

GUIDELINES
FOR
ORAL PILL
ADMINISTRATION
FOR MEDICAL OFFICERS



Issued by
Technical Operations Division
Ministry of Health & Family Welfare
(Department of Family Welfare)
Government of India
Nirman Bhavan, New Delhi-11.

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P R E F A C E

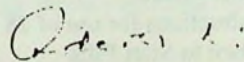
The Government of India is giving high priority to Family Welfare Programme, the ultimate objective being to reduce the country's birth rate to 21 per thousand by the year 2000 AD. In order to achieve this goal, efforts are being made to promote various contraceptive methods for birth spacing - especially for young couples. The oral contraceptive pill has been found to be a simple, safe, effective and reversible method of contraception. The composition of pill presently being used has been found to be most suitable for the Indian woman.

This brochure on oral contraceptive pills will help the medical officers at Primary Health Centres in proper selection of beneficiaries, proper counselling, follow up, regular reporting, etc.

My thanks are due to the experts and staff members of the Ministry who have helped to bring out the publication.

I hope this book will be useful to the doctors for promoting oral contraceptive pills in the National Family Welfare Programme.

NEW DELHI - 110011



(ADARSH MISRA)
Joint Secretary to the
Government of India

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OBJECTIVE

The objective of these guidelines is to enable you to have the necessary knowledge to provide oral contraceptive pill services including counselling, appropriate screening and selection of clients, management of side effects and offer follow up services

1.0 Facts about Oral Pill

At present about 70 million women worldwide and about 2.3 million women in India are using oral contraceptive pills. The first oral contraceptive pill in 1960s contained high doses of oestrogen and progestogens. Currently there has been a significant reduction in both components of oral contraceptive pills, which has led to a decrease in adverse effects. Oral contraceptive pills have been studied more thoroughly than any other medication in common use. The benefits of health apart from preventing pregnancy far outweigh the possible side effects and infrequent complications which may occur in a small number of women. Thus, the oral pill is one of the most effective (if used regularly), safe and reversible temporary method of contraception available at present. It is a contraceptive of choice available to women who want to postpone first pregnancy by a reliable method.

In spite of safety and high efficacy, the national usage is very low. The percentage of married women aged between 13 and 49 years who are currently using pills was only 1.2% according to National Family Health Survey 1992-93. To some extent this is because of misconceptions and misbeliefs regarding health hazards of pills in the minds of lay people. Even many medical practitioners are not fully aware of the safety aspects of the pills. In order to remove misconceptions and propagate correct and sustained use, the myths regarding the pills need to be clarified.

Myths

Reality

1. Pills may lead to cancer

. Pills offer protection against cancer of

Ovary and endometrium.

. No demonstrated increased risk of breast cancer.

2. Pills cause infertility

. Pills do not lead to permanent infertility.

. After discontinuation of pills fertility returns rapidly in majority of women.

3. Pills harm women's health permanently.

. Pills in current use contain very low amounts of hormones; and hence do not lead to major complications.

. Observations on millions of women have proved that when carefully chosen screened women are given oral pills

there are no permanent ill effects.

- . Taking pills is safer than pregnancy and childbirth.
- 4. Baby may be deformed . Even if pills are accidentally used during undiagnosed early pregnancy, there is no increase in the risk of foetal abnormalities.
- 5. Pills should be discontinued Intermittently . Pills can be safely used continuously for 5 years.
. Interruption of pills without use of another contraceptive can result in unwanted pregnancy.

1.1 Oral Contraceptives in National Family Welfare Programme

Based on the results of several clinical trials conducted in India and elsewhere, it has been decided to use low dose oral pills with the following composition in the National Family Welfare Programme.

DL Norgestrel 0.30 mg. per tablet
Ethinyl Estradiol 0.03 mg per tablet

Oral pills are being made available to acceptors under the brand name Mala-N under the free distribution scheme and Mala-D under social marketing programmes available over the counter at a subsidized cost.

These are monophasic combination pills containing the same amount of oestrogen and progestogen in each pill. Each packet of Mala-N and Mala-D contains 21 contraceptive pills and 7 iron tablets. Some other brands of oral pills available commercially are enlisted in Annexure - 1.

1.2 Mechanism of Action

Oral Contraceptive Pills provide effective protection against pregnancy in view of its multiple sites of action, which include:

- i. Inhibition of ovulation by suppressing FSH and LH release
- ii. Affecting implantation by altering endometrium
- iii. Reducing transportation of sperms by making cervical mucus scanty and viscid.

1.3 Selection of Acceptors

Careful selection of acceptors is essential to reduce the rare and serious risks associated with the use of oral pills. Complete clinical history and medical examination should be carried out including body weight and blood pressure recordings before starting pills. The medical examination should include abdominal and pelvic examinations to exclude contraindications. A check list is provided in Annexure II which will help proper selection of the client. After filling in check list, a decision about suitability of the acceptor for pill use can be taken.

Further a simpler check list for paramedical workers is provided in Annexure III. Where doctors are not available, the health personnel like Public Health Nurse/Lady Health Visitor/Auxillary Nurse Midwife/Multipurpose Worker (female)/Health Assistant (female)/ Doctors from indigenous systems of medicine should give oral pills to an acceptor only after making sure that all points listed in the check list are satisfied and also after checking the weight and blood pressure. They must ensure that the acceptor is examined by a doctor within 3 months of initial acceptance.

1.4 Absolute Contraindications

- i. Pregnancy
- ii. H/o Thromboembolism
- iii. H/o Cerebrovascular accident
- iv. Cardiac disease
- v. Malignancy of Breast
- vi. Malignancy of genital tract
- vii. Active liver disease
- viii. H/o Cholestatic jaundice during pregnancy.
- ix. Migraine

1.5 Relative Contraindications

- i. Undiagnosed abnormal uterine bleeding
- ii. Lactating mothers in first 6 months
- iii. Age over 40 years : : over 35 years if smoker
- iv. Mild Hypertension
- v. Gross Obesity
- vi. Diabetes Mellitus
- vii. Epilepsy
- viii. Recent history of depression
- ix. Recent history of oligomenorrhoea
- x. Recent history of amenorrhoea
- xi. H/o Jaundice within last 6 months
- xii. Sickle cell disease (trait not a contraindication)

2.0 Special Situations for Oral Contraceptive use

2.1 Lactation : Combined oral contraceptives containing oestrogen adversely affect both the quantity and quality of the breast milk and also reduce the duration of lactation. Combined oral contraceptives should be withheld until six months after delivery or till the infant is weaned; whichever is earlier. No deleterious effects have been so far reported from the transfer to the infant of a small amount of contraceptive steroids in the breast milk. However, long term epidemiological studies are still continuing.

2.2 Drug Interaction: Drugs which may reduce the efficacy of oral contraceptive pills are Rifampicin, Antibiotics, Anticonvulsants and Antifungal drugs. Management varies according to the duration of such medication. A back up contraceptive method; e.g. condom is recommended for short term use upto one week. Clients taking medication for more than one week should be advised to switch over to another contraceptive method.

2.3 Diarrhoea and Vomiting : Irregular absorption of drug during such illness can reduce the

efficacy. To avoid failure of pills a back up method such as condom should be used during diarrhoea and/or vomiting and continued for seven days after controlling the symptoms.

2.4 Planned Surgery in Oral Contraceptive user : Oestrogenic component of the pills increases the coagulability of blood. Hence oral contraceptives should be discontinued at least for four weeks prior to contemplated surgery to reduce the risk of post operative thrombosis.

2.5 The use of oral contraceptive steroids for pregnancy test is not recommended.

2.6 Adolescents - Caution is recommended until menstruation is established, while prescribing oral contraceptive for adolescents.

3.0 Effectiveness and Other Advantages :

- i. Highly effective method with correct and regular intake by the acceptor.
- ii. Safe
- iii. Reversible
- iv. User dependent : decision with women herself
- v. Non-invasive
- vi. Privacy not required

3.1 Beneficial Effects :

- i. Highly effective in preventing pregnancy if taken regularly.
- ii. Reduces the incidence of ectopic pregnancy - a life threatening condition
- iii. Menstrual benefits :
 - . Relief from menorrhagia, indirectly reducing chances of anaemia
 - . Relief from dysmenorrhoea
 - . Relief from premenstrual tension
 - . Regularisation of menstrual cycles
- iv. Reduced incidence of Pelvic Inflammatory Diseases as compared to nonusers
- v. Relief from acne - specially premenstrual type
- vi. Protection against neoplasia
 - . Benign breast tumours
 - . Benign ovarian cysts
 - . Carcinoma endometrium
 - . Carcinoma ovary

4.0 Side Effects and Risks :

Oral Contraceptives produce some metabolic, biochemical and functional changes which are responsible for a few minor side effects and adverse effects.

4.1 Minor Side Effects :

Women on oral contraceptive pills experience some minor side effects.

- i. Nausea, Vomiting
- ii. Breast tenderness
- iii. Headache
- iv. Depression
- v. Breakthrough bleeding
- vi. Mild elevation of blood pressure (which usually disappears on discontinuation of

- pills)
vii. Weight gain

Breakthrough Bleeding

Breakthrough bleeding is usually due to low oestrogen content in oral contraceptives. Mostly it stops with continued use. Disturbing Breakthrough Bleeding may be relieved by an additional Tablet for 2 - 3 days or changing to a preparation containing 50 ug. Ethinyl estradiol. Gynaecological pathology should be excluded before labelling the bleeding as Breakthrough bleeding

Many of these symptoms disappear on continued use of pills hence you need to assure the user for the first three cycles.

Some side effects are due to the oestrogenic component while some are due to progestogen in the pill. Few of them can be managed by changing the dose of oestrogen or progestogen (by changing the preparation). Recommended actions and management for persistent and unacceptable side effects are given in Annexure - IV.

4.2 Adverse Effects :

Major side effects are rare with currently used low dose pills. The reported effects include:

I. Atherosclerotic cardiovascular disease, hypertension and myocardial infarction. Progesterone component of the pill increases low density lipoproteins (LDL) and decreases high density lipoproteins (HDL), thus increasing the risk of atherosclerosis. The oestrogen component has got an opposite effect. As a result, these effects are balanced in currently used low dose pills. The risk factors for cardiovascular complications are :

- . Age > 40 years
- . Smoking
- . Hypertension
- . Diabetes Mellitus
- . Hyperlipidaemia

ii. Venous Thromboembolism : The oestrogen component of the oral contraceptive pill increases the coagulability of blood.

iii. Liver Disorder : Cholestatic jaundice may occur in women having a history of Cholestatic jaundice during pregnancy.

There is an increased risk of developing benign liver cell adenoma. However, this is an extremely rare condition.

iv. Carcinogenicity :

- . Breast : There is no conclusive evidence to indicate that oral contraceptives cause breast cancer.

Cervix : Epidemiologic studies of OC use and cervical cancer have been inconclusive, most early studies found no links but recent research has produced mixed findings. Although slightly higher risk of cervical cancer and precancerous lesions have been associated with prolonged OC use (more than 5-years) by some. However, the effect of other variables as sexual behaviour and smoking has not been considered in these studies.

In view of this, all oral contraceptive users should have periodic speculum examination and cervical cytology wherever possible.

. Liver : Long term oral contraceptive use may be associated with liver cancer which is an extremely rare cancer.

iv. Postpill Amenorrhoea :

- . Enquire about regularity of intake
- . Exclude pregnancy
- . Postpill amenorrhoea is usually seen in women with a previous history of infrequent periods. If amenorrhoea continues for two or more cycles, oral contraceptive pill should be discontinued.

4.3 Other Effects

- i. Return of Menstruation and Fertility : The incidence of post Oral Contraceptive pill amenorrhoea is low and there is no evidence of decreased fertility in oral contraceptive users.
- ii. Pregnancy Outcome : There is no evidence to indicate increased incidence of spontaneous abortion or foetal abnormalities in oral contraceptive users including in those who conceive soon after discontinuing Oral Contraceptives. Where pregnancy has occurred during oral contraceptive use and the woman has inadvertently continued pills after missing the period, no increased risk of foetal abnormality has been demonstrated. However, pills should be discontinued in the event of suspicion of pregnancy.

5.0 Instructions For Use Of 28 Pill Pack

5.1 When to start Pills?

Start the Pill

1. Day 5 of Menstruation
2. Day 1 of MTP/Spontaneous abortion
3. After delivery -
 - . Nursing mother : after 6 months
 - . Non-lactating : after 6 weeks

5.2 How to take the pill ?

- i. Before starting the pills, read the instruction leaflet carefully.
- ii. The first course should be started on the fifth day of the menstrual cycle (counting first day of bleeding as day number one, by taking the pill from the pack marked as START.
- iii. For subsequent days, one pill a day should be taken from the pack in the order indicated by the arrows; till all the pills in that pack are over.
- iv. The pill should be taken every day at a fixed time, preferably while retiring to bed.
- v. The next pack should be started the very next day by taking the first pill from the pack marked as START.
- vi. Consult a doctor within three months after starting the pill.
- vii. Keep the pills away from children.

5.3 If a Pill is missed

If a Pill is Missed

If a woman misses a pill on a particular night, the missed pill should be taken the next day as soon as she remembers. She should take another pill at night as usual. In other words, on the day following a missed pill day, she has to take two pills. If she misses 2-3 pills, she should continue taking pills regularly but in addition she should also use another contraceptive method like condoms till the next cycle starts.

5.4 Back up Contraception

In certain situations there is a possibility of reduced efficacy of the pill and use of additional contraceptive protection may be necessary. Condom can be a good back up contraceptive. Ten pieces of condom may be given to a pill user for use in situations like missing two or more pills, during diarrhoea and vomiting, or use of drugs reducing efficacy of the pills.

5.5 Duration of Use

In India continuous use of oral contraceptive pills over 5 years is not recommended. However, in women who are otherwise well, low dose oral contraceptives may be continued for several years under medical supervision and there is no need for periodic discontinuation. For women over 40 years of age, oral contraceptives may be prescribed with caution.

5.6 Danger Signs

Ask the oral contraceptive users to report immediately if:

A C H E S

Abdominal pain (severe)
Chest Pain, shortness of breath
Headache - Severe throbbing unilateral
Eye problems (visual loss, double vision, blurring of vision)
Severe leg pains or swelling

Refer such women to higher centre.

6.0 Follow up Services

Initially a woman can be given one packet of oral contraceptive pills. Later when the pills are found to be suitable for her, she can be given a supply for a further three months. She must return regularly to the clinic/service centres for getting the required supply and for necessary check-up at a regular interval every year thereafter. The follow-up services/visits to the acceptors of oral pills may be undertaken by paramedical staff working in the National Family Welfare Programme.

The Medical Officers will instruct the paramedical workers to follow the following schedule during routine home visits.

6.1 First Visit

Within 2 weeks after she has been put on pills:

- i. Enquire how she is feeling.
- ii. Treat minor ailments and reassure her.
- iii. Check the pill count from the packet.
- iv. Stress the need to take the pill regularly and to return for more pills before the packet is over.

6.2 Second Visit

The second visit is scheduled one month after she has been put on oral pills.

- i. Find out whether she is taking pills regularly, if not enquire as to why she has discontinued the pills.
- ii. Ask if she has any complaints; if none, give her 3 packets. Stress the need to take pills regularly and to return for more pills before the third packet is over.
- iii. Reassure the beneficiary in case of any complaints and persuade her to continue pills.

6.3 Subsequent Visits

Monthly : Until the side effects cease and the woman is well adjusted to taking the pills regularly.

After six months.

Annually thereafter; or earlier if there is any problem.

- i. Ascertain that she is taking pills regularly.
- ii. Reassure her as needed.
- iii. Treat or refer her for side effects.
- iv. Give her supplies of pills.
- v. Get following information:
 - . Date of LMP
 - . Make sure she does not have any problems
 - . If any problems, see as per check list and return to the Doctor.
 - . Any irregularity in periods

6.4 Medical Check up for Oral Contraceptive Users

First : Before starting the pills or within three months of starting the pills
Subsequently after 6 months, 12 months and then yearly or as and when referred by paramedical workers

- . Weight
- . Blood Pressure
- . Breast palpation
- . Per abdominal examination - Liver
- . Per speculum and per vaginal examination.
- . Urine examination for albumin and sugar
- . H.D. estimation.
- . Cervical smear (if available)

7.0 Logistics and Monitoring of Oral Pill Programme

7.1 Procurement and Storage of Oral Pills

The oral pills are procured by the Government of India, Ministry of Health and Family Welfare and are stored in various medical stores depots. These pills are supplied to States/Union Territories as per instructions from the Ministry of Health and Family Welfare on the basis of the requirements from States/Union Territories from time to time. A requisition in the following form is required to be sent by the States/Union Territories for supply of oral pills to them.

Requisition Form

1. Balance as on 1.4.
2. Stock received during the period/year under report.
3. Quantity (in cycles) consumed during the period/year under report.
4. Balance available as on / /
5. Quantity (in cycles) required
6. Instructions for supply if any.
7. Any other remarks.

It is important that the medical institution/hospital and other peripheral centres should

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normally have a stock of oral pills for 6-8 weeks depending upon their monthly consumption. It may be noted that the oral contraceptive pills have no expiry date. However, they should be stored by the acceptor with due care. The acceptor should also store the packet of pills carefully in her home and at such a place where children have no access

7.2 Management Information System

This is one of the most important components for the growth of oral pill acceptors in the National Family Welfare Programme. The working of the oral contraceptive programme should be monitored effectively for the reporting of information in time and regularity by the concerned peripheral centres etc. The following records of acceptors in the register for the users of oral pills may be maintained at the peripheral centres for reporting of information in the prescribed proforma from time to time.

Register for Users of Oral Pills	
1.	Serial No.
2.	Name of the oral pill acceptor
3.	Age of the acceptor (in years)
4.	Residential/Home Address
5.	Quantity of oral pill supplied (in cycles)
6.	Date of commencement of oral pills
7.	Follow up record
8.	Cumulative number of cycles of oral pills supplied from 1.4. To the date under report
9.	Remarks
	Discontinued
	Reasons
	No. Of cycles of use

7.3 Monthly Statistical Returns/Reports

With a view to monitor and evaluate the working of the oral contraceptive pill programme it is essential that the peripheral centres should report information regularly to the concerned District Family Welfare Officer for consolidation as per proforma given at Annexure VI. He would further be sending the consolidated monthly report for the entire district to the State Family Welfare Officer, who in turn would be compiling the information for all the districts in the state for onward transmission to the Government of India for evaluation and feed back to the State/UT Government with comments/views for further improvement in the reporting system of information.

The peripheral centres are required to submit their monthly reports on the working of the Oral Contraceptive Programme to the District Family Welfare Officer through the concerned authority.

The District Health Family Welfare Officer may send the information to the State Family Welfare Officer. Regular and timely reporting is an indicator for the efficient running of this programme and as such it is desirable that State Family Welfare Officer should ensure the submission of monthly progress report on oral contraceptive pill programme within 20 days after the close of the month.

ANNEXURE I

Other Brands of Oral Pills

Preparation	Progestogen	Oestrogen
1. Low Dose Pill		
. Oval L	L Norgestrel 0.15 mg	Ethinyl Estradiol 0.03 mg
. Primovlar 30	L Norgestrel 0.25 mg	Ethinyl Estradiol 0.03 mg
. Novelon	Desogestrel 0.15 mg	Ethinyl Estradiol 0.03 mg
2. Standard Dose Pills		
. Ovrall	Norgestrel 0.25 mg	Ethinyl Estradiol 0.05 mg
. Lyndiol	Lynestrenol 1.0 mg	Ethinyl Estradiol 0.05 mg
3. Triphasic Pill		
. Triquilar		
6 Tablets	Norgestrel 0.050 mg	Ethinyl Estradiol 0.03 mg
5 Tablets	Norgestrel 0.075 mg	Ethinyl Estradiol 0.04 mg
10 Tablets	Norgestrel 0.125 mg	Ethinyl Estradiol 0.03 mg

ANNEXURE II

Check List for Selection of Oral Pill Acceptors

History/Examination	No	Yes
1. Age more than 40 years		
2. Smoker + Age more than 35 years		
3. Taking Oral Contraceptive continuously over 5 years		
4. Pregnancy		
5. Nursing a baby less than 6 months		
6. H/o Jaundice within past 6 months		
7. H/o Jaundice during pregnancy		
8. H/o Migraine		
9. H/o Stroke		
10. H/o Thromboembolism		
11. H/o Fits		
12. Abnormal vaginal bleeding - intermenstrual/Post Coital		
13. H/o Amenorrhoea/Oligomenorrhoea		
14. H/o Taking Drugs - see Annexure V.		
15. Gross Obesity		
16. Hypertension		
17. Jaundice		
18. Dyspnoea		
19. Oedema over legs		
20. Severe varicosities		
21. Lump in breast		
22. CVS - abnormality		
23. Liver - enlarged/tender		
24. Sugar in urine		
25. Hb below 8 gm		

ANNEXURE - III

Check List

Fill the following check list before selecting an acceptor for oral pill.
If any of them is positive, then she should be referred to medical officer.

Yes No

1. Age above 40 years
2. Smoker aged above 35 years
3. Taking Oral Pills continuously for more than 5 years
4. Pregnancy
5. Lactating less than 6 months
6. Complaint of prolonged/frequent headache
7. Visual disturbances
8. Breathlessness on exertion
9. Fits
10. Persistent/frequent attacks of pain in abdomen
11. Irregular vaginal bleeding
12. History of taking drugs
13. Repeated skin rashes
14. Gross malnutrition
15. Gross obesity
16. Yellow skin and conjunctiva (Jaundice)
17. Pulse rate above 120/min
18. Oedema of extremities
19. Lump in breast
20. Sugar in urine - Diabetes
21. Albumin in urine

If the above are answered in negative, except No. 2, she may be selected for oral contraceptive. If any of the above, except 2, are answered in positive the patient must be seen by a physician before oral contraceptive is prescribed.

Patient with history of toxæmia of pregnancy should not be put on oral pill.

Management of Side Effects

Side Effect	Action	Management
. Nausea	Exclude pregnancy and Other causes (e.g. Hepatitis).	Instruct to take the pill at bedtime
. Weight gain	Enquire about diet and exercise.	Advise proper nutrition and exercise. Assure her that pills have only slight effect on weight.
. Spotting/ Breakthrough bleeding	Exclude gynaecological problem by doing P/S, P/V examination	Reassure If unacceptable - . Pills containing 50 ugm Ethinyl Estradiol or Triphasic pill may be tried for 3 cycles . Return back to low dose pills
. Acne	Enquire about cleaning face, use of face creams	Advise cleaning the face Stop using face creams Pills containing 50 ugm Ethinyl estradiol may be tried.
. Hypertension	. Check B.P. after rest for 15 minutes . Weekly record for 3 visits	. Discontinue if B.P. above 190 mm Systolic / 110 mm diastolic. . Discontinue if B.P. above 160 mm systolic/90 mm diastolic.
. Amenorrhoea	Ensure regular intake Exclude pregnancy	. Continue for 2 cycles . Discontinue if 2 periods are missed . For persistence of amenorrhoea even after discontinuation of pills, Investigate for secondary amenorrhoea . Use of pills containing 50 ugm Ethinyl estradiol may be tried.
. Headache	Worsening on pills	Discontinue
. Depression	Worsening on pills	Discontinue

Drugs Reducing Efficacy of Pills

Antibiotics	Anticonvulsants	Antifungal
. Rifampicin	. Barbiturates (Phenobarbitone)	. Griseofulvin
. Sulfonamides	. Carbamazepine (Tegretol)	
. Cephalosporins	. Phenytoin (Dilantin)	
. Metronidazole		

Efficacy of Drugs Affected by Pills

Drug	Effect
1. Phenytoin	Increased risk of toxicity
2. Aminophylline/ Theophylline	Increased risk of toxicity
3. Tricyclic antidepressants	Increased effect
4. Beta blocking agents	Increased effect
5. Diazepam	Increased effect
6. Antidiabetic agents	Decreased effect
7. Methyl Dopa	Decreased effect

Monthly report of Pill Usage

1. Name of the Centre

2. Number of New Users

3. Continuing Users

< 3 months

4 - 6 months

6 - 12 months

13 - 24 months

25 - 36 months

37 - 48 months

49 - 60 months

.> 60 months