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5 HORMONAL CONTRACEPTION

1 Introduction

Hormonal methods provide millions of users with safe and effective contraception. All hormonal methods are systemic in nature and are based on either a progestogen combined with an oestrogen or a progestogen alone. The methods discussed in this chapter are:

- Combined oral contraceptives (COCs);
- Progestogen-only pills (POPs);
- Progestogen-only injectable contraceptives (POIs);
- Combined injectable contraceptives (CICs); and
- Subdermal implants.

2 Combined Oral Contraceptives (COCs)

2.1 Definition

Combined oral contraceptives (COCs) are preparations of synthetic oestrogen and progestogen which are highly effective in preventing pregnancy. There are 2 types of COCs:

- *Monophasic*: A fixed concentration of oestrogen and progestogen hormones throughout the cycle. Currently available COCs are usually a combination of ethinyloestradiol in doses that range from 15 to 50 μg and a progestogen. These are taken in constant amounts for 21 days, followed by an interval of seven days. During the interval, no active pills are taken. However, in some brands either placebo or iron pills are taken.



- *Multiphasic*: 2 (biphasic) or 3 (triphasic) variations of concentration of oestrogen and/or progestogen throughout the cycle. There is no evidence that multiphasic COCs are more effective or safer than monophasic COCs, and their clinical effects are similar.



The progestogens contained in existing pills include levonorgestrel, norethisterone, desogestrel, gestodene, cyproterone acetate, drospirenone and norgestimate.

Mode of action: The contraceptive effect of COCs is mainly due to inhibition of ovulation; they also cause thickening of the cervical mucus, making it difficult for sperm to pass into the uterine cavity and move towards the fallopian tubes. The receptivity of the endometrium to the blastocyst is also reduced, although there is no evidence that this change contributes to the contraceptive effectiveness.

2.2 Indications

COCs should be provided to any woman who requests them after appropriate counselling and reaching an informed decision, and who does not have any contraindication (a condition that is category 4 in the World Health Organization (WHO) medical eligibility criteria) to their use.

COCs may be particularly appropriate for women who wish to use hormonal contraception and who:

- Want a highly effective method of contraception.
- Are motivated and willing to use a method which requires action daily, and will be able to obtain supplies on a continuous basis.
- May benefit from one or more of the ancillary protective health effects of COC use. This would apply to women who have:
 - Anaemia from heavy menstrual bleeding.
 - A history of ectopic pregnancy.

- Painful menstrual periods.
- Recurrent benign ovarian cysts.
- A history of, or are at risk of, acute pelvic inflammatory disease (PID).
- Family history of ovarian cancer.

2.3 Medical eligibility criteria

The International Planned Parenthood Federation and other bodies have collaborated with the WHO in the development of eligibility criteria for the use of various contraceptive methods. The following classification (the WHO medical eligibility criteria) was agreed:

- *Category 1:* A condition for which there is no restriction for the use of the contraceptive method.
- *Category 2:* A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
- *Category 3:* A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
- *Category 4:* A condition which represents an unacceptable health risk if the contraceptive is used (i.e., the contraceptive is contraindicated).

Pregnancy itself is no longer listed as a contraindication to starting or continuing use of a hormonal method of contraception because women who are already pregnant do not require contraception (i.e., there is no indication for contraceptive use). If COCs are used in the unknown presence of pregnancy, there is no harm for the woman, the course of her pregnancy or her fetus; however, they should be stopped if pregnancy is confirmed because there is no indication for their use.

Category 4 (contraindications)

COCs should not be used in the presence of:

- Breast-feeding and less than 6 weeks' postpartum.
- Current and history of ischaemic heart disease or stroke.
- Smoking 15 or more cigarettes daily in a woman aged 35 years or more.
- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).
- Hypertension with vascular disease.
- Migraine with aura.

- Diabetes mellitus with vascular complications (including hypertension, nephropathy, retinopathy or neuropathy) or of > 20 years' duration.
- Past or present evidence of deep vein thrombosis or pulmonary embolism (DVT/PE).
- Major surgery with prolonged immobilization.
- Known thrombogenic mutations (e.g., Factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiency).
- Complicated valvular heart disease.
- Breast cancer within the past 5 years.
- Active viral hepatitis.
- Benign or malignant liver tumour.
- Severe (decompensated) cirrhosis.

Category 3 COCs should generally not be used in the presence of:

- Smoking up to 15 cigarettes daily in a woman aged 35 years or more.
- Raised blood pressure (systolic 140-159 or diastolic 90-99 mmHg).
- History of hypertension (where blood pressure cannot be evaluated) or adequately controlled hypertension, where blood pressure can be evaluated.
- Known hyperlipidaemia.
- Migraine without aura in a woman aged 35 years or more (if migraine develops during use of COCs, it becomes a category 4 contraindication).
- History of breast cancer with no evidence of disease for the last 5 years.
- Breast-feeding from 6 weeks' to less than 6 months' postpartum.
- Less than 21 days postpartum.
- Mild compensated cirrhosis.
- History of cholestasis related to past COC use.
- Symptomatic gallbladder disease.
- Drug treatment affecting liver enzymes: rifampicin and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine).

When any category 3 condition is present explain the potential risks to the client and counsel her about alternative methods (see also chapter 2: Counselling). If the client chooses a COC because other contraceptive

options are not available or are unacceptable, the method should be provided by a properly qualified practitioner and she should remain under medical supervision.

If a woman has more than one of the first five conditions above, which increase the risk of cardiovascular disease, clinical judgment must be exercised. In most instances, the combined conditions should be regarded as belonging to category 4 (contraindication).

If the method is provided, record the woman's special condition in the clinical record and advise her of warning signs relevant to her condition.

Category 2

COCs can generally be used with precaution in the presence of:

- Smoking in a woman aged less than 35 years.
- Migraine without aura in a woman aged less than 35 years (if migraine develops during COC use, it becomes category 3).
- Diabetes mellitus without vascular complications.
- Family history of DVT/PE (in first-degree relatives).
- Breast-feeding and 6 months or more postpartum.
- Superficial thrombophlebitis.
- History of high blood pressure during pregnancy (where current blood pressure is measurable and normal).
- Uncomplicated vascular heart disease.
- Unexplained vaginal bleeding, suspicious of a serious condition, before evaluation.
- Cervical intraepithelial neoplasia (CIN) or cervical cancer (awaiting treatment).
- Undiagnosed breast mass.
- Symptomless gallbladder disease.
- Sickle cell disease.
- Obesity 30 kg/m² body mass index (BMI).
- Treatment with griseofulvin.
- Antiretroviral therapy.

When any of these conditions are present, careful screening and appropriate monitoring will allow the benefits of using COCs to outweigh any potential risks. However, when a woman has more than one of the first three conditions, which increase the risk of cardiovascular disease, clinical judgment must be exercised. In most instances, the combined conditions should be regarded as belonging to category 3.

If the method is provided, record the woman's special conditions in the clinical record and advise her of warning signs relevant to her condition.

2.4 Special situations

Special consideration needs to be given in certain circumstances (see Table 5.1).

Table 5.1—Conditions that require special consideration

First 3 weeks postpartum	Elective surgery	Sickle cell disease
Lactation	Drug interactions	Varicose veins
Adolescents	Abnormal vaginal bleeding	Parasitic diseases
Age over 35 years	Malignancy of the genital tract	Positive HIV status and AIDS

First 3 weeks postpartum

COCs should not be used during the first 3 weeks after delivery to avoid the risk of thromboembolic complications, whether or not the mother chooses to breast-feed. After 21 days, blood coagulation and fibrinolysis are essentially back to normal, and COCs can then be used if the mother chooses not to breast-feed. Progestogen-only pills (POPs) can be started at any time after delivery if the mother chooses not to breast-feed.

Lactation

During lactation, withhold COCs until 6 months after delivery or until the infant is weaned, whichever is earlier. Use of COCs during breast-feeding diminishes the quantity of breast milk, decreases the duration of lactation and may thereby adversely affect the growth of the infant. If the mother wishes to start oral contraception during breast-feeding, POPs should be recommended and can be started after the sixth week postpartum (see section 3.4).

Adolescents

The benefits of COCs are especially important for adolescents who are at risk of pregnancy. Indications and contraindications are the same in this age-group as for older women.

Women aged over 35 years

COCs can be used by most healthy women over 35 years of age if there are no cardiovascular risk factors, such as smoking, hypertension or diabetes mellitus.

Elective surgery

The degree of risk of DVT/PE associated with major surgery varies depending on the length of time a woman is immobilized. COCs should be stopped approximately 4 weeks before any elective surgery that involves prolonged immobilization, which increases the risk of deep vein thrombosis (DVT). COCs can be restarted 2 weeks after the woman is ambulant. Advise on the use of alternative effective contraception if needed during this time. In emergency procedures, the surgeon may consider the use of prophylactic anticoagulant measures and should encourage early mobilization.

Drug interactions

Drugs that induce liver enzymes, particularly those used in long-term treatments, may reduce the efficacy of COCs. Such drugs include rifampicin, griseofulvin, phenytoin, ethosuximide, carbamazepine, glutethimide, barbiturates, primidone, topiramate, oxcarbazepine and some antiretroviral agents. Interference should be suspected if a client has inter-menstrual bleeding and spotting when using any of the above drugs together with COCs. Advise on alternative or supplementary forms of contraception.

Abnormal vaginal bleeding

If a woman has vaginal bleeding suggestive of a condition related to pregnancy or of underlying pathology such as pelvic malignancy, it should be investigated before starting COCs. However, irregular menstrual bleeding patterns are not uncommon among healthy women: do not withhold COCs in the absence of any reason to suspect a pathological condition.

Malignancy of the genital tract

Women with cancer of the genital tract may use COCs while awaiting treatment. With most genital tract malignancies, the treatment is such that there will be no further pregnancies. *However, if the condition is diagnosed at a time when the woman is using no contraceptive method, she may need contraceptive protection while awaiting treatment.*

Women with pre-malignant disease of the cervix which has been successfully treated will generally preserve their fertility and can continue to use any method of contraception, including COCs.

The treatment of choriocarcinoma may not preclude further pregnancies; pregnancy should be avoided during treatment and follow-up so that the disease can be monitored properly, and COCs may be used if this method is chosen by the woman.

Sickle cell disease

Sickle cell trait is not a contraindication to the use of COCs, but women with homozygous sickle cell disease may be at increased risk of thrombosis. Recommend the use of other contraceptive methods to these women, especially long-acting progestogen-only contraceptives, which may have a beneficial effect on sickle cell disease.

Sexually transmitted infections (STIs)

There is some evidence that COCs may protect against pelvic inflammatory disease (PID). However, hormonal contraceptives do **not** protect against STIs, including HIV, and clients must be made aware of this fact. Advise use of condoms to any client at high risk of acquiring STIs.

Varicose veins

COCs may be used by women who have uncomplicated varicose veins with no history of DVT and who otherwise have no contraindications.

Parasitic diseases

The use of COCs has not been found to be affected by parasitic diseases although more research is needed in this area, particularly into any possible interactions with antiparasitic drugs.

Positive HIV status and AIDS

Although there is little scientific evidence on this subject, current opinion is that COCs are safe for use by women who are HIV positive. However,

interactions with some antiretroviral drugs (ARVs) may affect the efficacy or toxicity of the COC or the ARV.

2.5 Counselling and information

All clients must receive appropriate counselling for the selection and use of COCs before starting this method of contraception. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up at the outset. (See also chapter 2: Counselling.)

Selection of COCs as means of contraception

Discuss the following points clearly with each client in language that she understands:

- Advantages and disadvantages of COCs including effectiveness, risks and benefits, side-effects and cost. (Reassure clients that any increase in the risk of cancer would be minimal, and that there is definite evidence that COCs protect against cancers of the ovary and endometrium).
- Alternative family planning methods, including information on effectiveness, risks and benefits, side-effects and cost as appropriate.
- Selection of the most appropriate type of COC.
- Remind clients who smoke that smoking increases the risks of serious circulatory disorders, and advise all women who intend to use COCs to stop smoking.

Use of COCs

See section 2.9 of this chapter.

2.6 Who can provide COCs?

Doctors, non-doctor clinic personnel and community health workers trained in the education and counselling of clients can provide oral contraceptives, depending on local regulations and practice. Whoever normally meets the health needs of the community can be an appropriate person to distribute COCs. Community-based services (CBS) is the term used when COCs are provided in the community through non-clinical services (see Box 5.1).

Box 5.1-Provision of COCs by community-based services (CBS)

The community or field worker must: (a) be given appropriate training; (b) follow clear guidelines; and (c) have adequate supervision and back-up referral facilities.

Training should include the use of appropriate checklists (see checklist for dispensing COCs in CBS on page 144) to guide the worker in the identification of clients who need to visit a health care facility or SRH/family planning clinic for screening their eligibility for COC use.

Social marketing, by which contraceptives are provided over the counter through subsidized commercial channels, is another method of COC provision. **Social marketing programmes should ensure adequate client information and education about the proper use of the method and what to do if there are any concerns or need for further information, while protecting the rights of clients to privacy and confidentiality.**

See section 4 of this chapter for further information.

2.7 Health assessment

The purpose of the health assessment is to determine the client's suitability to use this method of contraception. It should also be taken as an opportunity to offer the client other available sexual and reproductive health services as appropriate.

Community-based family planning services (CBS)

The CBS health assessment consists of identification of those conditions which require referral for a more complete clinical assessment (see the checklist for dispensing oral contraceptives in CBS on page 144).

Workers in clinical facilities that provide COCs should be prepared to offer a health assessment to clients who are referred from the CBS or the social marketing system.

Clinical services

Health assessment at the clinic should include medical and relevant social history, physical examination and any necessary laboratory examinations.

- *Medical and social history:* At the clinic a medical and social history should be obtained with special attention to conditions relevant for medical eligibility (see sections 2.3 and 2.4 of this chapter). It should include age, relevant family and past medical history, gynaecological history including last menstrual period and menstrual pattern, smoking history and any current medications.
- *Physical examination:* The initial physical examination at the clinic should include weight, blood pressure, examination for varicosities or signs of deep vein thrombosis, check of the skin and eyes for jaundice, breast examination and other examinations as indicated by the medical and social history. Bimanual pelvic examination and speculum vaginal examination are not required for prescription and use of COCs, but whenever possible and appropriate they should be offered to women as part of reproductive health services.
- *Laboratory tests:* These are not routinely required for the use of COCs, except when indicated by medical history and physical examination. Whenever possible and appropriate, selected tests should be offered to women as part of reproductive health services, including:
 - Urine analysis for glucose and protein.
 - Syphilis screening (with VDRL).
 - Cervical cancer screening should start 2-3 years after the onset of sexual activity and be repeated every 1-3 years (see chapter 4: Reproductive health screening for well women).

If the medical history gives no reason to suspect a category 4 contraindication, COCs should not be withheld because part or all of the physical or laboratory examinations are lacking. COCs should be started, but all the required examination(s) should take place within the following 3 months.

The medical/social history and the results of the examinations must be documented in the clinical record of each client, especially the presence of any conditions that fall under category 2, 3 or 4 of the medical eligibility criteria.

2.8 Choice of COC

COCs that contain the lowest effective and acceptable dose of oestrogen and progestogen should be used for all clients.

- Start with a combined monophasic preparation which contains 30-35 µg of oestrogen.
- Change the dose or type of pill only if there are side-effects significant enough to cause the client to consider discontinuing or changing pills (see section 2.12).

The progestogens contained in the COCs presently available include levonorgestrel, norethisterone, desogestrel, gestodene, cyproterone acetate, norgestimate and drospirenone. There are no medical reasons to prefer any of them although they differ in cost and this will be a consideration. Desogestrel and gestodene may carry a small additional risk of DVT/PE beyond that of COCs which contain levonorgestrel. The 30 µg ethinyloestradiol/150 µg levonorgestrel combination is the pill for which the most information on safety is available, and is the most widely used.

NOTE: For information about brand names and composition of oral contraceptives available around the world, see the IPPF's *Directory of Hormonal Contraceptives* (available from IPPF's website at: www.ippf.org).

2.9 Instructions to the client

COCs are available in packets of:

- **21 pills**, where 1 pill containing the oestrogen/progestogen combination is taken every day for 21 days, then a break from pill-taking occurs for 7 days before starting a new packet; *and*
- **28 pills**, where 1 pill containing the oestrogen/progestogen combination is taken every day for 21 days then, instead of a break, 7 placebo or iron pills are taken as the other pills in each packet to complete a full 28-day cycle.

Use a sample pill packet to explain its use. If the client is to use a 28-day packet, explain to her about the placebo pills representing the week when the menstruation will occur. Show the client how to distinguish between the active and the placebo pills. The placebo pills usually have a different colour, different size or both. Provide the instructions clearly and in terms that will be readily understood by the client.

Starting the pill

The client can start the first cycle of pills within the first 5 days of her menstrual period, preferably on the first day. Some women find it convenient to start the pill on a particular day of the week (e.g., Sunday); if a woman wishes to do so and that day is beyond the fifth day of her menstrual cycle, make reasonably certain that she is not pregnant and advise her to use additional contraceptive protection against pregnancy for the next 7 days.

For the amenorrhoeic client

- She can start COCs at any time, if it is reasonably certain that she is not pregnant.
- She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

For the postpartum client

- If the client is breast-feeding and she wishes to use the pill, recommend the progestogen-only pill, which can be started after the sixth week postpartum (see section 3.8). COCs should be withheld until 6 months postpartum or until the infant is weaned, whichever is earlier.
- If not breast-feeding, the client can start the pill at 3-6 weeks' postpartum (blood coagulation and fibrinolysis are essentially back to normal 21 days after delivery). If the client wishes to start after the sixth week postpartum and she has not yet seen the first postpartum menses, rule out the possibility of pregnancy before starting the COC (see chapter 11: Diagnosis of pregnancy).

Switching from another hormonal method

- The client can start COCs immediately if she has been using her other hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- If her previous method was an injectable contraceptive, she should start COCs when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

- The client can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She can also start COCs at any time if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the first 7 days of COC use.

Switching from an IUD (including a hormone-releasing IUD)

- The client can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- The client can also start COCs at any time if it is reasonably certain that she is not pregnant.
- If the client has been sexually active in the current menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
- If she has not been sexually active in the current menstrual cycle and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the first 7 days of COC use. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- If she is amenorrhoeic or has irregular bleeding she can start COCs as advised for other amenorrhoeic women.

Taking the pill

The client should take 1 pill every day at the same time until the packet is finished; advise the client that she should not interrupt taking the pills before a packet is finished, even if she does not have sexual intercourse.

Starting a new packet

- If the client is using the 28-pill packet, she should start a new packet without a break the day after she finishes the previous packet.

- If the client is using the 21-pill packet, she should skip 7 days before starting a new packet.

If the pills are taken correctly, the client will always start a new packet on the same day of the week.

Missed pills

Emphasize the importance of not forgetting any pill. Advise the client that if she misses one or more hormonal pills, she may have some spotting or breakthrough bleeding and, more importantly, that she will be at a greater risk of becoming pregnant. The greatest risk is when the client misses hormonal pills at the beginning or at the end of the cycle, because that is equivalent to prolonging the interval during which she does not take hormonal pills. Give the client the following instructions:

For 30-35 µg ethinyloestradiol pills

- *If 1 or 2 hormonal pills are missed*, the client should take that pill as soon as she remembers. The client should take the next pill at the usual time; this might mean that she has to take 2 pills on the same day or at the same time. She does not need any additional contraceptive protection.
- *If 3 or more consecutive hormonal pills are missed or she starts a pack 3 or more days late*, the client should take the hormonal pill as soon as possible and then continue taking pills daily, one each day. She should also use condoms or abstain from sex until she has taken hormonal pills for 7 days in a row.
 - If she missed the pills in the third week she should finish the hormonal pills in her current pack and start a new pack the next day, not taking the 7 inactive pills.
 - If she missed the pills in the first week and had unprotected sex, she may wish to consider the use of emergency contraception (see chapter 10, Emergency contraception).

For 20 µg or less ethinyloestradiol pills

- *If the client misses 1 hormonal pill*, she should follow the above instructions for missing 1 or 2 30-35 µg ethinyloestradiol pills.

- *If the client misses 2 or more hormonal pills or if she starts the pack 2 or more days late, she should follow the above instructions for missing 3 or more 30-35 µg ethinylloestradiol pills.*

For 30-35 µg and 20 µg or less ethinylloestradiol pills

- *If 1 or more non-hormonal (placebo) pills are missed, the client should discard the missed placebo pill(s) and continue taking the remaining pills once daily. Start the new pack as usual. No additional contraceptive protection is required.*

Whenever possible, ensure that the supply given to the woman will allow her to have a standby packet of pills always available. It might be good practice to provide the woman with a supply of condoms when she is given her initial packets of pills in case she needs to use them for additional protection.

Vomiting and diarrhoea

Acute vomiting and/or diarrhoea will interfere with the effectiveness of COCs. If vomiting occurs within 1 hour after taking an active hormonal pill, the client should take another active pill. If symptoms persist for more than 24 hours, recommend the use of additional contraceptive protection until the client has been without these symptoms for 7 days. If severe vomiting or diarrhoea continues for more than 2 or more days, she should follow the procedure for missed pills.

Other medications

Tell the client that certain medicines reduce the effectiveness of COCs, so she must always share information on all her medications with all providers of health and family planning care, whatever the reason for her consultation.

Side-effects

Advise the client about possible side-effects (see section 2.12).

Warning signs

Advise the woman to consult a clinic if pregnancy is suspected or if she experiences any of the following warning signs of complications:

- Severe abdominal pain.
- Severe chest pain, cough or shortness of breath.
- Severe headache.
- Loss of vision or blurring.
- Severe pain in calf or thigh.
- Jaundice (yellowness of the eyes and skin).

To prevent anxiety, explain to the client that serious complications of COC use are very rare. You can reassure her that her health will be better protected by use of this highly reliable method of contraception than if an unintended pregnancy were to occur.

Follow-up

Advise the client to visit a clinic or to see a CBS worker about 3 months after starting COCs for a routine follow-up. Thereafter, a routine annual follow-up is advisable.

Tell the client the date of the next visit and the name of the pill she has been given. If the client is being seen at a clinic, make sure that she knows the clinic name, address and telephone number. If the client is being given pills through CBS, then give her the name, address and telephone number of the nearest clinical facility to consult if any problems should arise. This information, and a list of warning signs to look out for, can be put on a card or leaflet and given to the client: it should be written and presented in a way in which the client or somebody close to her (in case the client cannot read) can readily understand.

Encourage the client to ask questions to clear up any uncertainties and ask her to repeat the basic instructions to check that she understands them.

2.10 Follow-up care

Routine follow-up at a clinic or by a CBS worker is recommended at about 3 months after starting COCs, and annually thereafter.

3-month follow-up protocol

- Update the client's address and how to make contact with her.
- Assess the client's satisfaction with the method.
- Determine if the client has had any problems or possible side-effects and, if so, record them in the clinical record.
- If any serious problem or side-effect is detected in the CBS, refer the client to a clinical facility.
- At the clinic, update the medical history; measure blood pressure and weight; and perform any other examination which may be indicated by the history.
- Provide appropriate counselling and/or treatment as required.
- Review with the client her instructions for taking COCs and the warning signs to look out for, then re-supply her with COCs and give instructions for annual follow-up.
- Encourage the client to contact a CBS worker or the clinic at any time if she has any questions, complaints or problems.

Annual follow-up protocol

- Follow the 3-month protocol with an updated medical history and an assessment of satisfaction with the method.
- Offer the client other relevant reproductive health services available at the facility, such as cervical cancer screening.

Duration of use: In women who are otherwise well, COCs may be continued for many years, with no need for periodic discontinuation.

2.11 Provision of COCs

The supply system should be flexible, so that the client can obtain pills easily in the amount and at the time she requires. It is important to keep the number of re-supply visits to a minimum. In general, if the client does not request otherwise, provide 3 cycles of pills at the first encounter, then up to 10 cycles at the 3-month follow-up encounter if there are no problems. At the first annual follow-up, and annually thereafter, a full

year's supply of 13 cycles may be given if there continue to be no problems or conditions that require particular consideration. In certain cases service providers may find that a smaller supply is more convenient for some clients (e.g., those who may not be able to store so many pills safely).

2.12 Side-effects

The following side-effects (which should not be a reason to discontinue the method) are common during the first 3 cycles of COC use, and then usually disappear:

- Breakthrough bleeding;
- Mild nausea and/or dizziness;
- Breast tenderness; *and*
- Mild headaches.

Other side-effects include weight gain, fluid retention and depression.

Most side-effects are usually tolerated by clients if they are supported by counselling. Sometimes symptomatic treatment may be required. If this management does not help, or if the problem is of serious concern to the client, consider whether she should discontinue COCs and, if so, advise her about alternative methods of contraception.

Missed periods (amenorrhoea) may also occur because of taking COCs, which necessitates ruling out pregnancy (see chapter 11: Diagnosis of pregnancy), especially if pills have been missed or taken late. If missed periods continue in the absence of pregnancy, reassure the client that this does not mean any health risk. Another type of pill may be tried.

2.13 Service management

See section 4 of this chapter.

3 Progestogen-only pills (POPs)



3.1 Definition

The progestogen-only pill (POP) is an oral hormonal contraceptive that contains a progestogen only, in a smaller dose (typically 10-50%) than that used in the combined oestrogen/progestogen pill. Thus, depending on the type of progestogen, POPs may contain only 30 µg (e.g., for levonorgestrel) to 600 µg (e.g., for norethisterone) of progestogen (0.03-0.6 mg).

The most commonly available POPs contain levonorgestrel, desogestrel, norethisterone or lynestrenol. One pill is taken regularly at the same time every day, without a break, regardless of the bleeding pattern. The efficacy of the POP is slightly lower than that of the COC, especially in younger women, but is effectively similar to that of the COC in women aged over 35 years.

NOTE: For information about brand names and composition of oral contraceptives available around the world, see the IPPF's *Directory of Hormonal Contraceptives* (available from IPPF's website at: www.ippf.org).

Mode of action: As with other progestogen-only contraceptives, the POP has 2 modes of action:

- The effect of the progestogen on cervical mucus is the main factor in the contraceptive efficacy of POPs. The mucus becomes viscous and scanty, inhibiting sperm penetration.
- The progestogen acts on the hypothalamus and pituitary, and suppresses the LH surge responsible for ovulation. Ovulation is prevented in at least half of the cycles.

Progestogens also cause histological changes in the endometrium according to the dose administered; there is no evidence that these changes contribute to the contraceptive effect.

3.2 Indications

Progestogen-only pills should be provided to any woman who requests them after appropriate counselling and reaching an informed decision, and who does not have any contraindication (a condition that is category 4 in the WHO medical eligibility criteria) to their use.

POPs are particularly appropriate for women who wish to use oral hormonal contraception and have a condition that preclude the use of oestrogens, such as those who are breast-feeding.

3.3 Medical eligibility criteria

POPs have no effect on blood pressure or coagulation factors and a negligible effect on lipid metabolism and liver function. They therefore have fewer medical eligibility restrictions than COCs.

Category 4 (Contraindications)

POPs should not be used in the presence of:

- Breast cancer within the past 5 years.

Counsel any woman who has a contraindication to POPs as well as COCs about alternative methods of contraception (see also chapter 2: Counselling).

Category 3

POPs should generally not be used in the presence of:

- Current deep vein thrombosis or pulmonary embolism (DVT/PE).
- Active viral hepatitis.
- Liver tumour (benign or malignant).
- Severe decompensated cirrhosis.
- History of breast cancer with no evidence of disease for the last 5 years.
- Breast-feeding and less than 6 weeks postpartum.
- Drug treatment affecting liver enzymes: rifampicin and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine).

When any category 3 condition is present, explain to the client the potential risks and counsel her about alternative contraceptive methods.

If the client chooses POPs because other contraceptive options are not available or are unacceptable, it is particularly important to advise her that close medical follow-up is required.

Category 2

POPs can generally be used with precaution in the presence of:

- Current or history of ischaemic heart disease or stroke (if either develops during POP use, it becomes category 3).
- History of hypertension where blood pressure cannot be evaluated.
- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).
- Hypertension with vascular disease.
- Migraine with aura or development of migraine without aura at any age during POP use (if migraine develops during POP use, it becomes category 3) .
- Diabetes with or without complications (history of gestational disease is category 1).
- History of DVT/PE.
- Major surgery with prolonged immobilization.
- Mild compensated cirrhosis.
- Gallbladder disease.
- Undiagnosed breast mass.
- Previous ectopic pregnancy.
- Known hyperlipidaemia.
- Irregular, heavy or prolonged vaginal bleeding or unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.
- Treatment with griseofulvin.
- Antiretroviral therapy.

When any of these conditions are present, careful screening and appropriate monitoring will allow the benefits of using POPs to outweigh any potential risks.

3.4 Special situations

The advice given for use of COCs in relation to abnormal vaginal bleeding, drug interactions, STIs and malignancy of the genital tract (see section 2.4) also applies to POPs.

First 3 weeks postpartum

Progestogen-only pills (POPs) can be started at any time after delivery if the mother chooses not to breast-feed.

Lactation

Hormonal methods are not the first method of contraceptive choice for breast-feeding women. Although progestogen-only contraceptives do not seem to interfere with lactation, there is concern that they lead to release into the milk of orally active progestogens which are then absorbed by the infant. Any progestogen method should not be started before the sixth week postpartum by women who are breast-feeding, unless other contraceptive options are not available or acceptable. The estimated daily dose received by the infant is much greater with progestogen-only injectables than with POPs.

Other special situations

POPs may be used by women who otherwise have no contraindications and who:

- Are adolescents.
- Are aged over 35 years.
- Have varicose veins.
- Have sickle cell disease.

3.5 Counselling and information

All clients must receive appropriate counselling for selection and use of POPs before starting this method of contraception. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up at the outset. (See also chapter 2: Counselling.)

Selection of POPs as means of contraception

Please refer to chapter 2: Counselling and to section 2.5 of this chapter. In addition, raise the following points when counselling for the use of POPs:

- In general, the effectiveness of POPs is slightly lower than that of COCs, particularly when a pill is missed.
- Breakthrough bleeding and amenorrhoea are common with POPs.
- If the woman is breast-feeding and concerned about transmission of the

hormone in her milk, explain that there is no present evidence that the amount of hormone found in breast milk as a result of POP use has ever caused a baby any harm.

Use of POPs

See section 3.8 of this chapter.

3.6 Who can provide POPs?

The advice given for COCs in section 2.6 of this chapter also applies to POP provision.

3.7 Health assessment

The purpose of the health assessment is to determine the client's suitability for the use of this method. It should also be used as an opportunity to offer the client other available sexual and reproductive health services.

The guidelines for COC assessment (see section 2.7) also apply in general to clients who receive POPs. However, there are fewer medical eligibility restrictions for POPs (compare sections 2.3 and 2.4 with sections 3.3 and 3.4).

3.8 Instructions to the client

Use a sample pill packet to explain its use. Provide the instructions clearly and in terms that the client will readily understand.

Starting the POP

The client should ideally start the first cycle of pills within the first 5 days of her menstrual period, preferably on the first day. No additional contraceptive protection is then needed. She can also start POPs at any other time, if it is reasonably certain that she is not pregnant, but if it is more than 5 days since menstrual bleeding started she will need to abstain from sex, or use additional contraceptive protection, for the next 2 days.

For the amenorrhoeic client

- She can start POPs at any time, if it is reasonably certain that she is not pregnant.
- She will need to abstain from sex or use additional contraceptive protection for the next 2 days.

For the postpartum client

- If the client is breast-feeding and she wishes to use the pill, she can start POPs after the sixth week postpartum, but not earlier. If a client with lactational amenorrhoea requests the pill between 6 weeks and 6 months postpartum, give POPs if you can establish that she is not pregnant (see chapter 11: Diagnosis of pregnancy).
- If the client is more than 6 weeks postpartum and her menstrual cycles have returned, she can start POPs as advised for other women having menstrual cycles.
- If the client is not breast-feeding, she can start POPs immediately or at any time within the first 6 weeks postpartum. If the client wishes to start after the sixth week postpartum and she has not yet had the first postpartum menses, rule out the possibility of pregnancy before providing the POPs.

Switching from another hormonal method

- The client can start POPs immediately if she has been using her other hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- If her previous method was an injectable contraceptive, she should start POPs when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

- The client can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She can also start POPs at any time if it is reasonably certain that she is not pregnant. However, if it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the first 2 days.

Switching from an IUD (including a hormone-releasing IUD)

- The client can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

- The client can also start POPs at any time if it is reasonably certain that she is not pregnant.
- If the client has been sexually active in the current menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
- If she has not been sexually active in the current menstrual cycle, and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the first 2 days of POP use. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- If she is amenorrhoeic or has irregular bleeding she can start POPs as advised for other amenorrhoeic women.

Taking the POP

The client should take 1 pill every day at the same time until the packet is finished; she should start a new packet the day after she finishes the previous packet, without a break. If the pills are taken correctly, the client will always start a new packet on the same day of the week.

Missed pills

Emphasize the importance of not forgetting any pill, even just for a few hours. Advise the client that if she misses 1 or more pills, she may have some spotting or breakthrough bleeding and, more importantly, that she will be at a greater risk of becoming pregnant. She should restart taking the pills as soon as possible. If she missed taking the pill by more than 3 hours, advise her to abstain from sexual intercourse or use a barrier method of contraception during the first 48 hours after restarting the pills. The use of emergency contraception should be considered if she has already had intercourse during the unprotected period (see chapter 10: Emergency contraception).

If the client is breast-feeding and amenorrhoeic and has missed 1 or more pills by more than 3 hours, she should take the pill as soon as possible and continue to take the pill as usual. If she is less than 6 months postpartum, no additional contraceptive protection is needed.

Other medications

Tell the client that some medicines may reduce the effectiveness of POPs, so she must always share information on all her medications with all providers of health and family planning care, whatever the reason for her consultation.

Side-effects

Advise the client about possible side-effects (see section 3.10).

Follow-up

Tell the client the date of the next visit and the name of the pill she has been given. If the client is being seen at a clinic, make sure that she knows the clinic name, address and telephone number. If the client is being given pills through CBS, then give her the name, address and telephone number of the nearest clinical facility to consult if any problem should arise. This information, and a list of warning signs to look out for, can be put on a card or leaflet and given to the client: it should be written and presented in a way in which the client or somebody close to her (in case the client cannot read) can readily understand.

Advise the client to consult a clinic or to see a CBS worker (if applicable and more convenient) if she experiences a problematic side-effect or has any other concern or problem in relation to the pill.

Encourage the client to ask questions to clear up any uncertainties and ask her to repeat the basic instructions to check that she understands them.

3.9 Follow-up care and provision of POPs

Follow the guidelines given for follow-up and provision of COCs in sections 2.10 and 2.11 of this chapter.

Duration of use: When a special indication for POP use (such as breast-feeding) no longer exists, consideration should be given to the use of COCs, which are more effective and have a better cycle control. However, POPs can be used indefinitely if that is the wish of the client and there are no serious side-effects.

3.10 Side-effects

Common side-effects include breakthrough bleeding, amenorrhoea, breast tenderness and headaches. These side-effects are usually tolerated by the client if supported by counselling, although symptomatic treatment is sometimes required. If this management does not help, or if the problem is of serious concern to the client, consider whether she should discontinue the pill and, if so, advise her on alternative methods of contraception.

3.11 Service management

See section 4 below.

4 Management of oral contraceptive services

An SRH/family planning programme which provides oral hormonal contraception may use complementary approaches — for example, community-based services (CBS) and social marketing as well as clinical services.

CBS services reach individuals who:

- Are beyond the usual catchment area of the clinics; *or*
- Find CBS more acceptable and convenient.

Clinical services:

- Offer a more comprehensive reproductive health service to individuals within their catchment area; *and*
- Give clinical back-up to the CBS.

In addition, a third approach, social marketing, provides some contraceptive methods through subsidized commercial channels.

4.1 Community-based family planning services (CBS)

Health screening checklists

These should be used in CBS to help the service provider to identify possible contraindications to the use of oral contraceptives and/or clients who need to be referred to a clinical facility for further evaluation.

For an example of such a check-list see the work-sheet for dispensing oral contraceptives in CBS on pages 144.

Referral systems

These should be in place so that CBS clients who need further evaluation, request another method of contraception such as an IUD or sterilization, or require other sexual and reproductive health services can be referred to the most convenient and appropriate clinical facility.

- This facility could be a clinic of the government, a family planning association or another non-governmental organization. Links and collaboration between institutions need to be developed for this purpose.
- Physical and/or pelvic examinations are not essential for the provision of oral contraceptives. However, back-up clinical facilities are needed so that such examinations can be available and carried out if necessary.
- If a CBS client has a possible problem related to the use of oral contraception, she should be referred to a clinic. The care provider at the clinic will determine if oral contraceptives:
 - May be used under the supervision of a community health worker;
 - May be used under clinic supervision; *or*
 - Are not indicated and another method is recommended.

The outcome must be communicated to the CBS worker.

Stock of pills

Community-based services should stock no more than 2 types of pills:

- A COC containing 30-35 µg of oestrogen, which is suitable for most women; *and*
- A POP, mainly for use by breast-feeding clients.

Training

Community workers should be trained in the following:

- How to provide information on all available contraceptive options to help the user make her/his own choice of an appropriate method.
- How to provide education and counselling before, during and after the adoption of a contraceptive method.

- How to use checklists for screening of clients.
- How to recognize when the client requires referral to a clinic for further evaluation, based on use of the checklists.
- How to recognize the warning signs of pill complications, to explain them to the client, and to refer her to a clinical facility if required.
- The use of basic records for client management and programme evaluation.

4.2 Clinical services

Client records

A standard clinical record form should be used for all clients. This form serves:

- To document essential client information.
- As a guide for staff to ensure that medical eligibility for pill use is accurately and completely assessed.
- To record the contraceptive method provided and other services given to the client.
- To record follow-up services.

Stock of pills

No more than 4 formulations of COCs should be available:

- 2, or at the most 3, types of low-dose pills (30-35 µg of oestrogen); and
- Not more than 1 high-dose (50 µg oestrogen) pill.

Pills that contain 50 µg of oestrogen should be used only for emergency contraception and in the rare cases where specific conditions make this dose necessary (e.g., drug interactions or when the low-dose pill does not provide adequate cycle control).

- Start all new clients who request oral contraceptives, and for whom there is no contraindication, on low-dose COCs. If side-effects indicate a change of pill, document the reasons.
- In addition, **1 POP formulation should be available**, mainly for use by breast-feeding clients.
- Do not stock or use COCs that contain more than 50 µg of oestrogen.

Training

A system of training should exist so that providers of care obtain current information and skills on all aspects of quality of care and hormonal contraceptive practice. Training should include management of side-effects, as well as updates on the medical eligibility criteria and the possible risks of oral contraceptive use.

Equipment

The basic essential equipment for a clinic that supervises provision of oral contraception is:

- A sphygmomanometer (blood-pressure cuff); *and*
- A weighing scale.

Basic laboratory equipment and access to laboratory facilities at the clinic are desirable, but not essential.

4.3 Provision of pills

Provide 3 cycles of pills at the first encounter if there are no contraindications, then up to 10 cycles at the 3-month follow-up encounter if there are no problems. At the annual follow-up, a year's supply, 13 cycles, may be given if there continue to be no problems or contraindications. In some cases the service providers may find that a smaller supply is more convenient for certain clients. However, it is important to keep the number of re-supply visits to a minimum. **The re-supply system should be flexible, so that the client can obtain pills easily in the amount and at the time she requires.**

4.4 Storage, shelf-life and supplies

- Storage areas for oral contraceptives should be secure, pest-free, well ventilated and moisture-free. Stored packets should be kept out of sunlight. Keep boxes of oral contraceptives at least 10 cm off the floor and at least 30 cm from the walls. Put the date of arrival on each box and use the older ones first.
- Use oral contraceptives within 5 years of the stamped date of manufacture.
- Ensure sufficient supplies for continuing and new users. The necessary amounts for a particular year can be estimated as follows:
 - Multiply the number of expected continuing users by 13 cycles; *and*

- Multiply the number of expected new users by 6.5. The reason for multiplying the number of new users by 6.5 is that they will be starting the pill at different times during the year; on average, they will need only half the cycles required for a continuing user.

5 Progestogen-only injectable contraceptives (POIs)



5.1 Definition

Progestogen-only injectable contraceptives (POIs) are composed of synthetic steroid hormones which resemble the female hormone progesterone. The injectable preparation is released slowly into the bloodstream from the site of injection in the muscle. A single injection provides safe and highly effective contraception for 2 or 3 months. The most commonly used POIs are:

- Depot medroxyprogesterone acetate, or DMPA: each dose of 1ml contains 150 mg of DMPA and is given every 3 months.
- Norethisterone oenanthate, or NET-EN: each dose of 1ml contains 200 mg of NET-EN and is given every 2 months.

Mode of action: As with other progestogen-only contraceptives, POIs have 2 modes of action:

- Effect of the progestogen on cervical mucus, which becomes viscous and scanty, thus inhibiting sperm penetration.
- The progestogen acts on the hypothalamus and pituitary and suppresses the LH surge responsible for ovulation. Ovulation is prevented in at least half of the cycles.

In most cases the endometrium shows signs of suppression. However, this effect does not play an important role in the efficacy of POIs because the changes in cervical mucus and anovulation would prevent fertilization.

5.2 Indications

POIs should be provided to any woman who requests them after appropriate counselling and reaching an informed decision, and who does not have any relevant contraindication to their use.

POIs may be particularly appropriate for women who:

- Want a highly effective method of contraception.
- Are breast-feeding.
- Desire the convenience of not having to keep contraceptive supplies at home.
- Have problems remembering to take oral contraceptives.
- Should not use oestrogen-containing contraceptives.
- May clearly benefit from the ancillary protective health effects of POI use:
 - *Sickle cell disease*: Women who use DMPA have significantly fewer crises.
 - *Anaemia*: POIs can increase haemoglobin concentration, mainly by reducing blood loss.

5.3 Medical eligibility criteria

Historically, the contraindications to POIs were considered to be the same as for COCs. However, POIs have no effect on blood pressure or coagulation factors (and therefore pose no risk of venous thrombosis), have a negligible effect on lipid metabolism and have very little effect on liver function. Thus contraindications for POIs may be considered separately from those for COCs.

Category 4 (Contraindications)

Do not advise the use of POIs or provide them to women with:

- Breast cancer within the past 5 years.

Category 3

The use of POIs should generally not be used in the presence of:

- Current deep vein thrombosis or pulmonary embolism (DVT/PE).
- Current or history of ischaemic heart disease or stroke.
- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).

- Hypertension with vascular disease.
- Diabetes mellitus with vascular disease (including nephropathy, retinopathy or neuropathy) or of > 20 years' duration.
- Active viral hepatitis.
- Severe decompensated cirrhosis.
- Benign or malignant liver tumour.
- History of breast cancer with no evidence of disease for the last 5 years.
- Breast-feeding and less than 6 weeks postpartum.
- Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.

When any category 3 condition is present, explain to the client the potential risks and counsel her about alternative contraceptive methods. If the client chooses POIs because other contraceptive options are not available or are unacceptable, it is particularly important to advise her that close medical follow-up is required. (See also chapter 2: Counselling).

Category 2

POIs can generally be used with precaution in the presence of:

- Raised blood pressure (systolic 140-159 or diastolic 90-99 mmHg).
- History of hypertension where blood pressure cannot be evaluated (including hypertension in pregnancy) or adequately controlled hypertension where blood pressure can be evaluated.
- Diabetes mellitus (if vascular disease develops during POI use in diabetes mellitus it becomes category 3).
- Migraine with or without aura at any age (if migraine with aura develops during POI use, it becomes a category 3).
- Known hyperlipidaemias.
- History of deep vein thrombosis or pulmonary embolism (DVT/PE).
- Major surgery with prolonged immobilization.
- Mild compensated cirrhosis.
- Gall bladder disease.
- Undiagnosed breast mass.

- Cervical intraepithelial neoplasia (CIN) or cervical cancer (awaiting treatment).
- Irregular, heavy or prolonged vaginal bleeding.
- Drugs which affect liver enzymes (e.g., rifampicin, barbiturates, anticonvulsants etc.).
- Antiretroviral therapy.

When any of these conditions are present, careful screening and appropriate monitoring will allow the benefits of using POIs to outweigh any potential risks. However, if a woman has more than one of the first three conditions above, which may increase the risk of arterial cardiovascular disease, she should be considered to be at category 3 of the medical eligibility criteria.

If the method is provided record the woman's special condition in the clinical record and advise her of warning signs relevant to her condition.

5.4 Special situations

Lactation

Hormonal methods are not the first method of contraceptive choice for breast-feeding women. Although progestogen-only contraceptives do not seem to interfere with lactation, there is a concern that they lead to release into the milk of orally active progestogens which are then absorbed by the infant. Any progestogen method should not be started before the sixth week postpartum by women who are fully or nearly fully breast-feeding unless all other contraceptive methods are not available or acceptable. The estimated daily dose received by the infant is much greater with POIs than with POPs.

Adolescents

The benefits of progestogen-only contraception for pregnancy protection are particularly important for adolescents. However, there are concerns about the hypo-oestrogenic effects of POIs on women aged under 18 years because of possible changes in bone mass and density. Any obvious risk factors for osteoporosis, such as chronic corticosteroid therapy should be taken into account when advising such young women on the use of POIs. *Where available, a CIC may be the more suitable injectable contraceptive.*

Women aged over 35 years

POIs may be safely used by most healthy women over 35 years of age. Any risk of cardiovascular disease will be minimal for these women if they do not smoke and have no other risk factors such as hypertension or diabetes mellitus. There are some theoretical concerns with regard to the hypo-oestrogenic effect of DMPA in women aged over 45 years because of possible effects on bone density.

Drug interactions

Drugs which induce liver enzymes, particularly those commonly used in long-term treatments, may reduce the efficacy of hormonal contraceptives. Such drugs include rifampicin, griseofulvin, phenytoin, ethosuximide, carbamazepine, glutethamide, barbiturates, primidone, topiramate, oxcarbazepine and some antiretroviral agents. If a client is taking any of these medicines long term, advise her to use simultaneously a supplementary method of contraception, such as condoms.

Abnormal vaginal bleeding

If a woman has vaginal bleeding suggestive of a condition related to pregnancy or of underlying pathology such as pelvic malignancy, it should be investigated before starting POIs. However, irregular menstrual bleeding patterns are not uncommon among healthy women: do not withhold POIs in the absence of any reason to suspect a pathological condition. Nevertheless, advise the client that her bleeding problem may increase with the use of POIs and, if she chooses to use POIs, she should be closely monitored.

Malignancy of the genital tract

Women who are using POIs and who are diagnosed to have cancer of the genital tract may continue to use POIs while awaiting treatment. With most genital tract malignancies, the treatment is such that there will be no further pregnancies. Women with pre-malignant disease of the cervix which has been successfully treated will generally preserve their fertility and can use any method of contraception, including POIs. The treatment of choriocarcinoma may not preclude further pregnancies: pregnancy should be avoided during treatment and follow-up so that the disease can be monitored properly. POIs may be used if this method is chosen by the woman.

Sickle cell disease

POIs may be used by women who have sickle cell disease: in addition to the contraceptive benefit, progestogen-only contraceptives may have a beneficial effect on the underlying disease.

Sexually transmitted infections (STIs)

Hormonal contraceptives do not protect against STIs, including HIV, and clients must be made aware of this fact. Advise use of condoms to any client at high risk of acquiring STIs. Strict aseptic techniques should be maintained when giving the injections to avoid the risk of transmitting any infection, including HIV.

5.5 Counselling and information

All clients must receive appropriate counselling for the selection and use of POIs before starting this method of contraception. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up at the outset (See also chapter 2: Counselling).

Selection of POIs as means of contraception

Discuss the following points clearly with each client in language that she understands:

- Advantages and disadvantages of POIs including effectiveness, risks and benefits, the possibility of delayed return to fertility, other side-effects and cost.
- The possibility of change in menstrual bleeding patterns, including:
 - *Amenorrhoea*: Reassure the client that amenorrhoea is an expected side-effect, and that she can expect menstrual cycles to return to normal within 6 months of discontinuing the POI.
 - *Menstrual irregularity*: Breakthrough bleeding and spotting are common.
- Alternative family planning methods including information on effectiveness, risks and benefits, side-effects and cost as appropriate.
- *Timing of the injection*: When the woman will receive the first injection, when the next will be due, and how often she will receive the injections.
- The specific POI to be used.

Use of POIs

See section 5.9 of this chapter.

5.6 Who can provide POIs?

Any health care provider who has been trained in the education and counselling of clients and the administration of injectables may provide this method, depending on local regulations and practice.

5.7 Health assessment

The purpose of the health assessment is to determine the client's suitability for the use of this method. It should also be used as an opportunity to offer the client other available sexual and reproductive health services.

The guidelines for COC assessment (see section 2.7) also apply in general to clients who receive POIs. However, there are fewer medical eligibility restrictions for the POIs (compare sections 2.3 and 2.4 with sections 5.3 and 5.4).

5.8 POI provision

The initial injection

Give the initial injection within the first 7 days of the menstrual cycle. No additional contraceptive protection is required. The client can also have the first injection at any other time, if it is reasonably certain that she is not pregnant, but if it has been more than 7 days since menstrual bleeding started she will need to abstain from sex, or use additional contraceptive protection, for the next 7 days.

For the amenorrhoeic client

- The client can have the first injection at any time, if it is reasonably certain that she is not pregnant.
- She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

For the postpartum client

- If the client is breast-feeding and she wishes to use a POI, give the initial injection from the sixth week postpartum, but not earlier. If a

client with lactational amenorrhoea requests the POI after 6 weeks postpartum, give the initial injection if you can establish that she is not pregnant (see chapter 11: Diagnosis of pregnancy).

- If the client is not breast-feeding, she can receive the initial injection immediately or at any time within the first 6 weeks postpartum. If the client wishes to start the POI after the sixth week postpartum and she has not yet had the first postpartum period, rule out the possibility of pregnancy before giving the initial injection.

Switching from another hormonal method

- The client can have the first injection immediately if she has been using her other hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- If her previous method was another injectable contraceptive, she should start the POI when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

- The client can have the first injection immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period:
 - If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.
 - If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including a hormone-releasing IUD)

- The client can have the first injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- She can also start the POI at any time if it is reasonably certain that she is not pregnant.
- If the client has been sexually active in the current menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is

recommended that the IUD be removed at the time of her next menstrual period.

- If she has not been sexually active in the current menstrual cycle, and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- If she is amenorrhoeic or has irregular bleeding she can have the injection as advised for other amenorrhoeic women.

Repeat injections

Provide repeat injections as follows:

- *DMPA*: 1 ml (which contains 150 mg) at every 3 months.
- *NET-EN*: 1 ml (which contains 200 mg) at every 2 months.

If the client is early for an injection

- The repeat injection can be given up to 2 weeks early.

If the client is late for an injection

- The repeat injection for *DMPA* and *NET-EN* can be given up to 2 weeks late without any need for additional contraceptive protection.
- If the client is more than 2 weeks late for either *DMPA* or *NET-EN* she can have the injection if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- She may wish to consider the use of emergency contraception if appropriate (see chapter 10: Emergency contraception).

Switching between DMPA and NET-EN

- Interchangeable use of *DMPA* and *NET-EN* injections is not recommended.
- If it is necessary to change from one POI to the other, the switch should be made at the time when the repeat injection would have been given.

For a repeat POI when the previous type of injectable and /or the timing of injection is unknown

- The client can have the injection if it is necessary and it is certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- She may wish to consider the use of emergency contraception if appropriate.

Injection technique

- Use only sterile or high-level disinfected syringes and needles. Disposable syringes and needles must not be re-used (For instructions on the processing of syringes and needles see chapter 15: Infection prevention and control, section 5.7).
- Shake the vial thoroughly. (If the vial has been cooled, as may be the case with NET-EN, warm it to room temperature first).
- Remove the protective the cap of vial carefully, so as not to contaminate the stopper.
- Aspirate contents into a sterile syringe to the exact volume required.
- Clean the injection site.
- Insert the sterile needle deep into the gluteal (upper outer quadrant) or deltoid muscle. (Many providers prefer to give oil-based injections, such as NET-EN, only in the gluteal muscle to reduce any pain associated with injections).
- Do not massage the injection site.
- Dispose of the disposable needles and syringes as appropriate. (See chapter 15: Infection prevention and control, sections 5.7 and 8.5).

5.9 Instructions to the client

Before administering the first injection, it is essential that every potential user fully understands the following:

Repeat injections

Regular repeat injections are essential if pregnancy is to be avoided. The client needs to have an injection every 3 (DMPA) or 2 (NET-EN) months. Advise the client to visit the clinic as soon as possible if she is late for the next injection.

Side-effects

Advise the client about possible side-effects (see section 5.11).

Return to fertility

Women using POIs may remain with amenorrhoea and not become pregnant for several months after their last injection, but the injection will not harm their fertility in the long term.

Warning signs

Advise the client to consult or visit the clinic if pregnancy is suspected or if any of the following problems occur:

- Unusually heavy menstrual bleeding.
- Severe headaches.
- Unusual discomfort or other problem at the injection site.

To prevent anxiety in the client, explain to her that serious complications are very rare. You can inform her that her health will be better protected by use of this highly reliable method of contraception than if an unintended pregnancy were to occur.

Follow-up

Tell the client the name of the injection and the date when her next injection is due. This information, a list of warning signs, and the name, address and telephone number of the clinic can be put on a card or leaflet and given to the client. This should be written and presented in such a way that the client or somebody close to her (in case she cannot read) can readily understand it.

5.10 Follow-up care**Repeat injection protocol**

If practicable, do a follow-up review when the client obtains the first repeat injection:

- Update the client's address and how to make contact with her.
- Assess the client's satisfaction with this method of contraception.
- Determine if the client has had any problems or side-effects and, if so, record them in the clinical record.

- Update the medical history, measure blood pressure and weight, and perform any other examination which may be indicated by the history.
- Provide appropriate counselling and/or treatment as required.
- Encourage the client to get in touch with the clinic at any time if she has any questions, complaints or problems.

Annual follow-up protocol

- Follow the repeat injection protocol with an updated medical history and an assessment of satisfaction with the method.
- Offer the client other relevant reproductive health services available at the facility, such as cervical cancer screening.

5.11 Side-effects

Amenorrhoea

Amenorrhoea is a common side-effect and usually occurs by the third injection. If the possibility of pregnancy is excluded, there is no reason for concern. If the client finds it unacceptable, discontinue the POI and help her to choose another method.

Spotting or light bleeding

Spotting or light bleeding (breakthrough bleeding) is common, especially following the first 2 injections. These symptoms are often temporary, and are rarely a risk to health. Careful counselling of women starting to use POIs has reduced the number who discontinue this method because of these side-effects. Clients who are fully informed beforehand about what to expect will be better able to understand and cope with these and other side-effects, and this method usually results in a high degree of satisfaction among women. If minor bleeding persists, gynaecological problems should be excluded. If an STI or PID is diagnosed, the client can continue her injections while receiving treatment, and be counselled on condom use. If no gynaecological problem is identified, and she prefers to discontinue the POI, help her to choose another method of contraception.

Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

Explain to the client that heavy or prolonged bleeding is common in the first injection cycle. However, if bleeding persists or becomes too heavy it is essential to exclude any underlying gynaecological problem. When this

has been done, and heavy bleeding persists, treatment with oestrogens, combined oral contraceptives or non-steroidal anti-inflammatory drugs may be tried. To prevent anaemia, review the client's diet and, if necessary, provide an iron supplement. If treatment is not effective and the problem becomes unacceptable to the client or a threat to her health, POIs should be discontinued and the client should be helped to choose an alternative method of contraception.

Other minor side-effects

These include weight gain and mild headaches. These symptoms are not dangerous, and the client should be reassured and encouraged to continue with this method of contraception.

5.12 Service management

See section 7 of this chapter.

6 Combined injectable contraceptives (CICs)



6.1 Definition

Combined injectable contraceptives (CICs) contain a short-acting oestrogen and a long-acting progestogen. The injectable preparation is released slowly over the course of 28 days from the site of injection. A single injection is given each month.

The 2 preparations currently available are:

- 25 mg medroxyprogesterone acetate/5 mg oestradiol cypionate (*Cyclofem, Cycloprovera, Lunelle, and Novafem*).
- 50 mg norethisterone oenanthate/5 mg oestradiol valerate (*Mesigyna and Norigynon*).

In some countries other combined injectable contraceptive formulations are available; however, current data about safety and efficacy are not sufficient to make a recommendation about them.

Mode of action: CICs exert their contraceptive effect mainly by suppression of ovulation. The cervical mucus is also affected, mainly by progestogen, and rendered inhospitable to sperm penetration. The receptivity of the endometrium to the blastocyst is also reduced, although there is no evidence that this contributes to the contraceptive effectiveness.

6.2 Indications

Combined injectable contraceptives should be provided to any woman who requests them after receiving appropriate counselling and reaching an informed decision, and who does not have any relevant contraindication to their use.

CICs might be useful for women who:

- Want a highly effective method of contraception.
- Desire the convenience of not having to keep contraceptive supplies at home.
- Have problems of compliance with oral contraceptives.
- Want the convenience of an injectable contraceptive without the bleeding irregularities associated with POIs.

Although full data are not available for CICs, the ancillary protective health effects attributed to COCs, noted in section 2.2 of this chapter, may also apply to CIC use.

6.3 Medical eligibility criteria

When sufficient clinical data are not available, the medical eligibility criteria for CICs are based on data for combined oral contraceptives (COCs) and progestogen-only injectables (POIs).

Category 4 (Contraindications)

CICs should not be used in the presence of:

- Breast-feeding and less than 6 weeks postpartum.
- Past or present evidence of deep venous thrombosis or pulmonary embolism (DVT/PE).

- Major surgery with prolonged immobilization.
- Current and history of ischaemic heart disease or stroke.
- Complicated valvular heart disease.
- Raised blood pressure (systolic 160 or diastolic 100 mmHg).
- Hypertension with vascular disease.
- Migraine with aura.
- Breast cancer within the past 5 years.
- Diabetes mellitus with vascular complications (including nephropathy, retinopathy and neuropathy) or of > 20 years' duration.
- Active viral hepatitis.
- Malignant liver tumour.

Category 3

CICs should generally not be used in the presence of:

- Raised blood pressure (systolic 140-159 or diastolic 90-99 mmHg).
- History of hypertension where blood pressure cannot be evaluated or adequately controlled hypertension, where blood pressure can be evaluated.
- Smoking 15 or more cigarettes daily in a woman aged 35 years or more.
- Known hyperlipidaemia.
- Migraine without aura symptoms in women aged 35 years or more (if migraine develops during CIC use, it becomes category 4).
- Breast-feeding from 6 weeks to < 6 months postpartum.
- Less than 21 days in postpartum non-breast-feeding women.
- Severe decompensated cirrhosis.
- Benign liver tumour.
- History of breast cancer with no evidence of disease for the last 5 years.

When any category 3 condition is present, explain the potential risks to the client and counsel her about alternative contraceptive methods. If CICs are chosen because other contraceptive options are not available or are unacceptable, it is particularly important that this method should be provided by a properly qualified practitioner and that the woman be kept under medical supervision. If a woman has more than one of the first 5

conditions above, which increase the risk of cardiovascular disease, clinical judgment must be exercised. In most instances, the combined criteria should be considered as belonging to category 4 (contraindication).

Category 2

CICs can generally be used with precaution in the presence of:

- Smoking in women aged less than 35 years or smoking less than 15 cigarettes daily in a woman aged 35 years or more.
- Migraine without aura in women aged less than 35 years (if migraine develops during CIC use, it becomes category 3).
- Diabetes mellitus without vascular complications.
- Obesity $\geq 30\text{kg/m}^2$ body mass index.
- History of high blood pressure during pregnancy (where current blood pressure is measurable and normal).
- Superficial thrombophlebitis.
- Family history of deep venous thrombosis or pulmonary embolism (DVT/PE).
- Breast-feeding and 6 months or more postpartum.
- Uncomplicated vascular heart disease.
- Unexplained vaginal bleeding, suspicious of a serious condition, before evaluation.
- Mild (compensated) cirrhosis.
- Symptomatic or asymptomatic gallbladder disease or history of cholestasis.
- Sickle cell disease.
- Cervical intraepithelial neoplasia (CIN) or cervical cancer.
- Undiagnosed breast mass.
- Drug treatment affecting liver enzymes: rifampicin and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine).
- Antiretroviral therapy.

When any of these conditions are present, careful screening and monitoring will allow the benefits of CIC use to outweigh any potential risks. However, when a woman has 2 or more of the first 4 conditions

above, which increase the risk of cardiovascular disease, clinical judgment must be exercised. In most instances the combined conditions should be regarded as belonging to category 3.

If the method is provided, record the woman's special condition in the clinical record, and advise her of warning signs relevant to her condition.

6.4 Special situations

The advice given for use of POIs in relation to abnormal vaginal bleeding, drug interactions, malignancy of the genital tract and STIs also apply to CICs (see section 5.4 of this chapter).

Lactation

There are no data on the effects of CICs on the quantity and quality of breast milk or the duration of lactation. Until such data become available, CICs should be generally withheld until 6 months after delivery or until the infant is weaned, whichever is earlier. If the woman wishes to start an injectable contraceptive during breast-feeding, a POI should be recommended.

Adolescents

The benefits of CICs for pregnancy protection are especially important for young people and the indications and contraindications are the same in this age-group as for older women. When there is concern about a possible hypo-oestrogenic effect of POIs, the combined injectable is a more suitable option.

Women aged over 35 years

CICs can be used by most healthy women over 35 years of age. Any possible increased risk of cardiovascular disease would be minimal for these women if they do not smoke and have no other risk factors, such as hypertension or diabetes mellitus.

Elective surgery

It is advisable to stop using CICs approximately 4 weeks before elective surgery which involves prolonged immobilization, and to restart CICs 2 weeks after the woman is mobile. Advise the use of alternative effective contraception during this time. In emergency procedures, the surgeon may consider the use of prophylactic anticoagulant measures, and early ambulation should be encouraged.

Sickle cell disease

No data are available on the use of CICs by women who have sickle cell disease. Sickle cell trait is not a contraindication to the use of combined hormonal contraceptives, but women with homozygous sickle cell disease may be at increased risk of thrombosis. POIs are a more suitable choice than CICs for these women.

6.5 Counselling and information

All CIC clients must receive appropriate counselling for the selection and use of CICs before starting this method of contraception. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up (See also chapter 2: Counselling).

Selection of CICs as means of contraception

Discuss the following points clearly with each client in language that she understands:

- Advantages and disadvantages of CICs including effectiveness, risks and benefits, side-effects and cost. (Reassure clients about the lack of any conclusive evidence that CICs cause cancer, birth defects or future infertility).
- Alternative family planning methods including information on effectiveness, risks and benefits, side-effects and cost as appropriate.
- Remind clients who smoke that smoking increases the risk of serious circulatory disorders, and advise all women who intend to use CICs to stop smoking.
- *Timing of the injection*: When the woman will receive the first injection, when the next injection will be due, and how often she will receive the injections.
- The specific CIC to be used.

Use of CICs

See section 6.9 of this chapter.

6.6 Who can provide CICs?

Any health care provider who has been trained in the education and counselling of clients and the administration of injectables may provide this method, depending on local regulations and practice.

6.7 Health assessment

The purpose of the health assessment is to determine the client's suitability for the use of the method. It should also be used as an opportunity to offer the client other available sexual and reproductive health services.

The guidelines for COC assessment (see section 2.7) also apply to clients who receive CICs (compare sections 2.3 and 2.4 with sections 6.3 and 6.4).

6.8 CIC provision

The initial injection

Give the initial injection within the first 7 days of the menstrual cycle, preferably the first day. The client can also have the first injection at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started she will need to abstain from sex, or use additional contraceptive protection, for the next 7 days.

For the amenorrhoeic client

- The client can have the first injection at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

For the postpartum client

- If the client is breast-feeding and she wishes to use an injectable contraceptive, recommend the progestogen-only injectable. CICs should not be used earlier than 6 months postpartum or before weaning.
- If the client is not breast-feeding, she can receive the initial injection from 3-6 weeks postpartum. If the client wishes to start the CIC after the sixth week postpartum and she has not yet had the first postpartum period, rule out the possibility of pregnancy before giving the initial injection.

Switching from another hormonal method

- The client can have the first injection immediately if she has been using her other hormonal method consistently and correctly, or if it is

reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

- If her previous method was an injectable contraceptive, she should start the CIC when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

- The client can have the first injection immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- If she is within 7 days of the start of her menstrual bleeding no other contraceptive protection is needed.
- If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including a hormone-releasing IUD)

- The client can have the first injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- The client can also start the CIC at any time if it is reasonably certain that she is not pregnant.
 - If she has been sexually active in the current menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
 - If she has not been sexually active in the current menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.
- If she is amenorrhoeic or has irregular bleeding she can start CICs as advised for other amenorrhoeic women.

Repeat injections

Re-injection interval

- Provide repeat injections every 4 weeks (approximately monthly).

If the client is early for an injection

- When the standard 4-week re-injection interval cannot be adhered to for any reason, the repeat injection can be given up to 7 days early but may disrupt bleeding patterns.

If the client is late for an injection

- The repeat injection can be given up to 7 days late without any need for additional contraceptive protection.
- If the client is more than 7 days late for an injection she can have the injection if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.
- She may wish to consider the use of emergency contraception if exposed to unprotected intercourse (see chapter 10: Emergency contraception).

Injection technique

The technique used for CICs is the same as that for POIs (see section 5.8).

6.9 Instructions to the client

Before administering the first injection, it is essential that every potential user fully understands the following:

Repeat injections

Regular repeat injections are essential if pregnancy is to be avoided. The client needs to have an injection every 4 weeks (approximately every month). Advise the client to visit the clinic as soon as possible if she is late for the next injection.

Side-effects

Advise the client about possible side-effects (see section 6.11).

Return to fertility

There is no significant additional delay in the return of fertility after the client has had the last injection.

Warning signs

Advise the woman to consult or visit the clinic if pregnancy is suspected or if any of the following problems occur:

- Severe abdominal pain.
- Severe chest pain, cough or shortness of breath.
- Severe headache.
- Loss of vision or blurring.
- Severe pain in calf or thigh.
- Jaundice (yellowness of the eyes and skin).
- Unusually heavy bleeding.
- Unusual discomfort or problem at the injection site.

To prevent anxiety in the client, explain to her that serious complications are very rare. You can inform her that her health will be better protected by use of this highly reliable method of contraception than if an unintended pregnancy were to occur.

Follow-up

Tell the client the name of the injection and the date when her next injection is due. This information, a list of warning signs and the name, address and telephone number of the clinic can be put on a card or leaflet and given to the client. This should be written and presented in such a way the client or somebody close to her (in case she cannot read) can readily understand it.

6.10 Follow-up care

The repeat injection protocol and annual follow-up protocol for CICs are similar to those for POIs (see section 5.10).

6.11 Side-effects

- Changes in menstrual bleeding patterns are less common than with the use of POIs. The first cycle is usually short, between 10-20 days, with subsequent monthly bleeds. Irregular bleeding may occur in about 30%

of women during the first 3 months, but most users of CICs have a normal menstrual bleeding pattern by the end of the first year of use.

- Amenorrhoea is uncommon.
- Other minor side-effects may include weight gain, mild headaches and dizziness. Reassure the client that these symptoms are not dangerous; advice about diet and exercise may be appropriate.

6.12 Service management

See section 7 below.

7 Management of injectable contraceptive services

Client records

A standard clinical record form should be used for all clients. This form serves:

- To document essential client information.
- As a guide for staff to ensure that contraindications and conditions which require careful consideration for the use of injectable contraceptives are accurately and completely assessed.
- To record the contraceptive method provided and other services given to the client.
- To record follow-up services.

Stock of injectables

Problems can arise and mistakes can occur if different formulations of injectables are stocked and used in the same SRH/family planning programme. Therefore, SRH/family planning programme managers should select one progestogen-only injectable formulation and keep to it, or ensure that only one formulation is used in a particular geographical area. The same recommendations apply to combined injectables when they are available.

Needles and syringes

- Providers must have adequate supplies of appropriately sized needles and syringes: 2 ml or 5 ml syringes and intramuscular injection needles.

- Disposable syringes are more convenient if available.
- Disposables must **not** be reused and must be properly disposed of (see chapter 15, section 8.5).
- If a continuous supply of disposable syringes is not available, reusable syringes and needles may be used *if* they are properly decontaminated, cleaned, sterilized or disinfected by boiling before being used again (see chapter 15, section 5.7).

Storage and shelf-life

- Use single-dose vials only.
- Injectable preparations do not need to be refrigerated.
- Follow manufacturers' instructions about shelf-life.
- Inspect all vials for condition of the fluid and the expiry date.

Training

Health personnel who provide injectable contraception must be trained in all aspects of the services required for their provision, and in the education and counselling of clients. All staff must be familiar with procedures to ensure safe injections. Where both types of injectables are available, health personnel should be well aware of the differences between POIs and CICs.

8 Subdermal implants



8.1 Definition

Progestogen-only implants are placed subdermally and release progestogen at a controlled rate, thus providing very small daily doses to achieve the desired contraceptive effect.

Available proprietary implants include the 6-capsule *Norplant*, the 2-rod *Jadelle* and the 1-capsule *Implanon*.

The *Norplant* implant system is a highly effective, long-acting, reversible, low-dose progestogen-only contraceptive. The system consists of 6 slender, soft, *Silastic* (silicone rubber) capsules. Each capsule is 2.4 mm in diameter and 34 mm in length, and contains 36 mg levonorgestrel. Approximately 30 µg levonorgestrel a day is released and the effective life of the implant is 7 years (unless the woman weighs more than 70 kg).

Jadelle consists of two silastic rods which release levonorgestrel and is effective for up to 5 years. Each rod is 43 mm long and 2.5 mm in diameter, and contains 75 mg levonorgestrel.

Implanon is a single capsule which releases etonogestrel and has a life span of 3 years. It is 40 mm in length and 2 mm in diameter, and contains 68 mg etonogestrel.

Implants are inserted subdermally in the woman's upper arm or forearm by a minor surgical procedure under local anaesthesia. After insertion, the implants are palpable but barely visible. Contraceptive effect is achieved by a slow, steady release of progestogen by diffusion through the *Silastic* membrane into the bloodstream.

Protection against pregnancy starts within 24 hours after insertion and lasts approximately 7 years in the case of *Norplant*, 5 years for *Jadelle*, and 3 years for *Implanon*. Fertility is restored almost immediately after the implants are removed.

Mode of action: As with other progestogen-only contraceptives, implants have 2 modes of action:

- The effect of the progestogen on cervical mucus is the main factor in its contraceptive efficacy. The mucus becomes viscous and scanty, thus inhibiting sperm penetration.
- The progestogen acts on the hypothalamus and pituitary and suppresses the LH surge responsible for ovulation. Ovulation is prevented in at least half of the cycles.

In most cases the endometrium shows signs of suppression. However, this effect does not play an important role in the efficacy of progestogen implants because the changes in cervical mucus and anovulation would prevent fertilization.

8.2 Indications

Progestogen-only implants, where available, should be provided to any woman who requests this method after appropriate counselling and reaching an informed decision, and who does not have any contraindication to its use.

Progestogen-only implants are a suitable method for most women of reproductive age, but it is particularly indicated for women who:

- Want a highly effective method of contraception.
- Want a long-term contraceptive method.
- Desire a method that is not coitally related.
- Prefer a method that is not taken daily nor requires frequent re-supply.
- Have the number of children that they want, but do not wish to be sterilized.
- Are considering sterilization, but are not yet ready to make a final decision.
- Should not use oestrogen-containing contraceptives.
- Have problems remembering to take oral contraceptives.

8.3 Medical eligibility criteria

Historically, the contraindications to progestogen-only contraceptives were considered to be the same as for COCs. However, progestogen-only implants have no effect on blood pressure or coagulation factors (and therefore pose no risk of venous thrombosis), have a negligible effect on lipid metabolism and have very little effect on liver function. Thus contraindications for progestogen-only implants may be considered separately from those for COCs.

Category 4 (Contraindications)

Progestogen-only implants should not be used in the presence of:

- Breast cancer within the past 5 years.

Category 3

Do not advise the use of progestogen-only implants or provide them to women with:

- Present evidence of deep vein thrombosis or pulmonary embolism (DVT/PE).
- Active viral hepatitis.
- Severe decompensated cirrhosis.
- Benign or malignant liver tumour.
- History of breast cancer with no evidence of disease for the last 5 years.
- Breast-feeding and less than 6 weeks postpartum.
- Unexplained vaginal bleeding suggestive of a serious underlying condition (before evaluation).
- Drug treatment affecting liver enzymes: rifampicin and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine).

When any Category 3 condition is present explain to the client the potential risks and counsel her about alternative methods. If the client chooses a progestogen-only implant because other contraceptive options are not available or are unacceptable, it is particularly important that the method should be provided by a properly qualified practitioner and that the woman be kept under medical supervision (see also chapter 2: Counselling).

Category 2

Progestogen-only implants can generally be used with precaution in the presence of:

- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).
- Any history of hypertension where the blood pressure cannot be evaluated.
- Hypertension with vascular disease.
- Current and history of ischaemic heart disease or stroke.
- Diabetes with or without complications (history of gestational disease is category 1).

- Migraine with or without aura (if migraine with aura develops during implant use it becomes category 3).
- Known hyperlipidaemia.
- History of deep vein thrombosis or pulmonary embolism (DVT/PE).
- Major surgery with prolonged immobilization.
- Irregular vaginal bleeding patterns without heavy bleeding or heavy or prolonged bleeding (include regular or irregular patterns).
- Mild compensated cirrhosis.
- Gallbladder disease.
- Undiagnosed breast mass.
- Cervical intraepithelial neoplasia (CIN).
- Cervical cancer (awaiting treatment).
- Treatment with griseofulvin.
- Antiretroviral therapy.

When any of these conditions is present, careful screening and appropriate monitoring will allow the benefits of using an implant to outweigh any potential risks. However, if a woman has more than one of the first five conditions above, which may increase the risk of arterial cardiovascular disease, it should be considered as category 3 of the medical eligibility criteria. If the client chooses an implant because other contraceptive options are not available or acceptable, it is particularly important to advise her that close medical follow-up is required.

If the method is provided, record the woman's special condition in the clinical record and advise her of warning signs relevant to her condition.

8.4 Special situations

All the situations described for progestogen-only injectables also apply to progestogen-only implants (see section 5.4 of this chapter).

8.5 Counselling and information

All clients must receive appropriate counselling for the selection and use of this method of contraception. Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up at the outset (See also chapter 2: Counselling).

For selection of subdermal implants as means of contraception

Discuss the following points clearly with the client in language that she understands:

- The physical characteristics of the implants, how they are inserted and in which part of the body, and how they should feel under the skin.
- Advantages and disadvantages of implants including effectiveness and length of protection, risks and benefits, possible side-effects (particularly changes in menstrual pattern), the procedures of insertion and removal and cost.
- When implants should be removed.
- The importance of follow-up visits.
- After a client has chosen implants as her method of contraception make sure that she has understood the following points before insertion:
 - Possible changes in her menstrual bleeding pattern and the fact that these usually decrease with time.
 - Side-effects and complications to watch out for.
 - The importance of removal of the implant after its effective lifespan has expired (7 years for *Norplant*, 5 years for *Jadelle*, and 3 years for *Implanon*).
- Alternative family planning method including information on effectiveness, risks and benefits, side-effects and cost as appropriate.

Use of subdermal implants

See section 8.9 of this chapter.

8.6 Who can provide subdermal implants?

Doctors, nurses, midwives and other health professionals who have been trained in counselling and in implant insertion and removal procedures may provide this method, depending on regulations and practice.

8.7 Health assessment

The purpose of the health assessment is to determine the client's suitability for the use of the method. It should also be used as an opportunity to offer the client other available sexual and reproductive health services.

The guidelines for COC assessment (see section 2.7) also apply in general to clients who receive implants. However, the contraindications and

conditions that require careful consideration for subdermal implants are not the same as for COCs (compare sections 2.3 and 2.4 with sections 8.3 and 8.4).

8.8 Choice of implant

The two newer subdermal implants *Jadelle* and *Implanon* are easier to insert and remove than *Norplant*. In general, when renewing a subdermal implant, service programmes should replace *Norplant* with *Jadelle* or *Implanon*. Selection of the implant will depend mainly on availability and cost, as well as other factors.

8.9 Insertion and removal

Insertion

Insert the subdermal implant within the first 7 days of the menstrual cycle. No additional contraceptive protection is needed. The client can also have the implant inserted at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started she will need to abstain from sex, or use additional contraceptive protection, for the next 7 days.

For the amenorrhoeic client

- The client can have the implant inserted at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

For the postpartum client

- If the client is breast-feeding and she wishes to use a progestogen-only subdermal implant, insert the implant from the sixth week postpartum, but not earlier. If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have the implant inserted at any time. If she is fully or nearly fully breast-feeding no additional contraceptive protection is needed.
- If the client is not breast-feeding she can have the implants inserted immediately or at any time within the first 6 weeks postpartum. If the client requests the implant after the sixth week postpartum and she has not yet had the first postpartum period, rule out the possibility of pregnancy before inserting the initial implant (see chapter 11: Diagnosis of pregnancy).

Switching from another hormonal method

- The implant can be inserted immediately if the client has been using her other hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
- If her previous method was another injectable, she should have the implant inserted when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

- The client can have the implant inserted immediately if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.
 - If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.
 - If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including a hormone-releasing IUD)

- The client can have the subdermal implant inserted within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.
- She can also have the implant inserted at any time, if it is reasonably certain that she is not pregnant.
 - If the client has been sexually active in the current menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.
 - If she has not been sexually active in the current menstrual cycle, and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be

removed at the time of her next menstrual period.

- If she is amenorrhoeic or has irregular bleeding she can have the implant inserted as advised for other amenorrhoeic women.

Basic principles for insertion and removal

- Insertion and removal should only be performed by health personnel specially trained in these procedures.
- Proper insertion techniques are important to ensure ease of removal.
- Perform insertion and removal only in a properly equipped clinical facility.
- Maintain strict sterile techniques.
- Before and during the insertion procedure, tell the woman what will happen during this procedure and encourage her to ask questions. Explain to her that she may feel some discomfort during some of the steps.

Indications for removal of subdermal implants

- *User request:* Remove the implants without unnecessary delay when the client makes a firm request for it to be done.
- *Pregnancy:* Remove the implants as soon as pregnancy is confirmed.
- *Medical reasons such as:*
 - Heavy menstrual bleeding.
 - Repeated severe headache or migraine-type headache occurring for the first time.
 - Symptoms of acute liver disease.
 - Serious infection of insertion site not amenable to treatment with antibiotics and/or local measures.
- *At the end of 7/5/3 years after insertion:* If the woman wishes to continue with the method, you can insert a new set of implants after removing the old set.

8.10 Instructions to the client

Provide all instructions clearly and in a language appropriate to the background of the client.

Instructions after insertion

- After the effect of the local anaesthetic has worn off, there may be some discomfort and/or swelling at the site of insertion for 1 to 2 days.
- The woman must keep the site of insertion dry for 3 days.
- The gauze should be removed after 3 days and the bandage removed on the fifth day.
- The contraceptive effect of the implant starts soon after the capsules are inserted, so intercourse can be resumed the day after insertion.

Side-effects

- Advise the client about possible side-effects (see section 8.12).

Warning signs

Advise the client to make contact with the clinic or to return immediately if any of the following problems occur:

- Pain, pus or bleeding at the site of insertion.
- Expulsion of the implant.
- Unusually heavy vaginal bleeding.
- Menstrual bleeding has not occurred within 6 weeks after the previous menstrual period.
- Severe abdominal or pelvic pain.
- New or severe headaches.
- Yellow eyes or skin.
- Shortness of breath or severe chest pains.

To prevent anxiety in the client, explain to her that serious complications are very rare. You can mention that her health will be better protected by using this highly reliable method of contraception than if an unintended pregnancy were to occur.

Follow-up

Give the client the date of the next visit (within 1 month). Explain that the implant should be removed after 7/5/3 years and tell her the month and the year when it should be done. Also explain to her the importance of

returning to the same clinic for removal or, if this is not possible, to go to another clinic where there are staff trained to perform the removal. This information, the list of warning signs, and the name, address and telephone number of the clinic, can be put on a card or leaflet and given to the client. This should be written and presented in such a way that the client or somebody close to her (in case she cannot read) can readily understand it.

Removal

If the client has any problems with the subcutaneous implant or if she wishes its removal, she must return to a clinic which provides implant removal services by trained providers.

8.11 Follow-up care

The client should be seen within one month after insertion, mainly to check the insertion site and to discuss any questions or concerns that she may have. Thereafter she should be seen at least annually. The client should be given the option to attend the service delivery site most convenient to her, provided that the site has staff properly trained in implant services.

Annual follow-up protocol

- Update the client's address and how to make contact with her.
- Assess the client's satisfaction with this method of contraception.
- Determine if the client has had any problems or side-effects and, if so, record them in the clinical record. Update the medical history.
- Perform a physical assessment including:
 - Blood pressure
 - Breast examination (with instruction for self examination).
 - A bimanual pelvic examination, with a cervical smear if this is due and possible.
- Provide appropriate counselling and/or treatment as required.
- Review with the client the warning signs and instructions given at the previous visit, particularly the need for removal (at 7 years if using *Norplant*, at 5 years if using *Jadelle* or at 3 years if using *Implanon*), and the need to return to the same clinic or another competent clinic for removal (give information on that clinic if applicable). Give instructions for annual follow-up.

- Encourage the client to contact the clinic any time if she has any questions, complaints or problems.

8.12 Side-effects

- The most frequent side-effect is disruption of the menstrual cycle. This includes prolonged bleeding, spotting between periods or amenorrhoea. In general, the total monthly blood loss is less than in a normal menstrual period, but some women may experience heavy bleeding.
- Changes in menstrual bleeding patterns (breakthrough bleeding and spotting) are common, especially during the first year of use. They are often temporary, and are rarely a risk to health. Careful counselling of women starting to use subdermal implants has reduced the number who discontinue this method because of these side-effects. Clients who are fully informed beforehand about what to expect will be better able to understand and cope with these and other side-effects, and this method usually results in a high degree of satisfaction among women. If the problem persists or if bleeding becomes too heavy, gynaecological problems should be excluded. If an STI or PID is diagnosed, the client can continue to use implants while receiving treatment, and should be counselled on condom use. If no gynaecological problems are found treatment with ethinylloestradiol, low-dose combined oral contraceptives or non-steroidal anti-inflammatory drugs may be tried. If this treatment is not effective and the problem becomes a threat to the health of the woman or is not acceptable to her, the use of implants should be discontinued. Help her to choose another method of contraception.
- Headache is the second most frequent complaint. Less common side-effects include nervousness, nausea, dizziness, weight gain and skin side-effects such as acne.
- If any capsules are expelled (a rare problem), replace them with new capsules as soon as the area is healed. Provide an interim back-up method of contraception.

8.13 Service management

Progestogen-only subdermal implants require special attention by programme managers, mainly because use of this method requires a surgical procedure, long-term follow-up and readily available facilities for removal. SRH/family planning services therefore require the availability of a well designed information, education and communication system; suitable clinical facilities; the establishment of training centres; and

appropriate record-keeping and client follow-up systems.

Client records and follow-up

A record-keeping system which assures an up-to-date clinical record for each implant user is required. All client records should include findings from clinic assessment as well as insertion details. The record-keeping system should include a register for scheduled removals, and a mechanism for tracking clients so that the removal at 7/5/3 years may be accomplished in a timely fashion. The programme should have a system to ensure proper follow-up of all clients, including procedures to remind them to return to the clinic for check-ups and for removal at the end of the 7/5/3-year period.

Clinical facilities

Facilities should:

- Be sufficient for any demand which may be generated.
- Ensure permanent access to removal on demand for users.
- Have the essential equipment for insertion and removal.
- Have access to steam autoclave and other facilities for decontamination, cleaning and sterilization of equipment.
- Have permanent availability of trained staff.

Training

Clinic workers must receive training on counselling and screening of clients, insertion and removal of implants, and management of side-effects and complications.

Provide practical, hands-on experience in insertion and removal techniques during training. The goal of training should be to achieve competence, and it is recommended that 5-10 insertions and removals should be done during training. The use of anatomic models helps providers of care to acquire the necessary amount of practice, and minimizes discomfort or risk for the clients.

Storage, shelf-life and supplies

- Store implants at room temperature away from excess heat and moisture.
- Shelf-life is 5 years when stored as above.

9 Other delivery systems for combined hormonal contraceptives

9.1 Transdermal patch

The transdermal contraceptive patch is a novel delivery system for combined hormonal contraception which is easy to use and reversible. Its efficacy parallels that achieved with the combined oral contraceptive pill but has the benefit of weekly rather than daily administration, with improved compliance.

The patch is beige coloured and about 4 cm square. When applied to the skin it delivers norelgestromin 150 µg and ethinyloestradiol 20 µg to the bloodstream daily. It can be applied to the lower abdomen, buttocks, upper arm and upper trunk (but not the breasts). Each patch is designed to be worn for 7 consecutive days. Three patches are used in each cycle, followed by a 7-day patch-free interval. The patch is effective for prevention of pregnancy, but is less effective in women weighing more than 90kgs. The risks of using the patch are similar to the risks of using COCs. The patch does not protect against STIs and HIV/AIDS.

9.2 Vaginal ring

A vaginal ring is a thin, transparent flexible ring that is inserted into the vagina to provide contraceptive protection. It is an easy to use and reversible method of hormonal contraception. It works by releasing a continuous low dose of oestrogen and progestogen. It is worn continuously for 3 weeks then removed for 1 week; a new ring is inserted every month. It is highly effective when used correctly. The risks and side-effects are similar to the risks of using COCs. It does not protect against STIs and HIV/AIDS.

Checklist for dispensing oral contraceptives in community-based services

Client's name:

Age:

Address:

Date:

Date of last menstrual period or childbirth as applicable:

1 Has the client missed her period?

YES NO

If YES, don't offer pills unless you are reasonably sure she is not pregnant.

If NO, go to the next question.

2 Ask the client if she has or has had any serious illness:

If the answer is NO, go to question 3.

If YES, ask what that illness is or was. Record if any of the following applies to the client:

a) Takes medicine for tuberculosis or epilepsy	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
b) Experiences abnormal vaginal bleeding	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
c) Has or has had cancer of the breast	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
d) Has liver tumor or liver disease	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
e) Has or has had heart disease, blood clots or stroke	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
f) Has high blood pressure	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
g) Has Diabetes	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>

If YES to any item, refer the client to a clinic for evaluation and/or contraceptive advice.

Recommend the use of a barrier method (especially the condom) in the meantime.

If YES applies to items e, f or g, you can also recommend the use of a POP in the meantime.

If NO to all items, go to the next question.

3 Does the client have ANY of the following problems?

Smokes and is over 35 years old	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Yellow skin or yellow eye colour and feels ill	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Severe chest pains	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Unusual shortness of breath	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Severe headaches with blurred vision	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Lumps in a breast or blood discharge from the nipple	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Severe leg pain and/or swelling	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>

If YES to any item, refer the client to a clinic for evaluation and/or contraceptive advice.

Recommend the use of a POP or a barrier method (especially the condom) in the meantime.

If NO to all items, go to the next question.

4 Is the client breastfeeding?

YES NO

If YES, recommend only POP if the infant is under six months of age. If the infant is six months or older, you can provide either POP or COC, as acceptable to the client.

If NO, recommend the COC but you can provide either COC or POP, as acceptable to the client.

If the client needs to be seen at a clinic for further evaluation or for a method not provided in CBS, give her a Referral Card, and help her in any possible way to obtain a consultation.