yes.** This is because ECP is for a brief duration.

Question 7: If ECPs failed to prevent pregnancy, does a woman have a greater chance of that pregnancy being an ectopic pregnancy?

Answer: **No.** There is no evidence that ECPs increase the risk of ectopic pregnancy. Worldwide studies of progestin-only ECPs, including a United States Food and Drug Administration review, have not found higher rates of ectopic pregnancy after ECPs failed than are found among pregnancies generally.

Question 8: Can ECPs be used as a regular method of contraception?

Answer: **No,** they are meant for emergency use only. Nearly all other contraceptive methods are more effective in preventing pregnancy than ECP, however if a women has failed to initiate a regular method she can use again without any medical side effects

Question 9: If a woman buys ECPs over the counter, can she use them correctly?

Answer: **Yes.** Taking ECPs is simple and medical supervision is not needed. Studies show that young and adult women find the label and instructions easy to understand. ECPs are approved for over-the-counter sales or nonprescription use in many countries including India.

Role Play and Case Studies

7.1 Role Play

In a role-play two or more individuals enact parts in a scenario related to a training topic. The role-play technique allows participants to 'play' the role of one or more individuals in a real life situation. The role-play directly involves the individuals in the training session. When the role-play involves situations that individuals are likely to encounter, the methods can build self-confidence in training situation hence are better prepared to deal with such incidents.

Since participants have a chance to put themselves in the other person's position. By doing so, they can empathize and at the end of the exercise is typically a practical doable answer and a real world solutions. It provides an opportunity for learners to see how others might feel/behave in a given situation helps to change participant's attitude and enables participants to see the consequences of their actions on others. It is stimulating and fun. It engages the group's attention and simulates the real world.

The role-play is not without its disadvantages as it is done in an unreal or artificial atmosphere and some participants may have difficulty visualizing themselves in an imaginary situation. The trainees may feel very uncomfortable portraying any type of role. Without proper knowledge and understanding in advance, the role-play is nothing more than a game. This method is much more time consuming than other types of training. Role-plays may be made more effective if the participants are given time to prepare.

7.2 Process of Conducting Role Play

Select any three participants for the role play – one to enact the role of a 'client', another as a 'counsellor' and the third person to be the 'observer'. Select any of the sample role plays to be enacted out from the options given below. Prepare the participants to understand the situation and their respective roles, allowing only the 'client' to read through the case study.

Arrange the stage for optimal viewing and ensure that actors speak loudly and clearly. The 'counsellor' should enact the situation by assisting the client in the decision making process. Respect, care, honesty and confidentiality should be emphasized and form the basis of the interaction with the client.

The appointed 'observer' should share their observations about the role play which has been enacted. Thank the actors and ask for their feedback. Finally ask the audience for their observations of the role play and highlight the key principles as evinced from the play.

7.3 Sample Role Plays are given below.

Counselling of Client

7.3.1 Role Play - 1

A 20 year old lactating woman wants to postpone her next pregnancy. Her sister uses some pills and she likes that method very much. Client says she wants to use that type of pill. The health provider counsels her.

7.3.2 Role Play – 2

A 24 year old women comes to see her service provider because she has heavy menstrual periods lasting for 7-8 days each month. She feels run down since birth of her last child. She has two children, a boy of 7 months and a daughter of 3 years. She has never used a contraceptive method and she and her husband want to have one more child. The health provider counsels the couple.

Switching Methods

7.3.3 Role Play – 3

A young couple, woman age 18 years and the man age 22 years, married for 7 weeks come to see the FP Service provider because they want to postpone their first child until they both complete their university studies in two years. They are currently using condoms but neither like this method. She has heard about that some pills are available and wants to use them. Her husband is against this as he has heard that it could cause his wife to become sterile. The health provider counsels the couple.

7.3.4 Role Play – 4

A 41 year old woman with three teen age boys and one 6 months year old girl (who was a surprize baby following removal of an IUCD) wants contraceptive protection. She has used an IUCD in the past but had it removed because of heavy bleeding, cramping and pain. She is afraid and absolutely refuses to consider a tubectomy or IUCD. She has heard that she is too old to take the contraceptive pills. How health provider will respond?

7.4 Case Study

A case study is a written description of a hypothetical situation that is used for analysis, discussion, and problem solving. It can be used to discuss common problems in a typical situation. It provides a safe opportunity to develop problem-solving skills and promote group discussion and group problem-solving.

The case study is another important technique that trainers should become familiar with and know how to use properly. The case study is an actual presentation, either written or verbal, of an incident that either did or could happen in related areas.

After having read or being given the case, small groups typically spend a prescribed period of time discussing it and its possible solutions fully. Since the case should be an incident of relevance to the training situation, its "real world" application is obvious. The case study should be realistic so that learner can relate to the situation .The trainers can select or write cases that are of relevance and concern to the group at hand. If the case study does not reflect a real-life situation, trainees may view the case as being too theoretical.

7.5 Process of Discussing Case Studies

- Introduce the case study
- Give the participants time to familiarize themselves with the case
- Present questions for the discussion or the problem to be solved
- Give participants time to solve the problem/s
- Have some participants present their solutions/answers
- Ask the participants what they have learned from the exercise
- Ask them how the case might be relevant to their own environment, to their job experience
- Summarize

7.6 SAMPLE OCP CASE STUDIES

Counselling of Client

7.6.1 Case Study – 1

A 23 year old men and her 19 year old wife six weeks post-partum brings their baby for immunization. She is breast feeding the child. She uses this visit to ask how she can prevent another pregnancy for a year or two. She would like to try OCPs but her husband is not in favour of this because he believes it will harm the baby through the mother's milk.

Discussion Questions:

1. What will the health provider say to the couple regarding his belief that OCPs pills will harm the baby?
2. Is Combined Oral Pill an appropriate method for this woman?
3. Is Centchroman (Ormeloxifene) pill or POP an appropriate method for this woman?
4. What guidance regarding the effectiveness, safety, advantages, disadvantages/possible side effects health provider discuss with the couple.

7.6.2 Case Study – 2

A young married women age 20 years comes to the clinic and is accompanied with her mother –in-law. She has two children under age 5. She wants to use the OCPs but her mother-in-law is very much opposed to this because she has heard that the OCPs cause cancer.

Discussion Questions:

1. How will the health provider responds to the mother-in-law with regard to the OCPs causing cancer?
2. What will the service provider say regarding the effectiveness, safety, advantages, disadvantages/possible side effects of OCPs available when dealing with woman and mother-in-law?
3. What specific instructions will the health provider give in regards to the use of the OCPs?

7.6.3 Case Study – 3

A young couple, woman age 20 and the man age 24, married for 2 months come to see the FP Service provider because they were currently using condoms, but last night some how during the sexual contact the condom bursts and they are afraid that this may result in pregnancy. They absolutely want to postpone their first child for at least one year until they both complete their studies. Now they do not want to use the condom.

Discussion Questions:

1. How will the health provider responds to their concern regarding getting pregnant?
2. What instructions will health provider give for use of ECPs?
3. What will service provider suggest regarding future postponement of pregnancy?
4. What will the service provider say regarding the effectiveness, safety, advantages, disadvantages/possible side effects of methods?
5. What specific instructions will the health provider give in regards to the use of the method?

Annexure 8 Pre/Post-Test Questionnaire for OCPs

Name: Time: 15 min

Designation:

Place of posting:

Date:

Pretest/ Posttest (please encircle)

Please encircle most appropriate choice/choices. Please do not encircle more than one choice

1. What is the earliest time when breastfeeding women can start taking Progestin only Pills (POPs) after delivery?

a. After 6 weeks postpartum
b. Immediately after giving birth
c. After 6 months postpartum
d. Cannot start POPs while breastfeeding

2. When can a breastfeeding woman start combined COCs?

a. Immediately after delivery
b. 3 weeks postpartum
c. 6 months postpartum
d. 6 weeks postpartum

3. The primary mechanism of action of the COCs is:

a. Preventing ovulation by suppressing FSH and LH
b. Destroying the ovum
c. Helping prevent implantation by suppressing development of the endometrium
d. Hampering sperm transport by thickening cervical mucus
e. Destroying the sperm

4. POPs may not be an appropriate choice for:

a. Women who have breast cancer
b. Women who are breastfeeding
c. Women who have estrogen related side effects from COCs
d. Women who are over 35 and smoke

5. Which is the most popular method of contraception used in India:

a. Condoms
b. Oral pills
c. Female sterilization
d. Intra Uterine Contraceptive Device

6. If a client forgets to take 1 pill of COC, she should:

a. Take the pill as soon as possible and continue taking rest of the pills as scheduled
b. Discard the forgotten pill
c. Take 2 pills as soon as she remembers
d. Start a new pack of pills

7. Advantages of the COCs include the facts that:

a. It is highly effective if taken correctly
b. It protects against HIV/AIDS
c. It protects against ovarian and endometrial cancer
d. It decreases risk of ectopic pregnancy
e. It protects against breast cancer

8. POPs can be given to women who:

a. Have unexplained vaginal bleeding
b. Have breast cancer
c. Are over 35 and smoke
d. Have high blood pressure

9. Which is true for combined pills

a. Increases hair on face and body
b. Not helpful in relieving symptoms of endometriosis
c. Helps protect against Iron Deficiency Anaemia
d. Increases risk of ovarian and endometrial cancers

10. Combined pills should not be used by

a. Women suffering from chronic head aches
b. Heavy smokers
c. Women having 3 month old child and breast feeding
d. All of the above

11. EC Pill is most effective when taken within __ hours of last unprotected sex

a. 72 hours
b. 96 hours
c. 120 hours
d. Any time till the expected date of next menstrual period

12. EC Pills contain

a. High dose oestrogens
b. Low dose oestrogens
c. High dose progestins
d. Low dose progestins

13. Dosage of Centchroman is

a. Once a week
b. Twice a week
c. Once a week for 12 weeks followed by twice a week from the 13th week onwards
d. Twice a week for 12 weeks followed by once a week from the 13th week onwards

14. Centchroman is composed of

a. Estrogen and progesterone
b. Synthetic progestin
c. Norethindrone enanthate
d. Synthetic estrogen
e. Ormeloxifene

15. Who should NOT take Centchroman?

a. Women breastfeeding their babies
b. Women with anemia
c. Women with varicose veins
d. Women with polycystic ovarian disease

16. Which of the following is advised, if a woman misses a Centchroman pill?

a. To take the missed pill as soon as possible
b. If pill is missed by less than 7 days, she should continue normal schedule and no need of back up
c. If pill is missed by more than 7 days, woman needs to continue the usual schedule and back up for 7 days is advised ,
d. All of the above

17. Informed written consent signed by client is required for providing

a. COC Pill
b. POP
c. Emergency contraceptive Pill
d. Injection DMPA
e. Centchroman
f. IUCD
g. All of the above
h. None of the above

18. Which of the following is advised, if a woman misses a Progestin Only Pill (POP) or is more than 3 hours late?

a. Take the pill as soon as possible and continue taking rest of the pills as scheduled
b. Discard the forgotten pill
c. Start a new pack of pill
d. None of the above

19. In the National Family Planning Program EC pills are available as

a. 1 pill pack containing Levonorgestrol (1.5 mg per tablet)
b. 2 pill pack containing Levonorgestrol (0.75 mg per tablet)
c. Both a) & b)
d. None of the above

20. Which is not true for ECPs?

a. It is known as 'morning after pills'
b. It is known as 'post-coital pill'
c. It is taken within 72 hrs of unprotected intercourse.
d. It can be used as regular contraceptive method.

Annexure 8(a)

Pre/Post-Test Questionnaire (Answers) for OCPs

Name: Time: 15 min

Designation:

Place of posting:

Date:

Pretest/ Posttest (please encircle)

Please encircle most appropriate choice. Please do not encircle more than one choice

1. What is the earliest time when breastfeeding women can start taking Progestin only Pills (POPs) after delivery?

a. After 6 weeks postpartum
b. Immediately after giving birth
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2. When can a breastfeeding woman start combined COCs?

a. Immediately after delivery
b. 3 weeks postpartum
c. 6 months postpartum
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3. The primary mechanism of action of the COCs is:

a. Preventing ovulation by suppressing FSH and LH
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e. Destroying the sperm

4. POPs may not be an appropriate choice for:

a. Women who have breast cancer
b. Women who are breastfeeding
c. Women who have estrogen related side effects from COCs
d. Women who are over 35 and smoke

5. Which is the most popular method of contraception used in India:

a. Condoms
b. Oral pills
c. Female sterilization
d. Intra Uterine Contraceptive Device

6. If a client forgets to take 1 pill of COC, she should:

a. Take the pill as soon as possible and continue taking rest of the pills as scheduled
b. Discard the forgotten pill
c. Take 2 pills as soon as she remembers
d. Start a new pack of pills

7. Advantages of the COCs include the facts that:

a. It is highly effective if taken correctly
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10. Combined pills should not be used by

a. Women suffering from chronic head aches
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12. EC Pills contain

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e. Centchroman
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b. 2 pill pack containing Levonorgestrol (0.75 mg per tablet)
c. Both a) & b)
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a. It is known as 'morning after pills'
b. It is known as 'post-coital pill'
c. It is taken within 72 hrs of unprotected intercourse.
d. It can be used as regular contraceptive method.

Annexure 9

Evaluation of Training

Name---------- Designation----------

Date----------District----------

Put (√) in front of the your response

S. No.	Item	Excellent	Very Good	Good	Satisfactory	Poor
1.	Organization of the workshop					
2.	Subject matter covered					
3.	Duration of workshop					
4	Effectiveness of facilitators					
5	Overall evaluation of workshop					

6. Please share with us the sessions you found most useful (include reasons why)

7. Please share with us the sessions that you found least useful (include reasons why):

8. Please share any suggestions on how to improve the workshop or a particular session?

9. Please share how you will be using the knowledge gained in workshop to include Oral Contraceptive Services in your work place?

10. What support you will need to provide Oral Contraceptive Services in your work place?

11 Other Comments

Post Training Follow-up for OCPs

Instructions to trainer:

- Complete one form per trainee during follow up (Telephonic / Visit). Form has three parts: Part I-General assessment, Part II-Clinical Performance Assessment and Part III-Action Plan
- At the end of assessment review gaps identified with trainee and share the actions recommended.

Part I: General Assessment

State:	**District:**	**Facility Name:**
Facility type	**Date of Training**	**Date of follow up**
No. of this Follow up (Tick (√) one Choice)	1st/2nd/3rd	
Name of the person conducting follow up:		
Designation of the person conducting follow up:		
Name of the Trainee		Designation:
For services that are being provided, what are the numbers of services/procedures that were performed?		
Procedure	**Last month**	**Last quarter**
Counseling		
COC provision		
POP provision		
Centchroman (Ormeloxifene) provision		
ECP provision		

If services are not provided what difficulties have prevented you? (Tick (√) response that applies)		
1	Lack of confidence in skill	
2	Service is not provided in the facility	
3	Lack of demand or clients seeking for the service	
4	Time constraint due to excess workload	
5	Lack of supplies and equipment	
6	Other (specify)	
If services are provided, have you experienced any difficulties during service provision? If yes, tick (√) accordingly		
1	Shortage of Supplies	
2	Low case load	
3	High case load	
4	Periodic stock out of supplies	
5	Other (specify)	

Part II:

Assessment of Clinical Performance: (applicable for follow up visit)

Following the observation of procedures and based on the corresponding observation checklist (4.1/4.2/4.3/4.4)results, (in case a client is available) rate trainee's performance by checking in the appropriate box for each procedure.

Part III: Action Plan

Table below should be utilized by trainer for developing action plan based on gaps identified from above assessment for remedial actions and share with the trainee.

Trainers Action Plan				
S. No.	**Gaps identified**	**Support required**	**Timeline**	**Remarks**
1				
2				
3				
4				
5				
Signature of the trainer				

Annexure 11

Format of ASHAs Reporting under Home Delivery of Contraceptive Scheme

S No	ECR No.	Client's Name	Client's Age	Number of Living Children	Number of cycles/strips distributed and date on which the cycle/strip was given to the client																							
					Apr		May		Jun		Jul		Aug		Sep		Oct		Nov		Dec		Jan		Feb		Mar	
					Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles	Date	No. of cycles

Annexure 11A

Format of Facility Register for Contraceptive Distribution

Facility Register for Contraceptive Distribution

Monthly S.No	ECR No./ OPD No.	Client's Name	Client's Age	Client's Address and Telephone Number	No. of living Children	Last Child Birth	Type of contra-ceptive method preferred (Tick the appropriate option)				Quantity of contraceptive given (Condom- write number of pieces; Oral Pills- write number of cycles/ strips)	Remarks
							COCs (Mala N)	Centchroman (Ormeloxifene)	POPs	Condom		

Time	Topics / Activities	Session Plan	Methodology/ Resource Materials
DAY 1: Morning			
30 Minutes	• Introductions of Participants • Participants' Expectations, Group Norms	• Open course with welcome of participants by organizers, lead trainers • Facilitate the introductions of all participants and trainers. • Explore participants' expectations for the course by brain storming. Brainstorm the norms to be followed during workshop	• Prepared welcome sign • Flipchart and markers • Name badges

20 Minutes	• Course Goal and Objectives
	• Review the Course Agenda, Components of the Training Package and Course Materials Given to Participants.
		• Review the course goals and objectives; the course design and expected outcomes.
		• Review which expectations of participants can be met and which cannot be.
		• Review the course agenda, including starting and ending times and times for breaks and lunch
		• Review the materials to be used in the course and given to participants. Ensure that participants understand the use of the different materials.
			• Flipchart with Course Objectives
			• Copies of course agenda
			• Training folder for each participant, containing:
			  • Reference Manual on Oral Contraceptives
			  • Job-aids

20 Minutes	• Pre Course Knowledge Assessment	• Distribute the Pre-Test Questionnaire to each participant. • Assign a number to each participant and ask them to write the number on the Pre-Test sheet and remember the number till the end of the training. Ask them to answer each question. Allow 20 minutes for the Pre-Test Questionnaire.	• Copies of Pre-Test Questionnaire one for each Participant • Small pieces of paper with numbers

Time	Topics / Activities	Session Plan	Methodology/ Resource Materials
20 Minutes	• National Family Planning Program and Need for Expanding Contraceptive Choice, Global Use of Oral Contraceptives and in the National Family Planning Program	• Use the power-point slides to present information. • Ask questions to the participants and engage them in the discussion on the updated information . • Use the power point slides to present information on impact of pregnancy spacing on maternal, newborn and child health.	• PPT on Global use of oral contraceptives in India; Inclusion of new oral contraceptives in National Family Planning Program. • Sample of all contraceptives

60 Minutes	• Technical Update on Combined Oral Contraceptives, (COCs), Progestin Only Pills (POPs) & Emergency Contraceptive Pills (ECPs)	• Discuss Global evidence for use of oral contraceptives.
		• Review Oral contraceptive usage in National FP Program.
		• Share Technical information including mechanism of action, effectiveness, who should use and who should not, advantage and limitations (side effects) in participatory manner. Trainer may design some questions on following.
		  • Combined Oral Contraceptives (COCs)
		  • Progestin Only Pills (POPs)
		  • Emergency Contraceptive Pills (EC Pills)
		At the end trainer may give handouts of Summary of Key characteristics of COCs, POPs, ECPs for easy reference.
			• Power point slides on POP
			• Handouts of key characteristics of different oral contraceptives (COCs, POPs, ECPs)

Time	Topics / Activities	Session Plan	Methodology/ Resource Materials

30 Minutes	• Technical Update on Centchroman (Ormeloxifene)	• Share Technical information including mechanism of action, effectiveness, who should use and who should not, advantage and limitations (side effects) in a participatory manner.
		  • Centchroman (Ormeloxifene)
		• Volunteers to share their answers on following points for each oral contraceptive method:
		  • Mechanism of action
		  • Contraceptive effectiveness
		  • Benefits
		  • Possible side effects
		  • Limitations
		  • Who should and who should not use the method
			• Power point slides on Centchroman (Ormeloxifene)
			• Handouts of key characteristics of different oral contraceptives
			• Reference Manual for Oral Contraceptive Pills

Tea: 15 minutes			
45 Minutes	• Medical Eligibility Criteria and Client Assessment for Oral Contraceptives	• Recap on how to use the MEC. • Discuss from the reference manual what questions need to be asked for screening clients for different oral contraceptives. • Ask participants to collect one or two VIPP (Visualisation in Participatory Programme) cards per person, without seeing what is written on the card/s. Each card contains a name of a medical condition and question asking specific oral contraceptive can be given in this medical condition or not? • Now, ask the participants to write their answer on the VIPP card by using the MEC wheel. Collect all the cards. Ask participants to open the annexure of MEC in reference manual on oral contraceptives. • Read out from VIPP card (without taking the name of participant, who has written) what participant has written and discuss the correct response for each question.	• MEC wheel • Client assessment for oral contraceptives given in the Reference Manual for Oral Contraceptive Pills • PowerPoint slides • VIPP cards containing questions whether specific oral contraceptive can be given in the given medical condition/s.

Time	Topics / Activities	Session Plan	Methodology/ Resource Materials
60 Minutes	• Counselling for OCPs	• Demonstrate a role-play on counselling with method specific counselling for different oral contraceptives. • Project Role Play situation on FP counselling. Get volunteers to enact in front of all the participants. Remaining participants and trainer to observe the role-play through checklist and after the role-play, facilitate a discussion about what was done well, what was not done and what could be done differently. • Ask participants to observe the role-play through checklist and after the role-play, facilitate a discussion about what was done well, what was not done and what could be done differently. • Trainer observes and uses the counselling checklist to ensure that the counselling approach and technical information discussed in the role-plays is accurate. • Should address client assessment issues. • 3 Case Studies: Divide participants into small groups Give one case study (out of 3) to each group. Give 5-7 min to discuss case. • Trainer to discuss each case one by one and add when necessary • End the session by emphasizing that for side effects, reassurance and correct management can help clients to continue using the method and decrease drop outs. management of common side effects	• Copies of counselling role-plays and Case studies • Counselling checklists and Reference Manual for Oral Contraceptive Pills
30 Minutes	• Helping Continuing Users and Managing Side Effects and Problems of Oral Contraceptives	• Recap the possible side effects/problems of each oral contraceptives • Discuss in detail how to manage them. • Synthesize the session by emphasizing the importance of being able to manage side effects and complications related to the use of oral contraceptives	• Power point slides

Time	Topics / Activities	Session Plan	Methodology/ Resource Materials
Lunch: 45 Minutes			
30 Minutes	• Addressing Misconceptions on Oral Contraceptives	• Facilitate questions and answers on misconceptions on Oral contraceptives- COCs, POPs, Centchroman (Ormeloxifene), EC Pills	• Quiz questions (or Quiz session on computer) • Annexure in Reference Manual for Oral Contraceptive Pills
45 Minutes	• Skill Practice Using Checklist on Counselling Skills	• Skill assessment of participants on counselling skills by using skill assessment checklist for • FP • Method specific counselling on Oral contraceptives (COCs, POPs, Centchroman (Ormeloxifene))	• Counselling checklist • Method specific counselling checklist for COCs, POPs, Centchroman (Ormeloxifene)
30 Minutes	• Contraceptive Logistics and Record Keeping for Oral Contraceptives	• Discuss data collection records maintenance • Share the samples of records • Discuss how to fill them and report to higher managers • Discuss how to procure and maintain stock of oral contraceptives	• Power point slides • Samples of clients' cards and record/register
20 Minutes	• Post Course Knowledge Assessment and Course evaluation Formats • Course Closure	• Grade the Post-Test Questionnaire during the breaks • Use the answer sheets to prepare the Post-course Knowledge Matrix and then return the sheets. • Discuss the correct answers of the assessment questions, for which some participants have written incorrect responses. • Explain that the feedback of participants on the course evaluation form is very important and it will help in improving quality of future training on oral contraceptives. • Have participants fill-out and submit the course evaluation forms. • Closing remarks by training organizers.	• Post-Test Questionnaire

List of Experts

Dr. Alok Banerjee Technical Advisor Parivar Sewa Sanstha New Delhi	**Dr. B. P. Singh** President Enable Health Society New Delhi	**Dr. Ravi Anand** Director, Technical & Operations Abt Associates New Delhi
Dr. Sunita Singal Senior Clinical Advisor Engender Health New Delhi	**Dr. Saswati Das** Director, Clinical Services and Training Jhpiego New Delhi	**Dr. Vivek Yadav** Associate Director Jhpiego New Delhi
Dr. Abha Singh Director & Professor Dept of Obstertric and Gynaec LHMC, New Delhi	**Dr. Suneeta Mittal** Director and HOD, O & GFortis Memorial Research Institute Gurgaon	**Dr. Basab Mukherjee** Chairperson, Family Welfare Committee FOGSI Kolkata, West Bengal
Dr. Malabika Roy Scientist G & Head ICMR New Delhi	**Dr. Bulbul Sood** Country Director Jhpiego New Delhi	**Dr. Jyoti Vajpayee** FP Head BMGF New Delhi
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