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MEDICAL AND SERVICE DELIVERY GUIDELINES

FOR SEXUAL AND REPRODUCTIVE HEALTH SERVICES

THIRD EDITION 2004



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PREFACE

For fifty years IPPF has worked to make sexual and reproductive health education and services available to millions of people worldwide. Through its six regional offices and its global network of 149 Member Associations, IPPF is uniquely placed to provide, and campaign for, sexual and reproductive health care and rights.

IPPF's vision is of universal access to sexual and reproductive health care for women, men and young people. It is now more evident than ever that the right to decide the number and spacing of their children and to enjoy good sexual health helps people improve their lives.

Against a background of scarce resources and increasing opposition from conservative forces, IPPF's Strategic Plan, newly approved in 2003, focuses on four unresolved reproductive health challenges: (i) meeting the sexual and reproductive health needs of young people worldwide; (ii) the fight against HIV/AIDS; (iii) eliminating unsafe abortion and improving access to safe abortion, and (IV) addressing the sexual and reproductive health unmet need of the marginalized and the poor. A fifth priority area is advocacy, based on both evidence and experience, allowing IPPF to take the lead in defending and expanding the above reproductive rights. To ensure the success of the Strategic Plan, IPPF is also committed to ensure throughout its network the provision of high quality services. These guidelines are an important part of IPPF's ongoing commitment to raising standards of care.

The IPPF Medical and Services Delivery Guidelines are intended to improve knowledge, skills and confidence among service providers and to ensure that service providers are able to meet their clients' needs.

In order to do this, the guidelines have been designed to be technically sound (supported by scientific research), socially sound (acceptable to those who will use them) and operationally sound (validated and updated). The guidelines have also been written to be easily adapted to the needs and resources of different environments where they will be used.

This Third Edition builds on the success of previous editions and expands on them to reflect the needs and rights of both service providers and their clients. This edition includes four new chapters: The normal menstrual cycle, Reproductive health screening for well women, Safe abortion, and HIV infection and AIDS. Knowledge of contraception expands continuously; therefore, the existing chapters on methods have been updated. This has required a review of the recent contraceptive literature, and these chapters also incorporate the products of a very important consensus building activity - the review of Medical Eligibility Criteria for Contraceptive Use, sponsored by the World Health Organization (WHO) in October 2003, as well as the Selected Practice Recommendations meeting organized by WHO in April 2004.

All the leading organizations active in the field of family planning policy and programmes participated in these efforts, and IPPF and its International Medical Advisory Panel (IMAP) played an active role. Information on contra-indications and conditions requiring special consideration regarding the use of the various methods of contraception has been reviewed to make it consistent with the updated WHO criteria. As with previous editions the guidelines have been developed under the guidance of IMAP.

Experience has shown us that the guidelines are only effective if they are accessible to those who would benefit most from them. We would like you to use them as part of your own training and discussions, and would welcome comments and feedback to improve future editions.

I am pleased to commend these guidelines to all those working for better sexual and reproductive health.

A handwritten signature in dark ink, appearing to read 'Steven W. Sinding', written in a cursive, flowing style.

Dr Steven W Sinding
IPPF Director-General
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INSTRUCTIONS FOR USE

1 Purpose of the Guidelines

The IPPF *Medical and Service Delivery Guidelines for Sexual and Reproductive Health Services* are designed to be used in sexual and reproductive health service programmes, including family planning:

- *As a guide for the delivery of services*

These guidelines provide clear guidance to managers and service providers for the planning and performance of tasks which are related to their duties.

- *As a reference document for assessing quality of care*

The focus of the guidelines is on providing services which reach essential standards of quality. Therefore, the quality of services can be assessed by comparing actual performance with the recommendations and instructions contained in the guidelines.

- *As a training instrument*

Each chapter of the guidelines can serve as the basis for the development of training curricula.

- *As a tool for supervision*

The guidelines can serve as a reference to supervisors in identifying situations which require corrective actions and in identifying training needs. The supervisors can use the guidelines for bringing to the attention of service delivery personnel essential elements of quality of care and proper procedures.

2 Intended users

The intended users of the guidelines are: programme planners and managers, clinical services providers, and trainers and supervisors of clinical and community-based services. The guidelines are appropriate for doctors, nurses, midwives and other health professionals. The content of the guidelines relevant to community-based services can be used for developing materials for these workers, but this can best be done at the local level.

3 Format

The guidelines consist of 15 chapters.

As well as being extensively revised, this Third Edition includes 4 new chapters to the 1997 edition. These are: The normal menstrual cycle (chapter 3); Reproductive health screening for well women (chapter 4); Safe abortion (chapter 12) and HIV infection and AIDS (chapter 14).

Cross-references

To avoid unnecessary duplication of information provided, cross-references are made between and within chapters of the guidelines. These cross-references refer to the specific chapter by number and to the specific section of the chapter also by number. Most often the cross-references are to other sections of the same chapter.



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SEXUAL AND REPRODUCTIVE RIGHTS

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THE RIGHT to life

THE RIGHT to liberty
and security of the person

THE RIGHT to equality,
and to be free from all forms
of discrimination

THE RIGHT to privacy

THE RIGHT to freedom
of thought

THE RIGHT to information
and education

THE RIGHT to choose
whether or not to marry and
to found and plan a family

THE RIGHT to decide
whether or when to have children

THE RIGHT to health care
and health protection

THE RIGHT to the
benefits of scientific progress

THE RIGHT to freedom of
assembly and political participation

THE RIGHT to be free from
torture and ill treatment

1 CLIENTS' RIGHTS AND PROVIDERS' NEEDS

1 Introduction

The aim of sexual and reproductive health programmes is to improve the quality of life of all women, men, and young people. To achieve this aim, all services that clients receive must be of consistently high quality, and reflect this ideal.

Since the late 1980s, special focus on the concept of *quality of care*, and an increased attention to its importance, has enhanced client satisfaction and has led to increased demand for, and acceptability of, sexual and reproductive health services, including family planning. A high quality of care ensures that clients are empowered to make informed, confidential and timely decisions about their sexual and reproductive health.

Since access to sexual and reproductive health services and family planning has been recognized as a right of all individuals and couples, quality of care can now be understood as a *right of the client*, extending the definition of the client not only to those who approach the health care system for services, but also to everyone in the community who is in need of such services.

The client should be at the centre of all sexual and reproductive health and family planning activities. A client-centered approach means that providers of these services should be aware of clients' needs, and must meet and respect their rights. Managers and supervisors should also be aware that if the rights of clients are to be fulfilled, the *needs of the service providers* must also be met. Taken together, the **clients' rights** and the service **providers' needs** form the two pillars of quality of care in the provision of such services.

2 Clients' rights

The right of all individuals and couples to decide freely the number and spacing of their children has been internationally established for many years. The Tehran Declaration of Human Rights in 1968, for example, stated that "Parents have a basic human right to determine freely and responsibly the number and spacing of their children". The 1994 International Conference on Population and Development (ICPD) held in Cairo reinforced this declaration, and also stated that it is "the right of women and men to be informed and have access to sexual and

reproductive health services of their choices, which are safe, effective, affordable and acceptable”.

In line with these statements, **the rights of clients** can be outlined as follows:

2.1 Right to information

All individuals in the community have a right to know about the benefits and availability of sexual and reproductive health services for themselves and their families. They also have a right to know where and how to obtain more information and services for planning their families and for sexual and reproductive health care. All sexual and reproductive health programmes should be active in disseminating information about sexual and reproductive health and family planning not only at service delivery sites, but also at the community level.

2.2 Right to access

All individuals in the community have a right to obtain sexual and reproductive health services, regardless of their race, gender or sexual orientation, marital status, age, religious or political beliefs, ethnicity or disability, or any other characteristics which could make individuals vulnerable to discrimination. Fulfilment of this right requires ensuring access through various health care providers as well as service delivery systems.

Sexual and reproductive health programmes should take the necessary steps to ensure that services will reach all individuals who need them, especially those for whom health services are not yet easily accessible.

2.3 Right of choice

Individuals and couples have the right to decide freely whether or not to control their fertility and which method to use. When seeking contraceptive services, clients should be given the freedom to choose which method of contraception to use. Sexual and reproductive health programmes should assist individuals in the practice of informed, free choice by providing unbiased information, education and counselling, as well as an adequate range of contraceptive methods. Clients should be able to obtain the method which they have decided to use provided there are no contraindications to their use of that method.

A client's concept of acceptability and appropriateness changes with circumstances. Therefore, **the right of choice also involves clients' decisions about discontinuation of a method of contraception and method switching.**

Another aspect of choice should be considered: as far as is practical, clients have a right to choose where to go for sexual and reproductive health services, and the type of service provider with whom they feel most comfortable. Choosing where to go may involve a choice of physical location or a choice of service delivery mode (e.g., community-based services, pharmacy or over-the-counter service, hospital, health centre or sexual and reproductive health clinic). **Governmental, non-governmental and private sector providers should welcome the establishment of alternative service outlets.**

2.4 Right to safety

Clients have a right to be protected from unwanted pregnancy, disease and sexual violence and, when receiving sexual and reproductive health services, this right to safety implies the following:

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

Safety relates to the quality of service provision, including both the adequacy of the service delivery facility itself, and the technical competence of the service providers. Ensuring the client's right to safety includes assisting the client in making an informed choice of contraceptives, screening for contraindications, use of the appropriate techniques to provide the method (if applicable), teaching the client about the proper use of the method and ensuring proper follow-up. The conditions in service delivery sites, together with the materials and instruments, should be adequate for the provision of safe services.

Any complications or major side-effects should receive appropriate treatment. If this treatment is not available at a particular service site, the client should be referred to another facility.

2.5 Right to privacy

Clients have a right to discuss their needs or concerns in a private environment. Clients should know that their conversation with the counsellor or service provider will not be listened to by other people.

When a client is undergoing a physical examination, it should be carried out in an environment in which her/his right to bodily privacy is respected. The client's right to privacy also involves the following aspects related to quality of services:

- When receiving counselling or undergoing a physical examination, the client has the right to be informed about the role that each individual inside the room, besides those directly providing services, is playing (e.g., individuals undergoing training, supervisors, instructors, researchers, etc.). Where the presence of individuals undergoing training is necessary, the prior permission of the client should be obtained.
- A client has a right to know in advance the type of physical examination which is going to be undertaken. The client also has a right to refuse any particular type of examination if s/he does not feel comfortable with it or to request that this examination be done by another service provider.
- Any case-related discussions held in the presence of the client (particularly in training facilities) should involve and acknowledge the client.

2.6 Right to confidentiality

Clients should be assured that any information they provide or any details of the services received will not be communicated to third parties without their consent. The right to confidentiality is protected under the Hippocratic oath. As such, sexual and reproductive health services should be performed in conformity with local legal requirements and in accordance with ethical values.

A breach of confidentiality could cause the client to be shunned by the community or negatively affect the matrimonial status of the client.

It may also lessen a target group's confidence and trust in the staff of a service delivery programme. In accordance with the principle of confidentiality, service providers should refrain from talking about clients by name or in the presence of other clients. Clients should not be discussed outside service sites. Client records should be kept closed and filed immediately after use. Similarly, access to client records should be controlled.

2.7 Right to dignity

Clients have a right to be treated with empathy, courtesy, consideration, attentiveness and with full respect of their dignity regardless of their level of education, social status or any other characteristics which could single them out or make them vulnerable to abuse. In recognition of this right of the client, service providers must be able to put aside their personal gender, marital, social and intellectual prejudices and attitudes while providing services.

2.8 Right to comfort

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

2.9 Right of continuity

Clients have a right to receive sexual and reproductive health services and supplies, such as contraceptives, for as long as needed. The services provided to a particular client should not be discontinued unless this is a decision made jointly between the provider and the client. In particular, a client's access to other sexual and reproductive health services should not depend on whether s/he continues the contraceptive services or not. The client has a right to request transfer of her/his clinical record to another clinical facility, and in response to that request, the clinical record or a copy of it should be sent to that facility or given to the client.

Referral and follow-up are two other important aspects of a client's right to continuity of services.

2.10 Right of opinion

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

Any new programme or service delivery facility should ideally involve clients at the planning stage. The aim is to satisfy would-be clients' needs and preferences in ways that are appropriate and acceptable to them.

Programme managers and service providers should achieve fulfilment of all rights of the clients. This goal is directly related to the availability and quality of sexual and reproductive health and family planning information and services.

3 Providers' needs

The needs of service providers must also be addressed in order to make clients' rights a reality. Without these needs being met – in terms of adequate resources, support, knowledge and training, for example – it becomes impossible for service providers truly to meet clients' rights. The needs of the service providers can be outlined as follows:

3.1 Need for training

Service providers must have access to the knowledge and skills needed to perform all the tasks required to do their work. It would be most unfair to the service provider and her/his clients if providers were required to perform a task for which they had not received the appropriate training. It is, therefore, the responsibility of the managers to identify staff training needs and to take the necessary steps to provide all required training.

Programme managers should bear in mind that the training needs of service providers include technical aspects *and* communication skills. Effective communication is essential for clients to understand the background information, to which everyone is entitled, that will support the decision-making process and the implications of any choices made, including the personal risk/benefit balance. Effective communication is also required to establish the providers' perception and understanding of the clients' circumstances.

3.2 Need for information

All service providers need to be kept informed on issues related to their duties. Moreover, service providers do not work in isolation, and they can work more efficiently if they are also informed on aspects related to the work of their colleagues in the service delivery team and other areas of the programme. Access to updated technical information can assist service providers to talk with authority and to act with confidence.

3.3 Need for infrastructure

Service providers need to have the appropriate physical facilities and organization to provide services at an acceptable level of quality. This right to the appropriate infrastructure applies not only to services provided in a clinical environment, but also to services provided at the community level. The need for efficient organization at community level is just as important as it is for clinical services.

Service providers must also be assured their working environment is safe. This includes safety from being unnecessarily exposed to the risk of an infection, such as HIV/AIDS.

3.4 Need for supplies

Service providers need continuous and reliable supplies of the methods of contraception and materials which are required for the provision of sexual and reproductive health services at appropriate standards of quality. It is highly frustrating for a service provider who wants to do a good job to have to turn away clients without giving them the method of contraception they want to use. An adequate supply of materials should include educational materials, as well as those which are required to provide safe and effective services to the clients.

3.5 Need for guidance

Service providers need clear, relevant and objective guidance: the type of guidance which will reinforce their commitment and competence for delivery of high-quality services. This guidance should be in the form of written service guidelines, practical checklists and effective supportive supervision.

3.6 Need for back-up

Service providers need to be reassured that whatever the level of care at which they are working – from the community level to the most comprehensive clinical service delivery site – they are members of a

larger grouping in which individuals or units can provide support to each other. To fulfil their commitment for quality of care, service providers may find themselves needing to request a consultation or technical support, or to refer clients to another provider or another level of care. Sexual and reproductive health and family planning programmes should develop the mechanisms to facilitate this process.

3.7 Need for respect

Service providers need recognition from the programme of their competence and potential, and respect for their human needs. They also need the support of the system in their efforts to gain the respect of the clients. For example, referrals made by community workers to clinical facilities should be given adequate attention and clinic staff should show respectful consideration of the concerns of the community workers.

Behavioural factors which may negatively affect the respect of the clients towards a service provider must be avoided – e.g., calling the attention of the provider to mistakes or problems in the presence of the clients in a way which may cause embarrassment or shame.

Service providers must be protected from any verbal, psychological and physical harassment or abuse from clients, other staff and supervisors.

3.8 Need for encouragement

Service providers need stimulus in the development of their potential and creativity. They should be encouraged to work at a level of autonomy in accordance with their capabilities. Their motivation and commitment to quality of care should be strengthened. Motivation and commitment are the most essential ingredients for successful sexual and reproductive health and family planning services which work at acceptable levels of quality.

3.9 Need for feedback

Service providers need feedback concerning their competence and attitudes as judged by others. This knowledge will assist service providers in improving their performance and in being responsive to the clients' needs. Feedback is necessary from all those involved in the service delivery system, including managers, supervisors, other service providers and especially the clients. Feedback works best if given in a positive and constructive way. Providers should be given the opportunity to improve their performance based on the knowledge of how they are seen by

others. If service providers are motivated towards quality of care and are continuously encouraged to improve, feedback will be effective in improving the quality of care.

3.10 Need for self-expression

All service providers, regardless of the level of care at which they are working, need to express their views concerning the quality and efficiency of the programme. But they also need to be listened to and to know that their opinion is taken into account when making management decisions.

Policy makers and programme managers should assess and care for the needs of service providers in order to ensure good quality of services. This is the best way to meet the rights of the clients and maintain the credibility and reputation of the programme.

Photo: Fatiha Terki/Vietnam



2

COUNSELLING

2 COUNSELLING

1 What is counselling?

Counselling is a face-to-face process of communication by which one person helps another individual, couple, family or group to identify her/his or their needs and to make appropriate decisions and choices.

Counselling is a structured conversation between two or more people that assists one or more of the participants to work through particular issues that she or he faces with regard to sexual and reproductive health (SRH) needs and contraception, to explore their feelings and to find ways to deal with them. Counsellors encourage people to recognise and develop their own coping capacity, so they can deal more effectively with issues of concern.

Counselling not only helps people with their immediate needs, but also helps them to recognise and draw upon their own resources, which they can use for future problems they may encounter. Counselling is about creating new perspectives and change. The change may be inside the person (helping them to feel differently about a situation); or a change in their behaviour (e.g., practising safer sex); or a change in something in their environment.

Counselling aims to help people to:

- Understand their situation more clearly.
- Identify a range of options for improving that situation.
- Make choices, including contraceptive choices, which fit their values, characteristics, feelings and needs.
- Make their own decisions and act upon them.
- Cope better with any problems.
- Develop life skills such as being able to talk about sex with a partner.
- Provide support for others while preserving their own strength.

2 Counselling in sexual and reproductive health settings

In sexual and reproductive health settings, counselling can be used for a variety of tasks which include:

- To decide whether or not she, he or they need and want to use a method of contraception.
- To make an informed, free choice of a contraceptive method.
- To learn about the method of choice.
- To use the method of choice properly.
- To overcome anxieties and make adequate decisions if problems occur.
- To help with concerns about sexually transmitted infection (STI) and/or HIV infection.
- To prepare couples for parenthood.
- To make informed decisions about breastfeeding.
- To help women decide whether to terminate a pregnancy.
- To discuss any issues around sexuality and sexual relations, infertility, menopause and other sexual and reproductive health issues.

Effective counselling is particularly important in helping people with concerns about sexual and reproductive health because many people feel unable to talk with relatives or friends about these concerns. They may not even feel able to talk to their partner about contraceptives, safer sex or a diagnosis of STI. These situations can be complex and clients need time to talk them through and to make an appropriate decision.

Family planning/reproductive health counsellors have many opportunities to counsel clients on sexual and reproductive health issues including family planning. By expanding family planning counselling to sexual and reproductive health counselling, the client is looked at in a holistic way. This is more helpful to the client in terms of family planning and their sexual life generally, and makes clients feel that the counsellor cares about them as people rather than contraceptive acceptors. The use of the existing facilities is maximized. The counsellors have already been trained, are used to counselling and are trusted by the community, and the counsellor can reach a wider group of clients with unmet needs, including young people, men and those not at risk of pregnancy.

3 Who can do the counselling?

In many clinical settings, there may not be a formal specialist counsellor, but several clinic staff such as nurses, educators, receptionists, doctors and community workers could be trained to provide counselling. People who are motivated to counsel are more likely to make empathetic and proficient counsellors. Managers should motivate and support providers, community workers or volunteers to be involved in counselling. All staff members and community workers who provide counselling on a regular or occasional basis should be provided with appropriate training on counselling and communication skills.

To be a counsellor one needs:

- To have knowledge:
 - Of relevant sexual and reproductive health issues.
 - Of all available resources for sexual and reproductive health matters in their locality, including HIV prevention, support and/or care for victims of gender-based violence. (Counsellors might draw a map of all the resources in their district and use it to refer clients as appropriate).
 - Of trends and changes in sexual and reproductive health needs.
- To be motivated and committed.
- To have counselling skills including:
 - Active listening.
 - Non verbal communication.
 - Paraphrasing.
 - Asking questions.
 - Reflecting feelings.
 - Providing information.
- To have the right attitudes, including:
 - Being non-judgmental.
 - Not imposing one's own values on clients.
 - Being warm and approachable.
 - Being empathetic.
 - Having respect for clients.
 - Being committed to the client's well-being.

- Being willing to learn continuously and from one's own mistakes.
- Knowing oneself.
- Having knowledge of life and of people with different cultures and ways of life.

4 Environment

It is important to make clients feel at ease and to make them feel safe and confident. Creating a safe environment for counselling includes consideration of the physical environment. Wherever counselling takes place, whether at home or in the clinic, it must be held **privately**.

- Ensure that counselling is done in private and is confidential so that every client feels comfortable to discuss risk factors, including sexual behaviour.
- Provide a space where accompanying children can play with supervision while the mother is counselled.
- Make sure that the room is arranged in such a way that the communication between the client and the counsellor is private and confidential and that it facilitates communication between the client and the counsellor.
- Use visual aids to facilitate discussions, such as flip charts, anatomical and contraceptive posters or pelvic models.

The counsellor's approach and attitude is crucial. The counsellor can make the clients feel safe and confident by treating them in a warm and respectful way and communicating with them in a language and terminology they understand. The appearance and approach of the counsellor should be such that clients do not feel overpowered and feel secure enough to open up. Whenever possible and practical, counsel both the client and the partner and/or the family when appropriate.

- As soon as you meet a client, give them your full attention.
- Greet them politely and introduce yourself (name and title).
- Explain that any information they share with you is confidential.
- Ask the client what is the reason for their visit and how you may help them.

- Listen attentively and demonstrate this through positive body language and non-verbal communication.
- Give the client enough time to express her or his ideas and to make their own decision. Value silence while the client thinks deeply or copes with her or his emotions.
- Be aware of possible or known cultural differences between you and your client and ask for a fuller explanation if you do not understand or need to know more.
- Good interpersonal communication requires appropriate eye contact. However this may not always be culturally acceptable.
- Do not write and listen at the same time. Give your full attention to listening and then make notes with the client's permission if you need to.
- Encourage the client to speak or continue speaking by words such as "I see", "go on" etc. These small signs are vital to show that you are interested and pleased that the client is expressing her/himself.
- Assist the clients to talk about their needs and encourage them to ask any questions to help them with their sexual and reproductive health needs.
- Explain to them that you are asking questions to help them with their needs.
- Help the client to focus on issues where they can actively do some positive change, rather than being overwhelmed by the whole issue or problem. Help them to identify others that they can rely on and receive help from.
- Try to answer your client's questions honestly, accurately and fully, however difficult they are. It does not help the client to give false reassurance to stop them worrying.
- Involve new clients in the process of completing any acquired forms accurately and completely. For continuing clients, involve them in updating their records with any new information.
- If counselling is taking place in a clinic, as opposed to the client's home or other place in the community, explain the steps of the clinic visit, including who they will see, what examinations and tests will be performed and the reasons they are necessary, how long the visit will take and whether any payment is necessary.
- Refer the client to a range of services as needed.
- Provide ongoing support but avoid dependency and help clients to develop their own coping skills.

5 The link between education/information and counselling

Information obtained by clients before counselling will make the counselling process easier and will save time during personal interviews. Clients should learn about family planning, contraception, safer sex, STIs, HIV/AIDS and other sexual and reproductive health issues through other education activities, including posters and pamphlets (in appropriate languages) placed in waiting areas; films or videos; and by taking part in group discussions. **Time in waiting areas should be used to educate clients on reproductive health, contraception, STI/HIV/AIDS prevention and other sexual and reproductive health issues.**

Counselling is part of the information and education process. Giving information and education before the counselling can save some time in individual counselling but the counsellor still needs to check that the client understands the basic facts in relation to her or his own life.

During *individual counselling*, learning is enhanced by clients receiving information and education to their specific needs.

In *group information-giving*, the provider (or a video or printed pamphlet) gives the basic facts about an issue (e.g., family planning, contraceptives, safer sex, STIs, HIV/AIDS, transmission routes, potential advantages and disadvantages of having an HIV test and the process of counselling and testing). The provider or video needs to give the information in a clear and interesting way that relates to people's lives. Ask the group if they have any questions and encourage discussion through the information giving. If you have enough time, have some discussion after each topic. Warn the group that you cannot guarantee confidentiality and it is safest to talk about issues in a general way rather than disclose personal information. This can happen later in the individual counselling session. The ideal size for the group depends on the venue and the time available; between ten and twenty people gives opportunities for discussion.

In certain settings and cultural norms around sexual and reproductive health matters, *group counselling* such as in (extended) family or community groupings may be preferred. In group counselling, the counsellor guides a process of rapport building, exploration of the issues around prevention, options for risk reduction and other sexual and reproductive health information. The group is smaller (maybe up to ten people) and made up of people who will feel comfortable to talk together

(e.g., single-sex groups of a similar age and status, couples or families). They may share their feelings and experiences but with the understanding that confidentiality is not guaranteed. The group can share successful strategies for safer sex and, support and encourage each other and leave the session with more understanding of their options, their own feelings and values.

6 Contraceptive counselling

6.1 Choice of method

Clients should make their own decision on which contraceptive method is appropriate for them. The counsellor should help each client to match her or his family planning needs and preferences to a safe and appropriate method.

If the client is visiting the clinic to start using a method of contraception, ask the client if s/he has a particular method of contraception in mind.

If the client is considering a particular method:

- Try to determine by discussion and review of the client's medical and social history if the method is appropriate for the characteristics, needs and circumstances of the client.
 - If the method is appropriate, determine if the client knows about other contraceptive options and make sure that s/he is firm about her/his choice.
 - If the method is not appropriate (e.g., if she is breastfeeding, is less than 6 months postpartum and wants to use combined oral contraceptives; or if a barrier is unlikely to be used properly when an unwanted pregnancy would be a high risk), explain the disadvantages of using such a method and inform the client about other more appropriate contraceptive options.
- If, after discussing all the contraceptive options, the client chooses the originally preferred method, this method can be provided if the benefits outweigh the risks and there are no absolute contraindications.
- **If the client has a relative contraindication and the method is provided, advise her of the warning signs relevant to her condition.** In these cases, the participation of a senior member of staff in the screening and counselling process may be required.

If the client is not considering a particular method:

- Ask the client which methods of family planning s/he knows about. (This gives an opportunity to determine the client's level of knowledge as well as an opportunity to correct any misinformation).
- Briefly describe each method to the client. Provide additional information on the methods in which the client is interested. Show the methods to the client and let her/him examine them. Make sure information on all the following is included:
 - How the method works.
 - Effectiveness of the method.
 - Medical contraindications.
 - Possible side-effects.
 - Advantages.
 - Disadvantages.
- Encourage questions.
- Discuss advantages and disadvantages of the various methods in relation to the characteristics and needs of the client (e.g., current family situation, ability to remember to take a pill every day, partner's cooperation, frequency of sexual intercourse, number of partners). Advise the client that except for barrier methods no other method provides protection against STIs and that the condom is the only method demonstrated to protect against HIV (see chapter 14: HIV infection and AIDS).
- Determine if the client is ready to make her/his decision by specifically asking "What method have you decided to use?"
- After listening to all the contraceptive options available, the client may still be unable to decide and may ask you to recommend a method. Through continuous education and counselling, the choices will become clearer and the client will eventually be able to make her/his decision. In the meantime, suggest a method which is best suited to the client's particular characteristics and needs. If this is done, explain the reason for recommending that method and make sure that the client has understood those reasons and agrees with the recommendation. If the client does not agree, recommend another method until the client is satisfied. If there is still some hesitation, give the client some more time to consider before making her/his choice.

Never try to impose a method against the will of the client.

Special situations

- Some clients cannot use the method they choose for health reasons. When this occurs explain to the clients what the contraindications are and help them choose another method.
- **If the client chooses a method which you do not have in stock or do not offer, make a referral to a location where the method of choice may be obtained.** Help the client choose a method which can be used until her/his preferred method is available.
- If the client chooses female or male sterilization, she or he will have to receive special counselling, since this is a permanent method. The client must sign a specific informed consent form (see chapter 8: Male and female sterilization).

6.2 Explanation of how to use the method of choice

- The specific information that a client should receive about each method is stated in the chapters on each method. The following general areas must be covered when discussing the chosen contraceptive method:
 - How to use the method.
 - Possible side-effects.
 - Management of side-effects.
 - Warning signs that indicate need for medical follow-up, and where to obtain this follow-up.
 - Re-supply information, if applicable.
 - When the next follow-up visit should take place.
- Ask clients what they have understood about each of the above points by asking them to repeat the instructions in their own words. If necessary, repeat the instructions, emphasizing the points which the client has not understood well. Correct any misunderstandings and provide any information that is missing.
- Provide each client with printed information on the chosen method in a language appropriate to their reading level. When serving illiterate clients, provide carefully designed pictorial materials as a support for the one-to-one counselling. These materials are especially important

for methods such as the pill and barriers, which are dependent on correct use to be effective.

- Explain when the client should return for routine follow-up and re-supply. Also, explain the importance of a return visit if the client:
 - Is experiencing any side-effects.
 - Has any questions.
 - Wishes to switch to a different method.
 - Wants to stop using the method.

6.3 Return for follow-up

Enabling a client to understand complete information about family planning is not something that is usually accomplished in one visit; assisting clients to plan their families throughout their reproductive life is an ongoing process. Follow-up visits are an important opportunity to:

- Reinforce the decision clients have made to plan their family.
- Discuss any problems they are having with their method of choice.
- Answer any questions they may have.
- Explore changes in their current health status or life situation which indicate a need to switch to another contraceptive method or stop using any method.

During a follow-up visit:

- Briefly review the chart for the main details of the reproductive health history.
- Ask the client how s/he feels with the method and if there are any questions.
- If s/he is having any problems with the method, assess the nature of the problem and discuss possible solutions.
- If the problem is a side-effect, assess how severe it is and offer suggestions for managing it or refer the client for treatment.
- If the client is not using the method any more, ask why not (it may be due to problems related to misunderstanding, side-effects or supply). If the client still wishes to continue using a contraceptive answer her/his questions and provide information that will enable her/him to continue with a contraceptive of choice.

- If the client is still using the method, determine if it is being used correctly. Instruct the client on the correct use of the method if necessary.
- Ensure that the client receives re-supplies and an appropriate examination if necessary.
- Assist the client in selecting another contraceptive method if the client is not satisfied with a method, if her/his situation has changed, or if the method is no longer safe.
- If a client wishes to become pregnant, help her to stop her method and provide information on the return of fertility. Emphasize the importance of antenatal care and where to obtain it.

6.4 Problems using the method

- If a client seeks help because of problems with the method, it is important that service providers take care of the psychological needs of the client as well as the medical condition. **Comfort the client and give emotional support.**
- If the client is unhappy about the method being used, ask about the reasons; if appropriate, give reassurance about the method or advise about other contraceptive options.
- If a client is having complications which indicate that the method should be discontinued, give advice on other contraceptive options.

6.5 Method failure

If pregnancy has occurred, it is necessary to discuss it with the client (ideally with the couple) and to give her all the support and advice she may need. Try to determine if the pregnancy is the result of method failure and identify, if possible, any factors that may have contributed to it. (Please refer to chapters on specific methods).

It is usually impossible to anticipate accurately the effect of this event on the pregnant woman and her partner. The immediate reactions vary widely. Providers should be sensitive and understanding of changing feelings and provide support as required.

The client should be supported and encouraged to return for further counselling if desired.

- *If the woman plans to continue the pregnancy:* Advise her on the importance of early antenatal care and nutritional counselling and where and how to obtain it. A referral should be provided if necessary.
- *If the woman does not wish to continue the pregnancy:* Counselling should be provided in accordance with local laws and regulations. Explain to the client the dangers of unsafe abortion practices.

6.6 Integrating STI and HIV/AIDS counselling

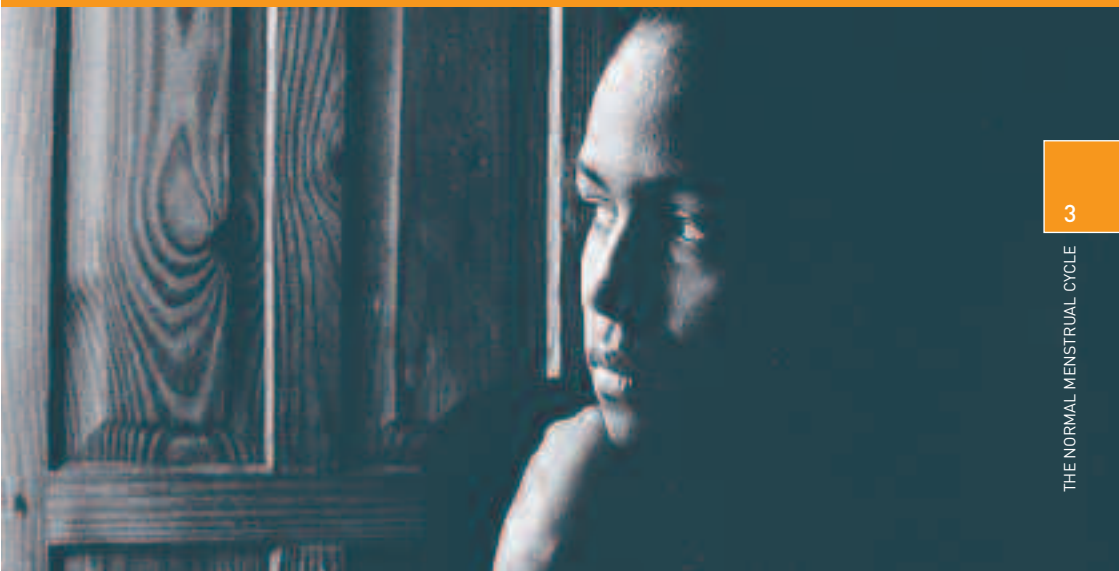
Counsellors who are mainly involved in family planning may feel that STI and HIV/AIDS counselling is an additional task that involves all kinds of problems that are difficult to resolve. They will need to understand the benefits of integrating STI/HIV counselling, given a chance to express their concerns, and to identify the support that they will need.

STIs, including HIV/AIDS are major problems, and clients should understand the risks and decide how to protect themselves. For each contraceptive method, providers should explain whether it protects or not against STIs/HIV and promote dual protection when appropriate (see chapter 14: HIV infection and AIDS).

7 Counselling for groups with special needs

Programmes serving clients with special needs should ensure that providers of counselling are well trained in the needs of these groups and what specific approaches may be useful. Examples of such client groups include adolescents, as well as non-literate or low-literate populations.

Photo: Miguel Cruz/Dominican Republic



3

THE NORMAL MENSTRUAL CYCLE

3 THE NORMAL MENSTRUAL CYCLE

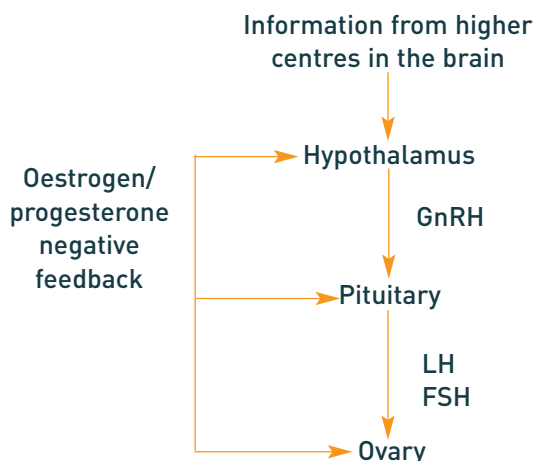
1 Introduction

Basic knowledge of the biology and physiology of the menstrual cycle facilitates understanding of the mechanisms of reproduction and of the action of various methods of contraception. Sexual development and reproductive function are regulated by interaction of the hypothalamus, pituitary gland and ovaries – the hypothalamic-pituitary-ovarian axis.

At the beginning of pubertal development, the sensitivity of the hypothalamic-pituitary-ovarian axis (see Figure 3.1) changes. The hypothalamus starts to release its main peptide, gonadotrophin-releasing hormone (GnRH), in a pulsatile fashion. This, in turn, stimulates the pituitary to release the gonadotrophins follicle stimulating hormone (FSH) and luteinizing hormone (LH). These pituitary gonadotrophins stimulate the ovaries in a cyclical manner, inducing the production of ovarian steroids – androgens, oestrogen and progesterone. The ovarian androgens and oestrogen, together with androgens from the adrenal glands (notably dehydroepiandrosterone), induce the pubertal changes in the female, in particular:

- Breast development;
- Sexual hair growth; *and*
- Maturation of the genital organs, including proliferation of the endometrium.

Figure 3.1 The hypothalamic-pituitary-ovarian axis



Menarche, or the first menstruation, is usually not preceded by an ovulation, but as the hypothalamic-pituitary-ovarian axis develops the ovarian cycle is established. Oestrogen and progesterone have an inhibitory effect on the hypothalamus and the pituitary (negative feedback), homeostatically regulating the release of gonadotrophins. In the periovulatory phase, increasing oestradiol concentrations stimulate the hypothalamus/pituitary to produce an LH surge, which in turn induces ovum release from the ovary.

Other factors can modulate the cyclical function of the hypothalamic-pituitary-ovarian axis. These influences include:

- Thyroid and adrenal gland activity, as shown by the association of hypothyroidism with menstrual disturbances.
- Olfactory, visual and emotional stimuli, some of which operate via neurotransmitters such as catecholamines, dopamine, serotonin and opioids. The limbic system and the pineal body also influence hypothalamic function, partly through melatonin.
- Nutritional factors, as shown by inhibition of the menstrual cycle in eating disorders or chronic diseases.

2 The ovarian cycle

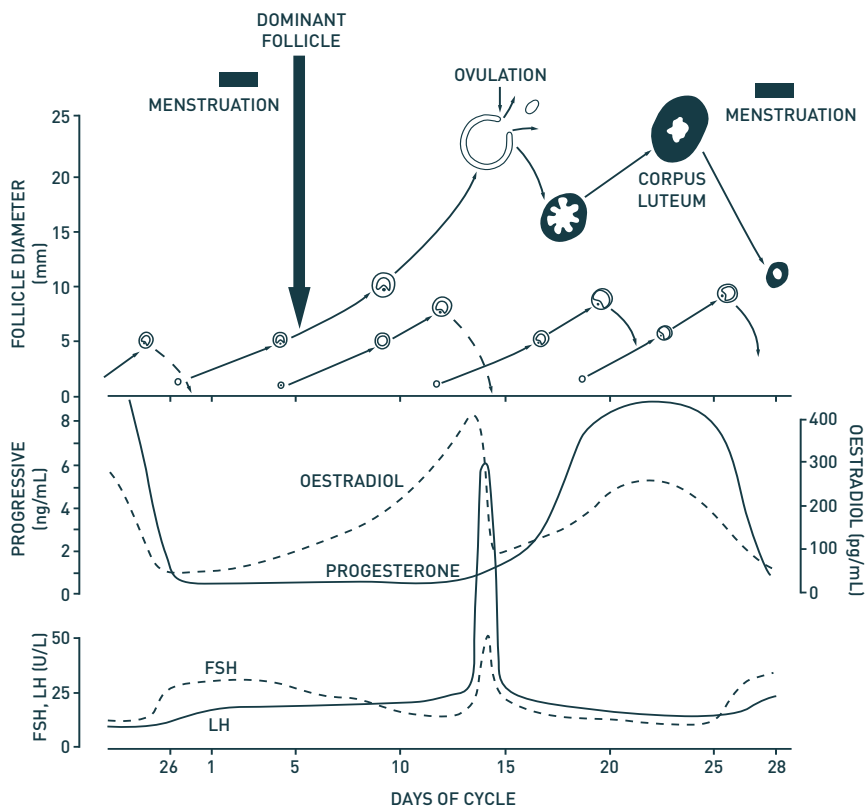
Each fetal ovary contains 6-7 million immature primordial follicles, only a few of which will develop and produce an ovum approximately every month during a woman's fertile life. Most of the follicles are destined to follow a cycle of growth and atresia until the follicle population "expires" at the menopause.

The ovarian cycle (see Figure 3.2) describes the events that occur in the ovary during a menstrual cycle before, during and after ovulation. The ovarian cycle is divided into the follicular phase (pre-ovulatory) and the luteal phase (post-ovulatory).

2.1 The follicular phase

FSH rises shortly before menstruation, stimulating the growth and maturation of a batch of ovarian follicles. The maturing follicles produce oestrogens, mainly oestradiol. By days 5-7 of the cycle one follicle becomes dominant, and the egg (ovum) which will be released from

Figure 3.2 The ovarian cycle



the ovary that month develops within it. The other maturing follicles in the batch recede and become atresic. Small amounts of LH are released continuously throughout the cycle, again in a pulsatile fashion. Some 24-48 hours before ovulation, a surge in oestradiol production by the dominant follicle triggers a surge of LH from the pituitary. This is the final stimulus to ovulation – rupture of the mature graafian follicle and release of the ovum.

FSH and LH can be measured in plasma. Their concentrations are inversely related to ovarian activity, and remain constantly high during the menopause.

2.2 The luteal phase

After ovulation the walls of the ruptured follicle collapse. The cells in the wall accumulate lipids and the pigment carotene, which gives them a yellow appearance. With this transformation the follicle becomes the corpus luteum (yellow body). The corpus luteum produces oestradiol, progesterone and androgens. Progesterone dominates this phase of the cycle and prepares the endometrium to receive the fertilized egg if fertilization occurs. If fertilization does not occur, or if the fertilized egg fails to implant, the corpus luteum regresses 11-14 days after ovulation. Oestradiol and progesterone concentrations in the mid-luteal phase suppress the release of FSH and LH from the pituitary. The atresia of the corpus luteum if no implantation occurs decreases oestrogen and progesterone in the circulation, thereby withdrawing the support of these hormones to the endometrium and leading to menstruation.

3 The endometrial cycle

The ovarian cycle of oestrogen production before ovulation, followed by oestrogen and progesterone in the post-ovulatory phase, is reflected in the endometrium. The endometrium proliferates in both glandular and stromal elements under oestrogen stimulation, in what is called the *proliferative phase*. After ovulation, under the effect of progesterone, the endometrium undergoes secretory changes in the glands and swelling of stromal cells, in what is called the *secretory phase*. As oestrogen and progesterone concentrations fall in the late secretory phase, the endometrial arterioles contract, leading to superficial ischaemia and subsequent shedding of the endometrium. The expulsion from the uterus of this endometrial material, together with blood, is what constitutes the menstrual period. The endometrium starts to repair through the proliferation of basal gland cells within 48 hours.

4 The cervical cycle

In the early pre-ovulatory phase of the menstrual cycle the cervical mucus is thick, sticky and opaque, and forms a plug blocking the cervical canal. With the increasing concentrations of oestrogen as ovulation approaches, the mucus becomes copious, thin, elastic and clear, reaching a peak at ovulation to facilitate the ascent of spermatozoa to the endometrial cavity and upper genital tract. Progesterone reverses these changes after

ovulation, producing viscid, scarce, sticky and opaque mucus, which again forms a barrier to spermatozoa. The changes in cervical mucus, accompanied by sensations in the vagina and vulva during the cycle, are the basis of the cervical mucus method of fertility awareness. Together with the physical changes in cervical mucus, there is a pH shift from an acidic pH of around 4 before ovulation to an alkaline pH of 7-8 in the periovulatory and post-ovulatory part of the cycle.

5 Conception

In a fertile cycle, coitus around the time of ovulation will result in rapid entry of sperm through cervical mucus to the upper genital tract. Spermatozoa have been demonstrated in the fallopian tubes 5 minutes after ejaculation (although most sperm take considerably longer), and they can survive in the female genital tract for 5 days or more. Fertilization usually occurs within a few hours of ovulation, in the outer third of the fallopian tube. The fertilized ovum starts to divide in the lumen of the fallopian tube, resulting in a ball of cells called the morula. By day 3 after fertilization the morula (or developing embryo) reaches the uterine cavity. It takes another 2-3 days to start implanting, and approximately another 3 days to implant successfully. On average it takes 6 days after ovulation for the developing embryo to start implantation. Once the embryo is in the uterine cavity, the cells surrounding it start to produce chorionic gonadotrophin, which is detectable in maternal blood from the 8th or 9th day after ovulation. Completion of implantation is regarded as the point of conception. Many fertilized ova (about 50%) do not implant and are lost during the next menstrual flow. Chorionic gonadotrophin maintains the corpus luteum, with continuing secretion of both progesterone and oestrogens until the placenta takes over this function later in the pregnancy.

Photo: Fatiha Terki/Vietnam



4

REPRODUCTIVE HEALTH SCREENING FOR WELL WOMEN

4 REPRODUCTIVE HEALTH SCREENING FOR WELL WOMEN

1 Introduction

Health screening is an important aspect of health care, which promotes population and individual wellbeing by early recognition of treatable disease and identification of those individuals who are at higher than normal risk of developing a particular disease and might therefore benefit from closer follow-up.

Sexual and reproductive health (SRH)/family planning clinics often provide the most convenient opportunity for the reproductive health screening of well women. Where available, well-woman screening should be offered to all clients of SRH/family planning clinics, especially to those women with a risk factor (see section 6). However, the provision of SRH/family planning services should *not* be conditional on women accepting any kind of well-women screening services.

In general, population screening programmes should target diseases that are:

- Prevalent enough and cause a sufficient degree of morbidity and mortality to merit a large-scale screening programme.
- Detectable by relatively simple means.
- Amenable to early treatment.

2 Health conditions targeted by reproductive health screening

These conditions fall into three main groups:

- Reproductive tract infections (RTIs) and sexually transmitted infections (STIs).
- Cancer (breast, cervical, endometrial and ovarian).
- The menopause.

3 Who is eligible for reproductive health screening?

Ideally, reproductive health screening should be available to:

- All women who attend SRH/family planning clinics.
- All women in high-risk groups.
- All women who request a check up.

4 Who can provide reproductive health screening?

With appropriate training, subject to local regulations and practice, reproductive health screening may be provided by:

- Doctors.
- Nurses.
- Midwives.

5 Requisites for a successful reproductive health screening programme

Key actions needed to provide a successful well-woman screening programme in SRH/family planning clinics include the following:

- Ensure that the clinic setting is user-friendly and easily accessible to clients in terms of its location, times of opening, and administrative procedures. Fees charged, if any, should be affordable to the target population. The environment should impart a sense of warmth and privacy.
- Set out clear protocols and establish proper staff training and supervision to ensure that appropriate service standards are met. Emphasize skills in communication as well as in performing clinical tasks.
- Create an environment where clients trust all staff and feel comfortable in talking about any fears that they may have about their own physical and psychological wellbeing. Client confidentiality must be maintained.
- Put across the message of the importance of regular reproductive

health checks and screening procedures in terms that are understood by clients.

- Provide information through the distribution of educational pamphlets and the organization of health talks and demonstrations, with the use of appropriate audiovisual aids where available.
- Keep accurate and complete records, and plan regular follow-up so that clients are not lost after the visit.
- Ensure that specially trained health professionals can provide proper counselling of women found to have a disease.
- Establish channels for referral to specialist care and further management, and make the referral process as efficient and trouble-free as possible.

The provision of reproductive health screening in SRH/family planning clinics should not overwhelm their facilities or personnel such that some women are denied the SRH/family planning services they are looking for. On the other hand, when SRH/family planning clinics do provide reproductive health screening services, these should not be made conditional on the use of any form of contraception.

6 Reproductive health screening

Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are discussed in detail in chapter 13. In this chapter, discussion centres on general aspects of reproductive health screening, and factors of special relevance to gynaecological cancers and the menopause.

6.1 Taking a history

As with all consultations, it is important to take an adequate medical history. All the usual aspects of the medical and social history should be covered (see Box 4.1), including demographic data; relevant family history; past general medical history, with identification of present and past illnesses including diabetes mellitus, anaemia, or immunodepression; menstrual, gynaecological, obstetric contraceptive and sexual history, with discussion of RTIs/STIs, including HIV, pelvic inflammatory disease (PID) and risk factors to STI such as multiple partners; and social history.

Box 4.1-Medical and social aspects to be covered in the history

- *Demographic data:* Age, parity.
- *Family history:* Health of parents, siblings.
- *Medical history:* Previous illnesses or operations, history of blood transfusion, any current medications or treatments, any allergies.
- *Immunization history:* Rubella, hepatitis vaccination.
- *Menstrual history:* Date of last menstrual period, age of menarche, regularity of cycles, amount and duration of menstrual flow, presence and severity of associated symptoms such as dysmenorrhoea and premenstrual tension, details about any abnormal vaginal bleeding (For a menopausal or perimenopausal woman, the presence and severity of postmenopausal symptoms).
- *Gynaecological history:* Previous illnesses including infections, any current or recurrent symptoms, such as vaginal discharge or vulval itchiness, RTIs/STIs.
- *Obstetric history:* Dates and details of past pregnancies and deliveries.
- *Contraceptive history:* Methods ever used and any side-effects.
- *Sexual history:* Age at first intercourse, number of sexual partners, any sexual problems including dyspareunia and post-coital bleeding.
- *Social history:* Smoking and alcohol intake.

In the well-woman health screening setting, most clients will be symptom free, so it is necessary to ask each client specific questions to elicit possible early symptoms related to high-risk conditions that might not otherwise be volunteered (see Box 4.2 for questions in relation to relevant high-risk conditions).

Box 4.2-Risk factors for breast, cervical, endometrial and ovarian cancers

Breast cancer:

- Age over 40 years.
- Family history of breast cancer, especially in a first-degree relative (mother/sister) who developed the disease before menopause.
- Early menarche or late menopause.
- Nulliparity or first pregnancy after the age of 30 years.
- History of atypical hyperplasia in the breast.
- High-fat diet and obesity.
- Had hormone replacement therapy (HRT) for 5 years or more.
- Never breast-fed.

Cervical cancer:

- Sexual intercourse before age 20 years.
- Multiple sexual partners.
- Infection with human papillomavirus (HPV).
- Cigarette smoking.
- History of sexually transmitted infections (STIs).

Endometrial cancer:

- Age over 50 years.
- Family history of endometrial cancer.
- Menstrual irregularity associated with anovulatory cycles.
- Late menopause.
- Nulliparity/infertility.
- Use of unopposed oestrogen.
- History of endometrial hyperplasia.
- History of diabetes mellitus and/or hypertension.
- High-fat diet, obesity.

Continued on following page

Box 4.2-continued

Ovarian cancer:

- Age over 50 years.
- Family history of ovarian cancer, especially in a first-degree relative.
- Early menarche and late menopause.
- Nulliparity or first pregnancy after age 30 years.
- High-fat, low-fibre diet.

6.2 Physical examination

The physical examination will be guided by the history elicited, including the method of contraception chosen by the client, and should include general routine clinical examination, breast examination and pelvic examination. These procedures should be fully explained to the client in terms that are readily understood, and the client should be encouraged to relax and be reassured that the examination can be stopped at any time if she so requests. Male health workers or the client may request a chaperone for the physical examination.

General examination

Cover the following aspects in the general examination:

- General appearance; build; gait and posture; speech pattern.
- Body weight and height; body mass index (especially if obese).
- Blood pressure; pulse.
- Presence of pallor, jaundice, leg varicosities, ankle oedema, abnormal skin pigmentation or markings.
- Thyroid enlargement (ask the client to swallow); cervical and supraclavicular lymph nodes and other neck masses on palpation.
- Breath and heart sounds.
- Presence of abdominal scars, enlargement or tenderness of the liver, spleen or kidneys; any other abdominal mass (e.g., gravid uterus).
- Presence of inguinal lymph nodes.

6.2.1 Breast cancer screening

Guidance on the value of breast cancer screening programmes should take into consideration the needs and realities of resource-constrained settings. In these settings, the benefit of putting resources into breast cancer screening programmes should be weighed against the benefits of allocating them to other health services. The risks and benefits of screening will vary from setting to setting. The provision of follow-up services is crucial for effective screening programmes.

Mammography

The best currently available method for early detection of breast cancer is mammography combined with clinical breast examination. Where resources are available, regular mammography is usually offered to women aged 50-70. The frequency of mammography will depend on age-specific incidence rates and local health policy but is normally every 1-2 years. Current evidence does not show a survival benefit for mass screening for breast cancer and evidence on breast cancer mortality is inconclusive.

Clinical breast examination

When mammography is not available, clinical breast examination may be offered. At present, it is not possible to make evidence-based recommendations on which women should be examined or how often. However, it is prudent to offer clinical breast examination to women over 40 and those under 40 with other risk factors, which are primarily related to family history (eg, breast cancer in a first-degree relative).

The breasts should also be examined, with palpation of the axillae to detect abnormal masses or tenderness.

Inspection:

- Explain the procedure to the client and the reason for doing it.
- Make the client sit at the end of the examination table with her arms relaxed by her side. Ask her to remove her gown up to the waist.
- Observe the following:
 - Contour and symmetry of breasts.
 - Any dimpling, swelling, discoloration and flattening of skin.
 - Nipple retraction or any discharge.

Palpation:

- Ask the client to lie down on her back, remove the gown from one breast and put her hand behind her head on that side.
- Use the pads of the three middle fingers. Wear gloves if there are open sores or any discharge.
- Begin palpation at the junction of the clavicle and sternum. Use small circular movements and vary the pressure applied by the fingers in three grades: light for the superficial layer, moderate for the middle layer and firm for deep layers.
- Palpate the breast in overlapping vertical strips and continue until the entire breast, including the axillary tail, has been covered.
- Palpate around areola and the depression under the nipple. Press the nipple between the thumb and index finger to see if there is any discharge.
- Lower the client's arm and palpate for axillary lymph glands.
- Repeat the same on the other side.

Instruction about breast self-awareness

Breast self-examination does not decrease mortality and should no longer be recommended as a screening tool. However, women should be "breast aware"; and a woman who finds an abnormality in the course of her regular activities should have it checked by a trained professional.

Service providers need to instruct the client about breast self-awareness. Explain to her that breast cancer is one of the most common forms of cancer in women, and in its early stages it rarely causes symptoms and often first presents as a painless breast lump or a change in the appearance or feel of the breasts. Some breast cancers are first identified by women themselves, and the earlier breast cancer is detected, the higher the cure rate.

Clients should be told to look for the following warning signs:

- Any lump or thickening in the breasts, whatever the size.
- Any change in the appearance or shape of the breasts.
- Alteration in the position or level of the nipples.
- Dimpling of the skin surface.

- Retracted nipples.
- Discharge or bleeding from the nipples.
- Puckering of the skin surface like that of an orange (*p'ean d'orange*).

Tell the client to go to a doctor to have a thorough examination if she finds any unusual changes in her breasts.

6.2.2 Pelvic examination

Pelvic examination should be offered to women as part of reproductive health screening and should only be carried out if the woman accepts it.

If this is the client's first gynaecological examination, it is particularly important to put her at ease by a careful explanation of the procedure involved and the reasons for doing it. Encourage her to relax, and reassure her that the examination can be stopped at any time if she so requests.

Pelvic examination wearing gloves (not necessarily sterile) must be done in all women requesting an IUD, surgical sterilization or diaphragm insertion, and it should be offered to all women who visit the clinic for the first time and are aged 18 years or older or have been sexually active before 18 years of age.

During the pelvic examination:

- Ask the client to lie in the supine position with her legs bent at the knees, with the knees apart and the ankles together.
- Inspect the external genitalia, including the labia, prepuce, clitoris, urethral opening, perineum and anal opening. (If there is a history of vaginal prolapse or urinary stress incontinence, the client should be asked to strain with a full bladder to see if any cystocoele, rectocoele or leakage of urine is found).
- Palpate the vulva for tenderness and/or masses, particularly around Bartholin's glands.
- Ensure an adequate, adjustable light source.
- Insert a vaginal speculum of the appropriate size. In general, a larger instrument will be needed for a multiparous woman with lax vaginal walls, and a narrow speculum should be used for a nulliparous woman. The most commonly used models are the bivalve Cusco's and Graves'

speculum or the Sims' speculum. Water may be used for lubrication: if a cervical smear is to be taken (see section 7), KY jelly must not be used, but in other circumstances application of a very small amount may be helpful.

- Inspect the vagina for rugae, discharge (noting its colour, amount, consistency and odour) and any protruding mass. If indicated and laboratory facilities are available, a vaginal swab can be obtained from the fornices for bacterial culture.
- Expose the cervix and inspect its appearance, the presence of any erosion or cyst, any masses, or contact bleeding. A cervical smear may be obtained from the squamo-columnar epithelium junction between the ectocervix and the endocervix (see section 7). If indicated (e.g., in a client with suspected pelvic inflammatory disease or at high risk of STIs), take an endocervical swab for culture.
- Withdraw the speculum and perform a bimanual examination, using KY jelly.
- With the index and middle fingers in the vagina, assess the vaginal tone.
- Feel the consistency of the cervix and note any pelvic tenderness on moving the cervix from side to side.
- Place the other hand suprapubically and palpate the uterus between two hands, noting its size, position, regularity, and any tenderness.
- Palpate each lateral fornix for abnormal masses or tenderness. Assess any masses detected for size, consistency, position, and mobility.
- A rectovaginal examination is not routinely carried out, but may be indicated if the client has symptoms and/or signs of pelvic tumour or endometriosis. With the index finger in the vagina and the middle finger of the same hand in the rectum, palpate the uterosacral ligaments and rectovaginal septum for nodularity and other lesions.

A bimanual pelvic examination is not necessarily indicated after routine cervical smear screening, but should always be performed in the presence of pelvic symptoms (see Box 4.3).

Box 4.3-Pelvic symptoms indicating a need for bimanual pelvic examination

- Very heavy or painful periods.
- Intermenstrual bleeding.
- Urinary symptoms.
- Abdominal swelling.
- Lower abdominal pain or discomfort.
- Dyspareunia (pain on sexual intercourse).

Remember at all times during the physical examination that the presence of abnormal vaginal discharge and foul smelling fishy or musty odour is suggestive of bacterial vaginosis and trichomonas vaginalis (see chapter 13 for discussion of the management of RTIs and STIs).

6.3 Other investigations

Urinalysis

Some clinics routinely do simple dipstick analysis to detect sugar, protein, blood and bilirubin.

Laboratory investigations

Some clinics may have their own laboratories, whereas others may need to send samples or refer clients for further testing. In some clients the following investigations may be indicated by the history or physical examination:

- *Haematology*: Haemoglobin, full blood count, clotting studies.
- *Biochemistry*: Renal function tests, liver function tests, fasting sugar, lipid profile, iron status.
- *Immunochemistry*: Syphilis serology, rubella and hepatitis serology, HIV antibody status (see chapter 14); hormone concentrations.
- *Microbiology*: Culture and sensitivity tests (particularly useful in cases of suspected RTIs/STIs (see chapter 13).

Ultrasonography

The use of routine ultrasound examination in early detection of pelvic masses, especially ovarian tumours, has not been universally adopted - mainly for logistical reasons. Staff must be adequately skilled and the equipment of sufficient resolution so as not to miss small symptomless lesions. Although ultrasonography may not be routinely available in the setting of an SRH/family planning clinic, there should be an established channel for the referral for further investigation of women in whom a pelvic mass has been detected on pelvic examination.

Endometrial biopsy

Women at high risk of endometrial cancer (see Box 4.2) and those with dysfunctional perimenopausal bleeding may be referred for endometrial sampling. Various techniques are available, including aspiration cytology and curettage.

Bone densitometry

Measurement of bone density may form part of the assessment of women being considered for hormone replacement therapy (HRT).

6.4 Frequency of reproductive health screening for well women

The age at which women should begin to have regular gynaecological examinations for the purposes of health screening, the interval between subsequent visits, and the age at which such screening programmes should stop depend on the availability of resources (e.g., clinic personnel, time, facilities) and on the presence or absence of risk factors in individual clients.

As noted above in specific relation to mammography, the provision of screening services is influenced by weighing the medical benefit appropriately against the economic and social costs of the examination, and different countries may come to different conclusions (see section 6.2.1).

In any discussion of recommended intervals for any screening programme, it should always be borne in mind that these are minimum standards; high-risk individuals may need to be screened more frequently, and if symptoms develop between screening intervals they should, of course, be dealt with appropriately. For gynaecological conditions, the existence of SRH/family planning clinics enables these services to be readily available (see section 7).

6.5 Other issues to consider during reproductive health screening

Reproductive health screening can also represent an opportunity to enforce proactively messages in relation to sexual health and healthy lifestyle issues. The latter are considered in section 8, but are generally applicable at all ages.

7 Cervical cancer screening

Cervical cancer screening may take place during the pelvic examination phase of reproductive health screening. The two techniques are:

1) Cervical cytology, involving:

- Obtaining an adequate cervical smear;
- Fixing the smear; *and*
- Laboratory processing and examination of the smear.

Cervical cytology does offer an indirect way to diagnose human papillomavirus (HPV) infection by means of highly specific and very sensitive tests for HPV DNA (e.g., by use of the polymerase chain reaction or hybrid 11 capture), but these techniques are very expensive and not widely available.

Although obtaining cervical smears for the purposes of screening for cervical cancer is an integral part of reproductive health screening, the particular features of this process are dealt with here in a separate section for ease of cross-reference. Other features discussed earlier in this chapter also apply to cervical cancer screening programmes.

Exfoliative cytology

Exfoliative cytology is the study of cells that have been shed by various membranes or epithelia, which can be collected, spread onto slides, and the resulting smears stained and examined under the microscope. In clinical practice, surfaces are usually scraped to provide cells for study. In the case of cervical cytology, examination of these cells shows whether the cervical epithelial lining is normal, inflamed, or has evidence of cervical intra-epithelial neoplasia (CIN) or carcinoma. The purpose of cervical cancer screening programmes is to detect cervical cancers from premalignant lesions, when the cure rate for intervention is very high.

Cervical cytology (pap screening)

Cervical cytology is currently the best available method for the detection of pre-malignant and malignant disease of the cervix. When routine pap screening is available it should start 2-3 years after the onset of sexual activity and be repeated every 1-3 years. When only limited pap screening is available, it should at the very least be offered at around the age of 35 to all women who have ever been sexually active.

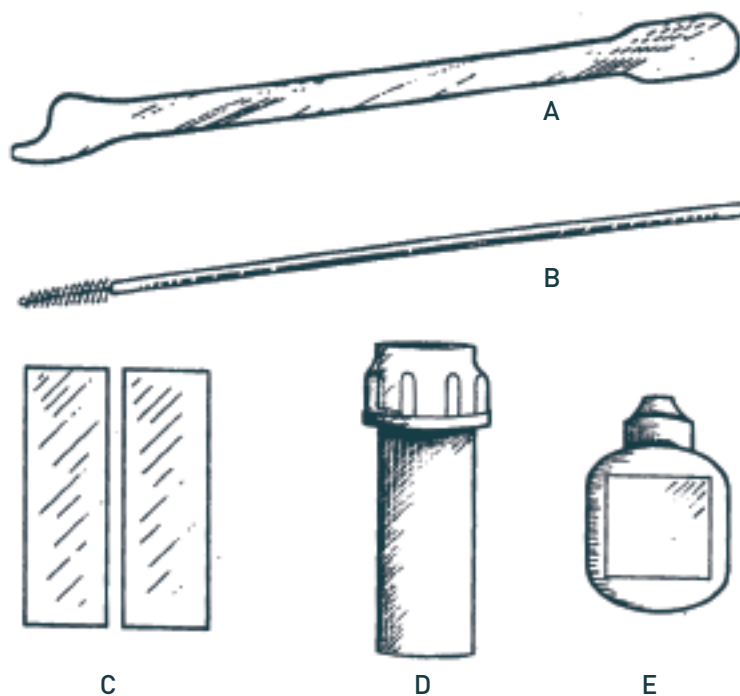
Screening for cervical cancer by means of cervical smears should be available in all reproductive health screening programmes. Ensure that there:

- Is access to reliable laboratory facilities for the cytological analysis of cervical smears;
- Are adequate facilities for tracing women with a positive result; and
- Are adequate facilities for referral.

The extra equipment needed for taking a cervical smear during the pelvic examination (see Figure 4.1) consists of:

- Aylesbury spatula.
- Endocervical brush.
- Glass slides.
- Fixing jar or spray fixative.
- Hard pencil.

Figure 4.1 Equipment required for cervical smear



A = Aylesbury spatula; B = Cytobrush; C = Glass slides; D = Fixing jar; E = Spray fixative.

Before collecting the cervical smear the essential equipment for making and fixing the smear should be assembled and preferably laid out on a tray. Slides should be carefully labelled with a hard pencil on the ground glass edge (or etched; ink will dissolve during processing). A simple information checklist for cervical cancer screening is shown in Box 4.4.

Box 4.4-Information checklist for cervical cancer screening

- First name and surname.
- Age.
- Clinic registration number.
- Date of last menstrual period (LMP).
- Length of menstrual cycle.
- Pregnancy status.
- Number of previous pregnancies.
- Date and type of previous gynaecological operations.
- Any history of radiotherapy treatment.
- Results of previous smears.
- Symptoms (if any).
- Any intrauterine device (IUD) fitted.
- Any oral contraceptives or other hormones taken currently or previously.

Site of collection

Material for cytological examination may be collected from the:

- Posterior, anterior, or lateral fornix of the vagina (for evidence of endometrial or endocervical adenocarcinoma).
- Ectocervix and squamo-columnar junction.
- Endocervical canal.
- Upper third of the lateral vaginal wall (for evidence of endometrial or endocervical adenocarcinoma).

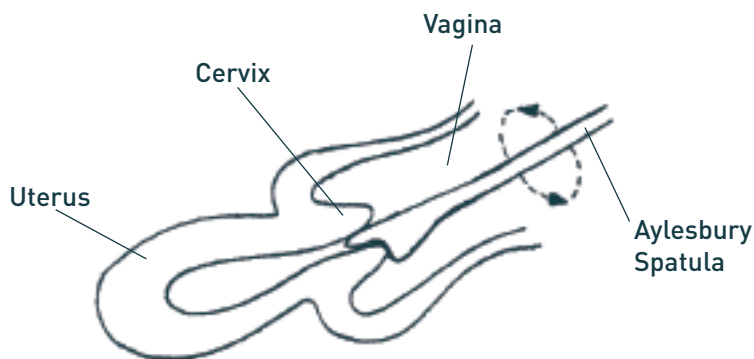
The choice of site and technique depends largely on the facilities available and the purpose of the examination. Most smears from the female genital tract are for the detection of cervical lesions, and for this purpose it is sufficient to collect material from the ectocervix, squamo-columnar junction, and endocervical canal (Exfoliative cytology for early detection of endometrial or endocervical adenocarcinoma is insensitive and unreliable).

Collection of the cervical smear

With the cervix exposed by an unlubricated speculum:

- Lightly scrape the ectocervix, any area that appears abnormal (e.g., an erosion) and the squamo-columnar junction between the ectocervix and endocervix, with the shaped end of the spatula (see Figure 4.2).

Figure 4.2 Scraping the squamo-columnar junction of the cervix



- Always scrape the full circumference of the squamo-columnar junction. When the squamo-columnar junction is well exposed, as in some multiparous women, better results are obtained with a larger spatula or by using the flatter end instead of the shaped end for scraping.
- Withdraw the spatula carefully from the vagina with the speculum still holding the walls apart.
- Place the scrapings immediately on one or two glass slides kept in readiness.
- Spread the secretions evenly over the previously prepared and labelled glass slide (see Figure 4.3):
 - Apply the spatula flat onto the slide and transfer the sample by a lengthwise sweep;
 - Repeat with the other side of the spatula (a circular or zigzag motion may be more effective in transferring the material);
 - Ensure that all the material is removed from both sides of the spatula; any material clinging to the spatula can be removed by scraping the

- spatula on the edge of the slide;
- Break up any lumps by exerting a little pressure with the spatula;
- If using a brush, spread the sample on the slide with a gentle rolling motion.
- Remember that speed is essential because air drying damages the cells in the smear and interferes with their staining properties and cytological interpretation.
- Fix the slides while the smears are still wet.
- Immerse the slides in jars filled with fixing fluid, or spray them with a commercial spray fixative (see Figure 4.4). Spraying is probably better and simpler, but sprays are expensive and not always readily available.
- Remove the speculum from the vagina after the smears have been fixed.

Figure 4.3 Spreading the cervical scrapings onto a glass slide



A single slide is almost always sufficient, but if there is a large amount of material a second slide may be needed. If only a scanty sample is obtained, a second scrape may be indicated. If two samples (e.g., scrape and brush or two scrape samples) are spread on one slide, the first sample should be fixed before the second sample is obtained.

Fix the slides immediately while the smears are still wet to stop them drying in the air. Rapid fixation is especially important for smears that contain blood and for smears from postmenopausal women, which dry very quickly.

Fixing in fluid

Suitable containers for fixing fluids are clean jam or honey jars and commercially available Coplin jars made of glass or plastic. When jam or honey jars are used, no more than one pair of slides should be immersed in each jar. Coplin jars can take up to five pairs of slides; these slides should be placed back to back (smear-carrying sides outwards) into the grooves of the fixing jar.

Fixing fluids commonly used are various alcohols (e.g., 95% ethyl alcohol, methyl alcohol, isopropyl alcohol) or mixtures of different alcohols, such as three parts of 95% ethyl alcohol with seven parts of tertiary butyl alcohol.

The slides should remain in fixative for at least 15 minutes, but may be left there for as long as 7 or even 10 days without deterioration.

Spray fixation

Spray fixation gives excellent results and overall is much simpler and more economical, with savings in both time and equipment. The spray fixative must be spread evenly over the whole of the smeared area on the slide (see Figure 4.4).

Figure 4.4 Spray-fixing smear



The spray must not be held closer than 15 cm from the slide or it may tend to wash the specimen away. The various spray fixatives marketed contain an aerosol agent and different mixtures of alcohol, acetic acid, or ethylene or propylene glycol. Once spray-fixed slides are dry (usually within 10 minutes), they can be dispatched to the laboratory for staining directly without additional measures. Commercially available spray

fixatives are relatively expensive; ordinary hair sprays are as effective and are considerably cheaper.

Staining

After adequate fixation, the slides are ready for staining. The staining procedure requires laboratory facilities and should be carried out by a trained technician. When such facilities are not available, it may be necessary to dispatch the slides to a laboratory for further processing. For transportation, slides fixed in fluid should be removed from the fixing jars after adequate fixation and dried in the air. Dry fixed slides should be sent to the laboratory in flat cardboard or wooden boxes. On arrival in the laboratory they will be resuspended in fixative and stained. This process often involves use of Papanicolaou stain, based on aqueous haematoxylin with multiple counterstaining dyes in 95% ethyl alcohol, which gives great transparency and delicacy of detail for examination by a skilled cytologist—hence the term Papanicolaou (or Pap) smear.

Errors in smear taking and processing

Typical causes of error in smear taking and processing are shown in Box 4.5.

Other aspects of reproductive health screening programmes related to cervical cancer screening are discussed earlier in this chapter.

Box 4.5-Causes of error in smear taking and processing

- Cervix not visualized adequately.
- Cervix not scraped firmly enough.
- Transformation zone not completely scraped.
- Material collected from wrong site (e.g., by scraping posterior vaginal wall instead of cervix).
- Slides insufficiently cleaned or degreased before use.
- Material incompletely transferred from spatula to slide.
- Sample poorly spread (too thick, too thin or distortion from excessive pressure).
- Air drying before fixation or during the staining procedure.
- Insufficient fixation (time too short or alcohol too weak).
- Incorrect staining (e.g., incorrect staining time, insufficient dehydration or mistakes in preparation of the stains).
- Smear consists mainly of blood or purulent exudates.

2) Direct visual inspection of the cervix

If pap screening is not available, visual inspection of the cervix should be offered. It should start 2-3 years after the onset of sexual activity and be repeated every 1-3 years.

In this simple test, during pelvic examination the cervix is visualized, washed with normal saline, inspected, and then washed with a solution of 3-5% acetic acid (e.g., vinegar) and inspected again after 1 minute to identify areas of acetowhitening suggestive of precancerous lesions by direct vision. It can be used for cervical screening where cost is a major consideration and cervical smear testing cannot be offered to the whole of a large population. In such circumstances the acetic acid test is held to be negative if no area of acetowhitening can be seen, and the client can be followed up at the normal screening interval, or earlier if symptoms develop. If infection is suspected, a swab should be taken and if confirmed it should be treated accordingly.

The extra equipment needed for direct visual inspection of the cervix during the pelvic examination consists of:

- Normal saline.
- A syringe for lavage.
- Acetic acid 3-5%.
- A bowl.

Do not perform the examination if the client is having her menstrual period or using intravaginal medication; ask her to come back after menstruation or treatment.

If acetowhitening is seen (a positive acetic acid test) on direct visual examination, with no evidence of infection, a cervical smear should be taken. If cervical cytological examination is not available, colposcopy, cryotherapy or loop electrosurgical excision could be considered – but may also not be available in such circumstances. Referral where further investigation and treatment can be carried out is indicated.

8 The menopause

Although strictly speaking not part of reproductive health screening or SRH/family planning services, the menopause is also discussed here. Apart from the gynaecological malignancies already mentioned, conditions associated with the menopause are increasingly gaining the attention of providers of health care, especially in developed countries, because of their potential effects on the physical and psychological wellbeing of many otherwise healthy women. The menopause is associated not only with short-term acute symptoms that may cause women discomfort and distress, but also, and more importantly, with long-term complications (particularly osteoporosis and cardiovascular disease, major causes of mortality and morbidity among postmenopausal women) that have a profound effect on the general health status of and cost of health care in the community. Screening women who are at high risk of developing these long-term complications, and advising them accordingly, forms an important function of reproductive health care. Clinical features of the menopause are shown in Box 4.6.

Box 4.6-Clinical features of the menopause

- Amenorrhoea.
- Hot flushes.
- Mammary atrophy.
- Atrophic vaginitis.
- Pelvic floor atrophy.
- Osteoporosis.

Counsel women about ways in which they can improve their overall health and quality of life by following a healthy lifestyle and eating a balanced diet. Particular points include:

- *Smoking*: Counsel women who do smoke about the hazards of smoking and encourage them to give up the habit.
- *Exercise*: Regular exercise (including swimming and aerobic exercises) promotes cardiovascular health; weight-bearing physical activity (such as brisk walking) slows down bone loss and stimulates regeneration of bone tissue. Therefore recommend moderate exercise three or four times each week.
- *Diet*: Encourage clients to have a balanced diet. This should be low in saturated fats, sugar and salt; include plenty of fresh fruit, vegetables, whole grain and fibre; and contain sufficient protein, vitamins and minerals.
- *Weight*: Monitor weight and note gains or losses; aim to avoid obesity.
- *Stress*: Advise clients to avoid unnecessary stress.
- *Alcohol*: Suggest that clients limit alcohol intake to no more than two units (one to two drinks) daily.

For women at high risk of osteoporosis (see Box 4.7), a calcium supplement (e.g., 1,000 mg daily) or other drug treatment (e.g., with vitamin D or a bisphosphonate) may be considered appropriate. For women at high risk of osteoporosis and/or with severe menopausal symptoms, hormone replacement therapy (HRT) may be considered.

Such interventions should be tailored to availability, feasibility, and individual circumstances, and must take account of the latest available evidence in relation to costs, potential benefits, side-effects and contraindications.

Box 4.7-Risk factors for postmenopausal osteoporosis

- Early age of menopause (idiopathic or due to ovarian ablation from surgery or irradiation).
- Thin build, fair complexion.
- Family history of osteoporosis.
- Smoking/excess alcohol intake.
- Sedentary lifestyle due to lack of exercise or chronic illness.
- Use of corticosteroids.

Photo: Fatiha Terki/Ethiopia



HORMONAL CONTRACEPTION

5

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:

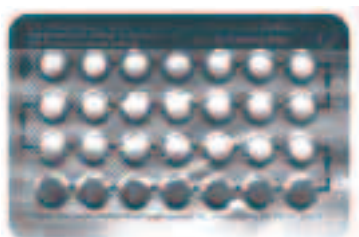
- Combined oral contraceptives (COCs);
- Progestogen-only pills (POPs);
- Progestogen-only injectable contraceptives (POIs);
- Combined injectable contraceptives (CICs); and
- Subdermal implants.

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 Lactation Adolescents Age over 35 years	Elective surgery Drug interactions Abnormal vaginal bleeding Malignancy of the genital tract	Sickle cell disease Varicose veins Parasitic diseases 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 ethinylloestradiol/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 Progesterone-only pills (POPs)



3.1 Definition

The progesterone-only pill (POP) is an oral hormonal contraceptive that contains a progesterone only, in a smaller dose (typically 10-50%) than that used in the combined oestrogen/progesterone pill. Thus, depending on the type of progesterone, POPs may contain only 30 µg (e.g., for levonorgestrel) to 600 µg (e.g., for norethisterone) of progesterone (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 progesterone-only contraceptives, the POP has 2 modes of action:

- The effect of the progesterone on cervical mucus is the main factor in the contraceptive efficacy of POPs. The mucus becomes viscous and scanty, inhibiting sperm penetration.
- The progesterone 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.

Photo: Jenny Matthews/Nepal



INTRAUTERINE DEVICES

6

6 INTRAUTERINE DEVICES

1 Definition

The intrauterine device (IUD) is a safe and effective method of reversible contraception. IUDs are small flexible devices made of metal and/or plastic; they may be inert, or may release copper or hormone. Copper-bearing devices include the 'Copper T 380A' (TCu 380A), the 'Copper T 220C' (TCu 220C), the 'Multiload Copper 375' (ML Cu 375) and the 'Nova T' (Nova T) (see Figure 6.1). A levonorgestrel-releasing IUD is available in a few countries.

Duration of use: The TCu 380A has proved to be highly effective for at least 12 years with a cumulative pregnancy rate of 2.2 per 100 women, while the TCu 220C is also effective for this length of time, but to a lesser degree. The ML Cu 375 is effective for at least 10 years. The Nova T200 is recommended for up to 3 years of use, after which failure rates increase substantially. The Nova T380 is effective for 5 years, with a cumulative pregnancy rate of 2.0.

The levonorgestrel-releasing IUD lasts for more than 5 years with a cumulative pregnancy rate at 5 years of 0.3–1.1 per 100 women.

The inert devices may be used up to the menopause. Although they are no longer recommended for new clients, there is no need to remove them before menopause if the woman is satisfied with the method and has no problems with it.

Figure 6.1 Copper-bearing IUDs



Mode of action:

Any IUD prevents pregnancy by a combination of mechanisms of action, including:

- Inhibition of sperm migration in the upper female genital tract.
- Inhibition of ovum transport.
- Inhibition of fertilization.

The levonorgestrel-releasing IUD, in addition to the above, causes changes in the amount and viscosity of the cervical mucus, inhibiting sperm penetration.

2 Indications

An IUD should be provided to any woman who requests it after receiving appropriate counselling and reaching an informed decision, and who has no contraindications to its use (see section 3 of this chapter).

An IUD may be particularly appropriate for women who:

- Are parous and want a highly effective, long-acting, reversible method of contraception.
- Prefer a method of contraception that does not require action daily or with every act of sexual intercourse.
- Are breast-feeding.
- May have difficulty obtaining contraceptives supplies on a regular basis.
- Lack privacy, making use of some other methods problematic (e.g., crowded living quarters, no storage space for contraceptives).
- Show risk status changes during use of another method of contraception (e.g., women who take contraceptives that contain oestrogen who start to smoke or who develop peripheral vascular disease or diabetes mellitus).
- Do not want to have any more children, but do not wish to be sterilized.

3 Medical eligibility criteria

The International Planned Parenthood Federation and other bodies have collaborated with the World Health Organization (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).

Category 4 (contraindications)

Do not advise the use of any IUD or provide it to women with:

- Known or suspected pregnancy.
- Puerperal or post-abortion sepsis current or within the last three months.
- Pelvic inflammatory disease (PID) current (if develops during IUD use becomes a category 2).
- Sexually transmitted infection (STI) current (refers to STIs that may produce cervical infection, chlamydia or gonorrhoea) (if these develop during IUD use becomes a category 2).
- Purulent cervicitis.
- Confirmed or suspected malignancy of the genital tract.
- Unexplained vaginal bleeding (suspicious for serious condition) (if develops during IUD use, becomes a category 2).
- Cervical cancer awaiting treatment (if develops during IUD use, becomes a category 2).
- Endometrial cancer (if develops during IUD use becomes a category 2).

- Congenital uterine abnormalities or benign tumours of the uterus (fibroids) which distort the cavity in a manner incompatible with proper IUD placement.
- Malignant gestational trophoblastic disease.
- Known pelvic tuberculosis (if develops during IUD use becomes a category 3).

For the levonorgestrel-releasing IUD, the following contraindication also applies:

- Current cancer of the breast.

Counsel any woman with any contraindication (other than pregnancy) about alternative methods of contraception (see also chapter 2: Counselling).

Category 3

There are conditions which require careful consideration when advising a client on the possible use of an IUD, because the potential risks may outweigh the benefits of using the method. When any of these conditions is present, explain to the client the potential risks and recommend alternative contraceptive methods. If the client chooses the IUD because other contraceptive options are not available or acceptable, it is particularly important to advise her that close medical follow-up is required. These conditions include:

- Ovarian cancer (if develops during IUD use becomes a category 2).
- Increased risk of STIs (e.g., multiple partners or partner who has multiple partners).
- Initiation for women living with AIDS (if develops during IUD use becomes a category 2).
- Benign gestational trophoblastic disease (there is an increased risk of perforation, and treatment of the disease may require multiple uterine curettage).
- From 48 hours to 4 weeks postpartum.

For the levonorgestrel-releasing IUD, the following conditions also require careful consideration:

- Active viral hepatitis.
- Severe (decompensated) cirrhosis.
- Benign and malignant liver tumours.
- Current deep vein thrombosis or pulmonary embolism (DVT/PE).
- <48 hours postpartum.
- History of breast cancer with no evidence of disease for past 5 years.

If an IUD is provided, record the woman's special condition in the clinical record. Advise her of warning signs relevant to her condition. In these cases the method should only be inserted by a trained medical doctor who should sign the client's record.

Category 2

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

- Menarche to < 20 years of age.
- Nulliparous (see section 4).
- < 48 hours postpartum (for the levonorgestrel-releasing IUD is a category 3).
- Post-abortion after second trimester abortion.
- Abnormalities (including cervical stenosis or cervical lacerations) which do not distort the uterine cavity or interfere with IUD insertion.
- Complicated valvular heart disease.
- Uterine fibroids without distortion of the uterine cavity.
- PID without subsequent pregnancy.
- Vaginitis without purulent cervicitis, chlamydia or gonorrhoea and other STIs (excluding HIV and hepatitis).
- High risk of HIV.
- HIV positive women and women with AIDS who are clinically well and on antiretroviral treatment (there may be an increased risk of PID due to suppressed immunological response).
- Anaemias including thalassaemia, sickle cell disease, iron deficiency

anaemia (not for levonorgestrel-releasing IUD).

- Severe dysmenorrhoea (not for levonorgestrel-releasing IUD).
- Heavy or prolonged bleeding (includes regular or irregular patterns).
- Endometriosis (not for the levonorgestrel-releasing IUD).

For the levonorgestrel-releasing IUD, the following conditions also require careful consideration:

- Multiple risk factors for arterial cardiovascular disease.
- History of hypertension (where blood pressure cannot be recorded).
- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).
- Hypertension with vascular disease.
- History of deep vein thrombosis or pulmonary embolism (DVT/PE).
- Major surgery with prolonged immobilization.
- Known hyperlipidaemia.
- Current and history of ischaemic heart disease (if develops during IUD use becomes a category 3).
- Stroke.
- Migraine with or without aura (if migraine with aura develops during IUD use becomes a category 3).
- Cervical intraepithelial neoplasia (CIN).
- Undiagnosed breast mass.
- Diabetes mellitus.
- Gallbladder disease.
- Mild (compensated) cirrhosis.

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

4 Special situations

Nulliparity

Nulliparity is not a contraindication for the use of an IUD. However, a history of pelvic infection, a previous ectopic pregnancy or multiple sex partners make the choice of an IUD inappropriate for a nulliparous woman. Clearly explain the possible increased risk of pelvic inflammatory disease and of possible subsequent infertility related to the use of an IUD before the client chooses this method.

Abnormal vaginal bleeding

Irregular bleeding patterns are common among healthy women. Do not withhold inserting an IUD in the absence of any reason to suspect a pathological condition. However, if a woman has vaginal bleeding suggestive of a condition related to pregnancy or a pathology such as pelvic malignancy, it should be investigated before an IUD is inserted.

Sexually transmitted infections (STIs)

If a client may be at a high risk of STIs, including HIV, advise the use of condoms in addition to the IUD.

HIV infection

If the client is HIV positive or if a client has AIDS and is being treated and is clinically well and healthy under antiretroviral drugs (ARVs) and, after proper counselling and discussion of other contraceptive alternatives, she chooses to use an IUD, recommend the use of condoms, in addition to the IUD, for prevention of STIs and HIV transmission.

5 Counselling and information

All clients for IUD insertion must receive appropriate counselling for selection and use of this method of contraception. Review the woman's history to determine the possibility of existing contraindications to the method, and take this into account when providing counselling. In general, the IUD is very safe for women in a mutually monogamous sexual relationship because these women are very unlikely to develop pelvic inflammatory disease associated with IUD use. **Encourage clients to ask all their questions so that any uncertainties and misunderstandings can be cleared up** (see also chapter 2: Counselling).

For selection of the method

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

- Advantages and disadvantages of the IUD, including:
 - Effectiveness;
 - Risks and benefits;
 - Side-effects, particularly the possibility of heavier menstrual periods;
 - The procedures of insertion and removal; *and*
 - Cost.
- Alternative family planning methods including information as appropriate on:
 - Effectiveness;
 - Risks and benefits;
 - Side-effects; *and*
 - Cost.
- The type of IUD to be inserted (a sample should be shown) and the proper time for its replacement.
- The importance of encouraging the client to come back anytime to discuss problems or have the IUD removed.

For use of the method

See instructions in section 11 of this chapter.

6 Who can insert IUDs?

Doctors, midwives, nurses and other health professionals can insert IUDs, provided that they have been properly trained and that this is in accordance with the country's regulations.

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 taken as an opportunity to offer the client other available sexual and reproductive health services as appropriate.

- *Medical/social history:* Include gynaecological and obstetric history; present illnesses, including diabetes mellitus, anaemia or immunodepression; and history of STIs, including HIV, PID and risk-factors to STI such as multiple sexual partners.
- *Physical examination:* Speculum visualization of cervix and bimanual pelvic examination must always be included and any other examination as indicated by the medical history.
- *Laboratory tests:* These are not routinely required for the use of an IUD except when indicated by the medical history and physical examination. Whenever possible and appropriate, selected tests should be offered to women as part of reproductive health services, including:
 - STI/HIV screening: laboratory tests.
 - Haemoglobin or haematocrit.
 - Cervical (Pap) smear.

8 IUD selection

- The smaller, copper-bearing devices have been shown to be appropriate, safe and effective, with a low pregnancy rate. Compared with the bulkier inert IUDs, they are easier to insert and usually cause fewer side-effects, such as pain and excessive menstrual blood loss. The newer copper-bearing devices (TCu 380A, TCu 220C, ML Cu 375 and Nova T) are more effective and offer a longer duration of use than older copper-bearing devices (e.g., 'TCu 200' and 'Copper 7'). For these reasons, older copper-bearing devices and the inert IUDs are no longer recommended. The levonorgestrel-releasing IUD may be an adequate choice for women who are likely to have pain or bleeding problems using the copper IUDs. However, their availability is limited.
- When one particular device has no significant medical advantages over another, bear cost factors in mind.
- Because of possible problems in the disinfection of bulk-package IUDs, use only individually packed, pre-sterilized IUDs.
- Different IUDs require different insertion techniques. It is recommended that only 1 type of IUD be used in any service delivery setting; at the most, 2 with similar insertion techniques may be used. This specialization will help the staff inserting the devices to maintain a high level of skill.

9 Timing of insertion

Unless otherwise stated, the following recommendations apply to copper-bearing IUDs and levonorgestrel-releasing IUDs alike.

Having menstrual cycles

- She can have an IUD inserted any time within the first 12 days after the start of menstrual bleeding, at her convenience. No additional contraceptive protection is needed.
- An IUD can also be inserted at any other time during the menstrual cycle, at her convenience, if it can be reasonably established that she is not pregnant (see chapter 11: Diagnosis of pregnancy). No additional contraceptive protection is needed.

Switching from another method:

An IUD can be inserted immediately, if it is reasonably certain that the client is not pregnant. There is no need to wait for her next menstrual period. No additional contraceptive protection is needed.

- *Advantages of insertion during the menstrual period:*
 - It is less likely that the device will be inserted into a pregnant uterus.
 - Insertion may be easier.
 - Any bleeding related to the insertion is less likely to cause anxiety.
- *After a full-term pregnancy:* If the provider has received proper training, a copper IUD may be inserted immediately after the placenta has been expelled, or within 1 to 2 days after delivery. Special care must be taken to ensure proper placement and to avoid perforation. If the IUD is not inserted by the second postpartum day, insertion should be delayed for 4 weeks. A levonorgestrel-releasing IUD should only be inserted after 6 weeks of delivery if the woman is breast-feeding or planning to breast-feed.
- *After spontaneous or medically induced first-trimester abortion:* An IUD may be safely inserted immediately at this time except in women with pelvic infection.

Immediate and early postpartum insertion, and immediate post-abortion insertion, should be performed only by specially trained health personnel.

10 Inserting the IUD

Minimum equipment requirements for IUD insertion:

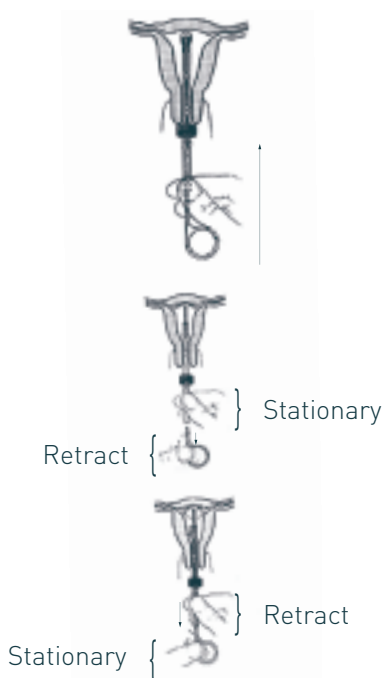
- 1 sponge-holding forceps.
- 1 tenaculum or Allis-Chalmers forceps.
- 1 Pean artery forceps, curved.
- 1 speculum.
- 1 uterine sound.
- 1 iodine cup.
- 1 pair of scissors.

Principles of safe and effective IUD insertion

- All equipment must be sterilized or high-level disinfected (see chapter 15: section 5.5). Disposable non-sterilized gloves may be used only if the IUD is loaded into the inserter tube inside the package and the no-touch technique is used for insertion.
- Before and during the insertion procedure, tell the woman what will happen during the procedure and encourage her to ask questions. Explain to her that she may feel some discomfort during some of the steps.
- Perform a bimanual pelvic examination to determine the size, shape, position and mobility of the uterus; to identify any adnexal lump; and to rule out any signs of pelvic infection or early pregnancy.
- Different IUDs require different insertion techniques. The safest rule is to follow the manufacturer's specific instructions meticulously.
- All steps in the insertion procedure should be performed slowly and gently.
- Take special care in cleaning the cervix with an antiseptic solution before insertion.
- The use of a tenaculum may be necessary to steady the cervix, particularly when the fundus is flexed sharply to the anterior or posterior.
- Always sound the uterus to confirm the direction and position of the uterine canal and to estimate its depth.

- Do not attempt to insert the IUD into a uterus which sounds less than 6.5 cm (6 cm or less for the Nova T).
- The sterility of the uterine sound must be meticulously maintained; do not allow it to touch any potentially contaminated surface, including the speculum or vaginal mucosa, before passing it into the endocervical canal.
- If there is an obstruction at the level of the internal os, a little movement or outward traction with the tenaculum may enable the sound to enter more easily. **Do not use force**, but maintain steady pressure with the sound gently against the internal os for 2 to 3 minutes to overcome any spasm. If it still does not pass, **stop the procedure**. Discuss with the client alternative methods of contraception or consult with the next most senior staff member if you are in doubt.
- Load the IUD inside the package, even when sterilized gloves are worn, to reduce the chances of contamination. All health personnel inserting IUDs should learn how to load the device inside the package and to perform the insertion of the IUD (see Figure 6.2) without contamination.

Figure 6.2 Inserting the Cu T 380A IUD



Prophylactic use of antibiotics for IUD insertion

- Prophylactic antibiotics are generally not recommended for IUD insertion. However, recommended infection prevention procedures should be strictly followed.
- In settings of high prevalence of STIs where there is limited STI screening, such prophylaxis may be considered.
- Counsel the client to watch for symptoms of PID, especially during the first month.

Figure 6.3 Cu T 380A IUD in place



11 Instructions to the client

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

Detecting if the IUD is properly placed

Explain to the client that the IUD can be spontaneously expelled, especially during the first 6 weeks after insertion or during a menstrual period.

Advise the woman to check that the IUD is in place by feeling for the IUD threads. The IUD threads should be checked after every menstrual period,

and any time that there is unusual cramping during a period. Some women may be reluctant to check for the threads; if this is the case, reinforce the above advice while showing understanding about her concerns and constraints. Use a sample IUD to let the woman practice feeling the threads and lower part of the device.

Advise the woman to return to the clinic as soon as possible if she:

- Cannot feel the threads;
- Feels the hard part of the device;
- Expels the device; or
- Misses a period.

In the meantime she should use a non-hormonal method of contraception such as condoms.

Side-effects

Advise the client about possible side-effects (see section 13).

Warning signs

Advise the client to return to the clinic if pregnancy is suspected or if she is experiencing any of the following signs and symptoms which might indicate a possible complication:

- Fever and/or chills.
- Pelvic pain or tenderness.
- Purulent vaginal discharge.
- Excessive abnormal bleeding.

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 allowing an unintended pregnancy to occur.

Follow-up

Advise the client to visit a clinic for a routine follow-up within 3 months, but not before the first menstrual period. The primary purpose is to check that the IUD has not been expelled and there are no major complaints. Thereafter a routine follow-up is advisable every year.

Tell the client the date of the next visit, the name and type of IUD she has obtained and when it should be removed or replaced (see section 1 of this chapter).

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 has to be written and presented in a way the client or somebody close to her (in case she cannot read) can easily understand.

12 Follow-up care

3 month and annual follow-up protocols

- Update the client's address and how to make contact with her.
- Discuss with the client any question, concern or problem she may have related to the method.
- Perform a vaginal examination and review instructions for checking the IUD threads.
- Perform additional examinations or laboratory tests depending upon the client's problems or questions.
- Treat any cervicitis, vaginitis or vulvovaginitis that has developed during use of the IUD.

At the annual follow-up perform breast examination (with instructions for self-awareness) and take a cervical (Pap) smear if this is due and possible.

If regular follow-up care as described above is not feasible, carefully counsel the user regarding possible complications and where to go for care.

13 Side-effects

- Cramping pain may occur for the first 24 to 48 hours after insertion of the device. If the woman experiences this, she can take pain-relief tablets such as aspirin, ibuprofen or paracetamol (acetaminophen). If the pain does not improve or becomes severe, she should visit the clinic. (Pain does not usually occur after 48 hours).

- Vaginal discharge may occur during the first few weeks due to the initial reaction of the lining of the uterus (endometrium). This should not be a cause for concern, but if the discharge is heavy, or accompanied by pelvic pain and/or fever, the woman should contact the clinic immediately.
- Changes in menstrual periods – including spotting or light bleeding between periods – are common during the first 3-6 months of use of a copper-bearing IUD. These are not harmful and usually improve over time. The client may be advised to take a short course of non-steroidal anti-inflammatory drugs during the bleeding days. If the changes persist or if her periods are more than twice as heavy as normal, underlying gynaecological problems should be excluded. If the client finds the changes unacceptable, remove the IUD and help her to choose another method of contraception.

14 Complications

When complications occur, the client may be in a state of emotional distress. It is important that service providers take care of the psychological needs of the client as well as of her medical condition.

Comfort the woman and give her emotional support.

Every IUD provider must be able to recognize the complications of IUD insertion and use, and be familiar with at least first-line management.

Specialist consultation should be called in as soon as possible when necessary.

Potential IUD complications include: perforation, excessive bleeding and pelvic inflammatory disease (PID).

14.1 Perforation

Perforation is a rare event which almost always occurs at the time of insertion, when it may be accompanied by sudden pain and/or bleeding. It may also be symptomless. There is a greater risk of perforation postpartum after second trimester abortion when the uterus is soft, or during lactation when the uterus can be very small.

If perforation is recognized or suspected at the time of sounding the uterus or inserting the IUD:

- Stop the procedure immediately. Remove the IUD by pulling the threads, if it has already been released from the inserter tube; otherwise, remove the IUD with the inserter tube.
- Keep the woman at absolute rest, and check vital signs every 5 to 10 minutes during the first hour post-perforation. Then check vital signs every 30 minutes until signs are normal and stable.
- If there is an alteration in vital signs or haematocrit, spontaneous pain, or peritoneal signs, start an intravenous line for fluids with a large-calibre needle, and arrange emergency admission into a properly equipped medical facility. Never try to manage problems in which you lack skills or experience or about which you feel uncertain. If necessary, call a gynaecologist or surgical specialist as soon as possible.
- If the perforation gives no signs or symptoms, the woman can be sent home 2 to 6 hours after the perforation, depending on how accessible an emergency facility is to the client's home.

If perforation is detected at a later time after the insertion and the IUD threads are not accessible [see section 16: Lost threads]:

- Retrieval may require a laparoscopy or laparotomy. This should be attempted only by a doctor trained in these techniques.
- Closed inert devices (such as rings) must be removed as they can cause bowel obstructions; open inert devices (such as the Lippes loop) can be left in the peritoneal cavity unless there are symptoms of problems or the woman requests removal. Copper-bearing IUDs should be removed to prevent adhesions. However, if adhesions have already developed and make access to and retrieval of an IUD too difficult, the IUD should be left in place.

14.2 Excessive bleeding

No standard effective medication is currently available for treatment of bleeding in IUD users, although non-steroidal anti-inflammatory drugs and anti-fibrinolytic agents have been used with some success. Proper counselling and empathetic attention, together with reassurance, help women to cope with this side-effect. Treatment with oral iron has been shown in some cases to compensate for blood loss. Irregular and excessive bleeding usually decreases after several cycles. If the bleeding is so excessive as to be a health threat or the woman is dissatisfied, then

remove the IUD and help her to choose another method of contraception. Treat anaemia with iron supplements and/or encourage foods containing iron, but avoid blood transfusion.

14.3 Pelvic inflammatory disease

Pelvic infection associated with IUD use may occur when the insertion is performed under unsanitary conditions, or when the IUD is inserted in the presence of an undiagnosed STI; it may also develop later in women at risk of STIs. The usual symptoms of pelvic infection are vaginal discharge, pelvic pain or tenderness, abnormal bleeding, chills and fever, but the infection can be silent. If PID is diagnosed:

- Treat the PID using appropriate antibiotics.
- There is no need for removal of the IUD if the woman wishes to continue its use.
- If the client does not want to keep the IUD, remove it after antibiotic treatment has been started.
- If the IUD is removed, the client can consider use of emergency contraceptive pills if appropriate (see chapter 10: Emergency contraception).
- If the infection does not improve, generally the course would be to remove the IUD and continue antibiotics. If the IUD is not removed, antibiotics should also be continued. In both circumstances, the client's health should be closely monitored.
- Provide comprehensive management for STIs, including counselling about condom use.

15 Pregnancy

Although highly effective in preventing pregnancy when fitted and used according to appropriate guidelines, pregnancy may occasionally occur among women who have an IUD in situ. Many women have successfully completed pregnancy under such circumstances, but there are significantly higher risks of spontaneous abortion, septic second-trimester abortion and premature delivery if the device is not removed. When pregnancy is detected in a woman with an IUD in place, explain to her the risks of keeping the IUD in place, and the smaller risks of its removal. If she agrees, carefully remove the IUD if the threads are

accessible. Advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever. If the threads are not accessible, try to determine the location of the IUD by ultrasound. If the IUD is not located, this may suggest that an expulsion has occurred without the client noticing (and may explain the pregnancy). If the IUD is in place, advise the woman about termination of pregnancy where national laws permit. If the woman elects to continue the pregnancy, ensure that close supervision will be maintained.

IUD use does not increase the overall risk of ectopic pregnancy. However, IUDs protect against intrauterine pregnancies better than against ectopic pregnancies. When an IUD user does become pregnant, the pregnancy is therefore more likely to be ectopic than in a non-IUD user. An ectopic pregnancy is a life-threatening condition. Any woman who has an IUD fitted who complains of pain with vaginal bleeding or with amenorrhoea must be seen by a doctor to exclude a possible ectopic pregnancy. If an ectopic pregnancy is suspected, a bimanual examination can prompt rupture; thus, perform this examination in a clinical site which has facilities for emergency laparotomy.

16 Lost threads

Lost threads are very often the first indication that perforation or expulsion has occurred. This observation may also indicate the possibility of pregnancy.

If the threads are truly lost, first rule out the possibility of pregnancy. Then explore the cervical canal with narrow alligator forceps. If the threads cannot be located in the cervical canal, use a helix to retrieve the threads from the uterus. If the threads cannot be retrieved, a uterine sound may be used to determine if the IUD is still in the uterus.

If the IUD cannot be located inside the uterus, ultrasonography (or radiography if pregnancy has been excluded) may be indicated to determine if a perforation has occurred. If the IUD is not located in the abdomen, then perforation can be excluded and expulsion can be assumed.

17 When to remove the IUD

The IUD should be removed:

- *When the client makes a firm request:* The IUD should be removed without unnecessary delay.
- *When there is a medical indication for removal:* These indications include pregnancy, acute pelvic inflammatory disease, endometrial or cervical malignancy, uterine perforation, partial expulsion or abnormal and excessive bleeding that affects the health of the woman.
- *When the effective lifespan of the IUD has expired:* This applies only to medicated IUDs, including levonorgestrel-releasing and copper-bearing IUDs (see section 1).
- *When the woman reaches menopause:* Remove the IUD 1 year after her last period.

18 Service management

18.1 Client records

- All clients must have a clinical record.
- The clinical record for each client must include documentation of counselling, medical history, physical and laboratory findings, IUD insertion and follow-up, including any complications.

18.2 Supplies

- The use of only 1 type of IUD (or 2 at the most) in a clinic is recommended. This specialization will benefit training efforts as well as service delivery.
- Inert IUDs (e.g., Lippes loop) should not be supplied.
- Use sterile, individually packed IUDs. Discard the IUD if the seal is broken.
- The new copper-bearing devices (TCu 220C, TCu 380A, ML Cu 375 and Nova T) are preferable to the older copper-bearing devices such as TCu 200 and Copper 7.

- Devices which are pushed out of the applicator are more likely to perforate the uterus during insertion than devices which are left in place, using the **withdrawal technique without a push from the applicator**. Those devices that use the withdrawal technique also ensure better fundal placement; thus, their use is recommended.

18.3 Training

- All clinical and counselling staff must be trained in theoretical and practical aspects of IUD services, including screening for contraindications and recognition of signs of danger in the IUD user.
- All health personnel inserting IUDs must be competently trained in IUD insertion techniques and how to load and insert the IUD within the package. Training should stress the importance of avoiding contamination.

Photo: Mark Edwards/Brazil



BARRIERS

7

7 BARRIERS

1 Introduction

Barrier methods of contraception prevent pregnancy by blocking the entrance of sperm into the uterine cavity. Some of the barrier methods, particularly condoms, help to protect against sexually transmitted infections (STIs), including HIV infection.

A major advantage of the barrier methods is their safety. They have only a few local side-effects and there are almost no medical contraindications to their use. Most are available without medical prescription and are well suited to community-based distribution systems.

A disadvantage is their lower use-effectiveness compared with hormonal methods, IUDs, and sterilization. Sexual and reproductive health (SRH)/family planning service providers should emphasize careful user education and counselling to ensure optimal effectiveness of barrier methods. Clients must understand that if a barrier is used as the only method, and if maximum effectiveness is desired, it must be used correctly for *every* act of sexual intercourse.

Barrier methods include the following:

- Condoms.
- Diaphragms.
- Spermicides: creams, jellies, suppositories, foaming suppositories or tablets and aerosol foams.

At least condoms and one or two types of spermicides should be available in all SRH/family planning service delivery programmes; diaphragms should be available whenever there is a demand for this method *and* trained staff to provide it.

1.1 General indications

Barrier contraceptives should be provided to any male or female client who requests them after receiving appropriate counselling and reaching an informed decision.

Barrier contraceptives are especially appropriate:

- When there are medical contraindications to other reversible methods

and when sterilization is not desired or desirable.

- For clients who have intercourse infrequently.
- As an interim form of contraception, for example:
 - During lactational amenorrhoea.
 - During the time just following vasectomy.
 - When IUD threads cannot be felt.
 - When the woman is taking drugs that interfere with oral contraceptive efficacy.
 - While awaiting another method (e.g., a sterilization procedure or IUD insertion).
 - During investigation of gynecological symptoms.
 - As a temporary alternative or back-up to another method.
 - In conjunction with fertility awareness, for use during the fertile phase of the menstrual cycle.
- For protection against STIs including HIV infection (condoms).

1.2 Medical eligibility criteria

The International Planned Parenthood Federation and other bodies have collaborated with the World Health Organization (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).

Category 4 (contraindications)

There are no general contraindications to use of barrier methods of contraception.

Category 3

Some conditions require careful consideration when advising a client on the possible use of a barrier method because they may represent a risk to the well-being and health of the client. Conditions specific to each type of barrier method are listed in the respective sections. The following conditions apply to all barrier methods:

- Client's inability to obtain or use a barrier method consistently.
- A need for highly effective protection against pregnancy (e.g., high-risk pregnancy in the event of method failure).

Refer to sections 2.3, 3.3 and 4.3 of this chapter for conditions relevant to particular barrier methods.

1.3 Health assessment

In general, health assessment is not necessary before providing a barrier method of contraception. However, a client's visit to a clinic for a barrier method should be taken as an opportunity to offer the client other available sexual and reproductive health services as appropriate.

When a physical examination is performed for a female client, it should include a pelvic examination with speculum visualization of the cervix and bimanual examination. A cervical (Pap) smear may be obtained if indicated and available.

1.4 Service management

Storage, shelf-life, quality control and supply

Any programme that makes barrier methods of contraception available must have a system to ensure that the products offered are of acceptable quality. This requires:

- Proper transport and storage.
- A system to ensure that the products are not used after their expiry dates or, if there is no expiry date, after their recommended shelf-life has elapsed.

- A procedure to ensure that samples of the products are checked every 6–9 months. If any products of questionable reliability are found, samples should be properly tested before distribution.

Training

Individuals providing barrier methods of contraception should be properly trained on counselling and the technical aspects related to the provision of the various types of barrier methods.

See sections 2.8, 3.12 and 4.8 for additional guidelines related to particular barrier methods.

2 Condoms

2.1 Definition

Male condom

This condom is a sheath made to fit over the erect penis. It collects semen and acts as a barrier preventing passage of sperm into the vagina. The condom is available rolled in individual packets, and is unrolled onto the erect penis before intercourse.

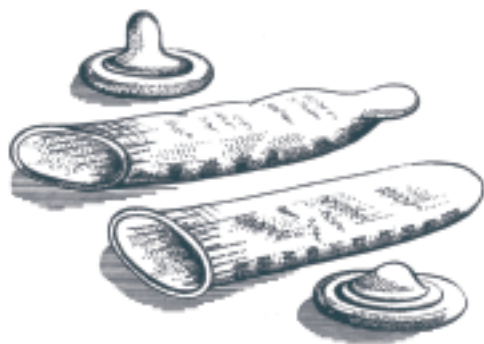
Most condoms are made of thin latex rubber.

When used correctly at every act of intercourse, the condom can be a reasonably effective method of contraception. The latex condom is also an effective barrier to protect against the transmission of STIs, including transmission of HIV/AIDS.

Many different kinds and brands of condoms are available (Figure 7.1). They differ in such qualities as:

- Shape (plain, reservoir tip, contoured for fit).
- Colour (opaque, transparent, various colours).
- Lubrication (with silicone oil, jellies, powders or non-lubricated).
- Thickness (ultra-thin to standard).
- Texture (smooth, textured or ribbed surface).
- With or without spermicide.

Figure 7.1 Condoms – rolled and unrolled, teat-shaped and plain



Service providers should be aware of the characteristics and differences among the brands and types of condoms available in the programme and be able to advise clients accordingly.

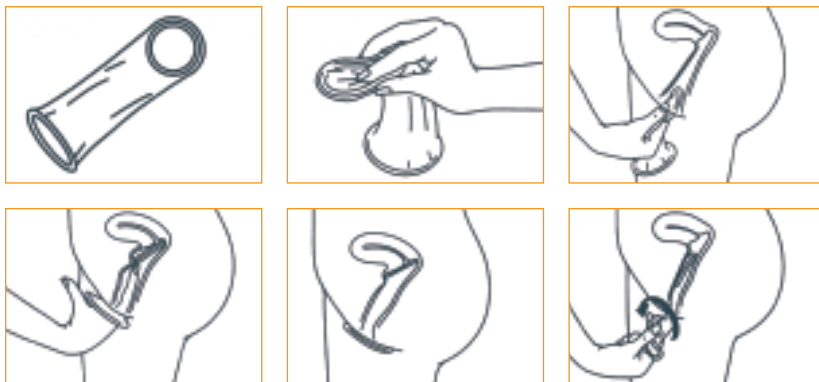
Female condom (Figure 7.2)

The female condom, is made of soft pliable polyurethane prelubricated with a silicone-based substance (dimethicone). It is inserted into the vagina before sexual intercourse. An inner ring is used for insertion and holds the condom in place high in vagina; an outer ring lies flat and covers the labia during sexual intercourse. After ejaculation, the female condom retains the seminal fluid, preventing it from coming into contact with the cervix.

The contraceptive efficacy of the female condom is within the wide range quoted for other barrier methods, but lower than that of male condoms.

Laboratory studies have shown that the female condom is an effective barrier not only to sperm but also to bacteria and viruses including HIV. The female condom is now available in many countries, but use is limited by its high cost. The safety and feasibility of re-use is currently the subject of research. In the meantime, re-use of female condoms is not recommended. However, given the diversity of cultural and social contexts and personal circumstances under which female condom reuse may be acceptable, feasible and safe, and since the balance of risks and benefits varies according to individual settings, the final decision on whether or not to support reuse of the female condom must ultimately be taken locally.

Figure 7.2 The female condom



2.2 Indications

The latex condom should be provided to all individuals who request them, even if these individuals are using another contraceptive method or are not formal clients of the programme. Formal registration in the programme should not be a requirement for obtaining condoms.

The condom may be particularly appropriate for couples who have decided to use a barrier method (see section 1.1) and when:

- The male partner wishes to take responsibility for contraception.
- Protection against STIs, including HIV transmission, is needed or desired.

Other indications include:

- Premature ejaculation.
- Female partner with a cervical lesion.

2.3 Medical eligibility criteria

Category 4 (contraindications)

None.

Category 3

In addition to the conditions that require careful consideration listed in section 1.2, the following is specific to the latex condom:

- Allergy or sensitivity to latex.

2.4 Counselling and information

Clients for condoms should receive appropriate counselling for the selection and use of this method of contraception, whenever possible and convenient for them. Counselling helps to ensure informed choice and proper condom use. However, counselling should not be a prerequisite for providing condoms.

For selection of this method:

- Discuss with the client the advantages and disadvantages of the condom and of alternative family planning methods.
- Explain that latex condoms help to protect against STIs, including HIV.
- Explain to the client that the condom can fail to protect against pregnancy and/or STIs, including HIV transmission, especially if not used correctly with every act of intercourse.
- Discuss the likelihood of partner co-operation with condom use.

For use of this method:

- Instruct very carefully and explicitly about correct use of condoms. Use a penis model for demonstrating correct fit if possible.
- Emphasize that a new condom must be used for each act of intercourse.
- Advise the client about the use of spermicide in addition to the condom in order to increase effectiveness.
- Encourage the client to return for advice if there are any doubts about or problems with the use of the condom.
- Advise the client that if the woman misses a period she should visit a clinic to exclude the possibility of pregnancy and for follow-up care.

Also see section 4.6: Instructions to the client (in relation to spermicides).

2.5 Condom selection

- *Pre-lubricated condoms versus non-lubricated:* Without lubrication, there may be more of a chance of intra-vaginal breakage if vaginal lubrication is insufficient.
- *Ultra-thin condoms are more prone to breakage.* If breakage has been a problem for the couple, advise a different type of condom.

2.6 Instructions to the client

Advise the client about the importance of following exactly the instructions for use and the reason for each of the steps (reasons are highlighted *in italics*).

Important rules for use to emphasize are:

- Put on the condom before any genital contact, *because otherwise sperm and/or infectious agents may be transmitted.*
- Compress the tip of the condom between finger and thumb, and leave a half-inch of latex material at the end of the erect penis. *This will leave a space for the ejaculate to collect and will decrease chances of condom breakage.*
- Use only spermicides or lubricants given or recommended by the programme. Do not use petroleum jelly ('Vaseline'), mineral oil, lotions, or other oil-based products for lubrication, *because they increase the chance of condom breakage.* The use of nonoxynol-9 is not recommended for protection against HIV (see section 4.1).
- After ejaculation withdraw the penis from the vagina while it is still erect, and hold the ring of the condom at the base of the penis firmly with the fingers *so that the condom will not slip off, releasing the ejaculate.*
- If the condom breaks or tears during intercourse, apply spermicide immediately (foam or gel), and consider the use of emergency contraception *for protection against pregnancy* (see chapter 10: Emergency contraception).
- Handle the condom carefully *to avoid punctures*; special care should be taken with long fingernails.
- Use a spermicide with the condom *for maximum effectiveness.*
- Store condoms in a cool, dry place. Do not use a condom if it appears damaged or brittle *because it is more likely to break.*

- After using the condom once, throw it away in a waste receptacle or toilet, *to prevent people, particularly children, from coming in contact with it.*

After explaining the instructions, ask the client to repeat them to you in his/her own words. If necessary, repeat the instructions emphasizing the points which the client has not understood well. This information can be put on a card or leaflet and given to the client. It has to be written and presented in a way that the client or somebody close to him/ her (in case the client cannot read) can easily understand.

2.7 Side-effects

- Side-effects from use of the condom are infrequent.
- Occasionally clients are allergic to latex rubber, or to the lubricant or spermicide used with the condom. If this occurs:
 - Recommend a change of condom brand or type.
 - If the client is using a condom with spermicide, recommend a condom without spermicide or with a different kind of spermicide.
 - If the client is allergic to latex, non-allergenic condoms, made of purified rubber, are available in some areas.
 - Advise another method if the problem continues.

2.8 Service management

Storage, shelf-life, sampling and testing

- The shelf-life of stored condoms depends on the conditions of storage. A safe storage time in hot and/or humid conditions may be as short as 3-6 months. In cool and dry conditions, sealed condoms should have a shelf-life of 3-5 years from the date of manufacture. The manufacture date or the expiry date is usually printed on the packets of condoms.
- Storage requirements are as follows: a cool room temperature, dry conditions, and a convenient and accessible place away from direct sunlight.
- Condoms should be sampled at least twice a year for deterioration, looking for any that are brittle, sticky or discoloured.
- Condom water-leakage tests can be conducted with simple, portable equipment and should be used:

- If visual inspection raises questions about quality.
- When large quantities of condoms are stored and distributed. Samples of stocks should be tested regularly.

Provision of condoms

- Acceptable older stocks of condoms should be distributed before those with more recent dates of manufacture.
- When possible, give the client a three-month supply of condoms or dispense according to the client's request. An approximate three-month supply is 40 condoms.

NOTE: The SRH/family planning programme is encouraged to expand educational efforts among clients and the community on the important protective effect of condoms against STIs, including HIV infection.

3 Diaphragms

3.1 Definition

A diaphragm is a shallow, dome-shaped rubber cup with a flexible rim. When correctly inserted into the vagina before intercourse, the dome covers the cervix. Spermicidal cream or jelly is placed in the dome before insertion. The contraceptive effect of the diaphragm depends partly on its function as a barrier between semen and the cervix, and partly on its function as a spermicide holder. When used correctly at every act of intercourse the diaphragm can be a reasonably effective method of contraception.

There are four types of diaphragm:

- *Flat-spring*, in which the spring is a flat band of metal;
- *Coil-spring*, with a firm, coiled wire spring;
- *Arcing-spring*, with a combination metal spring which allows the rim to assume an arcing rather than a flat, folded shape; and
- *The wide-seal rim*, available in both arcing and coil-spring types. This latter has a flexible flange approximately 1.5 cm wide attached to the inner edge of the rim; the purpose of the flange is to hold spermicide in place and to create a better seal between the diaphragm and the vaginal wall.

3.2 Indications

If available in the programme, **the diaphragm should be provided to any woman who requests it after receiving appropriate counselling and reaching an informed decision.**

The diaphragm may be particularly appropriate for a woman who has decided to use a barrier method (see section 1.1) and who:

- Wants her own method of contraception (as opposed to depending solely on her partner's use of a condom).
- Wishes to separate the time of application of the contraceptive from the time of intercourse.
- Can learn the insertion technique.
- Has an acceptable amount of privacy at home for the insertion, removal, care and storage of the diaphragm.
- Has facilities, such as clean water and soap, necessary to care properly for the diaphragm.

3.3 Medical eligibility criteria

Category 4 (contraindications)

None.

Category 3

In addition to the conditions listed in section 1.2, the following conditions require careful consideration before use of the diaphragm:

- History of toxic shock syndrome.
- Vaginal or uterine anatomical abnormalities that interfere with appropriate placement or satisfactory fit of the diaphragm, such as prolapsed uterus, poor vaginal tone, vaginal obstruction or poor retropubic ridge.
- High risk of HIV, HIV infection and AIDS.
- Allergy to latex and sensitivity to spermicides.
- Inability of client to insert diaphragm and feel cervix adequately.

Category 2

Precaution is needed in the presence of:

- Full-term delivery within the past 6-12 weeks. Diaphragms are unsuitable until uterine involution is complete.
- Parous women.
- Complicated valvular heart disease.
- Urinary tract infection.

3.4 Counselling and information

All diaphragm clients should receive appropriate counselling for selection and use of this method of contraception.

For selection of the method

- Discuss with the client the advantages and disadvantages of the diaphragm and of alternative family planning methods. Inform the client about the effectiveness of the method and the importance of using it with every act of intercourse. Take or check the medical history and follow with individualized counselling reflecting any specific concerns or questions the client may have.

For use of the method

See instructions in section 3.9 of this chapter.

- Inform the woman about the proper use and care of the diaphragm and the proper time for re-checks and replacement. The woman should know that if she misses a period or has problems with comfort or usage she should visit the clinic for follow-up care.
- *Side-effects*: Inform the woman about the signs of urinary tract infection, toxic shock syndrome and vaginitis. She should be counselled to seek help for these symptoms and signs. Inform her that there should not be any discomfort to either partner when the diaphragm is in place.
- Include counselling about the fertility cycle if the couple wishes to use condoms as a second method during the time when ovulation is most likely.

3.5 Health assessment

See section 1.3 of this chapter. In addition, pelvic examination should always be performed before providing the diaphragm to exclude conditions which require careful consideration for selection and use of this method of contraception.

3.6 Diaphragm selection

Arcing-spring diaphragm

- Most women find the arcing-spring diaphragm convenient and comfortable.
- The arcing-spring diaphragm helps to ensure that the posterior rim is inserted correctly behind the cervix.
- A woman with a retroverted uterus, a markedly anteverted uterus or a very long, firm nulliparous cervix may find it easier to insert an arcing-spring diaphragm than a coil-spring or flat-spring type.
- The arcing-spring diaphragm may be useful for a woman with a cystocele or mild prolapse.

Coil-spring and flat-spring diaphragms

- Either of these options may be useful for women who find the arcing-style diaphragm uncomfortable or who have exceptionally firm vaginal tone.
- The *flat-spring* is useful if the woman has a shallow arch behind the pubic symphysis; the *coil-spring*, if there is a deep arch.
- The *coil-spring* should only be used if there is no uterine displacement; the *flat-spring* may be used with an anteflexed uterus.

3.7 Who can provide diaphragms?

Medical doctors, midwives, nurses and other health workers who have been properly trained can provide this method, in accordance with local laws and regulations.

3.8 Fitting the diaphragm

The diaphragm (available in 50-95 mm sizes) must be fitted for size by personnel specifically trained for this procedure. Fitting can be carried out at any time during the menstrual cycle.

- Before fitting, perform a careful pelvic examination, looking for any pelvic pathology and conditions requiring careful consideration.
- Use actual diaphragm sets, not fitting ring sets, for fitting and practice.

Procedure for fitting the diaphragm

Choice of diaphragm type will depend on depth of vagina, vaginal muscle tone, and uterine position.

NOTE: A coil-spring or flat-spring must be used if a woman finds a diaphragm introducer necessary for insertion, although an introducer is rarely necessary. The diaphragm position still needs to be checked by hand.

- Obtain an estimate of the size needed by manually measuring the distance between the posterior fornix of the vagina and the pelvic ridge:
 - Insert the index and middle fingers into the vagina until the middle finger reaches the upper posterior wall of the vagina.
 - With the tip of the thumb, mark the point where the index finger touches the pubic bone. The distance between the tip of the middle finger and the thumb is the anticipated diameter of the diaphragm.
- Fit the diaphragm between the symphysis pubis and the posterior fornix of the vagina (cul de sac). It should cover both the cervix and the upper anterior wall of the vagina and touch both lateral vaginal walls.
- Select the largest diaphragm size that is comfortable for the client and is contained by the pubic bone. The client should not be able to feel the diaphragm once it is in place:
 - If the diaphragm is too large, it may cause discomfort or may distort and displace.
 - If it is not large enough, it may be displaced and not cover the cervical os.

Teaching the woman how to use the diaphragm

After selecting the type and size of the diaphragm, teach the woman how to feel the cervix under the dome of the diaphragm ("feels like the tip of your nose"), and to check the position of the anterior rim well up behind the pubic symphysis (Figure 7.3).

Give clear instructions about insertion and removal of the diaphragm and application of spermicide (see below).

- Instruct the woman to insert along the posterior vaginal wall, aiming the folded diaphragm towards the back, then to push the anterior rim up behind the pelvic ridge with the finger tip.
- For removal, instruct her to place one finger over the nearest (anterior) rim and pull the diaphragm down and out. Two fingers may also be used to grip and pull the rim as an alternative method.
- Use a plastic transparent pelvic model to demonstrate correct insertion and placement if possible.

Provide privacy for the client while she practices. Suggest a practical and comfortable position for insertion, such as standing with one foot propped up, squatting, or lying down. After the client inserts the diaphragm herself, check for correct position and re-check the fit of the diaphragm.

Prescribe the exact size and type of diaphragm that the woman could wear comfortably and successfully insert and remove. Provide a supply of spermicidal jelly or cream.

Figure 7.3 Feeling cervix through the diaphragm



3.9 Instructions to the client

When to insert the diaphragm

It may be inserted at any time before sexual intercourse.

Using the diaphragm

- At least a tablespoon of spermicide should be applied to the diaphragm before each use and additional spermicide should be used for each act of intercourse. If the diaphragm was inserted more than 2 hours before intercourse, it is advisable to apply additional spermicide before intercourse.
- The woman should check before intercourse that the cervix is covered and that the rim is placed comfortably tight behind the pubic bone.
- The woman should leave the diaphragm in place at least 6 hours after the last intercourse, but not more than 24 hours after insertion.

Cleaning, inspecting and storing the diaphragm

- The woman should wash the diaphragm with mild soap and warm water and dry. Cornstarch may be used to dust the diaphragm. The diaphragm should be stored in its container, away from heat. The woman should check for perforations regularly by holding the diaphragm up to light.
- Petroleum jelly, disinfectant, detergents or perfumed soaps and powders should not be applied to the diaphragm.

Replacing the diaphragm

- The woman needs to replace her diaphragm after 2 years of use.
- If the woman has given birth, or has gained or lost weight (3-7 kg or more), she needs to be refitted to ensure the diaphragm is appropriate.

A reminder for the couple: "The effectiveness of the diaphragm depends on using it every time you have intercourse".

Follow-up

Arrange a follow-up visit in 1-2 weeks to re-check fit and usage. Instruct the woman to wear the diaphragm for at least 8 hours before that visit.

After explaining the instructions, ask the client to repeat them to you in her own words. If necessary, repeat the instructions, emphasizing the points which the client has not understood well. Offer a printed instruction sheet with illustrations.

3.10 Follow-up care

- Carry out a routine follow-up at 1-2 weeks after the fitting to check usage and fit.
- Make plans for an annual re-check at this time.
- Encourage the client to return at any time for problems such as side-effects, weight gain or loss of more than 4.5kgs, or dissatisfaction with the method.

3.11 Side-effects

Side-effects related to use of the diaphragm are infrequent but do exist:

- *Urinary tract infection (UTI).*

Treatment: Treat UTI or refer for treatment. The woman should discontinue diaphragm use during treatment. Consider if diaphragm size is too large and, if so, fit a smaller one. Provide an interim contraceptive method during treatment.

- *Local irritation caused by sensitivity or allergy,* usually to the spermicide used with the diaphragm.

Treatment: Change to another spermicidal product which has a different active compound. If the problem persists, suggest changing to another method of contraception.

- *Partner or user discomfort* (cramps, bladder or rectal pressure) from mechanical contact or pressure from the diaphragm rim.

Treatment: Change diaphragm size or rim type if the client wishes to continue.

- *Vaginal discharge and odour* may occur if the diaphragm is left in the vagina longer than 24 hours.

Treatment: Provide reassurance and recommend hygienic measures if there is no vaginitis. Provide specific treatment or referral if symptoms recur and if any vaginitis organism is present.

- *Vaginal lesion caused by diaphragm rim.*

Treatment: The woman should temporarily discontinue use. Provide an

interim contraceptive method. Reconfirm diaphragm fit. The woman may resume use when the lesion has healed.

- *Anterior vaginal wall lesion* caused by removal of the diaphragm.

Treatment: The woman should temporarily suspend use until the lesion has healed. Provide an interim contraceptive method. Check extraction technique; check fingernail length.

3.12 Service management

Storage and shelf-life

The shelf-life of stored diaphragms should be limited to 3-5 years. The quality of the latex is affected by ultraviolet light and heat; thus, examine diaphragms every 6-9 months for deterioration, as well as before providing them to individual clients.

Supplies

Approximately 2 tubes of jelly are needed every 3 months. One tube contains about 25 applications; 6-8 tubes per year may be needed.

Equipment needed for fitting diaphragms

- Sterile or disinfected sample diaphragms in a range of sizes.
- Sterile jelly or boiled/disinfected water to lubricate diaphragms during fitting.
- Non-sterile gloves (reusable gloves should be sterilized or high-level disinfected between clients).

Care of fitting equipment

This refers to diaphragms and/or fitting rings which are used for fitting clients and teaching them how properly to use the method.

- Decontaminate by soaking in 0.5% chlorine solution for 10 minutes.
- Wearing utility gloves, wash with detergent and water removing any organic material.
- Dry before putting into disinfectant solution.
- Disinfect by soaking in 0.1% chlorine solution for 20 minutes. Alternatively disinfection can be done by boiling, but it reduces the lifespan of the diaphragms and/or fitting rings.
- Air or towel dry and store in a clean container.

Wherever an autoclave is available, the fitting sets could be steam sterilized after decontamination and washing.

Training

The diaphragm should only be provided in a family planning or sexual and reproductive health clinic where staff are specifically trained to provide it. Decisions on whether training of staff is necessary should be made by the programme manager, based on the demand for the method.

4 Spermicides

4.1 Definition

Spermicides are chemicals that inactivate and kill sperm. To a certain degree, they also form a barrier over the cervix. The principal spermicidal agents acting as surfactants are nonoxynol-9, octoxynol, menfegol and benzalkonium chloride.

The different kinds of carriers for spermicide include creams, jellies (gels), suppositories, foaming tablets or suppositories and aerosol foams.

Spermicides alone offer low contraceptive efficacy, but give high efficacy when used as a supplement to other barrier methods. There is no evidence that spermicides including nonoxynol-9 offer any protection against HIV and other STIs. Furthermore, there is some evidence that frequent use of nonoxynol-9 (twice a day or more) increases rather than reduces the chance of HIV transmission, perhaps by irritating the vaginal and cervical mucosa. For these reasons, spermicides are not recommended for protection against HIV or other STIs.

Service providers should be aware of the characteristics and differences among the types and brands of spermicides available in the programme and advise clients accordingly.

4.2 Indications

Spermicides should be provided to any individual who requests them for contraception including those who are not regular clients of the programme. Formal registration in the programme should not be a requirement for obtaining spermicides. Spermicides may be appropriate for couples who have decided to use a barrier method and:

- Are highly motivated to use spermicides effectively.
- The woman's natural fertility is decreased by age or lactation.
- A possible pregnancy would not pose a high risk to the woman's health.
- Wish to use a spermicide in association with a diaphragm or condom.

See also section 1.1 of this chapter.

4.3 Medical eligibility Criteria

Category 4 (contraindications)

- Clients at high risk of HIV infection.
- Clients who are HIV-positive.
- Clients who have AIDS.

Category 2

Spermicides can generally be used, but with precaution in certain circumstances:

- The low effectiveness of the spermicides should be an important consideration when method failure could result in a high-risk pregnancy.
- Sensitivity to the spermicide.
- Cervical cancer.

4.4 Counselling and information

Give appropriate counselling and information for selection and use of this method of contraception.

For selection of the method

The woman or couple must be informed of the advantages and disadvantages of using spermicides alone including:

- The higher risk of pregnancy as compared to other methods.
- The proper use and care of spermicides, including the need for a waiting interval for dispersal of suppositories and tablets.

For use of the method

See section 4.6 below.

4.5 Spermicide selection

- Foam is recommended if spermicides are to be used as the sole method. Foam in an aerosol container is active immediately; it requires use of an applicator.
- Foaming suppositories and tablets are convenient to carry and store; however, they require a waiting interval of 10-15 minutes after insertion and before intercourse.
- Melting suppositories also require a 10-15 minute waiting interval.
- Contraceptive jelly is usually used with diaphragms.

Spermicides containing mercuric compounds should never be recommended or stocked.

4.6 Instructions to the client about spermicides

Advise the client about:

- The importance of using spermicide before each act of intercourse.
- The need for a 10-15 minute waiting interval after insertion for foaming tablets or suppositories. There is no waiting interval for creams, jellies and gels.
- The importance of following the recommendations of the manufacturer for use and storage of each individual product (e.g., shaking aerosol foams before filling the applicator).
- The need for another application if intercourse takes place more than 1 hour after initial application.
- The importance of correct placement high in the vagina so that the cervix is well covered.
- The need to visit a clinic to exclude the possibility of pregnancy if the woman misses a period.

After explaining the instructions, ask the client to repeat them to you in her/his own words. If necessary, repeat the instructions, emphasizing the points which the client has not understood well. Offer a printed instruction sheet with illustrations.

4.7 Side-effects

Side-effects of the use of spermicides are infrequent and minor:

- *Local irritation caused by sensitivity or allergy.*

Treatment: Change to another spermicidal product which has a different active compound. If the problem persists suggest changing to another contraceptive method.

Concerns raised about congenital abnormalities in births following failure of spermicides have not been confirmed by several studies.

4.8 Service management

Storage and shelf-life

- Limit the shelf-life of stored spermicidal products to the times specified by the manufacturer of each product. Estimated shelf-life from the date of manufacture is 5 years.
- Test a sample of stocks in storage every 6-9 months:
 - For foaming tablets to ensure that the packaging has resisted moisture.
 - For aerosol foams to test that the container is functioning.

Supplies

When possible, give the client a 3 month supply or dispense according to the client's request. A 3 month supply is 1 bottle of foam, 2 tubes of cream or jelly, or 40 foaming tablets.

Photo: Fatiha Terki/Ethiopia



FEMALE AND MALE STERILIZATION

8 FEMALE AND MALE STERILIZATION

8

1 Introduction

1.1 Definition

Voluntary female and male sterilization (also known as tubectomy, tubal occlusion, tubal ligation or surgical contraception and vasectomy) are among the most effective contraceptive methods available for men and women who desire no more children. Sterilization is also one of the safest methods, with low mortality and complication rates for both men and women. The sterilization procedure blocks either the sperm ducts (the vasa deferentia) or the oviducts (fallopian tubes) to prevent the sperm and ovum from uniting.

1.2 General indications

Sterilization should be provided to any male or female client who has completed the desired family size and who requests it after receiving appropriate counselling and reaching an informed decision.

Note: Some complex, irreversible psychiatric or neurological conditions are not compatible with parenthood and may lead to a request for sterilization when the client is unable to give consent. For these cases, the opinion of a knowledgeable consultant should be obtained in writing, and documentation must be kept including a discussion of alternatives to sterilization.

1.3 Pre-operative screening

The objectives of pre-operative client screening are:

- **To ensure, through counselling and the informed choice process, that:**
 - The client is making a voluntary and informed choice without coercion by relatives or service providers.
 - Any non-medical factors likely to cause regret are identified (for example, clients who are too young, have no or few children, are in an unstable relationship or are uncertain about the decision).
- To determine, through the medical assessment:
 - The client's fitness for sterilization.
 - Whether there are any conditions present that may increase the risks associated with the procedure.

- The most appropriate surgical approach, anaesthetic regimen and type of facility best suited to the client.

Where national laws and regulations permit, sterilization should be made available based on what is best for the individual. Programmes should avoid establishing arbitrary criteria based on age, parity or marital status, and should interpret guidelines based on the needs of each individual client.

For some clients it may be necessary to postpone the sterilization procedure (e.g., when there is a medical condition that needs to be evaluated or corrected). When this is the case, the reasons must be explained to the client and documented in writing. The client should be advised about the use of temporary methods and plans should be made to provide sterilization at a later date.

1.4 Counselling and information

All sterilization clients must receive appropriate counselling for selecting the method.

- **Counsel both partners, if possible.**

- The question of which individual in a couple will be sterilized must be reviewed, and assistance given until the couple reach a firm and comfortable decision. If there are health risks for one partner to consider sterilization, this should be taken into account.
- One factor to take into account when discussing sterilization for either partner is a history of multiple caesarian section. If the woman is pregnant, sterilization can be performed at the time of the next caesarian section.
- Allow opportunity for individual counselling.

- **Encourage clients to ask all their questions and to express any concerns** so that misunderstandings and misinformation can be cleared up. For example, clients should be reassured that sterilization does not affect physical or mental health or normal sexual behaviour.

- **Clearly discuss the following points with each client, appropriately for his/her background and language:**

- *Alternative, temporary methods of family planning are available.* These methods must be available to the client, so that he or she may choose between temporary and permanent methods. Information on the temporary and permanent methods must include the

- effectiveness, benefits, risks and side-effects of each.
- *The procedure is surgical.* Review the details of the procedure. The client must understand: (a) the type of procedure to be performed, (b) where it will be performed, (c) the kind of anaesthesia to be used, (d) how he or she can expect to feel after the procedure, (e) the possibility of discomfort during the surgical procedure, and (f) if there will be any cost to the client for the procedure.
 - Although sterilization is a very safe procedure, there is a *small possibility of complications* related to the anaesthesia and to the surgery.
 - *The procedure has benefits*, including: an end to childbearing, no further pregnancy-associated risks, and no ongoing inconvenience or risks associated with temporary long-term contraceptive methods.
 - There is a *risk of failure*, even though sterilization is a very effective method of contraception.
 - *The results of the procedure are intended to be permanent*: after the surgical procedure, the client will no longer be able to have children. Notify the client that the procedure should be considered permanent (see also section 1.11).
 - Choosing the procedure must be *the voluntary, free choice of the client*, and it should not be forced in any way through coercion or inducements. Allow for any discussion and further exploration if there is any doubt that the client is choosing the operation of his or her own free will.
 - The client has *the right to change his/her opinion* at any time prior to surgery. The opportunity to review the decision and to change his/her mind before the procedure helps to ensure that the client's choice is voluntary and to prevent the possibility of coercion. A waiting interval of a few days is recommended when possible, although it should not be a strict requirement, especially if the client's decision is firm.
 - *Sterilization does not protect against HIV and other sexually transmitted infections (STIs). Couples who are at risk of these infections should be counselled about the use of condoms.*

1.5 Informed consent

Informed consent for sterilization surgery is an agreement by the individual based upon the exercise of free choice, with a full understanding of the nature and consequences of the surgical procedure. It must be obtained only after appropriate counselling as described above.

The primary ethical responsibility of the sterilization team is to ensure that the individual gives mature, informed, voluntary, unpressured consent to the operation, and that he or she is legally competent to give that consent.

Written informed consent must be obtained for all clients requesting sterilization:

- To document informed and voluntary choice, *and*
- To serve as a legal authorization for surgery.

Signatures:

- The form must be signed by the person undergoing sterilization.
- For non-literate clients, the form must be read aloud and explained, and a thumb print or mark of the client may replace the signature. The signature of a literate witness is also recommended.
- The surgeon or designated assistant should also sign the consent form. This signature indicates that he/she has established that the individual choosing sterilization understands and willingly elects to undergo the operation.

Language:

- The terms and words used on the consent form and in the counselling process should be understood easily by the client. Avoid complicated medical and legal terms.
- In settings where more than one language is spoken, forms should be available in the common languages spoken. When possible, staff members who speak commonly used languages should be available. If this is not possible, interpreters should be used.

1.6 Health assessment

An appropriate clinical record form should be used and completed for each client to ensure that the essential elements of the history and the physical and laboratory examinations are collected and recorded.

- *Medical history:* in addition to personal and family data, including number of children and use of family planning methods, the following information should be obtained:
 - Past and present illnesses and other conditions which may present a risk for the operation, including diabetes mellitus, heart disease, hypertension, lung disease such as asthma or bronchitis, renal disease, genito-urinary infection, STIs, anaemia, bleeding/clotting problems, convulsions, psychiatric conditions, and any current illness or infection.
 - Previous relevant operations, previous problems with anaesthesia, limitations on activity, addictions, and history of tetanus immunization.
 - Allergies, including drug reactions.
 - Current medications.
- *Physical and laboratory examinations:* Physical examination as described in section 2.6 (male sterilization) and section 3.6 (female sterilization) should always be conducted before performing surgical procedures. Laboratory examinations are generally not required but should be performed if indicated by medical history and physical examination.

Routine screening for HIV is not needed. Appropriate infection prevention procedures must be carefully observed with all surgical procedures.

1.7 Anaesthesia

Local anaesthesia is the preferred method for all types of sterilization procedure. General, spinal or epidural anaesthesia is seldom justified.

1.8 Surgical principles for ensuring safety

- Surgeons and staff must be skilled and well trained in the techniques they are using, as well as in the early recognition and prompt management of complications.
- Approved medical and surgical guidelines and procedures must be strictly maintained.
- The surgeon should refrain from treating other pathological disorders

during routine sterilization, except if this has been planned in advance and is performed in an adequately equipped facility. One exception would be when emergency treatment is required.

- Infection prevention measures must be strictly followed (see chapter 15: Infection prevention control).
- All instruments and equipment must be in good working order before the start of the surgical procedure.
- The facility must be well equipped with drugs and equipment to handle life-threatening situations and other emergencies.

1.9 Post-operative instructions

Provide written post-operative instructions for literate and illiterate clients in language or diagrams that the client will easily understand.

Review each point orally with the client before he or she leaves the facility. Include discussion of:

- How to care for the wound.
- How to use any post-operative medications that are given.
- Instructions to rest at home for the rest of the day.
- What warnings signs to look for and what to do about each of them.
- When to resume normal activities, including sexual intercourse.
- Where to go and whom to contact in case of emergency.
- When and where to return for a follow-up visit.

1.10 Complications

- Major complications occur in fewer than 1% of all vasectomy and tubal occlusion cases. Early recognition and prompt appropriate management are essential.
- **All major or minor complications and documentation of their management should be recorded in the client's clinical record.**
- If a local sterilization programme has an unusually high level of complications (e.g., wound infections), an investigation should be carried out to identify the cause so that corrective action may be taken.
- See sections 2.12 and 3.13 of this chapter for more details of complications specific to male or female sterilization.

1.11 Reversal

- **Sterilization should be considered permanent.** Several factors affect the success of reversal cases, in some cases it is not feasible or advisable.
- Reversal surgery is more complex than sterilization. If there is a request for reversal the client should be referred to the appropriate level of health care.
- Because there is an increased risk of ectopic pregnancy following reversal, all women having a reversal operation must be followed up closely. A woman having a reversal operation should be advised that future pregnancy has an higher risk of being ectopic and that she should seek medical care if she becomes or suspects that she is pregnant.

1.12 Service management

Facilities and equipment

- The following facilities are required for sterilization services:
 - A clean waiting room or reception area for new arrivals and follow-up clients. The environment should be consistent with local cultural background, and conducive to educational activities. Educational posters with information on all family planning methods should be displayed.
 - Space for counselling, preferably isolated or private.
 - An examining room for pre-operative and follow-up examinations.
 - A clean surgical area isolated from the outside and from clinic traffic.
 - Areas adjacent to the surgical area where surgical personnel scrub and change clothes.
 - Facilities for cleaning, sterilizing and disinfecting surgical instruments and materials, or access to them elsewhere.
 - Recovery room and rest area for clients after surgery.
 - Laboratory services or access to them elsewhere (e.g., blood, urine, semen analysis).
 - Arrangements for storage and retrieval of records.
 - Toilet and washing facilities for clients.
 - Laundry or access to a laundry.

NOTE: Some of the above functions may share a common space.

The above requirements are most often met in a hospital or a permanent clinic. Other facilities may meet the above criteria in specific circumstances and according to local needs.

- *When the sterilization procedure is not performed in a hospital:*
 - The facility must have links with an institution which will be able to assure prompt emergency admission for the management of surgical complications.
 - The facility in which the surgery is performed must be able to promptly transport the patient to the referral institution.
- *Local anaesthetic:*
 - Lidocaine (lignocaine).
- *Emergency equipment required for each facility offering sterilization:*
 - *For both male and female sterilization:*
 - Suction machine with tubing and 2 traps.
 - Oral and nasal airways (2 sizes of each).
 - One manual resuscitator or breathing apparatus.
 - Emergency drugs, such as epinephrine (adrenaline) and antihistamines, for managing adverse reactions.
 - *Only for female sterilization:*
 - Anaesthesia mask and self-inflating bag with oxygen nipple.
 - Oxygen tank with reducing valve, flow meter, tubing and mask.
 - Intravenous fluids such as dextrose solutions, and administration sets with large-calibre needles.
 - Venesection instruments.
 - Sterile laparotomy kit for emergencies.
 - Laryngoscope and endotracheal tubes (appropriate only when trained personnel are available).
 - Additional emergency drugs, such as atropine, naloxone, physostigmine and calcium chloride, for managing adverse reactions to anaesthetic agents and other medications.

The above equipment must be present and readily available for use during all sterilization procedures. There should be one person at the clinic site responsible for ensuring that the emergency instruments are sterile, functional and ready for use before each operation.

The surgical team must be sufficiently trained to be able to use the equipment effectively in case of emergencies.

Policies and guidelines

- Each programme offering sterilization services must maintain its policies and guidelines on the premises. Applicable references to sterilization-related local laws and regulations should also be available.
- Surgical and anaesthetic protocols, specific to the techniques used, should be available, as well as protocols for client monitoring and management of complications.
- Guidelines on infection prevention and control should be posted in the facility.
- The programme should have a mechanism to assure that all medical and paramedical staff understand and follow the practices set out in these guidelines.

Clinical records

The programme should ensure that all aspects of pre-operative assessment, type of procedure, technique of occlusion, anaesthesia, operative findings, post-operative management, and reports of any complications and their treatment are recorded in an accessible clinical record for each client. The informed consent form should also be kept in the record.

Mobile teams

Mobile teams consist of trained staff who periodically visit outreach areas to perform sterilization in existing permanent health facilities which do not have staff qualified to perform sterilization. If such facilities are not available, the team may operate in temporary medical settings such as schools or community buildings, taking great care to ensure that essential safety and medical standards are met in accordance with local regulations.

- Mobile teams should be staffed by the most highly trained, skilled and experienced personnel available for both counselling and surgical procedures.
- Appropriate infection prevention measures must be ensured.
- Measures to ensure follow-up care should be an integral part of any mobile-team system.

Referrals

- A system must be in place for referrals in case of emergencies, complications and medical problems. If necessary, written agreements with the medical institutions accepting these referrals should be obtained.
- In programmes where sterilization is not offered, referral procedures for sterilization services must exist.

Surgeons

The sterilization service should employ only those surgeons who have training, skill and experience in the standard sterilization techniques described in these guidelines. Job descriptions specifying these requirements should be used.

Work load

The surgical team should limit the number of procedures performed to a number appropriate to the delivery of safe and quality services.

Advocacy

Vasectomy is a much underutilized, safe and effective method. Programmes should implement strategies to clarify misconceptions that hinder acceptability of this method and to promote its use.

Female sterilization programmes should promote the availability of safe and convenient post-partum and post-abortion as well as interval sterilization services (see section 3.7 for definition). They should also encourage maternity services to offer antenatal counselling about sterilization and other contraceptive methods as well as immediate post-partum sterilization and other contraceptive services.

Training

- A written curriculum for sterilization techniques, client care, management of complications, and counselling should be used for training new staff.
- Training needs of existing staff should be periodically assessed and necessary training provided.
- All members of the surgical team should be considered in the training programme (i.e., doctors, assistant doctors, nurses, auxiliary nurses, aides).

2 Male sterilization

2.1 Definition

Male sterilization, or vasectomy, is the interruption of the male reproductive capacity for the purpose of permanently ending fertility. This is accomplished by a simple, safe, inexpensive and well-accepted operation which can be performed as an outpatient procedure. In a vasectomy, each vas deferens is occluded or cut so that sperm are not released into the ejaculate.

Vasectomy is one of the most effective methods of contraception. When performed correctly, vasectomy has a failure rate of 0.1 pregnancies per 100 women partners in the first 12 months of use.

2.2 Indications

In addition to the general indications for sterilization (see section 1.2), vasectomy should be the method of choice where a medical risk exists for the female procedure.

2.3 Medical eligibility criteria

The World Health Organization (WHO) medical eligibility criteria use a specific classification for surgical sterilization, which differs from other methods of contraception because there is no condition that should permanently restrict the eligibility of the client from voluntarily obtaining this method. The medical considerations consist of weighing the respective risks of sterilization against those of an unintended pregnancy. However, some conditions represent an indication to take specific precautions or to delay the procedure.

Conditions that require extra caution (category C of the WHO classification):

The procedure is normally conducted in a routine setting, but with extra preparation and precaution, in the presence of:

- Previous scrotal injury.
- Young age.
- Large varicocoele.
- Large hydrocoele.
- Cryptorchidism.
- Diabetes mellitus.
- Depressive disorders.

Conditions that require a delay in the sterilization procedure (category D of the WHO classification): The procedure is delayed until the condition is evaluated and/or corrected, with alternative temporary methods of contraception provided in the presence of:

- Local infections:
 - Scrotal skin infection;
 - Active sexually transmitted infection (STI);
 - Balanitis;
 - Epididymitis or orchitis.
- Systemic infection or gastroenteritis.
- Filariasis/elephantiasis.
- Intrascrotal mass.

Conditions that require special consideration (category S of the WHO classification): The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support after considered decision upon the most appropriate procedure and anaesthesia regimen, with alternative temporary methods of contraception provided if referral is required or there is otherwise any delay, in the presence of:

- Inguinal hernia.
- Coagulation disorders.
- AIDS.

A further consideration is a history of impotence or other sexual disorders in which vasectomy could possibly intensify any underlying psychological problem.

2.4 Counselling, information and informed consent

Follow the general guidelines in chapter 2 (Counselling) and in sections 1.4 and 1.5 of this chapter.

- The client must also be informed that the procedure does not affect the male hormones or cause any change in sexual performance or sexual satisfaction.
- Another form of contraception must be used until it is demonstrated that sperm are not present in the ejaculate, or at least 12 weeks after the vasectomy (The counsellor should assess if the client or his partner needs a temporary contraceptive method).

It is important to give clients an opportunity to express any concerns and to have all their questions answered before the procedure.

2.5 Who can perform vasectomy?

All doctors, including general practitioners, can perform vasectomies if they have been properly trained. Under certain conditions, other health personnel can be trained to perform vasectomy procedures if the country's laws and regulations permit. When a non-doctor performs the procedure, a doctor should be available for consultation and in case of surgical difficulties or complications.

2.6 Health assessment

- In addition to the information in section 1.6, the medical history for a man requesting vasectomy should also include:
 - A history of scrotal or inguinal surgery or trauma/injury.
 - A history of pre-existing sexual impairment, such as impotence.
- The *physical examination* for vasectomy must include:
 - Scrotal examination, checking for skin thickness, scars or infection.
 - Examination for presence of undescended testes, hydrocoele, varicocoele, intrascrotal mass, or inguinal hernia.
 - Other examinations as indicated by the medical history.
- The following pre-operative *laboratory evaluations* are required only if suggested by the history or physical examination:

- Haemoglobin and/or haematocrit.
- Urinalysis to identify the presence of glucose or protein.

2.7 Pre-operative preparation

- Ensure that medical history, physical examination and any necessary laboratory tests are completed and documented in the clinical record.
- Review informed consent and ensure that the signed form is in the client's record.
- Pre-operative medication is not necessary in most situations. If the client appears nervous, sedation could be administered (e.g., 5 mg diazepam given by mouth 30 minutes before surgery).

2.8 Anaesthesia and operative procedure

Local anaesthesia

Use the least possible quantity of local anaesthetic to ensure adequate comfort for the man. General anaesthesia is very rarely needed.

- Lidocaine (lignocaine) 1%, without epinephrine (adrenaline) is recommended (If only 2% lidocaine is available, dilute it to 1% by using saline solution).
- The maximum individual dose of lidocaine should not exceed 4.5 mg/kg (2 mg/lb) of body weight. In general, it is recommended that the maximum total dose should not exceed 300 mg (This equates to a maximum total volume of 30 ml 1% or 15 ml 2% lidocaine).

Operative procedure

While there are many ways to occlude the vas (e.g., ligation, cautery, clips) there are two basic approaches for scrotal entry:

- Conventional or incisional vasectomy; or
- No-scalpel vasectomy (NSV).¹

The NSV technique uses a vasal nerve block and two specialized instruments (a ringed clamp and dissecting forceps) (figures 8.1 and 8.2)

¹For more details about no-scalpel vasectomy refer to: *No-scalpel Vasectomy: An Illustrated Guide for Surgeons*, 3rd edition. New York: EngenderHealth, 2003.

to isolate and deliver the vas. Because the scrotal skin puncture made with the dissecting forceps is so small, sutures are not needed. NSV offers several advantages over conventional vasectomy, including fewer haematomas and infections and less pain during the procedure. However, it should not be used unless the surgeon has received appropriate training, has experience in the procedure, and has the required instruments.

Figure 8.1



Extracutaneous ringed forceps

Figure 8.2



Dissecting forceps

Vasectomy should include division of each vas or removal of a short segment of each vas. If ligation and excision is used as the method of occlusion, fascial interposition is necessary. Thermal or electro-cautery may provide more effective vas occlusion than ligation and excision with fascial interposition, even when cautery is used without fascial interposition.

Some basic procedural principles, in addition to those listed in section 1.8, include:

- Proper asepsis, which requires a surgical scrub and the use of sterile gloves. Cap, mask and sterile gown are desirable but not necessary for vasectomy.
- An effective antiseptic (e.g., a water-based iodine or a 4% chlorhexidine solution) is required to prepare the scrotum, thighs and perineum. The operative area should be draped.
- Careful haemostasis and gentle tissue handling are important for patient's comfort and safety.

2.9 Post-operative care

- A man who has undergone vasectomy without sedation may leave the clinic after resting 30 minutes if the operative site shows no sign of bleeding. If sedation has been used, the client should be monitored until the sedation has worn off before he can leave the clinic.
- Simple oral analgesics may be given if needed for discomfort.

2.10 Instructions to men after the procedure

Before the client is discharged, provide the following instructions orally and in writing:

- He should rest at home for the remainder of the day. He should refrain from sexual intercourse, heavy work or strenuous exercise for 48 hours. This time of rest is important to decrease the risk of complications.
- He should keep the wound clean and dry. He may bathe on the day after surgery, but must avoid allowing the wound to become wet. Soap and water may be used to wash the wound after 3 days, making sure to dry the wound.
- He should contact the provider if there is any fever, bleeding or pus at the incision, or excessive pain or swelling.
- He is not immediately sterile: he must use condoms or another temporary method until at least 12 weeks after the vasectomy or until his semen is sperm-free (where semen analysis is available).
- If conventional vasectomy was performed he should come for a follow-up visit approximately 1 week after surgery.

The client should have the opportunity to ask questions and express concerns.

2.11 Follow-up care

Post-operative follow-up examination

An appointment should be offered to the client for a follow-up visit approximately 1 week after surgery. Post-operative examination may be done by a trained, qualified health professional who is not a doctor, unless there are complications. During the follow-up visit:

- If conventional or incisional vasectomy was performed, examine the

scrotal area for proper healing.

- Review plans for semen analysis if available.
- Schedule another follow-up visit if further care is needed.

Semen analysis

- If available, offer semen analysis after 12 weeks after the procedure.
- If the client requests semen analysis and the facility is not equipped to do it, refer him for this service.
- If motile sperm are still present after 12 weeks, the service provider must re-evaluate the case and take appropriate steps. A repeat semen analysis is indicated, and a second vasectomy procedure may be offered if failure has occurred.

2.12 Complications

Vasectomy complications may include intra-operative bleeding; reactions to local anaesthetic; post-operative scrotal swelling, bruising and pain; haematoma formation; infection; and later, congestive epididymitis and granuloma formation. Early recognition and prompt treatment of complications are essential, and **training for vasectomy services should include how to identify and manage complications.**

Any surgical difficulties encountered during the procedure should be recorded, for these difficulties may explain complications that arise during the post-operative period. Any surgical incident should be recorded in the client's record even if it was successfully corrected during the operation.

3 Female sterilization

3.1 Definition

Female sterilization is the interruption of the female reproductive capacity for the purpose of permanently ending fertility. This is accomplished by bilateral occlusion or section of the fallopian tubes.

Tubal occlusion is a safe and well-accepted procedure which can be accomplished by ligation, ligation with resection, or mechanically with clips or rings.

3.2 Indications

The indications for female sterilization are discussed in section 1.2.

3.3 Medical eligibility criteria

As noted in section 2.3, the WHO medical eligibility criteria use a specific classification for surgical sterilization, which differs from other methods of contraception because there is no condition that should permanently restrict the eligibility of the client from voluntarily obtaining this method. The medical considerations consist of weighing the respective risks of sterilization against those of an unintended pregnancy. However, some conditions represent an indication to take specific precautions or to delay the procedure.

Conditions that require extra caution (category C of the WHO classification):

The procedure is normally conducted in a routine setting, but with extra preparation and precaution, in the presence of:

- Young age.
- Obesity ≥ 30 kg/m² body mass index.
- Hypertension:
 - History of hypertension, where blood pressure cannot be evaluated (including hypertension during pregnancy).
 - Adequately controlled hypertension, where blood pressure can be evaluated.
 - Raised blood pressure (systolic 140-159 or diastolic 90-99 mmHg).
- History of ischaemic heart disease.
- History of cerebrovascular accident.
- Uncomplicated valvular heart disease.
- Epilepsy.
- Current breast cancer.
- Uterine fibroids (with or without distortion of uterine cavity).
- Past pelvic inflammatory disease (PID) without subsequent pregnancy.
- Schistosomiasis with fibrosis of liver.
- Diabetes mellitus without vascular disease (insulin and non-insulin dependent).
- Hypothyroidism.
- Mild compensated cirrhosis.

- Benign and malignant liver tumours.
- Thalassaemia.
- Sickle cell disease.
- Iron deficiency anaemia (Hb 7-10 g/dl).
- Diaphragmatic hernia.
- Kidney disease.
- Severe nutritional deficiencies.
- Elective sterilization concurrent with abdominal surgery.
- Depressive disorders.
- Previous abdominal or pelvic surgery.

Conditions that require a delay in the sterilization procedure (category D of the WHO classification): The procedure is delayed until the condition is evaluated and/or corrected, with alternative temporary methods of contraception provided in the presence of:

- Pregnancy.
- Postpartum (7 to <42 days).
- Severe pre-eclampsia/eclampsia.
- Prolonged rupture of membranes (24 hours or more).
- Puerperal sepsis or intrapartum/puerperal fever.
- Severe antepartum or postpartum haemorrhage.
- Severe trauma to the genital tract at the time of delivery (cervical or vaginal tear).
- Post-abortion sepsis.
- Severe post-abortion haemorrhage.
- Severe trauma to the genital tract at the time of abortion (cervical or vaginal tear).
- Acute haematometra.
- Current deep vein thrombosis (DVT)/pulmonary embolism (PE).
- Major surgery with prolonged immobilization.
- Current ischaemic heart disease.
- Unexplained vaginal bleeding before evaluation.
- Malignant gestational trophoblastic disease.
- Cervical cancer awaiting treatment, or endometrial or ovarian cancers.

- Pelvic inflammatory disease (PID) current or within the last 3 months.
- Sexually transmitted infection (STI) including purulent cervicitis.
- Current gallbladder disease.
- Active viral hepatitis.
- Iron deficiency anaemia ($\text{Hb} < 7\text{g/dl}$).
- Local abdominal skin infection.
- Acute bronchitis or pneumonia.
- Systemic infection or gastroenteritis.
- Sterilization concurrent with abdominal surgery (emergency without previous counselling) or infectious condition.

Conditions that require special precautions (category S of the WHO classification): The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support after considered decision upon the most appropriate procedure and anaesthesia regimen, with alternative temporary methods of contraception provided if referral is required or there is otherwise any delay, in the presence of:

- Postpartum uterine rupture or perforation.
- Post-abortion uterine perforation.
- Multiple risk-factors for arterial cardiovascular disease (e.g., older age, smoking, diabetes mellitus and hypertension).
- Raised blood pressure (systolic ≥ 160 or diastolic ≥ 100 mmHg).
- Hypertension with vascular disease.
- Complicated valvular heart disease.
- Endometriosis.
- AIDS.
- Known pelvic tuberculosis.
- Diabetes mellitus with nephropathy/retinopathy/neuropathy.
- Diabetes mellitus with other vascular disease or of > 20 years' duration.
- Hyperthyroidism.
- Severe decompensated cirrhosis.
- Coagulation disorders.
- Chronic asthma, bronchitis, emphysema or lung infection.

- Fixed uterus due to previous surgery or infection.
- Abdominal wall or umbilical hernia.

3.4 Counselling, information and informed consent

Follow general guidelines in chapter 2 (Counselling) and sections 1.4 and 1.5 of this chapter. Explain to the client that:

- Female hormones are not affected, and there will be neither loss of femininity nor any change in sexual functioning or satisfaction.
- Menstrual cycles will continue as usual. (If she is discontinuing an IUD or hormonal method, she may experience a temporary change in menstrual pattern).
- There is a small risk of failure, and the resulting pregnancy could be ectopic.

The decision to be sterilized should generally not be made at a time of stress, such as immediately before, during, or after delivery or abortion.

- However, by the time of delivery, some clients may already have made a decision to choose sterilization without having yet made a formal request. Thus, sterilization should not be denied to a woman who voluntarily and spontaneously requests it after delivery or abortion, who has received counselling and who has made a well-considered decision.
- In some circumstances, a woman may learn about sterilization for the first time during the puerperal or post-abortion period and be able to make a voluntary and informed decision after careful counselling.

It is important to give clients an opportunity to express any concerns and to have all their questions answered before the procedure.

3.5 Who can perform female sterilization?

- Specialized or non-specialized doctors can perform minilaparotomy, provided they have been properly trained both in operative technique and in the technique of local anaesthesia.
- Under certain conditions, such as when demand for the operation exceeds the supply of trained doctors, nurses and midwives with surgical experience can be trained to perform the procedure if the country's laws and regulations permit.

- When a non-doctor performs the procedure, a doctor should be available for consultation and in case of surgical difficulties or complications. Protocols for exclusions should be clearly defined.
- All operators should be certified for competence in performing sterilization procedures by **an accredited training authority and should have done at least 10 solo cases in his/her training.**
- The minimum medical team for a female sterilization service is three people: a doctor, or nurse trained to do the surgery; a surgical assistant; and an auxiliary nurse or aide to give support to the operator and the assistant and to monitor the condition of the client.
- Only doctors with experience in abdominal and pelvic surgery should be trained to perform laparoscopic sterilization.

3.6 Health assessment

- *Medical history:* Refer to section 1.6 of this chapter. In addition, history for the female client should include:
 - Current contraceptive status.
 - Last menstrual period (LMP).
 - History of pelvic disease.
 - Obstetric history.
 - Previous abdominal or pelvic surgery.
- *The physical examination should include:*
 - Weight.
 - Temperature.
 - Blood pressure.
 - Pulse.
 - Auscultation of heart and lungs.
 - Abdominal examination.
 - Evaluation of nutritional status.
 - Examination of the skin of the operative area.
 - Other examinations as indicated by the medical history.

In addition, before an interval procedure, the surgeon must perform a careful bi-manual pelvic examination, noting in particular uterine size, position and mobility as well as signs of pelvic infection or masses which may require delay to a standard surgical approach.

Before a postpartum or post-abortion procedure, the surgeon must carefully check for complications of delivery or abortion to identify any temporary contra-indications. If the required medical history and physical examination are not documented in the clinical record, these must be carried out.

- *Laboratory investigations should include:*
 - Haemoglobin and/or haematocrit.
 - Other laboratory tests as indicated by the medical history and physical examination.
 - A cervical smear if possible and due. However, not obtaining the cervical smear or its result should not be a reason for postponing or denying the procedure.

All findings of the medical assessment must be documented in the client's record.

NOTE: If an IUD or an implant is used it may be removed immediately after surgery. In this way the client continues to be protected in the event that the tubal occlusion is not completed.

3.7 Timing of female sterilization procedures

Female sterilization may be safely performed at the following times:

- *Interval sterilization:* Not associated with a pregnancy.
- *Post-partum sterilization:* Within 1 week of delivery or concurrently with caesarean section. The optimal time for the post-partum procedure is within 48 hours of delivery. If surgery is performed on the 3rd to 7th day post-partum, the tubes may be difficult to reach from a subumbilical incision due to involution of the uterus. Careful palpation of the fundus must be performed to assess its position.
- *Post-abortion sterilization:* within 1 week after abortion.

Do not perform post-partum or post-second-trimester abortion procedures any later than the end of the 7th day following delivery or abortion. After the 7th day, the procedure should be postponed until after 28 days in order to avoid additional surgical difficulties and risks.

3.8 Pre-operative preparation

- Ensure that the medical history, physical examination and laboratory tests are completed and documented in the clinical record.
- Review the informed consent form and ensure that the signed form is in the client's record.
- Give pre-operative medications.

3.9 Anaesthesia and operative procedure

Anaesthesia

Use local anaesthesia with light sedation for female sterilization procedures. With proper training, local anaesthesia can be used for minilaparotomy and laparoscopy. The purpose of light sedation is to ensure a calm, relaxed client **while maintaining wakefulness**.

- Use only doses of analgesics (such as 25-50 mg meperidine) and sedatives (such as 5-10 mg diazepam) which allow the woman to stay awake. Doses which put the woman into a semi-conscious or unconscious state compromise ventilation and result in respiratory depression.

Technique for local anaesthesia:

- Infiltrate the skin, fascia and peritoneum with 1% lidocaine (lignocaine) without epinephrine (adrenaline) through a single puncture at the operative site. If only 2% lidocaine is available, dilute it to 1% by using saline solution.
- Wait 1-3 minutes for the local field block to take effect before making the incision.
- *The maximum safe dose of 1% lidocaine is 4.5 mg per kg of body weight. For a woman of 50 kg, that equates to 25 ml of 1% lidocaine.*

All staff need to be trained and aware of correct doses for all drugs in the anaesthetic protocol, understanding the need to decrease doses for the underweight client. If a new drug is introduced, clear instructions should be developed and added to the anaesthesia guidelines.

NOTE: General anaesthesia may be required in cases of extreme obesity, expected abdominal adhesions or some cases of mental illness. Spinal or

epidural anaesthesia is seldom justified for the short sterilization procedure.

Operative procedure

Some basic procedural principles, in addition to those listed in section 1.8, include:

- Proper asepsis with a surgical scrub and the use of cap, mask, sterile gown, and sterile gloves.
- Use of an effective antiseptic (for example, a water-based iodine or a 4% chlorhexidine solution) to prepare the operative area.
- Proper use of the uterine elevator for interval procedures.
- Careful haemostasis and gentle tissue handling are important for patient comfort and safety. Incisions should be as small as possible while allowing good access to the fallopian tubes.

Type of surgical approach

- **Minilaparotomy:** Minilaparotomy is a simplified laparotomy approach using an incision of 5 cm or less. A transverse or longitudinal incision is made under the umbilicus for post-partum cases (usually no more than 2 cm) and a transverse suprapubic incision is used for interval or post-abortion procedures.
 - Minilaparotomy may be difficult if the woman is obese, if the uterus is immobile, or if the tubes have adhesions from infection or previous surgery. In these cases, referral to another facility may be appropriate.
- **Laparoscopy:** The operator uses endoscopic equipment inserted through a 1.0-1.5 cm incision under the umbilicus.
 - Laparoscopy must *not* be performed immediately post-partum nor immediately after a second-trimester abortion.
- **Other surgical approaches:** Laparotomy uses an incision over 5 cm in length. It should not be used in routine sterilization procedures. It may be used when sterilization is performed in conjunction with caesarean section or another gynaecological operation. If a laparotomy is required, regional or general anaesthesia should be used.

Vaginal approaches (e.g., colpotomy, culdoscopy) are not recommended for routine use in sterilization programmes due to the increased infection

rates associated with these approaches.

Recommendation: Minilaparotomy is the preferred method for settings with basic resources and should be offered extensively in most facilities; laparoscopy should usually be reserved for referral centres where trained surgeons, properly maintained instruments, and immediate back-up for complications are available.

Method of occlusion

- Several methods exist for occluding the tubes. Procedures which cause the least damage to the tubes should be used routinely. These methods include *modified Pomeroy ligation, the ring and the clip*. The Parkland technique of double ligation of the tube, with resection of the portion between, is also appropriate.
- *Not* recommended for routine use in tubal occlusion are electrocoagulation, fimbriectomy, and salpingectomy.
- Hysterectomy should not be used for sterilization purposes alone. It should be reserved for women who have gynaecological conditions that require removal of the uterus.

Recommendation: Ligation or mechanical occlusion with clips or rings are the preferred methods of tubal occlusion.

Monitoring of the client during the procedure

- Take and record vital signs (pulse, respiration, blood pressure) in normal, uncomplicated procedures immediately before the operation, and monitor them as needed during the operation and just before the client is removed from the surgical table.
- If the procedure takes longer than usual or in the event of complications or prolonged general anaesthesia, then closer monitoring of vital signs is required.
- Members of the surgical team should talk to the woman during the procedure to give empathetic support and reassurance as well as to monitor the depth of analgesia and sedation.

3.10 Post-operative care

- Monitor pulse, respiration, blood pressure and general status every 15 minutes for at least 1 hour until signs are stable at pre-operative rates, then every hour until recovery and discharge. Vital signs must be recorded in the clinical record.
- Offer liquids such as fruit juice.
- The client may be discharged home the same day surgery is performed, after she has recovered from the procedure, the anaesthetic and the sedation.
 - The Romberg sign (client standing steadily with eyes closed) may be used as a sign of recovery.
 - Usually the woman can go home once she is fully ambulant, able to dress herself and converse coherently.
- As a general rule, do not use prophylactic antibiotics.
- Use simple oral analgesics for pain. Give the woman a 2 day supply on discharge.

3.11 Instructions to women after the procedure

Before the client is discharged, repeat all instructions related to post-operative care, and give the client written instructions.

Explain to the post-operative female client the following:

- That she should rest at home for 1 or 2 days. This rest is important to decrease the risk of complications.
- That she may resume light activities after 2 to 3 days and all normal activities, including intercourse, after 1 week.
- That she should keep the wound clean and dry. She may bathe after 24 hours, making sure that the dressing is kept dry.
- How to use any medications that are given.
- What warnings signs to look for and what to do about each of them (e.g., fever, pain, bleeding).
- Where to go and whom to contact in case of emergency, or for any other problem or questions.
- When and where to return for a follow-up visit.

In addition, inform the client that:

- She is sterile from the time the operation is completed.
- Her monthly periods will continue until menopause.
- If she misses a menstrual period, has any other signs suggestive of pregnancy or has abdominal or pelvic pain, she should contact the clinic.

The client should have the opportunity to ask questions and express concerns.

3.12 Follow-up care

The follow-up visit should take place within 7-10 days. It is desirable that the operating surgeon conducts the follow-up examination. However, another qualified health professional can conduct the examination and manage minor complications. During the follow-up visit:

- Discuss with the client any concern or question she may have.
- Examine the operative site, and remove sutures if required. Perform any other examination needed for that individual.
- Schedule another follow-up visit if continued care is needed.

Special efforts, including the use of community-based follow-up, should be made to contact any client who does not return for the follow-up examination.

Innovative ideas for follow-up should be encouraged; for example, some programmes give clients postcards to send if problems or questions arise.

3.13 Complications

Complications of tubal occlusion include intraperitoneal haemorrhage (seen primarily with laparoscopy), pelvic infection or peritonitis, haematoma formation, and bleeding or infection at the incision site. Rarely, surgical emergencies, such as injury to the uterus, bowel or bladder, or emboli or surgical emphysema (laparoscopy), may occur. Early recognition and prompt treatment are essential. In the event of method failure, the possibility of ectopic pregnancy should be excluded.

Training for tubal occlusion should include how to identify and manage complications.

Any surgical difficulties encountered during the procedure should be recorded, for these difficulties may explain complications that arise during the post-operative period. Any surgical accident should be recorded in the client's record even if it was successfully corrected during the operation.

Photo: Philip Wolmuth/Jordan



9 FERTILITY AWARENESS-BASED METHODS

1 Introduction

Fertility awareness-based methods are contraceptive methods based on an awareness of the start and end of the fertile time of a woman's menstrual cycle. The methods often include practising periodic abstinence – a method which provides a time barrier between spermatozoa and the ovum by avoiding sexual intercourse during the fertile phase of the menstrual cycle. Accordingly, this method depends upon the couple's ability *to identify* the fertile phase of each menstrual cycle, and their motivation and discipline *to practise abstinence* when required.

A significant proportion of couples find it difficult to predict or to identify accurately the onset and end of the fertile phase. They may also take chances when practising periodic abstinence, and break the rules. Accordingly, to be effective as a means of contraception, fertility awareness-based methods require:

- Appropriate counselling;
- Adequate teaching of the technique; *and*
- Supportive follow-up.

The results of some studies show very high failure rates, which fluctuate from 10 to 30 pregnancies per 100 users annually. Clients who find it difficult to use this method may wish to consider the use of another method.

The techniques used to identify the fertile phase of the menstrual cycle, and then to abstain from sexual intercourse, include:

- The basal body temperature (BBT) method.
- The cervical mucus or ovulation (Billings) method.
- The calendar or rhythm (Ogino-Klaus) method.
- The sympto-thermal method.
- The standard days method (SDM).

Fertility awareness-based methods can be used in combination with other contraceptive methods, whereby a couple use barrier methods only during the fertile phase of the cycle. Methods of ovulation prediction are valuable

in the management of infertility as well, in that couples who wish to achieve pregnancy can improve their chances of conception if they can recognize the fertile phase of the cycle.

Fertility awareness-based methods have the following advantages (summarised in Box 9.1):

- There are no physical side-effects.
- Couples have the opportunity to learn more about their sexual physiology and to gain a better understanding of their reproductive functions.
- The responsibility for family planning is shared by both partners, which may lead to increased communication and co-operation between them.
- After initial training and follow-up, many users are able to practise the method without additional assistance and at almost no cost.
- Thus, after initial training and follow-up, trained staff are not needed for service delivery.

Fertility awareness-based methods have the following disadvantages (summarised in Box 9.1):

- The method is highly dependent on the commitment and co-operation of both partners, which may be difficult to achieve.
- Use-effectiveness is lower than that of most other methods of contraception.
- A relatively long initial training is needed, which often requires a considerable amount of staff time. Thus some women may become pregnant while learning the technique.
- Daily monitoring and recording of signs of fertility may be bothersome to some women.
- Long periods of sexual abstinence may cause relationship difficulties and psychological stress.
- Women who have irregular cycles find the method difficult to use.
- Signs and symptoms used to predict fertility are highly variable during breast-feeding.

Box 9.1—Advantages and disadvantages of fertility awareness-based methods

<i>Advantages</i>	<i>Disadvantages</i>
No side-effects.	Needs co-operation and commitment.
Better understanding of sexual cycle.	Low effectiveness.
Shared responsibility.	Can fail during longish training period.
Once trained, no assistance needed.	Daily monitoring/recording can be a bother.
Once trained, negligible cost.	Difficult if cycles are irregular.
Once trained, no health personnel needed.	Unpredictable if breast-feeding.

1.1 General indications

Fertility awareness-based methods provide an alternative for couples who do not wish to use another, more effective method of contraception because of:

- Fear of side-effects.
- Religious or other cultural constraints.
- Difficult access to other methods.

1.2 Indications

None.

1.3 Conditions that require careful consideration

Some circumstances require particular consideration when advising a client on the possible use of fertility awareness-based methods as a means of contraception. These conditions include:

- A particular need for highly effective protection against pregnancy (e.g., it would represent a severe risk to maternal health).
- Inability to comply with sexual abstinence as required by the method.

1.4 Special situations

Some groups of clients present particular challenges to effective use of fertility awareness-based methods as a means of contraception.

Adolescents

Adolescent girls and women experience frequent anovulatory cycles, which can make learning and practising the techniques difficult. Moreover, young clients may find it particularly difficult to comply with abstinence when required.

Pre-menopausal women

Ovulation becomes erratic during the last few years of reproductive life. Anovular and irregular cycles may make it difficult for clients to assess signs and symptoms of fertility. However, such clients are more likely to be experienced with practising periodic abstinence, and so may find it easier to cope with these difficulties and to comply with longer periods of abstinence.

Post-partum women

After childbirth, the time when ovulation returns depends on whether or not the woman is breast-feeding. When ovulation resumes, the signs of fertility can be difficult to interpret and may lead to the need for prolonged abstinence. Any difficulty with sexual intercourse during the later stages of pregnancy might make such a period of abstinence seem longer.

1.5 Counselling and information

Use of fertility awareness-based methods for contraception is a responsibility that both partners must share. Proper counselling must be provided, ideally to both partners, when they are choosing the method, learning the technique and practising it. The counsellor should try to assess the likelihood that both partners will co-operate, especially if the male partner is not present during the counselling session. Discuss with the clients:

- The advantages and disadvantages of this technique, compared with other methods of contraception.
- The different ways to maximize the effectiveness of periodic abstinence, and the need to maintain a daily record of fertility signs.
- The need to complete the initial training, and to have regular follow-ups until confident of detecting signs of fertility.

- The need for strong commitment and strict adherence to such periods of sexual abstinence as required to maximize the effectiveness of this technique.
- The high failure rate of this method of contraception, especially when learning the technique, if other contraceptive precautions are not taken.
- The need to come back for consultation if there is any doubt in interpreting the signs and symptoms of fertility, or if the client misses a period.

1.6 Who can provide instructions about the method?

Health professionals, lay persons or experienced couples can teach the method, provided they have received adequate training.

1.7 Health assessment

Health assessment is not required before the use of fertility awareness-based methods. However, a woman's visit to a sexual and reproductive health (SRH)/family planning clinic to decide upon a method of contraception provides an opportunity for routine health screening.

1.8 Teaching the method

The success of fertility awareness-based methods depends upon the quality of the teaching provided to the clients, and upon their determination to make it work. The initial training should last until both partners are confident in their use of the method —a process that may take some 3 months, or longer. During this time, the clients should be seen by a service provider at least every month, and whenever they feel that they might have a problem.

Instructions should include:

- Elementary facts about reproductive physiology, with emphasis on the changes that occur during the menstrual cycle, and their timing and relationship to one another, so as to enable clients to identify the fertile phase.
- Instructions about how to use the technique selected to identify the fertile phase.
- Discussion of the timing of sexual intercourse.

1.9 Follow-up care

Once clients have learned the technique, there is no standard schedule for follow-up. However, clients should be encouraged to return whenever there is a problem, and to keep appointments for regular health examinations.

2 The basal body temperature (BBT) method

2.1 Definition

The basal body temperature (BBT) method is founded on the increase in body temperature that occurs shortly after ovulation, associated with the secretion of progesterone by the corpus luteum.

After ovulation, the body temperature rises 0.2-0.4°C (0.4-0.8°F), and remains high until the next menstruation. The couple are advised to refrain from sexual intercourse from the start of menstruation until the night of the third consecutive day of raised temperature following the onset of this rise in temperature (representing ovulation). This cannot be less than 9 days after the period has ended.

2.2 Indications

Couples who have decided to use periodic abstinence may find the BBT method appropriate if:

- The woman is reluctant to touch her genitals, as is required for the cervical mucus method.
- The couple is willing to abstain from sexual intercourse for the required time.
- The woman has irregular menstrual cycles, preventing meaningful use of the calendar method.

2.3 Counselling and information

In addition to matters outlined in section 1.5, the clients must be advised that long periods of abstinence will be required because sexual intercourse is restricted to the post-ovulatory phase of the menstrual cycle.

2.4 Instructions to clients

Taking the temperature

Advise clients to use an ovulation thermometer; this has an expanded narrow scale ranging from 35-39°C (96-100°F), so that the temperature is easier to read. If an ovulation thermometer is not available, a clinical thermometer (which has a scale with a wider range) may be used. Instruct the clients to:

- Keep the thermometer near the bed within hand's reach.
- Shake the thermometer to lower the mercury below 35°C (96°F) at night before going to bed. Avoid touching the bulb end. Before the woman's temperature is taken in the morning, check the thermometer again to make sure that it reads below 35°C (96°F). If necessary, shake the thermometer again; preferably this should be done by the male partner or someone else because this action may raise the shaker's temperature and produce a false reading.
- Take the temperature immediately after waking up, before getting out of bed or doing anything such as having a hot or cold drink. If the woman is working on a night shift, take the temperature during the day or in the evening after at least 3 hours of rest.
- Take the temperature at the same time each day during a particular menstrual cycle, as far as possible.
- Take the temperature by the oral, rectal or vaginal route. Rectal and vaginal routes are more reliable, but the oral route is adequate if used correctly.
 - *Oral route:* Place the bulb of the thermometer under the tongue, with lips closed for 5 minutes before reading.
 - *Rectal route:* Use a rectal thermometer. Smear a little KY or petroleum jelly on the bulb and gently insert the thermometer into the rectum for about 2.5 cm while lying down on one side with the knees drawn up. Keep the thermometer inside the rectum for 3 minutes before reading.
 - *Vaginal route:* Insert the thermometer gently into the vagina for about 4.5 cm and leave it for 3 minutes before reading.
- Always use the same route and the same thermometer throughout a menstrual cycle. Always keep a spare thermometer. If a thermometer breaks, use another one but make a note on the chart.
- After removing the thermometer, take the reading and record it on the chart. If the mercury stops between two marks of the thermometer

(e.g., between 36.6°C and 36.7°C) record the lower temperature (i.e., 36.6°C).

- Rinse the thermometer clean, using cool water, and return it to its usual storage place. **Never use hot water to clean the thermometer.**

Recording the temperature on the chart

Provide the clients with a special temperature chart (see Figures 9.1, 9.2 and 9.3). The calendar date is written at top of the chart. The days of the menstrual cycle are marked on the horizontal axis at the bottom of the chart. The temperature is printed on the vertical axis at the left of the chart. The chart should have 5 mm squares as a minimum. The first day of menstruation is day 1 of the menstrual cycle. Instruct the clients to:

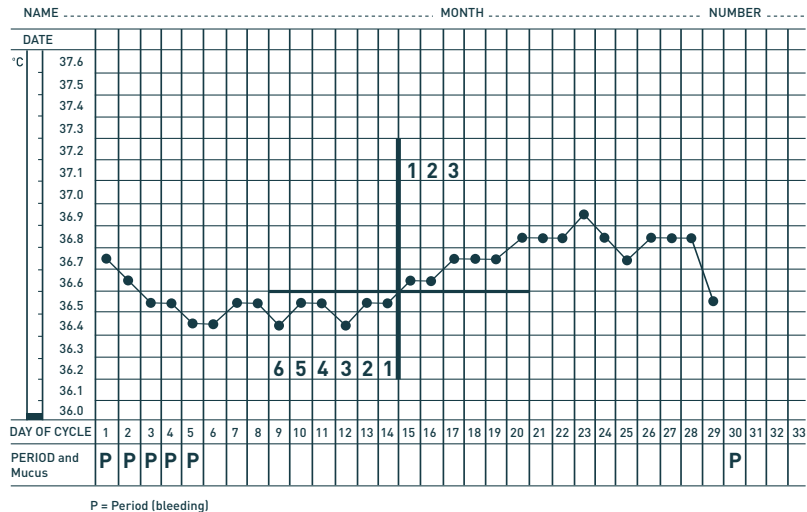
- Place a dot in the centre of the relevant square that corresponds to the temperature and the day of the menstrual cycle.
- Join up the dots progressively with a continuous line from the first to the last day of the cycle.
- Start a new chart on the first day of every menstrual cycle.
- Make a note of anything which may affect the BBT against the day of the menstrual cycle on which it occurs. (See below for factors which may affect the BBT.)

Interpreting the chart

An ovulatory cycle is generally characterized by a biphasic temperature chart. The temperature remains at a lower level before the time of ovulation. It rises shortly after ovulation, with a shift of about 0.2-0.4°C (0.4-0.8°F) or more, and remains higher until just before (or at the onset of) the next menstrual cycle.

Great care is required when interpreting the charts. Temperature levels can vary from cycle to cycle in the same woman. Furthermore, the BBT may rise in different ways: acutely, slowly, in a stepwise pattern, preceded by a sharp drop or, less frequently, in a sawtooth pattern. Figures 9.1, 9.2 and 9.3 show examples of these different types.

Figure 9.3 Chart showing a stepwise rise in basal body temperature related to ovulation demonstrated by the “3 over 6” rule.



To identify the beginning of the infertile phase of the cycle, give the client the following instructions:

- Ignore the temperatures of the first 4 days of the cycle, and any later temperatures which are obviously raised by an incidental disturbance.
- The infertile phase starts when 3 consecutive temperatures which are higher than the previous 6 consecutive ones have been recorded: this is called the “3 over 6” rule.

Timing of sexual intercourse

From day 1 of the menstrual cycle, sexual intercourse can resume no earlier than the night of the third day of consecutive daily temperatures which are above the level of the previous 6 (“3 over 6”). It is then safe to have intercourse until the start of the next menstrual period.

Factors affecting basal body temperature

The following circumstances may raise, or appear to raise, body temperature:

- Temperature taken at a different time from the usual one.
- Temperature taken when basal conditions (immediately on waking or after at least 3 hours of rest, without taking a hot drink) are not met.
- Illness.
- A disturbed night's sleep.
- A change in environmental temperature.
- Emotional stress.
- Intake of alcohol.

The BBT method is not widely used on its own. More commonly, it is used as part of the sympto-thermal method.

3 The cervical mucus (Billings') method

3.1 Definition

The cervical mucus method is based on recognizing and interpreting cyclic changes in cervical mucus that occur in response to changing oestrogen levels.

During a menstrual cycle a woman may experience different sensations at the opening of the vagina, and changes in the characteristics of the cervical mucus. Couples who practise this technique can have sexual intercourse on some days during both pre-ovulatory and post-ovulatory phases of the menstrual cycle, because the infertile phase in both parts of the cycle can be identified by monitoring the cervical mucus pattern.

Pre-ovulatory phase

- The menstrual period is followed by dry days. The cervical mucus is thick and sticky and forms a plug blocking the cervical canal, and there is a sensation of dryness in the vagina. There is no visible mucus at this stage.
- As the levels of circulating oestrogen increase, mucus appears in the vagina. At first it is scanty, and the woman has a sensation of moistness

or stickiness at the vulva. The mucus appears thick, sticky, cloudy or opaque, and is not elastic.

- As oestrogen levels continue to rise with approaching ovulation, the mucus becomes more profuse and feels slippery and lubricative, giving rise to a sensation of wetness at the vulva. It appears thin, white and transparent, and is extremely elastic. It may be similar to raw egg white. This type of mucus indicates fertility.
- The last day of this watery mucus is called the peak mucus day.

Post-ovulatory phase

- The slippery sensation is lost and there is a relatively abrupt return to stickiness, followed by dryness at the vulva.

3.2 Indications

The cervical mucus method may be appropriate for couples who have decided to use a fertility awareness-based method, but find it difficult to abstain from sexual intercourse for the long periods of time required by the BBT method. The woman must be willing to touch her genitals to assess the state of her cervical mucus.

3.3 Conditions that require careful consideration

In addition to those outlined in section 1.3, certain conditions must be taken into account when considering use of this method:

- The presence of any vaginal or cervical infection, which may affect the ability to recognize the mucus pattern.
- Breast-feeding, which can decrease and change the quantity and quality of the mucus.

3.4 Counselling and information

As well as the issues noted in section 1.5, clients should be informed about:

- The need for the woman to touch her genitals to identify changes in the mucus. Some women may be able adequately to assess the characteristics of the mucus by relying on sensation without having to touch the genitals; this is an ability which may be developed with experience.

- The need for abstinence during the entire first month of learning the technique, so as to avoid confusion of cervical mucus with seminal fluid or vaginal secretions following sexual stimulation.

3.5 Instructions to clients

Checking and recording the cervical mucus pattern

Provide the client with a chart to record the cervical mucus pattern. It may be convenient to use a chart on which both the BBT and the mucus pattern can be recorded in a simple way (see Figure 9.4). Instruct the client to:

- Record the sensation of either dryness, moistness or wetness felt at the opening of the vagina. Observe the mucus pattern at convenient times (e.g., when going to the toilet) *at least* twice a day, with the first check in the morning and the last check in the evening.
- Check for the presence of mucus by wiping the vagina with a paper tissue or by using a finger.
- Collect mucus, when present, on a paper tissue or on the fingertip.
- Note its colour as white, cloudy or clear, and its physical characteristics as thin and lubricative, or thick and viscid.
- Check for elasticity by opening the paper tissue or the fingers on which mucus has been collected. If the threads of mucus stretch easily between the leaves of the paper tissue or the fingers without breaking, it is highly elastic (see Figure 9.5).
- Record the daily changes in the mucus and the sensations felt in the vagina on the chart every night. This may be done by coded letters such as D for dry and M for mucus. Symbols, coloured pencils or coloured stamps may also be used. In addition, a word or two to describe the mucus (such as thick, sticky, clear, thin, slippery, etc.) should be written.
- Mark the last day of slippery mucus, which is the peak mucus day, by a cross, and the following three days as days 1, 2, and 3. The peak mucus day can only be recognized retrospectively, when the mucus is no longer slippery and elastic in comparison with the mucus of the previous day.
- If slippery mucus reappears after a peak mucus day has been recorded, disregard the earlier peak mucus recording on the chart. Record instead the second peak, which will be the correct peak mucus day.

Figure 9.4—Chart showing how to mark changes in cervical mucus.

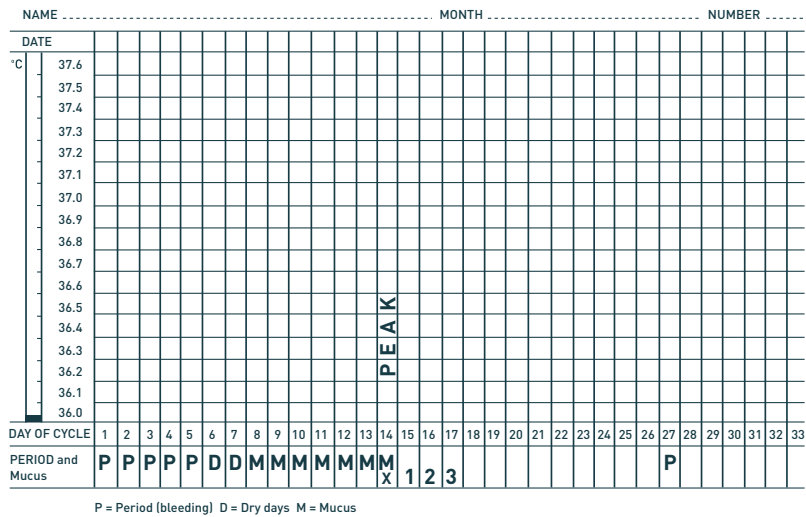


Figure 9.5—Mid-cycle elastic mucus



Timing of sexual intercourse

Sexual intercourse is permitted:

- Immediately following menstruation until the first sign of cervical mucus.
- On the evening of the fourth day after the peak mucus day and until menstruation starts.

Recommend that the client restrict sexual intercourse to alternate days during the pre-mucus infertile phase (before cervical mucus appears), because seminal fluid and increased vaginal secretions due to sexual stimulation make it difficult to interpret cervical mucus status.

Sexual intercourse should be avoided:

- From the first day that cervical mucus is observed after menstruation until the end of the fourth day after the peak mucus day.
- At any time if the client has any doubt about the mucus pattern.

Factors affecting the cervical mucus pattern

- Vaginal or cervical infection.
- Vaginal secretions due to sexual stimulation.
- Drugs used for colds or sinusitis, which may also dry the cervical mucus.
- Physical or emotional stress.
- Breast-feeding.

3.6 The modified mucus method

Some programmes use a modified mucus method (MMM). The rules of this modified method are less restrictive than the original mucus method and differ in respect of the following points:

- The MMM allows sexual intercourse on appropriate days during the first month of use, whereas the original method does not.
- In women who have regular menstrual cycles, the MMM allows sexual intercourse on pre-mucus days when thick mucus is present, contrary to the original method.

- With the MMM, sexual intercourse is permitted on the third day after the peak mucus day, in contrast to the fourth day in the original method.

4 The calendar or rhythm (Ogino-Knaus) method

4.1 Definition

The calendar or rhythm method is reportedly the most widely used of all fertility awareness-based methods. It involves numerical calculations based on previous menstrual cycles to estimate the fertile period. It has a high failure rate because it relies on past information to predict the length of future cycles, a prediction which has limited accuracy.

4.2 Indications

Women who have reasonably regular cycles may find it more convenient to use this method than other fertility awareness-based methods since it does not require daily monitoring of fertility signs.

4.3 Conditions that require careful consideration

In addition to those noted in section 1.3, the following circumstances require particular attention if considering use of this method:

- Irregular cycles.
- Breast-feeding.

4.4 Counselling and information

In addition to the issues noted in section 1.5, inform clients that, in order to predict the length of future cycles, they will need a record of at least 6 consecutive cycles. While this information is being gathered, they can use non-hormonal methods of contraception (hormonal methods would alter the woman's cycles).

4.5 Instructions to clients

The client should be instructed to:

- Record the number of days in 6 consecutive menstrual cycles, recording the first day of menstruation as the first day of each cycle.

- Calculate the *first* fertile day by subtracting 18 from the *shortest* cycle, i.e.:

$$\text{First fertile day} = \text{shortest cycle} - 18.$$

- Calculate the *last* fertile day by subtracting 11 from the longest cycle, i.e.:

$$\text{Last fertile day} = \text{longest cycle} - 11.$$

- Sexual intercourse should not take place during the fertile phase. For example, if the last six cycles were 28, 26, 29, 27, 29 and 27 days long:

$$\text{The first day of the fertile phase} = 26 - 18 = 8;$$

$$\text{The last day of the fertile phase} = 29 - 11 = 18.$$

- Accordingly, **avoid sexual intercourse from days 8 to 18 of the menstrual cycle (both days inclusive).**

5. The sympto-thermal method

5.1 Definition

The sympto-thermal method (STM) combines various periodic abstinence techniques, especially cervical mucus changes, the calendar method and BBT. The use of multiple techniques is more accurate than a single method for identification of the fertile phase of the menstrual cycle, so that the days of required abstinence can be kept to a minimum.

5.2 Indications

This method may be appropriate for clients who have decided to practise periodic abstinence as their method of contraception and would like to achieve the highest degree of protection offered in conjunction with shorter periods of abstinence.

5.3 Counselling and information

In addition to the issues outlined in section 1.5, inform the clients that they may need longer training than when a single technique is being learned.

5.4 Instructions to clients

Instructions on the individual techniques are given in sections 2.4, 3.5 and 4.5. When used in combination, give the following instructions in relation to the time of sexual intercourse:

- *Identify the onset of the fertile period*, when sexual intercourse should stop, by means of the cervical mucus method and/or calendar calculations. When using the cervical mucus method, sexual intercourse should take place on alternate days (see the discussion of the timing of sexual intercourse in section 3.5), and the onset of the fertile period is determined by the first appearance of mucus, when sexual intercourse should stop. Women who have difficulty in identifying the first mucus may find it convenient to use the calendar method, which allows couples to have intercourse every day before the established onset of the fertile period. Here, that day is calculated by subtracting 18 from the number of days in the shortest of the last 6 previous menstrual cycles. For example, if the shortest cycle was 27 days long, abstinence should be observed from day 9 ($27 - 18 = 9$) of the menstrual cycle. If mucus appears before day 9 of the cycle, sexual intercourse should cease then.
- *Estimate the end of the fertile period*, when it is safe to resume sexual intercourse, by use of the BBT and/or cervical mucus methods. Sexual intercourse can take place as soon as 3 consecutive daily temperatures have been higher than the previous 6. When using the cervical mucus method, sexual intercourse can be resumed on the fourth day after the peak mucus day. When both techniques are used, sexual intercourse can be resumed when both techniques have indicated that it is safe.

6 The standard days method (SDM)

6.1 Definition

The SDM is based on the fact that a woman can become pregnant only during certain days in each menstrual cycle (the egg is fertilizable for approximately 1 day after ovulation, and sperm lose their fertilizing capability some 4-5 days after ejaculation). A woman who has a regular menstrual cycle of between 26 and 32 days in length will usually ovulate between day 13 and day 17 of her cycle. Avoidance of unprotected intercourse from day 8 through day 19 (both days inclusive) of her menstrual cycle should therefore allow enough time for the gametes to lose their capacity to fertilize or to be fertilized.

Because the standard formula to define the fertile period is already theoretically established, users of the SDM do not need to keep records of cycle lengths or to do any calculations.

6.2 Indications

Couples who have decided to use periodic abstinence for contraceptive purposes may find the SDM appropriate if:

- The couple is unwilling or unable to make or to record the observations needed to be able to implement the other techniques (e.g., the woman is reluctant to touch her genitals, as is required for the cervical mucus method).
- The couple is willing to abstain from sexual intercourse, or to use another method of contraception (e.g., condoms), for 12 days in the middle of the menstrual cycle.

6.3 Instructions to clients

The woman is given a set of beads as a necklace ('CycleBeads'). Each bead represents a day of the menstrual cycle and she can keep track of where she is in the cycle by moving a tight-fitting black rubber ring along the beads. The beads have different colours: the red bead marks the day the menstrual period begins. The brown beads mark the days when the woman is unlikely to be fertile and the white beads mark the days when the woman is likely to be fertile (see Figure 9.6). Instruct the client to:

- Put the black ring on the red bead on the first day of her menstrual period.
- Move the black ring forward, one bead each day.
- Abstain from sexual intercourse or use another method of contraception (e.g., condoms) when the black ring is on any of the white beads.

Figure 9.6 CycleBeads



CycleBeads can also help to monitor cycle length. If the woman starts her period before she moves the ring to the dark brown bead, her cycle is less than 26 days. If she moves the ring to that last bead before the red one, and her period does not start by the next day, her cycle is longer than 32 days. If either of these occur more than once in twelve months, she should consider another method because the SDM will not be as effective for her as for women with cycles within the 26-32 day range.

Photo: Marieka Vandewiele/Romania



10 EMERGENCY CONTRACEPTION

EMERGENCY CONTRACEPTION

10

1 Introduction

Emergency contraception refers to the type of contraception that is used as an emergency procedure to prevent unintended pregnancy following an unprotected act of sexual intercourse.

Emergency contraception is sometimes referred to as the “morning-after pill” or “post-coital contraception”. This terminology can be confusing since the contraceptive is not necessarily a pill and can be used within 5 days after unprotected intercourse and not merely the morning after. The term “emergency contraception” is also preferred because it conveys a sense of urgency.

Since the mid-1960s, the postcoital use of certain orally administered steroid hormones has been shown to be effective in preventing pregnancy. In addition, the copper-releasing IUDs are also highly effective for emergency contraception.

1.1 General Indications

Emergency contraception is meant to be used following an unprotected act of sexual intercourse. For example:

- When no contraceptive has been used.
- When there has been a contraceptive accident or misuse:
 - Three or more combined oral contraceptive pills missed in consecutive days.
 - One progestogen-only contraceptive pill taken 3 or more hours late.
 - Condom rupture or slippage.
 - Diaphragm dislodgement or early removal.
 - Failed coitus interruptus (e.g. ejaculation in vagina or on external genitalia).
 - Miscalculation of the safe period when using a fertility awareness-based method.
 - IUD expulsion.
- When the woman has been a victim of sexual assault.

1.2 Types of emergency contraception

The following methods can be used for emergency contraception:

- *Emergency contraceptive pills (ECPs)*: progestogen-only or combined oestrogen/progestogen oral contraceptives.
- *Copper-releasing IUDs*.

2 Emergency Contraceptive Pills (ECPs)

2.1 ECP regimens

Progestogen-only pills

The most convenient regimen is a single dose consisting of 1.5 mg levonorgestrel taken as soon as possible after unprotected intercourse; alternatively, one dose of 0.75 mg levonorgestrel can be taken as soon as possible after unprotected intercourse followed by a same dose taken 12 hours later.

For both regimens, the sooner they are taken after unprotected intercourse, the more effective they are. They are most effective if taken within 3 days (or 72 hours). However, new evidence shows that there is still some effect up to 5 days after unprotected intercourse.

Where pills containing 0.75 mg levonorgestrel are not available, levonorgestrel pills, each containing 0.03 mg used for regular contraception (mini-Pill), are being used instead. Twenty-five of these mini pills should be taken initially, to be repeated 12 hours later. *(There is a possibility that absorption of the hormone may be less when the dose is taken in a large number of pills).*

Combined pills

Combined oestrogen/progestogen pills, containing ethinyl oestradiol and levonorgestrel, can be taken in a regimen known as the "Yuzpe method".

When pills containing 50 µg ethinyl oestradiol and 0.25 mg levonorgestrel are available:

- 2 pills should be taken as the first dose as soon as convenient but no later than 72 hours after unprotected intercourse. These should be followed by another 2 pills 12 hours later.

When only pills containing 30 µg ethinyl oestradiol and 0.15 mg levonorgestrel are available:

- 4 pills should be taken as the first dose as soon as convenient but no later than 72 hours after unprotected intercourse. These should be followed by another 4 pills 12 hours later.

For information on brand names of pills containing this formulation that are available in specific countries, see IPPF's *Directory of Hormonal Contraceptive* at IPPF web page: www.ippf.org

Mode of action

Hormonal emergency contraception achieves its contraceptive effect by several mechanisms depending on the time in a woman's cycle it is taken. It can inhibit or delay ovulation and may also interact with ovum and sperm transport, and fertilization. Studies differ on whether hormonal emergency contraception can cause changes in the endometrium that would be sufficient to interfere with implantation. There is no evidence that hormonal emergency contraception dislodges the embryo after implantation has occurred. Hormonal emergency contraception does not cause an abortion.

2.2 Efficacy

The progestogen-only regimen reduces the risk of pregnancy after a single act of sexual intercourse by about 60%-93% and the combined regimen by about 56%-89% if taken within 72 hours. This means that if a woman has an 8% probability of pregnancy after unprotected intercourse, these regimens would reduce that probability to about 1% or 2% respectively. The efficacy is better the sooner the method is used after sex.

2.3 Side-Effects

- *Nausea*: occurs in about 50% of clients using combined ECPs, but it does not usually last more than 24 hours. Nausea occurs in approximately 20% of women using progestogen-only ECPs.
- *Vomiting*: occurs in about 20% of clients using combined ECPs and 5% of women using the progestogen-only ECPs. When the combined regimen is used, anti-emetic pre-treatment may be considered; with the levonorgestrel-only regimen this is unnecessary.

If vomiting occurs within one hour after taking a dose, it is common practice to repeat the dose. However, there is no evidence that this improves efficacy; indeed, vomiting can be an indication that the hormone has been absorbed.

In case of vomiting, further pills may be administered vaginally. Although there are no clinical data supporting the efficacy of this practice, contraceptive steroid hormones are known to be readily absorbed from the vagina.

- *Irregular uterine bleeding*: some women may experience spotting after taking ECPs. The majority of women will have their menstrual period on time or early; if there is a delay of more than 1 week, the possibility of pregnancy should be excluded.
- *Other side-effects*: breast tenderness, headache, fatigue, abdominal pain and dizziness.

2.4 Indications

See section 1.1 of this chapter.

2.5 Medical eligibility criteria

No known contraindications exist to the use of hormonal emergency contraception. Although this method is not indicated for a woman with a known or suspected pregnancy, it will not affect the course of her pregnancy, or cause harm to the foetus if hormonal emergency contraception is used. There is no need for a physical examination before providing it.

Suspected pregnancy:

If a woman wants ECPs and you cannot rule out pregnancy with absolute certainty, it is permissible to give ECPs if you explain to the client that she

could already be pregnant, in which case the regimen will not be effective.

Because the dose of hormones used in emergency contraception is small and the pills are given for a short time, the medical eligibility criteria for continuous use of combined oral contraceptives and progestogen-only pills do not apply.

Drug interactions:

Women should be advised that effectiveness of ECPs may be reduced if they are taking drugs which reduce the efficacy of regular oral contraceptives (including but not limited to rifampsin, griseofulvin, barbiturates). At the current time there is insufficient information on the possible interaction of hormonal emergency contraception with other drugs to make any specific recommendations on increasing ECP dosing schedules.

2.6 Who can provide ECPs?

Doctors, nurses, midwives, other clinical personnel, pharmacists and community health workers who have been properly trained may provide ECPs, in accordance with local laws and regulations.

All ECP providers should receive appropriate training and follow clear service guidelines. When emergency contraceptive pills are provided through non-clinic outlets, the providers must have access to referral facilities for those cases where it may be required (e.g. if more than 72 hours have elapsed since the act of intercourse and hormonal emergency contraception is no longer the first choice).

When ECPs are available through pharmacies, adequate client information should be ensured.

2.7 Counselling and information

Counsel clients in a private and friendly environment. Reassure them about absolute confidentiality. This should extend to young people. Be as supportive as possible and refrain from making judgemental comments or indicating disapproval through body language or facial expressions. In situations where it is difficult to maintain privacy (e.g. in pharmacies), give the method to the client with appropriate instructions for using it, and advise her to attend a clinic or contact a health care/family planning provider for counselling on regular contraception.

Counselling on emergency contraception

Counselling on emergency contraception should be responsive to the client's concerns and circumstances. Some clients may not wish to discuss their decision for requesting emergency contraception. In this case, clients should be given the method with appropriate instructions for using it and encouraged to return at a convenient time for counselling on the use of regular contraception. Some issues which clients may wish to discuss include:

- Mode of action (some clients may need reassurance that emergency contraception is not an abortion).
- Emergency contraception options.
- Possibility that the emergency contraceptive may fail.

Inform the client that the use of emergency contraceptive pills cannot protect them from the possibility of pregnancy if unprotected intercourse occurs later in the cycle.

Advise that emergency contraception does not protect against sexually transmitted infections (STIs), including HIV, and that unprotected sex may have exposed her to this risk. After assessment of the risk of exposure to a STI, a woman should be counselled and offered services as appropriate.

Advise the client who takes ECP that, if they have intercourse in the same cycle after ECP have been taken, a risk of pregnancy still exists, particularly since the method sometimes alters the timing of ovulation. They should use a method of contraception (e.g. condoms) for the rest of the cycle after taking emergency contraception.

Counselling on regular contraception

Whenever possible, clients seeking emergency contraception should be offered counselling on regular contraception. Contraceptive counselling should not be a prerequisite for providing emergency contraception but should be given whenever it is requested or accepted by the client.

- Find out the current method of contraception, if any.
- If the reason for requesting emergency contraception is an accident or misuse of the regular contraceptive method, discuss with the client how to prevent that situation in the future.
- Discuss future contraception in an empathetic way (see section 2.11).

2.8 Health Assessment

Exclude the possibility that the client may be pregnant by:

- Assessing the date of the last menstrual period and whether it was normal.
- Assessing the date and time of the last episode of unprotected intercourse.
- Establishing whether any other act of unprotected intercourse has occurred earlier in the cycle.

Other health assessment (e.g. pelvic exam, laboratory tests) is not required.

2.9 Instructions to the client

Provide the method to the client with appropriate oral and written instructions for using it.

- Explain the correct use of the method (see section 2.1). Make sure the client understands when to take each dose of pills.
- Advise the client to drink milk or eat a snack with the pills to reduce nausea.
- Explain to the client that ECPs will not protect her from pregnancy if she engages in unprotected intercourse in the days or weeks following treatment. Advise her to use a barrier method until her next menstruation if she has sexual intercourse.
- Emphasize that ECPs are not suitable for regular contraception. Repeated use would result in a high risk of pregnancy and side-effects are common.
- Explain that after the use of ECPs most women will have the next menstrual period early or on time. If the menstrual period is delayed more than 1 week the possibility of pregnancy should be considered.
- Advise the client to come back or visit a referral clinic (as appropriate) if there is a delay in her menstruation of more than 1 week; if she has any reason for concern (e.g. lower abdominal pain, heavy bleeding); or as soon as possible after the onset of the menstrual period for contraceptive counselling.

2.10 Follow-up care

If the client has already adopted a method of contraception for regular use, no follow-up should be required in relation to the use of emergency contraception, unless she has a delay in her menstruation, suspects she may be pregnant or has other reasons for concern.

During the follow-up contact

- Record the client's menstrual data to verify that she is not pregnant. If in doubt, perform a pregnancy test (see chapter 11: Diagnosis of pregnancy).
- Discuss suitable contraceptive options (see section 2.11).
- If the woman wishes, provide a contraceptive method according to her choice .

ECP failure

- Advise the client on available options and let her decide which is most appropriate for her situation. Her decision should be respected and supported. Refer the client to other service providers as appropriate.
- If the client decides to continue the pregnancy, reassure her that there is no evidence of any teratogenic effect following ECP use.
- While ECPs are unlikely to increase a woman's overall risk of ectopic pregnancy, there may be a higher percentage of ectopic pregnancies among ECP failure cases than among the general pregnant population. Be certain to rule out the possibility of ectopic pregnancy in all cases of ECP failure.

2.11 Initiating regular contraception after ECP use

Condoms: can be used immediately.

Diaphragms: can be used immediately.

Oral contraceptives: There is no need to delay starting oral contraception until the onset of the next menstrual period – it can be started the day after the single or second dose of ECP is taken.

Injectables: the first injection can be given within 7 days of the beginning of the next menstrual cycle.

Subdermal implants: the implants can be inserted within 7 days of the beginning of the next menstrual cycle.

IUD: the IUD can be inserted during the next menstrual period. If the client intends to use an IUD as a long-term method and meets IUD screening criteria, emergency insertion of a copper-releasing IUD may be a convenient alternative to ECP use (see section 3).

Fertility awareness-based method: this method may be initiated at the next menstrual cycle if there are no bleeding irregularities. If this method is new to the woman, she should use another method of contraception (non-hormonal) while learning the technique.

Sterilization: the operation should be performed only after informed, free choice has been ensured. It is not recommended that clients make this decision under the stressful conditions that often surround ECP use.

3 Copper-Releasing IUDs

A copper-releasing IUD can be used within 5 days of unprotected intercourse as an emergency contraceptive. When the time of ovulation can be estimated, the IUD can be inserted beyond 5 days after intercourse, if necessary, as long as insertion does not occur more than 5 days after ovulation.

3.1 Efficacy

This method has been reported to be highly effective. After an act of unprotected sexual intercourse, less than 1% of women become pregnant if they use a copper-releasing IUD as an emergency contraceptive.

3.2 Indications

In addition to the indications stated in section 1.1 of this chapter, the IUD is especially indicated when:

- When the hormonal methods are less effective because more than 72 hours have elapsed.
- The client is considering using an IUD for continuous, long-term contraception.

3.3 Medical eligibility criteria

The eligibility criteria for regular use of IUDs generally apply to emergency use.

Category 4 (contraindications)

Do not advise the use of any IUD or provide it to women with:

- Known or suspected pregnancy.
- Puerperal or post-abortion sepsis current or within the last three months.
- Pelvic inflammatory disease (PID) current (if develops during IUD use becomes a category 2).
- Sexually transmitted infection (STI) current (refers to STIs that may produce cervical infection, chlamydia or gonorrhoea) (if these develop during IUD use becomes a category 2).
- Purulent cervicitis.
- Confirmed or suspected malignancy of the genital tract.
- Unexplained vaginal bleeding (suspicious for serious condition) (if develops during IUD use, becomes a category 2).
- Cervical cancer awaiting treatment (if develops during IUD use, becomes a category 2).
- Endometrial cancer (if develops during IUD use becomes a category 2).
- Congenital uterine abnormalities or benign tumours of the uterus (fibroids) which distort the cavity in a manner incompatible with proper IUD placement.
- Malignant gestational trophoblastic disease.
- Known pelvic tuberculosis (if develops during IUD use becomes a category 3).

For the levonorgestrel-releasing IUD, the following contraindication also applies:

- Current cancer of the breast.

Counsel any woman with any contraindication (other than pregnancy) about alternative methods of contraception (see also chapter 2: Counselling).

3.4 Special situations

Risk of STIs

For a woman without a clinically obvious gynaecological infection, but at high risk of STIs (e.g. multiple sexual partners), ECPs are a better option than an IUD. However, she can use an IUD for emergency contraception, but advise her to switch to another contraceptive method at the next menstrual period.

Rape

Insertion of an IUD may be emotionally traumatic for a woman who has been a victim of sexual abuse. There is also a possibility of STI/HIV transmission. Therefore, ECPs provision should be the first choice. However, an IUD may be provided on condition that women are appropriately counselled and STI/HIV risk properly assessed.

3.5 Who can provide IUDs?

Doctors, midwives, nurses and other health professionals who have been properly trained may insert IUDs, in accordance with the local laws and regulations.

3.6 Counselling and information

The general aspects of counselling described in section 2.7 of this chapter also apply to emergency use of an IUD.

When counselling on future contraception, discuss the possibility that the client may keep the IUD for continuous contraception. If she wants to continue using the IUD, see chapter 6 for further counselling points. If she does not want to continue using the IUD, tell her to return during or soon after her next menstrual period for removal.

3.7 Health assessment

Exclude the possibility that the client may be pregnant by:

- Assessing the date of the last menstrual period and whether it was normal.
- Assessing the date and time of the last episode of unprotected intercourse.
- Establishing whether any other act of unprotected intercourse has occurred earlier in the cycle.

- Performing a bimanual pelvic examination.

If after doing the above you are in doubt, perform a sensitive urine pregnancy test (see chapter 11: Diagnosis of pregnancy).

Record:

- Gynaecological history.
- Present illnesses, including history of STIs and risk factors for STI such as multiple sexual partners.

Perform a physical examination:

- Speculum visualization of cervix and bimanual pelvic examination.
- Any other examination as indicated by the medical history.

3.8 Insertion of the IUD

Insertion is the same as for continuous IUD use (see chapter 6: Intrauterine devices, section 10).

3.9 Instructions to the client

- Advise the client that cramping pain may occur for the first 24 to 48 hours after insertion of the device. If she experiences this she can take pain-relief tablets such as aspirin, ibuprofen or paracetamol.
- If the client does not plan to keep the IUD for continuous contraception, instruct her to come back during or soon after her next menstruation for removal of the IUD.
- If the client plans to keep the IUD for continuous contraception, advise her according to instructions provided in chapter 6: Intrauterine devices, section 11).

3.10 Follow-up care

Advise the client to return during or soon after the next menstrual period.

- If the client does not wish to keep the IUD, remove it and provide counselling on alternative contraceptive options and relevant services, as necessary.

- If the client wishes to keep the IUD for continuous contraception, check that the IUD is properly placed and provide information related to continuous use and follow-up (see chapter 6: Intrauterine devices, sections 11 and 12).

If the menstrual period is delayed after insertion of an IUD for emergency contraception, consider the possibility of pregnancy (see chapter 11: Diagnosis of pregnancy). If the client is pregnant, proceed according to guidelines in chapter 6, section 15.

3.11 Side-effects

Side-effects are the same as for continuous IUD use (see chapter 6, section 14). If the client does not keep the IUD for continuous contraception, any side-effect will usually disappear after the IUD is removed.

4 Service management

4.1 Advocacy

Those involved in SRH/family planning should advocate for the availability of emergency contraception. All efforts should be made to increase awareness among policy makers to gain their support. It is important to collaborate in this regard with women's organizations and sexual and reproductive health advocacy groups.

4.2 Providing information

People need to know about emergency contraception and how to obtain it, so that they can consider its use in the event of having had unprotected intercourse.

The lack of information on emergency contraception is not limited to potential users but also extends to health care and family planning providers. It is therefore important that sexual and reproductive health programmes develop strategies to:

- Address providers' concerns and attitudes.
- Increase providers' knowledge on methods available and their use by giving appropriate training.

- Develop awareness among potential users, including adolescents, by advertising the methods available for emergency contraception and where to obtain them. Information on emergency contraception should be included in sexual and reproductive health education provided at service delivery outlets and in communities.

4.3 Increasing accessibility

In order to make emergency contraception more accessible, sexual and reproductive health programmes should keep the following points in mind when offering emergency contraception:

- Provide an affordable service.
- Make the service available to all potential users who need it.
- Provide ECPs through clinical and non-clinical outlets to reach individuals who reside in outreach areas (e.g. rural) or who are too embarrassed to visit a clinic (e.g. single women, adolescents or victims of sexual assault).
- Maximise the use of emergency contraception by carefully studying existing restrictions on its use and removing unnecessary obstacles.

4.4 Service delivery outlets

Clinical outlets

- Sexual and reproductive health /family planning clinics.
- Other health care facilities.
- General practitioners/family doctors.

Non-clinical outlets

- *Community-based services (CBS)*: community-based services are a very practical approach for providing hormonal emergency contraception to individuals beyond the usual catchment area of the clinic. A referral system is needed for clients who contact the community worker 72 hours or more after unprotected intercourse as they may require insertion of a copper-releasing IUD or other sexual and reproductive health services including the diagnosis of pregnancy. Workers in clinical facilities that provide oral contraceptives should be prepared to offer

services to clients who are referred from the non-clinical CBS system. See chapter 5, section 4.1.

- *Commercial outlets:* commercial outlets such as pharmacies can be very useful in providing hormonal emergency contraception. These are easily accessible and service is fast. Pharmacies should be supplied with printed brochures providing detailed information on emergency hormonal contraception and staff should be trained. They should be able to refer clients to a clinical facility if they come 72 hours or more after unprotected intercourse and if other clinical care is required. Social marketing of pills specifically packaged for emergency contraception may be an effective way of making emergency contraception easily accessible.

Youth advisory centres

Emergency contraception is particularly important for adolescents, who are in the process of establishing their sexuality. Teenage pregnancy poses health risks and use of emergency contraception would reduce the number of teenage pregnancies. Young women may find it difficult to access relevant emergency contraception information and/or services because they:

- Are unaware of the availability of emergency contraception.
- Lack confidence or feel embarrassed to visit an SRH/ family planning clinic.
- Do not know where a service delivery site is located.
- Find the hours of the clinic inconvenient.
- Fear a pelvic examination, which is not a requirement for ECPs.
- Are concerned that providers will be judgemental.

Youth advisory centres could provide information on emergency contraception in their counselling sessions, and some centres, if necessary, may provide emergency hormonal contraception.

Teenagers are best helped by empathetic counselling, in confidence, and by helping them to have access to measures that will minimize risks.

Photo: Spanish Family Planning Association/Charlton Margüelles/Spain



11 DIAGNOSIS OF PREGNANCY

1 Introduction

Diagnosis of pregnancy is an important component of sexual and reproductive health (SRH)/family planning and other reproductive health services. SRH/family planning clinics can offer pregnancy diagnosis services for women who:

- Have planned a pregnancy and are hoping to be pregnant;
- Have had unprotected intercourse and suspect they might be pregnant;
- Want to start certain methods of contraception (e.g., IUD) and need to exclude the possibility that they might be pregnant; *or*
- May have experienced contraceptive failure.

A broad range of techniques are available for the diagnosis of pregnancy. Different methods may be used in particular settings according to their affordability and feasibility: for example, many areas do not have access to biochemical pregnancy tests. Although pregnancy may be diagnosed by clinical (non-laboratory) means, this technique begins to be reliable only after some 8-10 weeks of amenorrhoea.

In the event of pregnancy, determination of the gestational age is important to give the woman an estimated date of delivery. This determination is also useful in the diagnosis of certain pregnancy complications (e.g., ectopic pregnancy or threatened abortion). When a client is considering an abortion, information about gestational age helps the woman to make a decision, and where legal, is essential for selection of the appropriate technique.

2 Clinical (non-laboratory) diagnosis

Diagnosis of pregnancy by clinical (non-laboratory) means relies on the detection, through a careful medical history and physical examination, of the signs and symptoms associated with pregnancy. The most important symptom is amenorrhoea which, when it is accompanied by other symptoms, is highly suggestive of pregnancy. Pelvic examination is useful in the diagnosis of pregnancy after 6 weeks' gestation.

3 Symptoms and signs of pregnancy

3.1 Symptoms

Symptoms of pregnancy include:

- Absent menses (amenorrhoea).
- Nausea (with or without vomiting) and changes in appetite.
- Persistent fatigue.
- Breast tenderness and breast enlargement.
- Increased frequency of urination.
- Perception of fetal movements (late symptom, at 16-20 weeks' gestation).

3.2 Signs

Signs of pregnancy include:

- Uterine softness, roundness and enlargement begins to be noticeable at 6 weeks' gestation.
- Hegar's sign becomes manifest at about 6 weeks' gestation. The isthmus between the cervix and the body of the uterus is felt to be soft and compressible on bimanual pelvic examination.
- Uterine pulsations may be a helpful sign of pregnancy at less than 6 weeks' gestation.
- The enlarged uterus is palpable above the pubic symphysis after 12 weeks' gestation.
- Fetal heart tones are detectable with a stethoscope at 18-20 weeks' gestation.
- Fetal movements can be perceived by an examiner at 18-20 weeks' gestation.

4 Laboratory diagnosis

All biochemical laboratory tests involve antibodies that detect the presence of human chorionic gonadotrophin (HCG) in a woman's urine or blood sample. HCG is a protein produced by the placenta or its precursor and is closely related to luteinizing hormone (LH), follicle-stimulating hormone (FSH) and thyrotrophin. Each of these hormones has two subunits, alpha and beta. The alpha subunits are almost identical, so only

a test that selectively identifies the beta subunit of HCG is specific for HCG. HCG can be detected as early as 7-9 days after ovulation. Pregnancy tests can be divided into 2 groups:

- Agglutination inhibition slide tests; and
- Immunometric tests and radioimmunoassays.

Immunometric tests and radioimmunoassays are more sensitive and specific than agglutination inhibition tests, but are more expensive.

4.1 Agglutination inhibition slide tests

These tests are inexpensive, easy to use and reliably detect pregnancy about 6 weeks after the last menstrual period or 2 weeks after a missed period. As women normally request pregnancy testing only after missing a period, agglutination tests are sufficient for most cases. Antibodies to HCG bind with HCG in the woman's urine sample to produce a positive pregnancy test. Because these antibodies are not specific to the beta subunit of HCG, there is a possibility of cross-reaction with LH, FSH or thyrotrophin. To prevent false-positive results, the sensitivity of these tests (about 2,000 mIU/ml HCG) is set such that high concentrations of HCG are required for a positive result, thereby lessening the chance of cross-reactions. These tests are appropriate for confirmation of pregnancy between 6 and 16 weeks of amenorrhoea. False-negative tests can occur with low concentrations of HCG, as may be found in early pregnancy, pregnancy after 16-20 weeks' gestation, ectopic pregnancy and impending abortion.

4.2 Immunometric tests and radioimmunoassays

These tests reliably detect low concentrations of HCG and are therefore appropriate for detection of early pregnancies, including ectopic pregnancy. These tests are specific for the beta subunit of HCG and so will not cross-react with other hormones.

Immunometric tests can detect HCG concentrations as low as 5-50 mIU/ml in a woman's urine sample. These tests are now available in kit form, for home and clinic use. Test results are positive for 98% of women 3-4 days before the expected menstrual period.

Radioimmunoassays use radioisotopes to detect HCG in serum, so are generally carried out in hospital laboratories. They give accurate results with 5 mIU/ml HCG within 7 days of fertilization.

5 How to be reasonably sure that the woman is not pregnant

Service providers need to exclude the possibility of pregnancy before providing methods of contraception, particularly hormonal contraceptives and IUDs.

To be reasonably sure that a woman is not pregnant, she should have no symptoms and no signs of pregnancy. In addition, the woman should:

- Not have had intercourse since her last normal menstrual period;
- Have been correctly and consistently using a reliable method of contraception;
- Be within the first 7 days of the start of the last menstrual period;
- Be within 4 weeks post-partum (for non-lactating women);
- Be fully or nearly fully breast feeding, amenorrhoeic and less than 6 months post-partum; or
- Be within the first 7 days post-abortion.

A false-negative diagnosis of pregnancy is always possible, although a false-negative diagnosis is much less likely with biochemical tests than with history and physical examination alone.

6 Counselling after diagnosis of pregnancy

Offer counselling about her options to any client with a positive pregnancy diagnosis. In particular, give a woman who is unsure about continuing the pregnancy whatever support and information that she needs to make an informed decision. Refer the client to other service providers as appropriate. If the client plans to continue the pregnancy, counsel her about the importance of prenatal care, and on how and where to obtain it.

Photo: Spanish Family Planning Association/Claudia Ferreira/Brazil



12 **SAFE ABORTION**

1 Introduction

Induced abortion is a common procedure throughout the world. It is estimated that 46 million procedures are performed each year, and out of those nearly 20 million are unsafe. About 67,000 of the pregnancy-related deaths that occur annually are attributed to unsafe abortion. Restrictive abortion legislation does not substantially reduce the overall number of abortions, but greatly increases the proportion performed unsafely.

Since the decision to seek an abortion usually results from an unwanted pregnancy, expanded and improved family planning services should be the highest priority to prevent such pregnancies and decrease recourse to abortion.

In circumstances where abortion is not against the law, health service providers should be trained and equipped to offer a safe and accessible service. Provision of, or referral for, abortion services is an essential part of women's sexual and reproductive healthcare: fulfilment of a woman's right to choice should be a high priority for such programmes. As with all sexual and reproductive health services, the client's right to confidentiality and privacy must be sustained.

1.1 Definition

An "abortion" is the termination of a pregnancy. It can be spontaneous (also called miscarriage) or induced. Abortion can be induced surgically (e.g., by vacuum aspiration, or dilation and curettage) or medically (e.g., using an antiprogestogen and/or prostaglandins), safely or unsafely. The World Health Organization (WHO) defines "unsafe abortion" as "a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking the minimum medical standards, or both".

When trained health care providers with proper equipment, and correct technique and sanitary standards, perform induced abortion in early pregnancy, it is one of the safest medical procedures. Beyond 10 weeks since the last menstrual period (LMP) the health risks, while rare, rise slightly with each week of pregnancy. These risks include: incomplete or failed abortion, haemorrhage, infection, uterine perforation, anaesthesia-related complications, and long-term sequelae which sometimes follow the early complications.

Thus, efforts should be made to inform the public that abortion is safest when performed early, and women who seek abortion should be encouraged to attend as early in the pregnancy as possible, preferably before 12 weeks, and even 7 or 9 weeks (according to local guidelines) if medical abortion is used. Services should ensure there is minimum delay in the provision of abortion. Since the skill of the provider is fundamental to safe abortion, health personnel who offer abortion services must be properly trained. Those who work in services providing only early abortions must know about the facilities to which they can safely refer clients whose pregnancies are of longer duration. The techniques used after 12 weeks need specially trained providers, who can use dilation and evacuation, or mifepristone with repeated doses of prostaglandins such as misoprostol or gemeprost, or intra-amniotic injections of hypertonic solutions, or intra/extra-amniotic prostaglandins.

1.2 General indications

In almost all countries, abortion is legally permitted to save a woman's life. Other reasons, which permit abortions in a large number of countries, are:

- To preserve the physical or mental health of the woman.
- Pregnancy after rape or incest.
- Foetal impairment.
- Economic and social grounds.
- On request.

Where law permits, countries should provide safe and accessible services to women who request an abortion. Health care providers should make every effort to make full use of the law and translate it into practice, by providing services to the full extent the law permits.

1.3 Counselling and information

Many women will have decided firmly, before coming to the health service, that their pregnancy should be terminated. Some, however, will be uncertain whether or not to have an abortion, and be troubled by anxiety or guilt; adolescents, in particular, may lack support from partners or family. Although counselling must never be imposed, every woman contemplating abortion should have access to supportive empathetic

counselling responsive to her personal circumstances and cultural background. Providers, when counselling, should keep in mind:

- The reason for abortion. If coercion is suspected, this possibility should be discussed in private with the woman.
- The different options open to her, and the opportunities for assistance that exist in society. Victims of sexual abuse may need referral for additional care.

Even with counselling some women require extra time to come to a decision. After the woman has made up her mind she should be informed about the details of the procedure and the contraceptive choices:

- What will be done during and after the procedure, and the duration of the procedure.
- If medical, the drug regimen to be used, and the amount of bleeding and pain to be expected.
- If surgical, the procedure to be performed, including the medication for pain management, and the type of anaesthesia.
- The safety of the procedures.
- The immediate and late side-effects, and the possible complications.
- When she will be able to resume her normal activities, including sexual intercourse.
- The follow-up care.
- Contraceptive counselling, before abortion as well as at any follow-up visits. She should be informed that ovulation can return as early as two weeks after the abortion, and unless she uses an effective method of contraception she is at risk of becoming pregnant again. If she is seeking abortion because she thinks that it was a contraceptive failure, the provider should discuss and find out whether the pregnancy was due to incorrect use or method failure and advise her accordingly.
- The possibility of getting sterilized. However, the time of an abortion is not usually an ideal moment for a woman to make a major decision such as whether to be sterilized. Nevertheless, where a woman will have difficulty returning later for the procedure, sterilization by minilaparotomy or laparoscopy can be safely combined with the abortion.
- Encourage clients to ask all their questions and to express any fears.

2 Informed consent, confidentiality and privacy

Women who come for abortion should be treated with respect and understanding. Providers should be supportive to the clients and give them full information in a way that they can understand, so that they can make a choice about having or not having an abortion, free of inducement, coercion or discrimination.

Providers have a duty to protect clients' information against unauthorized disclosures, and to ensure that clients who do authorize release of their confidential information to others do so freely and on the basis of clear information. In some countries the provider cannot release medical information, even at the request of the patient.

Health providers should ensure that facilities provide privacy for conversation between clients and providers, as well as for the actual service.

3 Pre-abortion care

An appropriate clinical record form should be completed for each client to ensure that the essential elements of history and physical and laboratory examinations are collected and recorded.

3.1 History

In addition to the client's personal data, including number of children, the following information should be collected:

- Last normal menstrual period (LMP), to establish the duration of pregnancy (the number of completed days or weeks since the first day of the LMP). The risk associated with induced abortion increases with the duration of pregnancy, and the selection of the method will depend on it.
- Symptoms of early pregnancy (e.g., breast tenderness and engorgement, nausea, fatigue, changes in appetite, and increased frequency of urination) in clients where the LMP cannot be established accurately and the diagnosis of pregnancy has not been established.
- Past and present illnesses and other conditions that may affect provision of abortion (e.g., bleeding disorders).

- Allergies.
- Current medications that could interact with drugs used during the procedure or make the procedure risky (e.g., anticoagulation).

3.2 Physical examination

- General health of the client. It is important to ensure that there are no existing medical conditions that may increase the risk related to an abortion. If there is a serious medical condition, the client should be referred to a specialized facility where the risk can be reduced and complications can be treated properly.
- Bimanual pelvic examination to:
 - Confirm pregnancy. The signs of early (6-8 weeks) pregnancy include softening of the cervical isthmus, and softening and enlargement of the uterus.
 - Confirm that the size of the uterus corresponds to the duration of pregnancy. A smaller than expected uterus could be due to a pregnancy that is less advanced than estimated from date of LMP, an ectopic pregnancy, or a missed abortion. A larger than expected uterus may indicate pregnancy that is more advanced than calculated from the date of LMP, a multiple pregnancy, the presence of fibroids or a molar pregnancy.
 - Determine the position of the uterus; anteverted or retroverted or positioned in a way to affect assessment of the length of pregnancy or complicate a surgical abortion procedure.
 - Detect any signs of reproductive tract infections (RTIs) and sexually transmitted infections (STIs). The presence of any RTI or STI will increase the risk of post-abortion pelvic infection. When infection is clinically present or identified by screening, antibiotics should be started before the abortion is performed.

3.3 Laboratory testing

- Pregnancy test is not required unless the typical signs of pregnancy are not clearly present and the provider is unsure of the woman's pregnancy.
- Haemoglobin/haematocrit if physical examination suggests anaemia, or in areas where this condition is prevalent, to prepare the provider for prompt action should haemorrhage occur.

- Tests for ABO and Rhesus (Rh) blood groups typing when available, in case of complications that might require blood transfusion.
- Ultrasound for detection of ectopic pregnancy beyond 6 weeks. If ectopic pregnancy is suspected, it is essential to confirm diagnosis immediately and initiate treatment or transfer the woman to a facility where the diagnosis can be confirmed and treatment initiated.
- In facilities where Rh-immunoglobulin is routinely provided to Rh-negative women, it should be administered at the time of the abortion procedure. When medical methods are used it should be provided at the time of prostaglandin administration.
- Cervical cytology may be offered to women, especially in settings where there is a high prevalence of cervical cancer and STIs. However, accepting this service must never be a pre-condition for providing the abortion.
- HIV testing can be proposed, as well as other tests related to STIs or specific diseases.

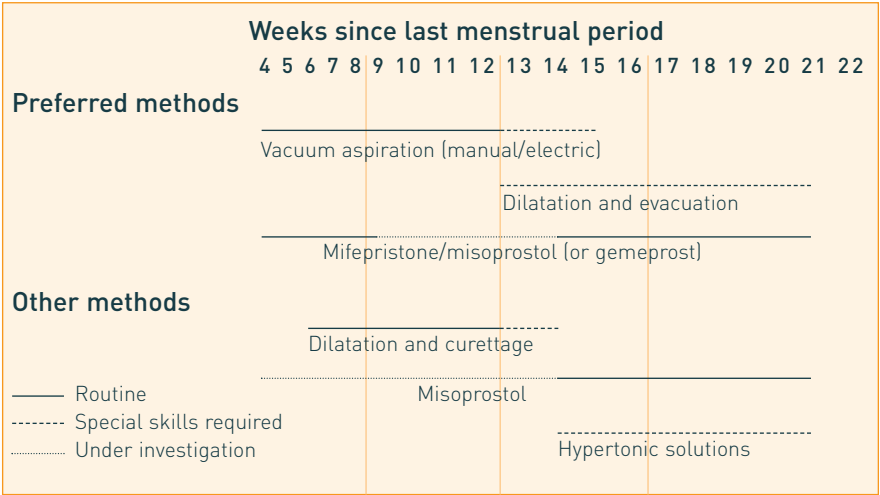
4 Methods of abortion

The method for inducing abortion will depend upon the duration of the pregnancy, the training and skills of the provider, the facilities available and the preference of the woman. In most cases, the gestation can be determined reliably from the date of the LMP and the findings on pelvic examination. Ultrasound investigation is necessary only when there is clinical doubt about the period of gestation or suspicion of ectopic pregnancy. Unless the woman has a serious pre-existing medical condition, or the chosen method requires an inpatient stay, both surgical and medical abortion should be done as outpatient procedures. Figure 12.1 illustrates the appropriate methods in relation to gestation duration.

4.1 Medical methods

The most widely used medical regimens to terminate pregnancy combine treatment with the antiprogesterone mifepristone and with a prostaglandin, such as misoprostol. Medical methods of abortion up to 9 weeks are safe and effective. From 9 to 14 weeks, surgical abortion is at present recommended since the efficacy of medical abortion with current dosage regimens is lower, blood loss is greater, and products of conception are more likely to be retained. Beyond 14 weeks, when the placenta tends to

Figure 12.1 Methods of abortion by weeks of pregnancy



be completely expelled, medical methods of inducing abortion offer a safe and effective alternative to surgical procedures. Fewer than 5% of women undergoing medical abortion will require surgical intervention for continuing pregnancy or incomplete abortion. Services that offer medical abortion must have access to facilities for surgical intervention.

Both early and late medical abortions involve the administration of mifepristone followed, after a variable interval (up to 48 hours), by a prostaglandin. After 14 weeks the prostaglandin usually needs to be given more than once.

An alternative to the prostaglandin/antiprogesterone combination after 14 weeks is the prostaglandin analogue misoprostol alone, although this seems less effective, slower to act, more painful, and more prone to gastrointestinal side-effects. Treatment regimens with misoprostol up to 14 weeks are under investigation because of the wide availability and low cost of this agent. In view of concerns about teratogenicity, women who choose misoprostol to induce abortion should be warned that, if it fails, abortion should be completed surgically.

The combination of methotrexate with a prostaglandin is not recommended since it is less effective than mifepristone/prostaglandin, the procedure is slow, and, again, there is concern about teratogenicity.

Some of the commonly used mifepristone plus prostaglandin regimens recommended by the WHO are shown in Box 12.1.

Side effects of medical methods include:

- Cramping and prolonged menstrual-like bleeding. Bleeding usually lasts for 9 days but can be prolonged for up to 45 days in rare cases.
- Nausea.
- Vomiting.
- Diarrhoea.

Box 12.1—Commonly used mifepristone plus prostaglandin regimens	
Up to 9 completed weeks since LMP	After 12 completed weeks since LMP
200 mg mifepristone followed 36-48 hours by: 1 mg vaginal gemeprost; <i>or</i> 800 µg vaginal misoprostol; <i>or</i> 400 µg oral misoprostol up to 7 completed weeks	200mg mifepristone followed after 36-48 hours by: 1 mg vaginal gemeprost (repeated every 6 hours up to a maximum of 4 doses, and if necessary every 3 hours up to 4 additional doses); <i>or</i> 400 µg misoprostol orally every 3 hours up to 5 doses; <i>or</i> 800 µg vaginal misoprostol <i>followed by</i> 400 µg oral misoprostol every 3 hours up to a maximum of 4 doses

4.2 Surgical methods

Who can perform surgical procedures?

These can be performed by a:

- Gynaecologist.
- Trained physician.
- Trained mid-level provider (only for vacuum aspiration), where legislation allows. Mid-level providers are non-physician clinicians (e.g., midwives, nurse practitioners, physician assistants).

Cervical preparation

Cervical preparation, or priming, is sometimes done before first-trimester surgical abortions to make the procedure easier and to reduce immediate complications. It is done by using osmotic dilators or pharmacological agents. It is recommended for women:

- Nulliparous with pregnancy over 9 completed weeks.
- Younger than 18 years.
- With pregnancy over 12 completed weeks.

Cervical preparation is also beneficial in women:

- With cervical anomalies.
- Who have had previous cervical surgery.
- Who have high risk of cervical injury or uterine perforation which may cause excessive bleeding.

Medication for pain

The pain threshold is variable and depends on age, length of pregnancy, previous vaginal delivery and fearfulness of the woman. Counselling and sympathetic treatment is likely to reduce women's fears and perceptions of pain. Presence of a family member also helps in alleviating her fears. However, medication for pain management should always be offered.

The following drugs can be used either singly or in combination:

- Analgesics to alleviate sensation of pain.
- Tranquillizers to reduce anxiety.
- Anaesthetics to numb physical sensation.

Anaesthesia

A paracervical block with a local anaesthetic such as lidocaine (lignocaine) should be used when mechanical cervical dilation is required to perform a surgical abortion procedure.

- Ensure that there are no known allergies to lidocaine or related drugs.
- Prepare 20 ml of 0.5% lidocaine solution without epinephrine.
- Inject beneath the cervical mucosa at the “four quadrant” positions around the cervix, taking care not to inject into a blood vessel.

The use of general anaesthesia is not recommended for abortion procedures, as it increases the clinical risks. However, some women may want general anaesthesia, and its use may be preferable in difficult procedures. Any facility that offers general anaesthesia must have skilled staff to administer it and to manage complications.

Surgical principles to ensure safety

Staff must be well trained in the techniques they are using, as well as in the early recognition and prompt management of complications.

- Facilities must be approved according to countries’ licensing criteria.
- Infection prevention measures must be strictly followed (see chapter 15: Infection prevention and control).
- All instruments and equipment must be in good working order before the start of the surgical procedure.
- The facility must be well equipped with drugs and equipment to handle life-threatening situations and other emergencies.
- Approved medical and surgical guidelines and procedures must be strictly maintained.

Types of surgical techniques

- Vacuum aspiration.
- Dilatation and curettage.
- Dilatation and evacuation.
- Other methods.

Vacuum aspiration

Vacuum aspiration is a very safe procedure, which involves evacuating the contents of the uterus through a plastic or metal cannula attached to a vacuum source. The vacuum can be generated either by an electric pump or with a hand-held plastic 60-ml syringe. Available aspirators can accommodate different sizes of plastic cannulae, ranging from 4 to at least 12 mm in diameter.

It is the preferred surgical method up to 12 weeks since the LMP, and some skilled practitioners can do it safely at up to 15 weeks. A paracervical block or light sedation, or both, are required.

The cannula may be inserted

- Without cervical dilatation, if performed in early pregnancy (before 6 weeks).
- Cervical dilatation is usually required from 6 to < 9 weeks.

Cervical dilatation can be done with mechanical dilators or with osmotic hydrophilic dilators such as laminaria tents. A prostaglandin (such as misoprostol) and/or mifepristone can also be used to prepare the cervix.

Vacuum aspiration can be performed as an outpatient procedure. Women who have first trimester abortions with local anaesthesia can leave the health facility after observation for about 30 minutes in the recovery room. However, longer periods of observation may be necessary when abortion is performed in later pregnancy or when sedation or general anaesthesia has been used.

Dilatation and curettage (D&C)

Dilatation and curettage (D&C) involves dilating the cervix with mechanical dilators or pharmacological agents and using sharp metal curettes to scrape the walls of the uterus. It is less safe than vacuum aspiration and more painful. It is applicable for abortion up to 12 weeks, although specially skilled providers can do it up to 14 weeks. D&C should be used only where vacuum aspiration or a medical method is not available, since sharp curettage carries higher risks. Health service managers should make every effort to replace sharp curettage with vacuum aspiration.

Dilatation and evacuation

Dilatation and evacuation (D&E) is used from about 12 completed weeks of pregnancy. It requires preparing the cervix with mifepristone, or a prostaglandin such as misoprostol, or laminaria tents or a similar hydrophilic dilator, dilating the cervix and evacuating the uterus using electric vacuum aspiration with 14–16 mm diameter cannulae and forceps. Depending on the duration of pregnancy, adequate dilatation can require from 2 hours to a full day. D&E does require special skills and should be performed only in facilities where providers have skills and experience.

Other methods

The intra-amniotic or extra-amniotic instillation of various solutions is less safe and less effective than D&E and should be discouraged. Abdominal or vaginal hysterotomy is very seldom indicated for late abortion. Hysterectomy should be used only for women with a condition that would warrant the operation independently.

Tissue examination following surgical abortion

After the abortion procedure it is important to examine the products of conception. Examine the products for:

- Ensuring complete evacuation of the intrauterine pregnancy.
- Visual identification of products of conception, especially chorionic villi; their absence will signal an ectopic pregnancy.
- Ensuring that the contents of the aspirate confirm to the estimated length of the pregnancy to rule out incomplete abortion.
- Appearances suggestive of molar pregnancy.

Routine laboratory examination is not essential.

Instruments and supplies for manual vacuum aspiration

Basic supplies

- Intravenous infusion set and fluids (sodium lactate, glucose, saline).
- Syringes (5, 10, 20 ml).

- Needles (22 gauge spinal for paracervical block; 21 gauge for drug administration).
- Sterile gloves (small, medium, large).
- Cotton swabs or gauge sponges.
- Water-based antiseptic solution (not alcohol-based).
- Detergent or soap.
- Clean water.
- Chlorine or glutaraldehyde for disinfection/decontamination.
- High-level disinfection or sterilization agent.

Instruments and equipment

- Vaginal speculum.
- Tenaculum.
- Sponge (ring) forceps or uterine packing forceps.
- Pratt or Dennison dilators: sizes 13 to 27 French.
- Container for antiseptic solution.
- Strainer (metal, glass, or gauze).
- Clear glass dish for tissue inspection.

Medications

- Analgesia medication (e.g., paracetamol [acetaminophen], ibuprofen, or pethidine).
- Anxiolytic medication (e.g., diazepam).
- Anaesthetic – chloroprocaine (1-2%) or lidocaine (0.5-2%) without epinephrine.
- Oxytocin 10 units or ergometrine 0.2 mg.

Vacuum aspirator instruments

- Vacuum aspirator.
- Flexible cannulae of different sizes.
- Adapters, if needed.
- Silicone for lubricating syringes, if needed.

5 Follow-up

5.1 Monitoring during recovery period

- Take vital signs while the patient is still on the treatment table.
- Allow the patient to rest comfortably where her recovery can be monitored.

After a surgical procedure

- Record pain as it may be due to uterine perforation or acute haematometry (blood filling the uterus).
- Size of uterus, particularly with late abortions: confirm the size through the abdominal wall, bimanually.

Most women can leave the facility as soon as they feel able to and their vital signs are normal. The drugs used for pain and anxiety management can cause dizziness: the woman should be accompanied or be very careful (falls in stairs and traffic accidents have been described).

After a medical procedure

- Keep the woman under clinical observation for 4-6 hours after taking a prostaglandin.
- Inspect all sanitary pads and bedpans used during the period of observation to confirm an abortion during this period.
- When abortion is done after 12 completed weeks of pregnancy, keep the woman under observation until both fetus and placenta have been expelled.

5.2 Instructions for care after abortion

Before the patient is discharged give her simple and clear oral and written instructions. Inform her:

- That a normal menstrual period should begin within 4-8 weeks.
- That she should not have intercourse or put anything into the vagina until a few days after bleeding stops (no sex, no douching, no tampons).
- That some uterine cramping over next few days may occur, which can be relieved by analgesics.

- That light menstrual bleeding or spotting may continue for several weeks if surgical abortion is done.
- Nausea, sometimes accompanied by vomiting, usually subsides within 24 hours after surgical methods.
- How to use any prescribed medications.
- What problems to look for and what to do about each of them (e.g., pain, bleeding).
- Where to go and whom to contact in case of emergency or for any other problem.
- When and where to return for follow-up.
- Her fertility will return soon after the procedure. Provide contraceptive counselling, and help her choose a method, if desired.

5.3 Signs and symptoms requiring urgent attention

- Prolonged bleeding (more than two weeks).
- Bleeding more than normal menstrual bleeding.
- Severe or increased pain; pelvic pain.
- Fever lasting more than one day; chills.

5.4 Management of abortion complications

All health delivery sites where abortion is performed should be adequately equipped and have trained personnel to recognize complications of abortion and to provide prompt treatment. If facilities are not available an efficient referral system should be in place.

Incomplete abortion

Incomplete abortion is more common with medical methods. It should be suspected if visual examination of the tissue aspirated during surgical procedure does not confirm to estimated duration of the pregnancy. Signs and symptoms include:

- Vaginal bleeding.
- Abdominal pain.
- Signs of infection.

Staff must be trained to re-evacuation of the uterus.

Failed abortion

Continuation of pregnancy as a result of failed abortion can occur with both surgical and medical methods. This will require a vacuum aspiration or D&E for second trimester pregnancies.

Haemorrhage

Haemorrhage can result from:

- Retained products of conception.
- Trauma to the cervix.
- Uterine perforation.

Provide appropriate treatment after the cause has been assessed.

Infection

Post-abortion infection is rare if abortion is performed properly under asepsis.

Symptoms include:

- Fever or chills.
- Foul-smelling vaginal or cervical discharge.
- Abdominal or pelvic pain.
- Prolonged vaginal bleeding or spotting.
- Uterine tenderness.
- Raised white blood cell count.

Provide antibiotics. If there is a likelihood of retained products of conception the uterus should be re-evacuated. Women with severe infection may need hospitalization.

Uterine perforation

Uterine perforation usually goes undetected and resolves without any need for intervention. However, when suspected the patient should be given antibiotics and observed.

Anaesthesia-related complications

Staff should be skilled in management of complications where general anaesthesia is used. Narcotic reversal agents should always be available.

Long-term sequelae

There is no evidence that having an uncomplicated abortion has any bearing on future fertility or causes adverse outcomes in subsequent pregnancies. The preponderance of evidence does not suggest an increased risk of breast cancer after induced abortion. Adverse psychological sequelae may occur in a small number of women and may be the continuation of pre-existing conditions. They seem to be more frequent when the woman cannot or does not want to discuss her experience with another person.

6 Contraceptive and STI counselling

Women should be given information and counselling on post-abortion contraception before they leave the health facility, and a method started, if desired.

- All methods of contraception including intrauterine device (IUD) and hormonal methods can be used as long as the woman fulfils eligibility criteria for the method.
- After second trimester abortion, diaphragm and cervical cap should not be used until about 6 weeks. IUDs should not be inserted immediately after second trimester abortion, due to high risk of expulsion.
- Fertility awareness-based methods should only be started three cycles after an abortion. Meanwhile, another method should be used, if desired.
- When sterilization is requested it should be ensured that the choice is not influenced by the crisis nature of the moment, to avoid later regret.

Providers should discuss with all women prevention of STIs, including HIV, and the importance of condom use regardless of the contraceptive method chosen. Voluntary testing for HIV and counselling for prevention of HIV/AIDS should be discussed, especially in women who are at a high risk or living in areas of known high risk.

Contraceptive methods should be available at the health site. If the method chosen by the woman is not available, she should be told where she can get it. In the meantime she should be given an interim method. All women should be informed about emergency contraception and consideration should be given to providing it in particular to women who choose not to start using a regular contraceptive method immediately.

Photo: Maryse Hodgson/Haiti PDB clinic



13 REPRODUCTIVE TRACT INFECTIONS AND SEXUALLY TRANSMITTED INFECTIONS

REPRODUCTIVE TRACT INFECTIONS AND SEXUALLY TRANSMITTED INFECTIONS

1 Introduction

Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are an important public health concern worldwide. On average over **1 million people** are infected every day with an STI. The high incidence of RTIs/STIs among women attending antenatal, sexual and reproductive health or gynaecological clinics indicates the extent of the RTI/STI problem.

People who have an RTI/STI are at increased risk of becoming infected with HIV or transmitting HIV to their partner(s). In people with HIV infection, any other RTI/STI may be more difficult to treat, meaning that the concurrent RTI/STI may last longer, thereby increasing the likelihood of HIV transmission.

1.1 Definition

The term RTI/STI includes 4 types of infection:

- Infections which affect the reproductive tract.
- Infections of the female reproductive tract which are not transmitted sexually, but are the result of an overgrowth of organisms normally present in the vagina (e.g., bacterial vaginosis and yeast infections).
- Infections which are transmitted sexually to areas beyond the reproductive tract, such as syphilis and HIV infection.
- Infections of the female reproductive tract due to complications of reproductive events or procedures performed on the reproductive tract (e.g., childbirth, miscarriage or abortion, insertion of an IUD and gynaecological or obstetric surgery).

The focus of this chapter is on the prevention of the first 3 types of RTIs/STIs and the management of the first 2 types of RTIs/STIs.

The prevention and management of the fourth type of infection are either beyond the scope of sexual and reproductive health (SRH)/family planning services or are included in other chapters of these guidelines (e.g., chapter 6 on IUDs and chapter 15 on infection prevention and control).

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) are discussed in chapter 14.

1.2 The role of sexual and reproductive health/familyplanning services

Many people, particularly women, who have an RTI/STI do not receive proper care and treatment for the following reasons:

- Both men and women may be asymptomatic. Studies have shown that as many as 70% of infected women and 30% of infected men do not have symptoms.
- Individuals may have symptoms, but they do not identify them as an infection. Many women lack information about normal vaginal discharge. Some women may have had an infection for so long that they have come to think their symptoms are normal.
- Many people suspect they may have an RTI/STI, but do not seek care because:
 - They do not recognize the seriousness of the RTI/STI.
 - They are too embarrassed to attend a clinic.
 - STIs carry a social stigma.
 - They have no access to treatment.
 - They cannot afford treatment.

The consequences of untreated RTIs/STIs can be devastating to the health of men, women and their children. These conditions can lead to infertility, chronic ill health, sexual dysfunction, disseminated disease and death. In women they can also lead to chronic pelvic pain and pregnancy complications such as ectopic pregnancy.

Any untreated STI in a pregnant woman can affect the unborn or newly born child. Problems include low birthweight, premature delivery and neonatal infection. Both gonococcal and chlamydial infection can be transmitted directly into the neonate's eye and cause blindness.

SRH/family planning clinics are in a key position to provide RTI/STI services because:

- They are often the only place where women receive health care.
- They often have the confidence of clients, particularly women, for discussing problems related to sexual and reproductive health.
- They can provide screening services for women attending for SRH/family planning but who may have an RTI/STI.

- Clinic waiting rooms offer an opportunity for education on the prevention of STIs.
- It costs less to add RTI/STI services to an existing clinic than to set up a new STI clinic.

The RTI/STI services which SRH/family planning clinics may offer depend on the available resources. Services may include all or some of the following:

- Education about STI prevention and the recognition of the signs and symptoms of RTIs/STIs.
- RTI/STI counselling.
- Screening for RTIs/STIs, including vaginal examinations (either routinely or with particular emphasis for those at high risk).
- RTI/STI management, including treatment.
- Referral to a facility better equipped to manage RTIs/STIs.

2 Prevention

Prevention is the most important strategy for the control of STIs, including HIV infection (see chapter 14). This is mainly done through education. The spread of STIs is influenced by several factors, including sexual behaviour and attitudes, and the availability of facilities for early diagnosis and treatment. It is important that these factors be borne in mind so that effective programmes aimed at preventing the spread of STIs can be designed and implemented. SRH/family planning programmes are well placed to disseminate information on the risks and complications of STIs and to promote low-risk behaviour. They can also encourage the use of condoms, not only for the prevention of pregnancy but also for the prevention of STIs.

People need education on the symptoms and signs of STIs and confidence to seek early treatment when required. Education on the prevention of STIs can be included in the educational activities of SRH/family planning programmes inside and outside clinics. Community-based workers can play an important role in this regard.

Box 13.1—Contraceptive methods and protection against STIs

Latex condom	The best method for protection against STIs, including HIV infection, when used correctly and consistently. Condoms do not protect against infection from lesions in the groin that are not covered.
Female condom	Although clinical data are limited, laboratory studies have shown that the female condom is an effective barrier not only to sperm but also to bacteria and viruses including HIV. The female condom is an alternative for women who want protection when it is not possible to use a male condom. The use of female condoms is limited by cost factors.
Spermicides	Do not protect against STIs including HIV; therefore the use of spermicides alone (i.e., without additional barrier protection) should not be recommended. In addition, spermicides containing nonoxynol-9 may even increase the risk of HIV infection in women using these products frequently.
Diaphragm	Used with spermicides, this method reduces the transmission of some STIs. Protection against HIV has not been demonstrated. The diaphragm may be an alternative if condom use is not possible.
Other methods	All other methods do not protect against STIs, including HIV. Women at risk of STIs need to use condoms in addition to these methods.

There is no evidence that contraceptives *per se* increase the incidence of STIs; rather, increased incidence is more likely to be due to changes in sexual behaviour. What is evident is that condoms provide protection against STIs (see Box 13.1). People who have chosen family planning methods that do not offer STI protection should use the condom as well whenever there is a risk of STI transmission.

3 Management of RTIs/STIs

There are 4 levels of management for RTIs/STIs:

- Syndromic management.
- Syndromic plus clinical management.
- Syndromic plus clinical management and limited laboratory tests.
- Clinical management plus laboratory tests (aetiological diagnosis).

The level of management used in a service site depends on the knowledge and skills of service providers and on the availability of laboratory facilities.

3.1 Syndromic management

The syndromic approach bases treatment on groups of symptoms (client complaints) and signs (client and provider observations) which can be explained by more than one possible infection. These groups are called syndromes. This approach requires that providers of health care know the most common causative organisms for each syndrome and the appropriate anti-microbial treatment.

One example of syndromic management applies to painless genital ulcers that can be caused by either chancroid or syphilis. Service providers using syndromic management in areas where both chancroid and syphilis are prevalent treat patients for both causative organisms.

Syndromic management enables providers of health care to offer treatment when service sites lack laboratory facilities or skills that would allow the specific causative organism to be identified. Providers of primary health care can start treatment immediately, instead of referring the client to a more complex service facility which may not be easily accessible.

In syndromic management, flow charts and accompanying guidance (set out in this chapter) give health-care providers step-by-step instructions about how to manage and treat RTIs/STIs.

The most relevant RTI/STI syndromes are:

- Urethral discharge.
- Genital ulcer.

- Vaginal discharge.
- Lower abdominal pain.

STI risk assessment

STI risk assessment is particularly important for the syndromic management of vaginal discharge.

To assess if a woman is at risk of STI, ask the following:

- Does her sexual partner currently have symptoms or has he had them in the last 3 months (e.g., urethral discharge, pain on passing urine, or open sores anywhere in the genital area)?
- Is there any possibility that her partner has recently had sexual intercourse with someone else?
- Has she had sexual intercourse with more than 1 partner in the last 4 weeks?
- Has she recently started a new sexual relationship?

If the answer to any of these questions is yes, or if the woman is obviously uncertain, then she should be considered to be at risk of having a STI.

An alternative approach to asking the questions directly is to list them orally during group education or during counselling to the individual client and/or to present them on a handout or flip chart. Then ask each client privately if, based on that information, she feels that she may be at risk. If the client indicates with certainty that she is or is not at risk, do not question her further. If she has indicated that she is at risk or remains in doubt, consider her to be at risk of having a STI.

Selection of anti-microbial drugs

The selection of anti-microbial drugs for treatment of each RTI/STI syndrome can be guided by the following parameters:

- Prefer drugs that treat more than 1 pathogen.
- Prefer single-dose therapies.
- Consider the cost of different drugs.
- Use drugs with a long shelf-life and storage requirements which the programme can manage.

- Use drugs recommended by the national RTI/STI programme.
- Avoid using drugs for which resistance has been established.

The selected drugs should reflect a balance of the above criteria. In some circumstances, for example, the best choices may not necessarily be the cheapest drugs. It is important to remember:

- Always provide a complete course of treatment. A partial course of drugs may not cure the client's RTI/STI and may lead to drug resistance.
- If the clinic is unable to provide the drugs, give the client a prescription to obtain them.

The following pages provide the flow charts and accompanying guidance for the syndromic management of the most relevant RTIs/STIs.

Box 13.2—Syndromic treatment of urethral discharge

Examine male patients complaining of discharge and/or pain during urination for evidence of discharge. If none is seen, massage the urethra gently from the base of the penis towards the opening of the urethra and see if any discharge is produced. Then proceed following the instructions in the flow-chart (see Figure 13.1).

Presumptive diagnosis: gonorrhea and chlamydia

Suggested treatment:

Use any of the single-dose therapies recommended **for gonorrhea**, basing selection on known local effectiveness and price (see Table 13.1).

Plus: Doxycycline, 100 mg by mouth 2 times daily for 7 days;

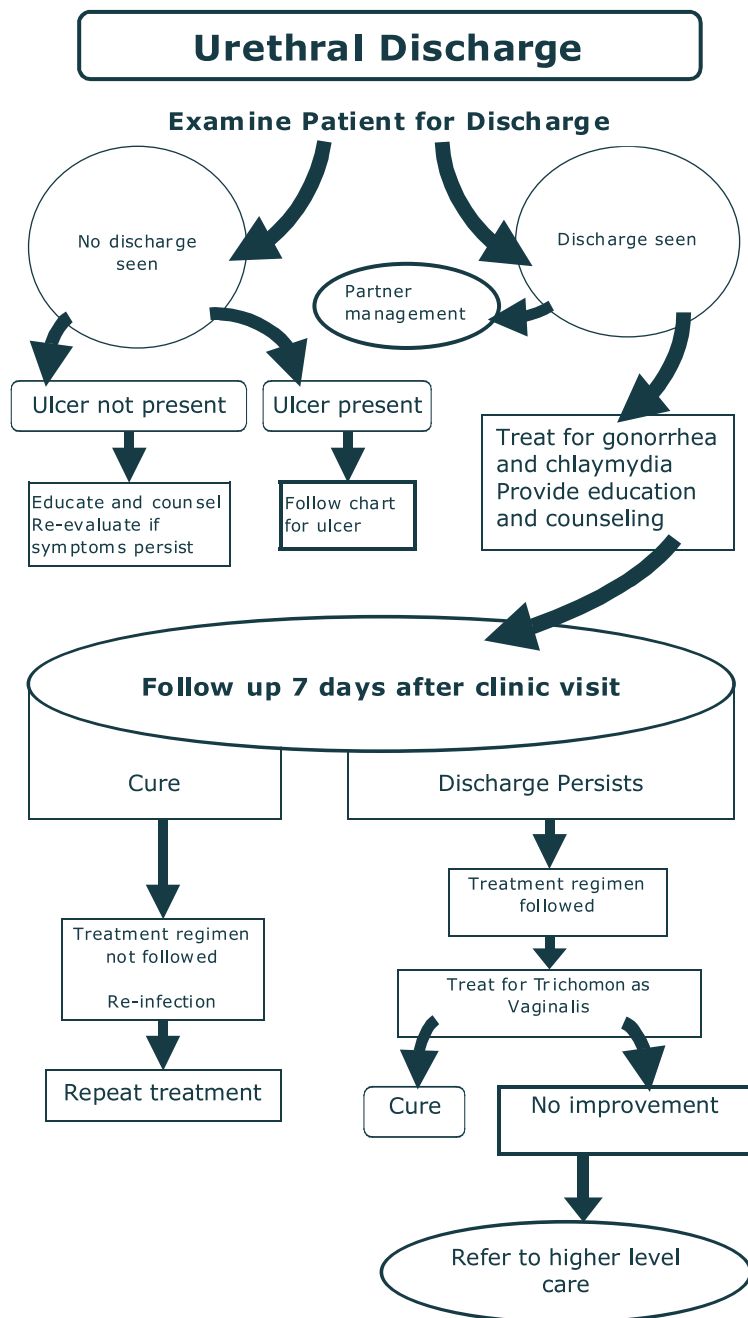
Or azithromycin, 1g by mouth single dose;

Or tetracycline, 500 mg by mouth 4 times daily for 7 days **for chlamydia**.

Note: Doxycycline and other tetracyclines are contraindicated in pregnancy and lactation. A single dose of azithromycin is cheaper than tetracycline

Stress the importance of completing the full course of treatment, notifying the partner(s) and not having intercourse until both the patient and partner(s) have completed the treatment and any symptoms have disappeared.

Figure 13.1 Urethral Discharge



Box 13.3—Syndromic treatment of genital ulcer

Record any symptoms and examine the patient to confirm the presence of genital ulceration.

Presumptive diagnosis: chancroid or syphilis

Suggested treatment:

Benzathine penicillin G **for syphilis**, 2.4 million IU in 2 intramuscular injections during 1 clinic visit; give 1 injection into each buttock.

Plus: Ciprofloxacin, 500 mg by mouth 2 times daily for three days;

Or azithromycin, 1 g by mouth as a single dose;

Or erythromycin, 500 mg by mouth 4 times daily for 7 days **for chancroid**.

Note: Ciprofloxacin is contraindicated in pregnant and lactating women.

If the client is allergic to penicillin, give **for syphilis**: *Either* tetracycline, 500 mg by mouth 4 times daily for 15 days;

Or doxycycline, 100 mg by mouth 4 times daily for 15 days.

If the client is allergic to penicillin and pregnant, give **for syphilis and chancroid**: erythromycin, 500 mg by mouth 4 times daily for 15 days.

Note: These suggested treatments for syphilis apply only to early syphilis; later cases require special evaluation and other treatment is required.

Stress the importance of completing the full course of treatment, notifying the partner(s) and not having intercourse until the patient and partner(s) have completed the treatment and any symptoms have disappeared.

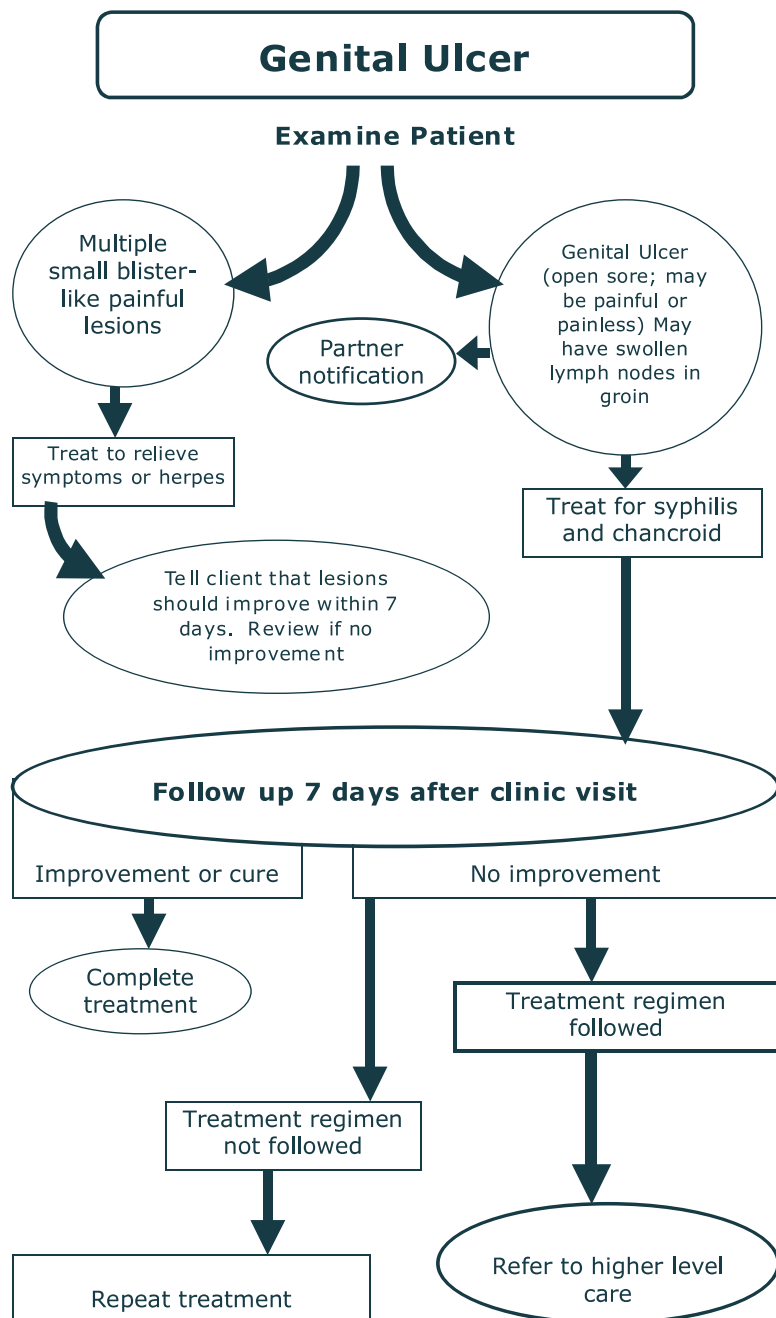
Presumptive diagnosis: genital herpes

Suggested treatment:

There is no cure for genital herpes but symptoms should be treated as follows: Advise clients to wash genital area regularly with soap and water. Prescribe paracetamol (acetaminophen), aspirin or similar pain-relief medication.

If available you may provide acyclovir treatment as indicated in Table 13.5.

Figure 13.2 Genital Ulcer



Box 13.4—Syndromic treatment of vaginal discharge

Perform STI risk assessment and proceed accordingly, as indicated in Figure 13.3. The guidelines below assume that a speculum examination will be done. Performing a speculum examination should be part of the training of health-care providers where RTI/STI management is offered to women.

1. Suggested treatment for candidiasis:

Clotrimazole, 500 mg tablet inserted in the vagina once;

Or clotrimazole, 2x100 mg tablets inserted in the vagina once daily for 3 days;

Or miconazole, 200 mg suppository inserted in the vagina once daily for 3 days.

2. Suggested treatment for trichomoniasis and bacterial vaginosis:

Metronidazole, 2 g by mouth as a single dose for **trichomoniasis**, and

metronidazole, 400-500 mg by mouth 2 times daily for 7 days for **bacterial vaginosis**.

Note: Do not prescribe during first three months of pregnancy; delay treatment until the fourth month. Caution the client to avoid alcohol while taking metronidazole.

3. Suggested treatment for gonorrhoea and chlamydia:

Use any of the single-dose therapies recommended for gonorrhoea, basing selection on known effectiveness and price (see Table 13.1).

Plus: Doxycycline, 100 mg 2 times daily for 7 days;

Or azithromycin, 1 g by mouth as a single dose;

Or tetracycline, 500 mg by mouth 4 times daily for 7 days **for chlamydia**.

Note: Do not use doxycycline and other tetracyclines during pregnancy and lactation.

4. Suggested treatment for candidiasis, gonorrhoea and chlamydia:

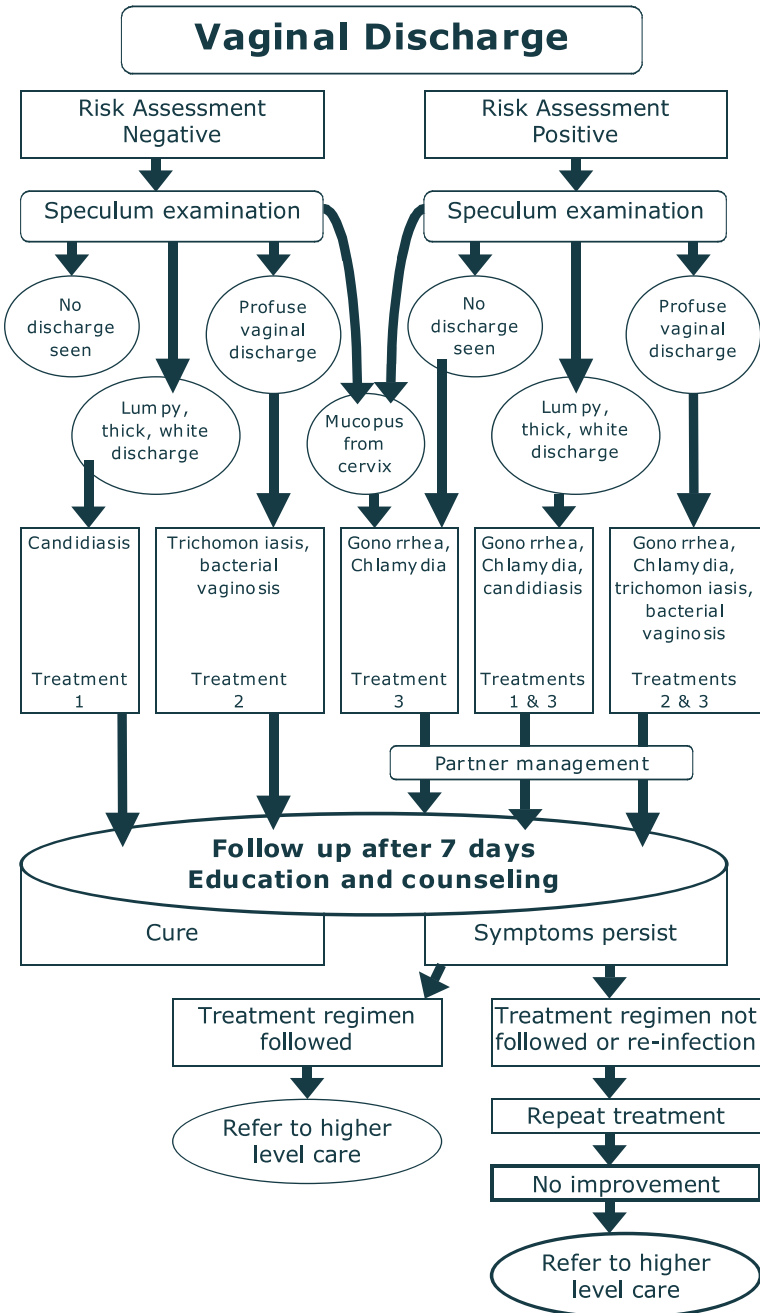
Use treatments 1 plus 3 above.

5. Suggested treatment for trichomoniasis, bacterial vaginosis, gonorrhoea and chlamydia:

Use treatments 2 plus 3 above.

Stress the importance of completing the full course of treatment, notifying the partner(s) and not having intercourse until the patient and partner(s) have completed the treatment and any symptoms have disappeared.

Figure 13.3 Vaginal Discharge



Box 13.5—Syndromic treatment of lower abdominal pain

Ideally, all cases of abdominal pain should be managed in a facility where the necessary investigations can be done without delay. However, it is sometimes not easy or practical to refer all cases of abdominal pain to a higher level of care. In this situation, the syndromic approach could be a reasonable practice (see Figure 13.4).

As a general rule, use the syndromic management of abdominal pain if the client is well enough to take food and liquids, walk unassisted, take her medication and return for follow-up. Otherwise refer her to a higher level of care.

Presumptive diagnosis: pelvic inflammatory disease

Suggested treatment:

Use any of the single-dose therapies recommended for uncomplicated gonorrhea (see Table 13.1), basing selection on known local effectiveness and price;

Or ceftriaxone, 250mg single dose intramuscular injection.

If single-dose therapy for gonorrhoea is not available give trimethoprim 80mg/ sulfamethoxazole 400mg (co-trimoxazole), 10 tablets orally once daily for 3 days and then 2 tablets orally twice daily for 10 days.

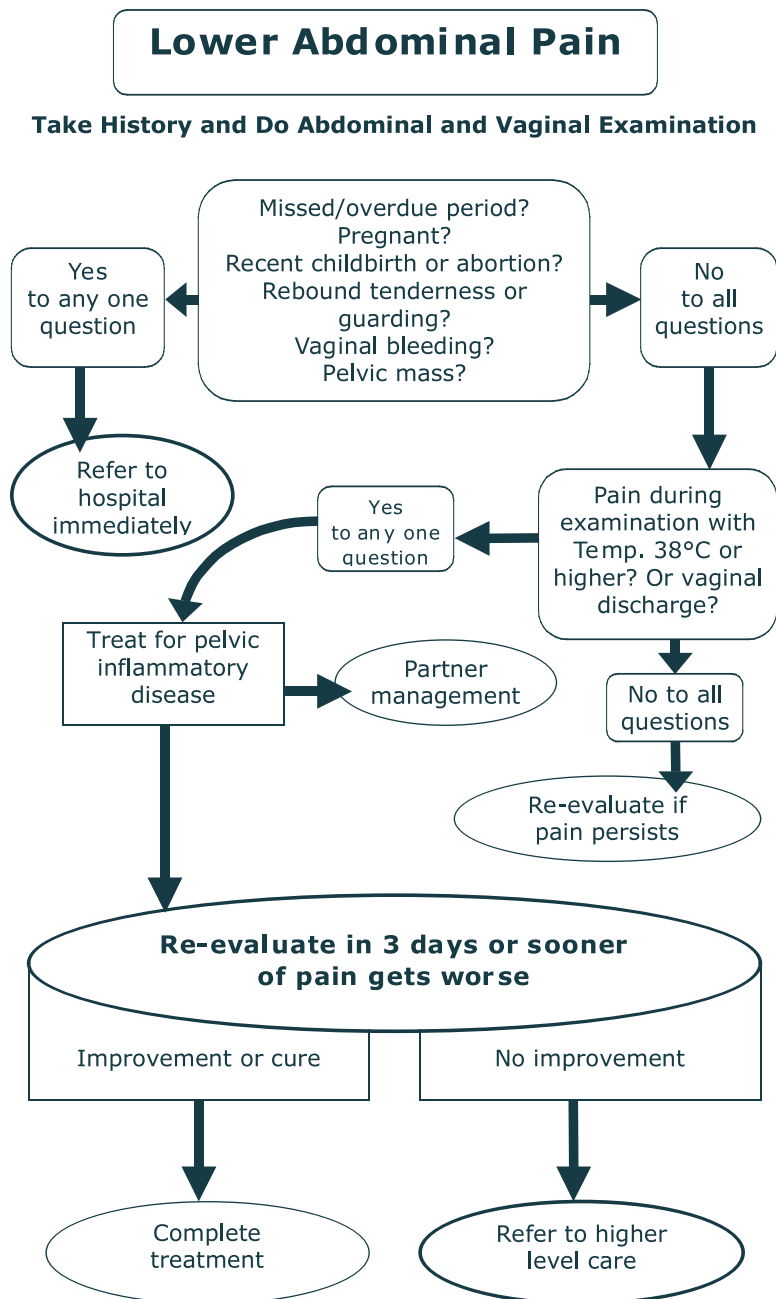
Plus: doxycycline, 100 mg by mouth 2 times daily for 14 days;

Or tetracycline, 500mg 4 times daily for 14 days;

Plus: metronidazole, 400-500 mg by mouth 2 times daily for 14 days.

Stress the importance of completing the full course of treatment, notifying the partner(s) and not having intercourse until the patient and partner(s) have completed the treatment and any symptoms have disappeared.

Figure 13.4 Lower Abdominal Pain



3.2 Syndromic plus clinical management

In addition to using syndromic management, providers can rely on clinical judgment to exclude certain causative organisms from the syndrome. This may reduce the number of drugs required for treatment. See Tables 13.1-13.8, which describe clinical features, diagnosis and treatment of infections included in the syndromes.

Service providers who are experienced in the management of RTIs/STIs may be able to eliminate certain pathogens as possible causative agents. However, when the symptoms and signs are not typical enough for clinical judgment, it is better to provide treatment based on the syndromic approach alone. For example, when a clinician is uncertain about the underlying diagnosis for a genital ulcer, it is preferable to treat for both chancroid and syphilis rather than for only one of them.

3.3 Syndromic plus clinical management and limited laboratory tests

Where limited laboratory facilities are available, some tests may be used in addition to the syndromic approach and clinical judgment to exclude certain causative organisms (see Tables 13.1-13.8). This process may further reduce the number of drugs required for treatment. In some cases, a specific diagnosis may be possible (e.g., when using serological tests for syphilis and microscopy for gonococcus).

For any laboratory facility, even a limited one, to be cost-effective, staff performing laboratory tests must be competent. **Unless staff are well trained, laboratory tests can be misleading, and the resulting management of the client's condition may be less effective than using syndromic management alone or syndromic management backed with clinical judgment.**

When deciding whether to have limited laboratory facilities, programme managers need to consider:

- Whether there is sufficient demand for this service.
- The cost of initial and ongoing staff training.
- The investment in equipment and physical facilities.

If demand is not sufficient the financial investment may not be justified, and staff may lack the practice needed to develop and to maintain skills.

When laboratory facilities are not available, the clinic should consider the value of doing serological tests for identifying symptomless syphilis in women. In this case, the clinic can take specimens and send them to outside laboratories. It is essential that all specimens are taken, labelled and stored correctly, and transported following recommended guidelines.

3.4 Clinical management plus laboratory tests (aetiological diagnosis)

When comprehensive laboratory facilities are available, it may be possible to identify the specific causative organism and provide specific treatment for an RTI/STI. Sensitivity tests can also be done to guide treatment (see Tables 13.1-13.8).

Some laboratory results may be available immediately, making it possible to start specific treatment without delay. However, some tests require several days before the results are available; in these situations:

- If the symptoms are mild, you may choose to wait until the results are available before providing treatment.
- If the symptoms are moderate to severe, you may decide to start treatment based on the syndromic approach and clinical management. At follow-up, when results are available, review the treatment and modify it if necessary.

Any clinic considering having comprehensive laboratory facilities needs to address the following:

- The cost of laboratory diagnosis needs to be weighed against the cost of providing treatment for more than one possible causative organism, as is often required when using syndromic management. When health-care resources are limited, programme managers should consider using existing clinics with comprehensive laboratory facilities primarily as referral centres for special cases.
- In addition to the cost factor, the convenience of the client should be taken into account. The number of visits required for treatment should be kept to a minimum. Having to return to a service delivery site for the results of laboratory tests before receiving treatment may be frustrating or inconvenient for some clients. Some clients may not make those visits, and so remain untreated.

4 Counselling and information

Clients usually find it very difficult to talk about RTIs/STIs and their sexual activity, especially if the provider is hesitant or embarrassed. Providers of health care must have the necessary communication skills and attitudes to feel comfortable when asking clients about sexual activity. In addition, the following guidelines are specific to RTI/STI counselling:

- Behave in a way that is sensitive to the client's feelings, and avoid being judgmental.
- Reassure clients about confidentiality; otherwise, they may withhold information because they fear what they say will be revealed to others.
- Explain to clients why you are asking 'personal' questions.
- Allow sufficient time for the consultation, especially if the client is embarrassed.

Counsel clients who have an RTI/STI on the importance of future prevention (see section 2). It is also necessary to discuss the need of treating the sexual partner(s); (see section 5). Since this is a delicate matter and most clients will find it difficult talking about the problem with their partner(s), this topic should be discussed thoroughly; make clients aware that not all RTIs are transmitted sexually, but that treatment of the partner is essential in order to avoid being re-infected.

4.1 Instructions to clients

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

- To take all medication as instructed, even if symptoms disappear.
- Not to have sexual intercourse until the treatment has been completed and symptoms have disappeared.
- Not to have sexual intercourse until the partner is treated; if that is not possible, the client should use condoms.
- To return to the clinic to ensure that the condition is fully cured.

If possible, give to the client the relevant information and instructions in writing.

Encourage the client to ask questions to clarify any uncertainties and request her/him to repeat the basic instructions to check for understanding.

5 Partner management

The purpose of notifying the client's sexual partner(s) is to treat people who are very likely to have RTIs/STIs and to prevent the client from becoming re-infected. Managing these sexual partners may be difficult for several reasons:

- The concept of notification may be very threatening to the client. It is essential to respect the client's wishes and to maintain her/his trust. Providers of health care need to recognize that many clients are so scared of notifying their partner(s) that they will provide information only if the clinic has earned a reputation for maintaining confidentiality.
- Many clients, especially women, find it very difficult to discuss the problem with their partner.
- Some partners do not believe that they have a disease, especially if they have no symptoms, so they refuse to come for treatment.
- Some clients may not know the names and addresses of their partners, or they may give (or have been given) false names and addresses.
- Some addresses may be hard to locate.

Depending on the characteristics of the client and the circumstances of the case, providers should choose one of the following approaches:

- *Client-led system of notification and referral:*
 - Some clients may have the confidence to talk to their partner(s) directly and refer them for RTI/STI management.
 - Ask clients to bring or send in their partner(s) to the clinic. If possible, give them referral slips to hand to their sexual partner(s).
 - Recommend an alternative clinic if that is more convenient for the partner.
- *Client-led system of treatment:* Some clients know their partner will not attend for RTI/STI management, but they are willing to take treatment to their partner. Give the client information and sufficient drugs or prescriptions for their sexual partner or partner(s).

- *Provider-led system of notification:* Some clients may prefer that the clinic contact their sexual partner(s). Ask for the name(s) and address(es) of the partner(s), and try to contact them by telephone, mail or visiting them at home.
- *Combined approaches:* In many cases, more than 1 approach may be required. For instance, if a client offers to notify the sexual partner(s) you may wait for a reasonable amount of time (about a week), then try another approach if the partner has not appeared for treatment.

When a partner comes to the clinic, treat him/her for the same RTIs/STIs that the initial patient had. If the clinic has access to laboratory facilities, treat for the initial infection and also take samples to test for other RTIs/STIs.

Provider-led notification can bring up to 3 times as many partners for treatment as patient-led notification and referral, but it is more costly and most clinics do not have enough staff to make visits. It may, however, be justified for serious RTIs/STIs (e.g., syphilis or HIV infection), or for individuals who have been named as partners by many RTI/STI patients (sometimes referred to as *core transmitters*).

6 Follow-up care

When clients return for follow-up, ask the following:

- Do they have any symptoms of an RTI/STI?
- Have they completed their course of treatment?
- Have their partner(s) been treated?

Counsel clients about prevention of RTIs/STIs in the future.

6.1 Treatment failure

RTI/STI management and treatment may fail for the following reasons:

- The client may have failed to take the full course of medication.
- The client may have been re-infected because the partner was not treated.
- The causative organism is resistant to the treatment regimen.

- The treatment was not appropriate. Syndromic management does not address all causative organisms, as in the case of uncommon infections (e.g., lymphogranuloma venereum and donovanosis that cause ulceration).

If clients have not followed the course of treatment, provide further treatment and counselling.

If the client has been re-infected by the partner, provide further treatment and re-emphasize the importance of treating the partner. Offer the client any possible assistance for treating the partner.

7 Service management

Programme managers have to decide the level of contribution of the SRH/family planning programme to the prevention and treatment of RTIs/STIs. This depends to a large extent on the availability of financial and human resources.

As a minimum, education for prevention and referral to adequate services should always be provided. However, the syndromic approach widens the possibility that any SRH/family planning service delivery facility can provide services for the management and treatment of RTIs/STIs.

The success of activities for the prevention and management of RTIs/STIs requires careful planning and efficient management. The following aspects should be properly addressed:

- Administration.
- Training.
- Services guidelines.
- Referral system.
- Monitoring and supervision.

7.1 Administration

Managers should ensure that the programme has the necessary resources to properly meet its commitment to the prevention and treatment of RTIs/STIs.

Staff

Determine whether the existing staffing is sufficient to undertake the various tasks related to the prevention and treatment of RTIs/STIs. Activities include education, counselling, clinical management of cases, follow-up, contacts tracing and laboratory tests (the last are not necessary in clinics that use the syndromic approach).

Physical facilities

Make an assessment of the physical facilities to ensure that the available space is sufficient to accommodate any additional staff, equipment and clients. In some cases it may be necessary to reorganize the allocation of space. It is important to remember that the prevention and treatment of RTIs/STIs require the availability of adequate space for education activities and private areas for counselling, which should already exist in properly organized SRH/family planning clinics.

It may be convenient to provide RTI/STI services at the same time as services for family planning or other components of sexual and reproductive health, so that people consulting for RTIs/STIs can do so with confidence that the purpose of their consultation will not be identified by third parties.

It may be necessary to allocate special working hours to meet the needs of certain groups such as adolescents and men. Adolescents of both sexes may feel inhibited to request RTI/STI counselling and/or services from an SRH/family planning clinic which normally provides services to adult clients. Male sexual contacts of women with an STI will be more likely to visit the clinic if they could do so at special hours when they do not have to mix with female clients.

Equipment

The equipment required for the management of RTIs/STIs, except for laboratory facilities, are normally available in SRH/family planning clinics (basically specula, gloves and syringes and needles). Programme managers must ensure that they are available in sufficient quantities to meet the needs of the programme.

Educational materials

As for SRH/family planning education, managers must ensure that educational materials such as posters, flipcharts, leaflets and videos are available for education in the prevention of RTIs/STIs. Written material for

individuals who have an RTI/STI is also needed to emphasize the importance of completing treatment, referring their partner(s) to the clinic, how to protect themselves against re-infection and what to do if symptoms persist. These materials should be in a language people can easily understand, and as much as possible consistent with their cultural background.

Supplies

Programme managers must ensure that antibiotics and other drugs required for the treatment of RTIs/STIs are available at all service delivery sites at which such treatment is provided. It requires an efficient system for forecasting the needs of the programme and deciding the type of antibiotics which are to be made available (see section 3.1: Selection of anti-microbial drugs).

The supply system would run more efficiently if only a small range of the most suitable antibiotics is made available in the programme, as opposed to a wide variety. This will simplify the procedures for forecasting the amounts needed, distribution and storage of supplies. Also, service providers will become more familiar with the prescription regimens. If a particular treatment regimen does not cure the RTI/STI, service providers can refer a client to another site which provides more comprehensive services or can give the client a prescription for buying antibiotics not available at the service delivery site.

7.2 Training

Pre-service and in-service training of service providers is essential in order to secure the efficiency and quality of RTI/STI services.

Training should have the purpose of developing the knowledge, skills and attitudes which are required for providing education and services in a sensitive and caring environment.

Aspects of education should include:

- Interpersonal communication.
- The mechanisms of disease transmission.
- The magnitude of the RTI/STI problem.
- The various types of RTIs/STIs.
- How to provide treatment.

Depending on the characteristics of the staff and on programme resources, service providers should be trained in the appropriate level of management for RTIs/STIs (see section 3). Training should be provided within the concepts of quality of care, to ensure that service providers will have a positive attitude towards all individuals in the community for whom they provide education and services, including those who may be at high risk of STIs or who have a STI (see chapter 1: Clients' rights and providers' needs).

7.3 Guidelines

Establish written policies and procedures for the prevention and management of RTIs/STIs. These should be presented in a language and format that facilitates understanding by all relevant staff of the programme.

- Guidelines should be accessible to all members of the staff, and they should be discussed periodically.
- Guidelines should emphasize pathogens which may be highly prevalent in the area. They should also take into account the sensitivity and any known resistance of pathogens to the various treatment regimens.
- Some of the procedures outlined in the guidelines (e.g., flow charts for the syndromic management of RTIs/STIs) can be presented as posters and placed where the relevant tasks are performed.
- The guidelines should be used or referred to during training and supervision activities.

Conduct regular reviews to ensure the adequacy of the recommended diagnostic procedures and treatment regimens.

7.4 Referral system

An efficient referral system is essential in any programme which is working for the prevention and management of RTIs/STIs. While easy access to services is needed by people who suffer from a RTI/STI, it is unrealistic to expect that all service delivery sites would be able to provide comprehensive services. It is necessary to have a system by which individuals requiring special facilities for diagnosis and treatment would move from a basic level of service, such as clinics that work with the syndromic approach, to a more comprehensive service, such as those able to provide clinical management with laboratory tests.

The referral system should be based on linkages between institutions as well as across different levels of care within the same institution. It is the responsibility of the manager to develop those linkages.

7.5 Monitoring and supervision

Regular monitoring and supervision of education and service activities are important to ensure the efficiency of the programme in quantitative and qualitative terms. Proper monitoring and supervision will also assist in the identification of areas in which more emphasis is required, and should encourage all staff to be innovative and creative in all the tasks required for the prevention and treatment of RTIs/STIs.

Table 13.1—Clinical features, diagnosis and treatment of gonorrhoea

Causal organism	<i>Neisseria gonorrhoeae</i> .
Incubation period	1 to 14 days. Most symptoms develop within 2 to 5 days.
Symptoms and signs in women	Often there are no symptoms. The woman may complain of vaginal discharge, pain on urination, spotting after sexual intercourse, lower abdominal pain or pelvic inflammatory disease symptoms. On examination it is possible to see inflamed urethra and/or prevalent vaginal or cervical discharge.
Symptoms and signs in men	Urethral discharge, pain on urination.
Transmissibility	50-90% of female sexual partners of infected men are infected after 1 exposure. 20% of men are infected after 1 exposure; 60-80% after 4 exposures. Once urethritis has disappeared, most men are not infectious. 2% to 50% of infants exposed during birth develop eye infections (ophthalmia neonatorum).
Diagnosis	Observation of Gram-negative intracellular diplococci on direct microscopy examination of Gram-stained urethral or endocervical discharge specimen; or culture of specimen.
Treatment	It is recommended that dual therapy for gonorrhoea and chlamydia infections should be given in areas where prevalence of chlamydia infection is high.

Continued

Table 13.1—Continued

Treatment (continued)	<p>Single dose: ciprofloxacin, 500 mg by mouth (contraindicated in pregnancy); <i>Or</i> cefixime, 400 mg by mouth; <i>Or</i> ceftriaxone 125 mg intramuscular injection (at a dose of 125 mg ceftriaxone is more effective than 400 mg of cefixime, but cefixime has the advantage of being given orally while ceftriaxone is given intramuscularly); <i>Or</i> spectinomycin, 2 g intramuscular injection; <i>Or</i> azithromycin 2 g by mouth (azithromycin has the advantage of being effective against chlamydia, but at the dose of 2 g orally it causes gastrointestinal distress and is expensive; 1g is not recommended for gonorrhoea); <i>Or</i> kanamycin, 2 g intramuscular injection.¹</p> <p>Multiple dose: trimethoprim 80 mg/ sulfamethoxazole 400 mg (co-trimoxazole), 10 tablets by mouth once daily for 3 days.¹</p>
Complications if infection is not treated in women	<p>Leads to salpingitis in 10-20% of women, which may result in infertility or increased incidence of ectopic pregnancy. Other complications include endometritis, cervicitis, urethritis and Bartholinitis. The infection may disseminate via the bloodstream resulting in fever, rash and arthritis.</p>
Complications if infection is not treated in men	<p>Urethritis and epididymitis. Without treatment, up to 20% of infected men develop epididymitis which may result in infertility. It may also cause urethral stricture. The infection may disseminate into the bloodstream resulting in fever, rash and arthritis.</p>

¹Use only in areas where the possibility of drug resistance can be excluded.

Table 13.2—Clinical features, diagnosis and treatment of chlamydia

Causal organism	<i>Chlamydia trachomatis</i> (serovirus D to K).
Incubation period	7 to 21 days.
Symptoms and signs in women	<p>Often there are no symptoms. The woman may complain of vaginal discharge, pain on urination, spotting after sexual intercourse, lower abdominal pain or pelvic inflammatory disease symptoms.</p> <p>On examination it is possible to see prevalent vaginal or cervical discharge and frequently a red cervix which bleeds easily.</p>
Symptoms and signs in men	<p>Urethral discharge, pain on urination.</p> <p>May have no symptoms.</p>
Transmissibility	<p>Transmission partner to partner(s) occurs regardless of whether the infection is symptomatic or symptomless.</p> <p>60-70% of infants exposed at birth develop respiratory infection, pneumonia or chlamydial ophthalmia (eye infection).</p>
Diagnosis	<p><i>Presumptive:</i></p> <p>Clinical evidence of cervicitis and absence of Gram-negative diplococci at direct microscopy examination (Gram stain).</p> <p><i>Definitive:</i></p> <p>Serological tests or culture.</p>

Continued

Table 13.2—Continued

Treatment	<p>Doxycycline, 100 mg by mouth 2 times daily for 7 days; <i>Or</i> azithromycin, 1g by mouth in a single dose (although doxycycline is cheaper than azithromycin, the latter has the advantage of being given as a single dose, which is an important consideration when compliance could be a problem); <i>Or</i> tetracycline, 500 mg by mouth 4 times daily for 7 days; <i>Or</i> ofloxacin, 300mg by mouth 2 times daily for 7 days; <i>Or</i> amoxycillin, 500mg orally 3 times daily for 7 days.</p> <p>Note: Doxycycline, other tetracyclines and ofloxacin are contra-indicated during pregnancy and lactation.</p>
Complications if infection is not treated in women	<p>Can cause pelvic inflammatory disease, salpingitis and endometritis which may result in infertility or increased risk of ectopic pregnancy. It may also cause cervicitis, urethritis and bartholinitis (infection of Bartholin's gland). In pregnant women may cause premature rupture of membranes and pre-term delivery.</p>
Complications if infection is not treated in men	<p>Can cause urethritis and epididymitis which may result in infertility. Accounts for 35-50% of non-gonococcal urethritis in heterosexual men.</p>

Table 13.3—Clinical features, diagnosis and treatment of syphilis

Causal organism	<i>Treponema pallidum</i> .
Incubation period	10 to 90 days; average 21 days.
Early symptoms and signs in women	<p>Painless ulcer (chancre) at the site of exposure; it may be on the vulva, cervix, nose, mouth or anus.</p> <p>In women, internal lesions may be missed and the first apparent symptom may be the rash of secondary syphilis.</p>
Early symptoms and signs in men	Painless ulcer on penis, nose, mouth, testicle or anus.
Transmissibility	<p>30-60% of sexual partners become infected after 1 exposure.</p> <p>The infection may be passed from mother to fetus through the placenta as early as the ninth week of pregnancy in two thirds or more of pregnancies. In 40% of cases it causes spontaneous abortion, stillbirth or neonatal death; otherwise it causes congenital syphilis.</p>
Diagnosis	Dark-field microscopy of secretion from a primary or secondary lesion, or serological tests (RPR or VDRL).

Continued

Table 13.3—Continued

Treatment of early syphilis

Benzathine penicillin G, 2.4 million IU in 2 intramuscular injections during 1 clinic visit; give 1 injection into each buttock;
Or aqueous procaine benzathine penicillin G, 1.2 million IU daily by intramuscular injection for 10 days.

For penicillin-allergic non-pregnant patients:
doxycycline, 100 mg by mouth 2 times daily for 15 days;
Or tetracycline, 500 mg by mouth 4 times daily for 15 days.

For penicillin-allergic pregnant patients:
erythromycin, 500 mg by mouth 4 times daily for 15 days.

Complications if early infection is not treated

The early primary syphilis develops into secondary and early latent syphilis. The painful lesion heals in a few weeks; this is followed by non-itchy body rash, malaise, fever, general lymph-node enlargement, hepatitis, arthritis and/or hair loss usually beginning days, weeks or months after the painless lesions disappear. These symptoms last several weeks or occasionally months. Without treatment, late syphilis (not infectious) will develop in about 25% of cases; gummas (large lesions) in soft tissue or viscera, neurosyphilis, and cardiovascular syphilis begin 1 to 20 years later (sometimes up to 40 years later). Untreated symptomatic neurosyphilis and cardiovascular syphilis are often fatal.

Table 13.4—Clinical features, diagnosis and treatment of chancroid

Causal organism	<i>Haemophilus ducreyi</i> .
Incubation period	Usually 3 to 7 days; up to 10 days.
Symptoms and signs in women	Painful, irregularly shaped ulcers at the entrance of the vagina and around the anus. May cause pain on urination or defecation, rectal bleeding, pain on intercourse or vaginal discharge. There may be no symptoms.
Symptoms and signs in men	Painful, irregularly shaped ulcers on penis and/or tenderness in groin.
Transmissibility	People are infectious as long as they have ulcers. No transmission from mother to fetus or during delivery.
Diagnosis	<p><i>Presumptive:</i> Clinical features, particularly painful ulcers (syphilitic ulcers are usually not painful), and exclusion of syphilis by laboratory means.</p> <p><i>Definitive:</i> Observation of Gram-negative coccobacilli in chains at direct microscopy examination (Gram stain), or culture.</p>

Continued

Table 13.4—Continued

Treatment ¹	<p>Ciprofloxacin, 500 mg by mouth 2 times daily for 3 days (contraindicated in pregnancy and women who are lactating); <i>Or</i> ceftriaxone, 250 mg intramuscular injection as a single dose; <i>Or</i> azithromycin, 1 g by mouth as a single dose; <i>Or</i> erythromycin, 500 mg by mouth 4 times daily for 7 days.</p> <p>Note: Azithromycin is more effective and cheaper than erythromycin and is a single-dose treatment.</p>
Complications if infection is not treated	<p>Ulcers disappear without treatment usually in about a month but may last for 12 weeks. Causes inguinal buboes (swollen lymph nodes in the groin) in up to half of those infected.</p>

¹In patients with HIV infection, treatment regimens other than erythromycin often seem ineffective, and more prolonged courses of therapy may be necessary.

Table 13.5—Clinical features, diagnosis and treatment of herpes

Causal organism	Herpes simplex virus (HSV) types 1 and 2.
Incubation period	1 to 26 days; average 6 to 7 days.
Symptoms and signs in women	<p>Painful blister-like lesions in and around vagina, around anus or on thighs. Pain may be more severe than in men. It may cause painful urination, watery vaginal discharge, cervicitis or proctitis.</p> <p>Systemic symptoms may include headache, backache, fever and malaise.</p> <p>There are no symptoms in as many as 70% of cases. The first episode will clear in 2-4 weeks.</p>
Symptoms and signs in men	<p>Painful penile lesions. May cause urethral discharge or pain on urination. Systemic symptoms may include headache, backache, fever and malaise.</p>
Subsequent symptoms in women and men	<p><i>Recurrent episodes:</i> half of those infected have recurrences. Compared with first episode, recurrent episodes involve smaller and fewer lesions, and systemic symptoms are less common. Pain, numbness or tingling in buttocks, legs or hips may precede a recurrent outbreak.</p>
Transmissibility	<p>Transmission partner to partner(s) occurs during symptomatic and symptomless stages, but more often during the symptomatic stage.</p> <p>Transmission from mother to infant is very likely if the mother has a primary infection during labour. In many centres caesarean section is recommended. There is a high mortality rate among infants with herpes simplex virus infection.</p>

Continued

Table 13.5—Continued

Diagnosis	<p><i>Presumptive:</i> By clinical evidence, and often by exclusion.</p> <p><i>Definitive:</i> Tissue culture.</p>
Treatment is for symptoms only. There is no cure and people get recurrent episodes	<p>Advise clients to wash genital area regularly with soap and water. Prescribe paracetamol (acetaminophen), aspirin or similar pain-relief medication. When acyclovir is available it can be prescribed as follows: <i>First episode:</i> acyclovir, 200 mg by mouth 5 times daily for 7 days. <i>Recurrent episodes:</i> acyclovir, 200 mg by mouth 5 times daily for 5 days.</p>

Table 13.6—Clinical features, diagnosis and treatment of trichomoniasis

Causal organism	<i>Trichomonas vaginalis</i> .
Incubation period	3 to 28 days.
Symptoms and signs in women	Green or yellow, abundant, frothy vaginal discharge with foul odour, itching, pain on urination, pain on intercourse.
Symptoms and signs in men	Usually without symptoms but may involve urethral discharge, pain on urination or itching.
Transmissibility	Up to 85% of female sexual partners of infected men become infected. Up to 30-40% of male partners of infected women become infected. About 5% of girls born to infected women become infected during birth.
Diagnosis	Observation of the parasite in whipping motion (flagellating) at direct microscopic examination of a swab of vaginal fluid or urine sediment on saline wet mount. Culture of vaginal fluid (women) or urine specimen (men).

Continued

Table 13.6—Continued

Treatment	<p>Metronidazole, 2 g by mouth in a single dose; <i>Or</i> metronidazole, 400-500 mg by mouth 2 times daily for 7 days.</p> <p>Note: Do not give metronidazole during the first three months of pregnancy; delay treatment until the fourth month. Caution patients taking metronidazole to avoid alcohol as it causes vomiting. Metronidazole gel is not recommended for use as it is considerably less efficacious for treatment of trichomoniasis than oral preparations.</p>
Complications if infection is not treated in women	<p>Without treatment symptoms may persist for years. Symptoms worsen during or after menses. No complications or sequelae in most cases.</p>
Complications if infection is not treated in men	<p>Most cases resolve spontaneously. Sequelae may include urethritis, prostatitis and infertility.</p>

Table 13.7—Clinical features, diagnosis and treatment of bacterial vaginosis

Causal organism	Caused by a mixed over-growth of organisms that usually exist within the vagina.
Symptoms and signs	Vaginal irritation and soreness, vaginal discharge with fishy odour.
Transmissibility	Usually not sexually transmitted.
Diagnosis	Observation of more than 20% vaginal epithelium cells covered with bacteria (clue cells) at direct microscopic examination of a saline wet mount (or Gram stain); pH greater than 5; fishy odour on application of 10% potassium hydroxide solution (positive whiff test).
Treatment	<p>Metronidazole, 2 g by mouth as a single dose; <i>Or</i> metronidazole, 400-500 mg by mouth twice daily for 7 days; (Note: Although metronidazole as a single dose is cheaper it has a lower efficacy for the treatment of bacterial vaginosis.) <i>Or</i> Clindamycin vaginal cream 2%, 5 g at bedtime intravaginally for 7 days; <i>Or</i> 0.75% metronidazole gel, 5 g twice daily intravaginally for 5 days; <i>Or</i> clindamycin, 300 mg orally twice daily for 7 days.</p> <p>Note: Do not give metronidazole during the first three months of pregnancy; delay treatment until the fourth month. Caution patients taking metronidazole to avoid alcohol as it causes vomiting.</p>

Table 13.8—Clinical features, diagnosis and treatment of candidiasis

Causal organism	<i>Candida albicans</i> .
Symptoms and signs in women	Itching and soreness in the vagina, which may extend to around the vulva and perineum. A “curd-like” thick white discharge is sometimes present.
Symptoms and signs in men	Itching and soreness of the penis, sometimes with small papules and broken skin. Men often have no symptoms.
Transmissibility	Frequently not sexually transmitted. Sometimes it is not necessary to treat the sexual partner. In cases of recurrent candida infection, it is important to rule out underlying causes.
Diagnosis	Direct microscopic examination of a saline or potassium hydroxide wet mount preparation.
Treatment	<p>Clotrimazole, 500 mg tablet inserted in the vagina as a single dose; Or clotrimazole, 2x100 mg tablets inserted in the vagina once daily for 3 days; Or miconazole, 200 mg suppository inserted in the vagina once daily for 3 days; Or fluconazole, 150 mg orally as a single dose; Or nystatin, 100,000 IU tablet inserted in the vagina once daily for 14 days.</p> <p>Note: For women with vulvar candidiasis and men with candida balanitis, recommend topical application of an antifungal cream such as nystatin cream.</p>

Photo: Manuelle Hurwitz/Guinea



14 HIV INFECTION AND AIDS

1 Introduction

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) are major health problems. HIV/AIDS affects all ages, rich and poor. It is estimated that some 40 million people are living with HIV/AIDS. The International Planned Parenthood Federation (IPPF) is committed to mainstream management of HIV/AIDS into sexual and reproductive health services. Individual IPPF Member Associations and other sexual and reproductive health (SRH)/family planning services have opportunities to play an important role in fulfillment of this commitment: they are well placed to meet the challenges and to provide services for HIV/AIDS within their programmes.

1.1 Definition

HIV (human immunodeficiency virus) causes AIDS. An HIV-positive person develops AIDS (Acquired Immune Deficiency Syndrome) - the late stage of HIV disease - after years of infection. AIDS involves the loss of function of the immune system as CD4 cells are infected and destroyed, allowing the body to succumb to opportunistic infections (e.g., *Pneumocystis carinii* pneumonia, toxoplasmosis) that are generally not pathogenic in people with intact immune system.

1.2 Transmissibility

HIV may be passed directly from one person to another, either by sexual contact, transfusion of blood and blood products, perinatal transmission and use of contaminated needles and syringes.

The routes of mother-to-child transmission (MTCT) are:

- In-utero transplacental transmission.
- Intrapartum transmission during labour and delivery by inoculation or ingestion of blood or other fluids.
- Postpartum transmission via ingestion of infected milk.

1.3 The role of sexual and reproductive health services

This role encompasses:

- Prevention information and counselling messages directed to infected and uninfected individuals.
- The provision of family planning services.

- The provision of voluntary counselling and testing (VCT).
- Access to antiretroviral (ARV) therapy including prevention of mother-to-child transmission (PMTCT) and management of opportunistic infections when indicated.
- Referrals and palliative care and support.
- Increasing access of young people and vulnerable groups to information, education and services.

The HIV/AIDS services that SRH clinics can offer will depend upon their resources. These services may include all or some of the following:

- Education about integrated HIV/AIDS prevention.
- Voluntary counselling and testing.
- HIV/AIDS counselling, including advice on lifestyle management.
- Contraceptive counselling.
- PMTCT services, HIV/AIDS management, including treatment.
- Provision of ARV treatment, PMTCT services and management of opportunistic infections when indicated.
- Identification of referral services and referral networks.

2 Prevention

In the absence of curative treatment the only way to stop the spread of disease is by prevention. This is mainly done through increasing awareness and education in the community and increasing access to male and female condoms. The spread of HIV/AIDS is influenced by several factors, including sexual behaviour and attitudes, as well as the availability of facilities for early diagnosis and treatment. These factors should be borne in mind so that effective programmes to prevent the spread of HIV/AIDS can be designed and implemented. SRH programmes are well placed to disseminate information on the risks and complications of HIV/AIDS and to promote low-risk behaviour. They can also encourage the use of condoms, not only for the prevention of pregnancy but also for the prevention of HIV infection.

2.1 Prevention of sexual transmission

Sexual transmission can be prevented by:

- Consistent use of male condoms whenever there is a risk of infection, by sero-discordant couples to protect the other partner, and when both partners are positive to prevent re-infection with different viral mutations and exposure to new sexually transmitted infections (STIs).
- Use of female condom if male condom cannot be used in heterosexual relationship.
- Rapid and effective treatment of STIs.

2.2 Prevention of non-sexual transmission

- People who have or are vulnerable to HIV infection such as sex workers, men who have sex with men, injecting drug users should not donate blood, semen, or organs or tissue for transplantation.
- Special education activities should be targeted at injecting drug users to make them aware of the high risk of sharing needles and syringes. Needle exchange programmes should also be implemented.
- Efforts should be made to discourage practices such as female genital mutilation and scarification.
- Avoidance of unhygienic habits such as sharing razors and toothbrushes.

2.3 Prevention of perinatal transmission

- Prevent HIV infection among women.
- Prevent unwanted pregnancies in HIV-infected women.
- Provide counselling and safe delivery practices and antiretroviral drugs to HIV-infected mothers.

2.4 Prevention of transmission in health care facilities

Health care facilities should observe proper practices of infection prevention and control in providing care (see chapter 15: Infection prevention and control).

3 Management of HIV/AIDS

HIV management includes:

- Voluntary counselling and testing (VCT).
- Prevention messages directed to infected and uninfected individuals.
- Partner notification.
- Sexual behaviour.
- Reproductive decision-making.
- Contraception.
- Treatment.
- Care and support for people living with HIV/AIDS (PLWHA).

3.1 Voluntary counselling and testing (VCT)

Voluntary counselling and testing (VCT) is an integral component of SRH services and should be offered to high-risk/vulnerable groups. It allows individuals to know their HIV status and thereby provides an early access for HIV counselling, treatment and care. VCT should not take place in isolation but be part of a continuum of care. It should be linked with a referral system to appropriate treatment, care and support services to help to reduce barriers to testing.

VCT services must adhere to local and national protocols, laws and regulations governing the provision of HIV-related services.

VCT comprises:

- Knowledge of status is *voluntary*.
- Pre-test counselling.
- Informed consent.
- HIV testing.
- Post-test and follow-up counselling including positive prevention.

Pre-test counselling

Counselling should be confidential, non-judgmental, and be tailored to the needs and realities of the client. This enables clients to make

an informed choice about learning about their HIV status and to take appropriate action (see chapter 13: Reproductive tract infections and sexually transmitted infections, section 4).

The client should be aware that the process is entirely voluntary and confidential. The session should also:

- Provide clear information about HIV, its spread, how it differs from AIDS.
- Accurately describe the testing process.
- Ensure the client understands the advantages and implications of knowing their HIV status.

Informed consent

This is an authorization given by the client to the service provider to undergo testing for HIV after receiving relevant information about the risks and benefits of HIV testing. Only then can the client make an informed choice. Informed consent is necessary as HIV infection is life threatening and may cause harm to the client in the way of emotional stress, social stigma and discrimination in many forms.

HIV testing

HIV testing is performed by use of approved HIV test kits and testing protocols. HIV testing is not recommended without pre-test and post-test counselling.

Post-test counselling

Negative test result

Discuss with the client

- About the window period and the limitations of the test.
- The need for a repeat test after three months if exposure was within the last six weeks.
- Risk reduction strategies including safer sexual behaviour and the correct use of condoms.

Positive test result

- Reassure the clients and give emotional and psychological support.
- Explain the difference between HIV infection and AIDS and that people with HIV infection can remain healthy for a long period.
- Help them to identify sources of support, both personal and in the community (treatment and access, psychosocial support, networks, etc.).
- Review with them their immediate plans, intentions and actions.
- Discuss partner notification and assess risk of domestic violence; provide a referral, where necessary.
- Discuss the risk of transmitting HIV to others, risk of re-infection with HIV or other STIs.
- Discuss risk reduction strategies.
- Encourage partner testing as well as any children who could be infected.
- Establish a follow-up counselling plan with the client to discuss future issues, such as further testing and immune T cell testing (CD4), management, treatment and access, being part of a support group, healthy living, advantages of early access to care, etc.

3.2 Follow-up counselling

The first weeks and months are important for people when they learn that they are HIV positive. They need access to:

- Social and psychological services.
- Medical services to obtain treatment.
- Other support services to establish and maintain behaviour changes that reduce the likelihood of transmitting the virus to others as well as keeping themselves healthy to reduce the risk of re-infection.

It is important that HIV positive people retain their self worth and remain productive members of society. HIV-positive people may develop internalized stigma, which can have a negative impact on their mental health and well being. For some people, the knowledge of their HIV status may precipitate significant depressive symptoms. Providers of care should be aware of these possibilities and provide treatment and support where required.

When counselling, providers of services should stress that successful treatment does not prevent HIV transmission. Preventive actions, such as condom use, safer sex practices and clean needles for injecting drug users should be emphasized. Women with HIV are often caregivers themselves, accustomed to attending to others, such as children, a spouse, parents, etc. As a result, they may postpone their own self-care. Providers should counsel the client appropriately, explaining that care for oneself is an integral component of effective HIV management.

3.3 Partner notification/counselling

Partner notification involves the process of contacting sexual and/or injecting partners of an HIV-positive person in order to advise these partners that they may have been exposed to HIV and to encourage them to attend for voluntary and confidential HIV testing and counselling.

Providers of services should be sensitive to the complexities of partner notification, as this situation poses a conflict of rights: the right of the HIV-positive person to confidentiality and privacy versus the right of the partner to protection against HIV infection. It is not a straightforward issue which remains unresolved and needs to be handled with sensitivity. Partner notification is important and should be encouraged and discussed.

Providers should explain the aims and benefits of partner notification:

- It helps individuals who have been exposed to HIV to learn about their risk and encourages testing.
- If they are positive, they can learn how to protect others from HIV infection by **practising safer sex** and not sharing needles, and how to get access to treatment and support.
- If they are negative, they can get information on how to remain uninfected.

In many cases, individuals are not notified about their partner's HIV status, or when they are, they do not volunteer to be tested themselves. This provides a challenge to providers of services, as it may have an impact on the practice of safer sex. Moreover, there may be problems around adherence to ARV therapy and/or self-medication of the untested partner.

In certain countries it is compulsory for health care providers to inform partners of the status of their HIV-positive partner in the event that the individual refuses to disclose the information themselves. In these circumstances, the potential for violence and for serious disruption to the relationship should be assessed and necessary steps taken. Counsellors should be appropriately trained on how to provide counselling and advice, especially where there is the potential for violence and all attempts must be made to provide support to the HIV-positive individual.

Providers should create an enabling environment for disclosure.

3.4 Sexual behaviour

On diagnosis there is often a reappraisal of sexual behaviour, leading to the adoption of safer sex practices. However, in cases where the client has not disclosed to the sexual partner, it may be difficult to initiate/maintain safer sex practices. Clients may require intensive counselling and support to deal with these challenges. At all times providers need to maintain a non-judgmental supportive attitude.

Advances in HIV treatment and care have helped many HIV-positive people to enjoy an increase in life expectancy. For many, this allows for a renewed interest in sexual activity. It is essential that HIV-positive clients have a clear understanding of the gradient of risk between various sexual practices. Providers should be able to explain sexual practices and their associated risks in explicit terms to ensure complete understanding and openness. Clients should be aware of the correct use of sex toys and the dangers of sexual practices such as dry sex, douching, the use of intra-vaginal herbs to promote dryness of the vagina, etc. Creating an environment in which the client does not feel stigmatized or judged is crucial to encourage openness. It is important that providers be aware of different cultural sexual practices. Service providers should provide an environment that is secure for the disclosure of these private sexual practices.

Successful HIV treatment through provision of ARVs can lower a client's viral load which may reduce, but does not exclude, the risk of HIV transmission to an HIV-negative partner. There are also other factors that influence sexual transmission of HIV, such as:

- The presence of other STIs—e.g., herpes simplex type II or human papilloma virus infection.

- Genital irritation.
- Menstruation.
- Malnutrition and vitamin and mineral deficiencies.

3.5 Reproductive decision-making

HIV infection raises difficult issues relating to contraception and pregnancy. Because of the special circumstances of HIV-positive clients, counselling should be conducted with particular sensitivity. Once pregnant women decide about whether or not to continue their pregnancy they should be counselled and offered services based on their choice. Providers have an important role to play in facilitating a woman's decision-making process. Whenever possible, the partners should be counselled both separately and together.

Couples where one or both partners are positive face challenging reproductive decisions which include:

- Desire for pregnancy.
- Contraceptive practices.
- Choices for the outcome of an unintended pregnancy.

HIV-positive couples should be able to make informed choices, free of coercion and have access to quality services to implement these choices.

Desire for pregnancy

HIV-positive individuals or couples who are considering pregnancy should be informed clearly of the risk of transmission to the uninfected partner during the unprotected sexual intercourse required to achieve pregnancy. They should also know that, for an infected woman who is already showing symptoms of AIDS, pregnancy might accelerate the course of the disease. If an HIV-positive woman wishes to become pregnant, she should be educated about the local fertility and prenatal services, as well as the types of chemoprophylaxis available to reduce the risks of transmission to her child.

Prevention of mother-to-child transmission (PMTCT)

Transmission of HIV from an infected mother to her infant can occur in utero; at the time of delivery; and through breast milk. To reduce the risk of transmission from mother to child providers should keep in mind:

- The use of ARV treatment (different ARV regimens can be used determined by local availability and guidelines).
- Delivery by caesarian section.
- Breastfeeding choices.

Antiretroviral therapy (ARVs)

The use of antiretroviral drugs (ARVs) during pregnancy and delivery has been shown to be effective in reducing transmission of HIV from mothers to infants. ARVs reduce the risk of transmission by decreasing viral replication in the mother and through prophylaxis of the infant during and after exposure to the virus. There are many regimens differing in terms of efficacy, costs, practicality and safety. All these regimens include an intrapartum treatment, with varying durations of antepartum and/or postpartum treatment. Regimens which start early in pregnancy and are relatively complex have shown to be more effective than those that are simple and start late in pregnancy or just during labour. However, the practicality of the latter regimens makes them an attractive option for women who obtain antenatal care late in pregnancy and/or who cannot easily adhere to the ARV regimen. The choice of antiretroviral prophylactic regimen to be included in a service delivery programme will depend on availability, feasibility and cost.

Delivery by caesarian section

About 60% of HIV transmissions from mother to child occur around the time of labour and delivery. Vaginal deliveries increase the risk while delivery by elective caesarian section reduces the risk of MTCT irrespective of viral load and prophylactic ARV therapy. However, the potential benefits have to be balanced against the risk to the mother. Caesarian sections should be done in settings where the operation can be safely carried out and where overall maternal mortality is low. In facilities where caesarian section is not available, vaginal cleansing by use of chlorhexidine 0.25% to cleanse the birth canal after each vaginal examination and during labour and delivery has been shown to be effective in reducing MTCT.

Breastfeeding choices

The risk of MTCT increases if a woman breastfeeds her infant. The decision to breastfeed or not has to be weighed against the benefits of breastfeeding. It is the best way to feed an infant as it not only provides essential nutrients but also protects the infant from gastrointestinal

infections and malnutrition. In certain cultures it is the normal practice and therefore its avoidance may lead to stigma and discrimination as the community will suspect that the woman has HIV. A decision regarding replacement feeding should be made after ensuring that it would be:

- Acceptable;
- Feasible;
- Affordable;
- Sustainable; *and*
- Safe.

Providers of services should:

- Educate the woman about safe preparation of replacement feeds, correct cleaning of utensils, and methods of sterilization.
- Monitor the growth and development of the child to ensure adequate infant feeding and nutrition.
- Teach the mother to inspect her child's mouth for thrush and breakages in the mucous membrane (an added risk for HIV transmission).
- Teach the mother about the increased risk of HIV transmission should she suffer from mastitis, breast abscesses, and bleeding or cracked nipples.

If the woman decides to breastfeed her infant she should be advised on exclusive breastfeeding for the first six months. It should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).

Options for unintended pregnancy

HIV does not necessarily have a negative impact on the pregnancy but might have an adverse effect on the health of the mother especially if her CD4 count is low and ARVs are not available. HIV also leads to increased rates of complications after delivery and is associated with an increase in maternal mortality. If the client is currently pregnant but does not wish to continue her pregnancy, she should be referred to safe abortion services, where legally permitted. Postpartum contraception should be offered as an option for those who do not wish to become pregnant again.

3.6 Contraception

If an HIV-positive woman or a woman with an HIV-positive partner does not wish to become pregnant, she and her partner should be advised of the appropriate methods of contraception as well as the best way to avoid transmission of the infection.

In this case, the couple should be provided with contraceptive counselling and services or be referred to an SRH/family planning programme. To optimize reproductive choices, VCT services should link directly with family planning and antenatal preventive services.

Highly effective contraceptive methods should be recommended. In discordant couples, the correct and consistent use of condoms is the only method to prevent HIV transmission. They should be used even when another method is chosen to prevent pregnancy.

In general, HIV-positive women have the same range of contraceptive options as other women. The World Health Organization (WHO) medical eligibility criteria (MEC) have been developed for women with HIV infection and include specific circumstances under which the use of certain methods is restricted, as outlined below.

Male condom

The correct and consistent use of male condoms has high efficacy against both unintended pregnancy and STI/HIV transmission whenever there is a risk of infection. The proper use of male condoms effectively prevents HIV transmission within HIV-discordant couples. When male condoms fail to protect against pregnancy and infection, the main reason is that they were used incorrectly; only a small fraction of these failures occur because of condom breakage/slippage.

Clients should be given clear instructions on the proper use of the method (see chapter 7: Barriers) including a demonstration, together with advice on the correct lubrication, storage and handling. Emergency contraception should be provided as a back up method.

Female condom

The female condom is available in many countries and offers an alternative to male condoms. The female condom affords women more control over the initiation of barrier contraception and can be inserted hours before intercourse. The contraceptive use-effectiveness of the

female condom is within the wide range quoted for other barrier methods, but lower than that of male condoms.

Although clinical data are limited, laboratory studies have shown that the female condom is an effective barrier not only to sperm but also to bacteria and viruses including HIV.

The use of female condoms is limited by cost factors. While it is always preferable to use a new female condom for each act of intercourse, under certain circumstances re-use of the female condom may be acceptable, feasible and safe. The final decision about whether or not to support re-use of the female condom should be taken locally.

Diaphragm

The diaphragm has the advantage of being woman controlled and can be inserted several hours before intercourse. It offers contraceptive protection similar to other barrier methods (see chapter 7: Barriers).

For discordant couples, and whenever there is risk of infection, the use of diaphragms with spermicides is not recommended because of a possible increased risk of HIV infection associated with the use of spermicides containing nonoxynol-9 (N-9). Studies are under way to determine whether the diaphragm reduces the risk of transmission of STIs and HIV.

Spermicides

When used on their own, spermicides have lower contraceptive efficacy than other barrier methods and they do not protect against STIs. Spermicides containing nonoxynol-9 (N-9) do not protect against HIV infection and may even increase the risk of HIV infection in women using these products frequently. This method is therefore not recommended for HIV-negative women in a discordant couple. This method may be used by HIV-positive women only if no other options are available and acceptable. If a spermicidal method is chosen, the client should be advised to use it in combination with another barrier method.

Hormonal contraceptives

The correct use of hormonal contraceptives is highly effective for pregnancy prevention. Available evidence also indicates that hormonal contraceptives are safe for use by HIV-positive women and for uninfected women in a discordant couple. They do not protect against STIs/HIV, therefore the correct and consistent use of condoms is recommended.

ARV drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. The limited data available indicate that potential drug interactions between many ARVs and hormonal contraceptives may alter the safety and effectiveness of both the hormonal contraceptives and the ARVs. If a woman on ARV treatment decides to start or continue hormonal contraceptive use, the consistent use of condoms must be recommended to prevent HIV transmission and may also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

IUDs

The IUD is a highly effective method of contraception, which can be used by HIV-positive women without AIDS and women with AIDS who are clinically well on ARV therapy. Women with AIDS who are not clinically well should generally not have an IUD inserted unless other methods are not available or acceptable (see chapter 6: Intrauterine devices). IUDs do not protect against STIs/HIV, therefore the correct and consistent use of condoms is recommended.

Emergency contraception

For HIV-positive women who have unprotected sex and may be at risk of an unwanted pregnancy, access to emergency contraception is essential. The IUD can be used by an HIV-infected woman for emergency contraception provided she meets the medical eligibility criteria (see chapter 6: Intrauterine devices).

Male or female sterilization

Sterilization can be provided to HIV-positive clients if an informed voluntary choice is made (see chapter 8: Female and male sterilization). Appropriate infection prevention procedures must be carefully observed (see chapter 15: Infection prevention and control). However, this method does not protect against STIs/HIV transmission and therefore the correct and consistent use of condoms is recommended following the procedure.

3.7 Treatment

Antiretroviral therapy

Antiretroviral drugs (ARVs) inhibit the replication of HIV. When given in combination they:

- Inhibit HIV replication.
- Delay immune system deterioration.
- Improve survival and quality of life.

ARVs should be introduced as part of SRH/family planning services and introduced at the primary care level. ARVs are effective in decreasing HIV-related morbidity and mortality. Community ARV roll-out may decrease the incidence of HIV in the community by reducing high risk behaviour, and decrease the risk of transmission in discordant couples by the increased use of condoms and mother-to-child transmission. ARV treatment helps to:

- Keep an individual in the asymptomatic phase.
- Improve symptoms.
- Return individuals to the asymptomatic stage of illness.

Although access to treatment can change HIV from a deadly disease to a chronically managed condition, it is important to highlight that there is still no cure for HIV.

HIV treatment involves the use of antiretroviral drugs to keep an HIV-positive person at all stages of HIV progression healthy by dropping their viral load to an undetectable level (below 50 copies) within 16-20 weeks.

Providers of services should be aware that HIV drug treatment is complex and adverse events manifest differently among different clients. They should:

- Follow national treatment guidelines.
- Monitor compliance by the client as drug resistance can develop if doses are skipped.
- Ensure patient's adherence to ARV regimen to get optimal results from treatment and minimize the emergence of viral resistance.

Post Exposure Prophylaxis (PEP)

PEP is a short-term antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure, either occupationally or through sexual intercourse. PEP should be commenced as soon as possible after the incident and ideally within 2-4 hours. Combination therapy is recommended, as it is believed to be more effective than a single agent. However, provision of ARV therapy should be provided according to national protocols and guidelines.

Sexually transmitted infections (STIs)

In populations with a high HIV prevalence, patients presenting with STIs are more likely to be HIV infected and, if infected, are more likely to transmit HIV to susceptible partners. Patients who do not know their HIV status should be referred to VCT services for counselling and testing. HIV-positive people, because of compromised immune systems, have more frequent and severe episodes of recurrent viral STIs. Treatment and/or prophylaxis where available should be offered.

Opportunistic infections

HIV-positive people have compromised immune systems and are more susceptible to a range of opportunistic infections (OIs), such as tuberculosis, malaria, candidiasis, toxoplasmosis, cryptococcal meningitis, *Pneumocystis carinii* pneumonia, toxoplasmosis, chronic diarrhea and malaria in endemic areas. Symptoms for these infections may manifest themselves differently in HIV-positive people.

The risk of acquiring an OI increases with lower CD4 counts. Where possible, treatment should be offered to patients who have stage 4 HIV or CD4 counts of less than 200. If treatment is not available at a particular site, patients should be referred to appropriate services. Treatment should follow national protocols.

Left untreated, infections may become more difficult to diagnose and require hospital admission for expensive investigation procedures. With the timely provision of ARVs, this can be avoided by strengthening the immune system, saving both time and money.

In HIV high-risk areas, tuberculosis (TB) is a marker for HIV. A person presenting with TB should also be referred to VCT for testing and counselling.

3.8 Care and support for infected individuals

General health advice

A healthy lifestyle is particularly important for the HIV-positive person.

Nutrition care and support services

HIV infection affects nutrition through increases in resting energy expenditure, reductions in food intake, nutriment absorption and loss, as well as complex metabolic alteration that culminate in weight loss and wasting common in AIDS. Therefore, proper nutrition is a vital component of healthy living for HIV-positive persons and nutrition counselling, care and support are integral to comprehensive HIV care.

Well balanced nutrition:

- Helps to maximize medical treatment.
- Boosts immunity.
- Reduces side-effects of ARVs.
- Improves physical health and enjoyment of life.

Diet specifications differ among individuals and depend on the stage of illness, social situation and a client's unique health concerns. The daily diet recommendations for those with HIV will depend on the country and local guidelines. They should generally include a diet with:

- High protein.
- High calories.
- Daily requirements of vitamins and minerals to ensure that micronutrient needs are met.

Service providers should work with communities and investigate all options to provide appropriate diet including referral to food-based interventions and programs where needed, in particular for pregnant and lactating HIV-positive women.

Lifestyle

Clients should be encouraged to lead a healthy lifestyle. Programmes should include counselling on:

- Exercise.
- Adequate sleep.
- How to reduce stress.
- Advice on unhealthy behaviours such as smoking and excessive drinking; both of which should be discouraged. Where required, patients should be referred to drug or alcohol prevention and treatment programmes.

Providers should encourage ongoing counselling to address new issues as they arise. Left unaddressed, these issues can negatively impact a client's mental health and adherence to treatment.

Support services

HIV infection affects all dimensions of a person's life: physical, psychological, social and spiritual. Counselling and social support can help people and their carers cope more effectively with each stage of the infection and enhances their quality of life. With adequate support clients are more likely to be able to respond adequately to the stress of being infected and are less likely to develop serious mental health problems.

Assessment and interventions may be aimed at the acutely stressful phase following notification of HIV infection, the ensuing adjustment period, and the process of dealing with chronic symptomatic HIV infection and disease progression through to death.

HIV infection often can result in stigma and fear for those living with the infection, as well as for those caring for them, and may affect the entire family. Infection often results in loss of socio-economic status, employment, income, housing, health care and mobility. For both individuals and their partners and families, psychosocial support can assist people in making informed decisions, coping better with illness and dealing more effectively with discrimination. It improves the quality of their lives, and prevents further transmission of HIV infection.

Referral

An efficient referral system is essential for the management of HIV/AIDS programmes. It is not possible for all the delivery sites to provide access to comprehensive services needed by people who suffer from HIV/AIDS. It is necessary to have a system by which individuals requiring special facilities for diagnosis, treatment and care would move from a basic level of service, such as clinics, to a more comprehensive service, such as those able to provide clinical management with laboratory tests.

The referral system should be based on linkages between institutions as well as across different levels of care within the same institution.

Photo: Fatiha Terki/Vietnam



15 INFECTION PREVENTION AND CONTROL

1. Introduction

The primary objective of infection prevention in sexual and reproductive health care facilities, whether free-standing or mobile is:

- To minimize the transmission of infections to clients, service providers and others who may be exposed to disposed contaminated wastes.

As the prevalence of HIV infection and AIDS is increasing, more people are concerned about the possibility of becoming infected. It is of utmost importance that transmission of the HIV virus to clients and service providers be prevented, and they should be reassured that all necessary precautions are taken.

The spread of infection during clinic procedures can be prevented by the use of aseptic techniques, avoidance of cross-infection, proper processing of clinic instruments and equipment, and proper waste disposal.

2 Definitions

- **Micro-organisms** are the causative agents of infection. They include bacteria, viruses, fungi and parasites. Bacteria which produce endospores (e.g., *Clostridium* species causing gangrene and tetanus) are the most difficult to kill due to their protective coating.
- **Asepsis or aseptic technique** are general terms used in health care settings to describe the combination of efforts made to prevent entry of micro-organisms during service delivery procedures into any area of the body where they are likely to cause infection. The goal of asepsis is to eliminate, or reduce to a safe level, the number of micro-organisms on both animate (living) surfaces (e.g., skin, mucous membranes and tissues) and inanimate objects (e.g., surgical instruments).
- **Antisepsis** is the prevention of infection by killing or inhibiting the growth of micro-organisms on skin and mucous membranes prior to a service delivery procedure which involves contact with tissues where micro-organisms may cause infection.
- **Decontamination** is the process that makes inanimate (non-living) objects safer for people to handle. Such objects include large surfaces (e.g., pelvic examination or operating tables) and instruments and gloves contaminated with blood or other body fluids.

- **Cleaning** is the process that physically removes all visible blood, other body fluids, tissues or any foreign material such as dust or soil from skin, mucous membranes or inanimate objects.
- **Disinfection** is the process that eliminates bacteria, viruses, fungi and parasites from inanimate objects, but does not reliably eliminate bacterial endospores. The procedures for **disinfection** have been reviewed during recent years to ensure effectiveness against viruses such as HIV and hepatitis B virus. The revised procedures have been labelled as **High-Level Disinfection (HLD)**. **HLD** is, at the present time, the only acceptable level of disinfection and the only one recommended in these guidelines.
- **Sterilization** is the process that completely eliminates all micro-organisms, including bacterial endospores, from inanimate objects.

3 Antisepsis

Antisepsis involves cleaning of the client's skin or mucous membrane with an antiseptic substance to remove or eliminate as many micro-organisms as possible, prior to any procedure. Care should be taken not to irritate or damage the skin or mucous membrane.

3.1 Indications

- Skin preparation for procedures such as minilaparotomy, laparoscopy, vasectomy, insertion/removal of Norplant implants and injections.
- Cervical and vaginal preparation for IUD insertion/removal and insertion of uterine elevator in surgical sterilization.
- Handscrub prior to putting on gloves for surgical procedures such as minilaparotomy or vasectomy.

3.2 Selection of antiseptics

Antiseptics are made to be used on skin or mucous membranes, as opposed to disinfectants that are stronger solutions used for inanimate objects. Antiseptic solutions should *never* be used to disinfect inanimate (non-living) objects such as instruments and re-usable gloves. *Never* leave items such as pick-up forceps (lifters), surgical scrub brushes, scissors or suture needles soaking in antiseptic solutions.

The following antiseptic solutions are safe and commonly available:

- Centrimonium/cetrimide with ethyl alcohol 70% (Cetavelon).¹
- Cetrimide and chlorhexidine gluconate (CHG), various concentrations (e.g., Savlon).
- Chlorhexidine gluconate 4% (e.g., Hibitane, Hibiscrub).
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations 0.5%-3.75% (e.g., Dettol).
- Hexachlorophene 3% (e.g. pHisoHex).
- Iodines 2%-3%, tincture¹ and aqueous (e.g., Lugol's).
- Iodophors, various concentrations 0.5%-10% (e.g., Betadine).
- Alcohols (60%-90%), ethyl, isopropyl or methylated spirit.¹
- Hydrogen peroxide 3%.
- Acridine derivatives (acriflavine and proflavin).

Solutions to avoid:

- *Benzalkonium chloride (Zephiran)*. It has several distinct disadvantages:
 - It takes at least 10 minutes to kill HIV.
 - It has repeatedly been shown to become contaminated by *Pseudomonas* and other common bacteria.
 - It is easily inactivated by cotton gauze and other organic material and is incompatible with soap.
- *Mercury laurel or other mercury-containing compounds*. Although frequently sold for antiseptics, mercury-containing chemicals should be avoided due to their high toxicity.
 - Skin exposure to low levels of mercury causes blister formation and contact dermatitis.
 - Inhalation or ingestion of low levels of mercury causes central nervous system effects (numbness, speech impairment, deafness) and higher levels (200 mg) are fatal.

3.3 Preparation, storage and dispensing of antiseptics

Antiseptics are commercially available either as concentrates from which solutions have to be prepared or as solutions ready for use. Proper

¹ Solutions containing alcohol (e.g., ethyl alcohol, tincture iodine, methylated spirit etc.) should not be used on mucous membrane such as vagina.

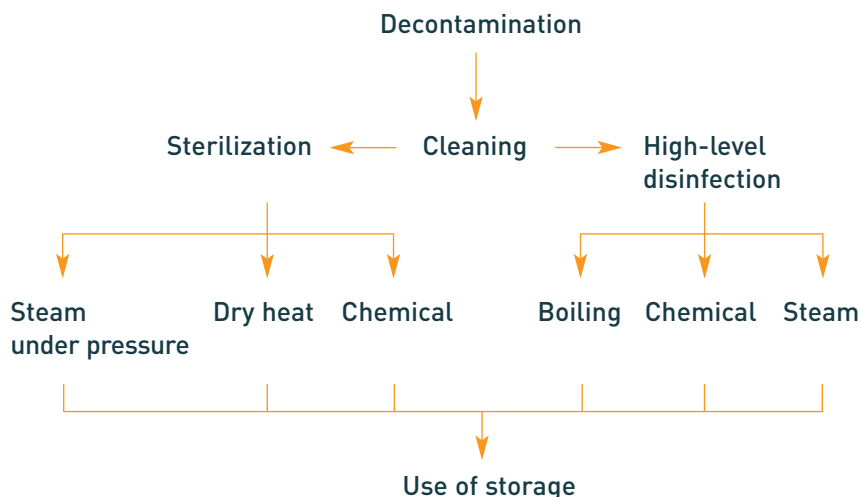
handling of antiseptic solutions is important in order to prevent their contamination. Micro-organisms which can commonly contaminate antiseptic solutions include Gram-negative bacilli, all endospores and rarely *Staphylococcus*. These micro-organisms can cause subsequent infection when contaminated solutions are used for handwashing or on a client's skin or mucous membrane. To prevent contamination of antiseptic solutions:

- Pour the antiseptic, unless supplied commercially in small quantities, into small reusable containers for daily use. This prevents evaporation and contamination, which would occur if the large container were opened too often.
- Establish a routine schedule (e.g., each week) for preparing solutions and cleaning reusable containers. (Solutions are at increased risk of becoming contaminated after one week of being prepared.)
- Do not store gauze or cotton wool in aqueous antiseptics as this promotes contamination.
- Wash the reusable container thoroughly with soap and water and dry before refilling. Label it with the date every time it is washed, dried and refilled.
- Store antiseptics in a cool, dark area. Never store chemicals in direct sunlight or in excessive heat (e.g., upper shelves in a tin-roofed building).
- When using antiseptic solutions, always pour the solution out of the container. Touching the rim or contents of the container with gauze, cotton swab or hand contaminates the entire bottle of antiseptic.

4 Procedures for processing of equipment and instruments

The procedures include decontamination, cleaning, high-level disinfection and sterilization.

Figure 15.1 The steps for processing



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4.1 Decontamination

Decontamination is important for pre-treating instruments and objects that may have come in contact with body fluids, to make them safer to handle by personnel who clean them. It must be understood, however, that chemical disinfectants cannot be 100% relied upon to penetrate blood, mucus etc. on an unwashed item. Therefore, the strictest precautions should be maintained when cleaning instruments and other items, including the use of gloves, even after decontamination (see section 4.2). When performing decontamination, wear rubber (household or utility) gloves. Always use plastic containers because a metal container will accelerate corrosion of stainless steel instruments, which are electroplated.

Decontamination of used instruments and other items

- Provide a fresh plastic bucket containing 0.5% chlorine solution at the beginning of each working session, or more often if the solution becomes dirty.
- Immediately after each procedure, place the used items in 0.5% chlorine solution for 10 minutes. Do not wait too long before starting decontamination because it will allow organic material to dry and become hard to remove.
- Soaking instruments for prolonged periods (or in high concentrations of chlorine) may damage instruments. Rinse instruments with cold water immediately after decontamination to prevent corrosion and to remove gross organic material before being cleaned.

In clinics where numerous procedures are performed during a session, it may not be practical to decontaminate instruments immediately after each procedure. In such situations, an alternative procedure may be followed:

- Pour into a plastic bucket the measured amount of water that is required to prepare a 0.5% chlorine solution. For example, if using bleach which requires 1 part of bleach to 6 parts of water, pour into the bucket the corresponding 6 parts of water.
- Place the used instruments immediately after each procedure in the bucket containing the water, ensuring that the instruments are kept below the water level. Once the maximum number of instruments that can remain below the water level have been placed in the bucket, or at the end of a working session, whichever comes first, pour into the bucket the amount of chlorine required to make a 0.5% solution and stir to mix. Make sure that the bucket containing water is not overloaded with instruments, so that enough space is left for the chlorine to be added without the water overflowing.
- Keep the instruments in the chlorine solution for 10 minutes, and then rinse immediately with cold water.

Decontamination of large surfaces

Decontaminate large surfaces (e.g., the top of the examination table) by wiping them with 0.5% chlorine solution.

Preparation of chlorine solutions

Chlorine solutions can be made from liquid household bleach (sodium hypochlorite) (see Table 15.1) or from other chlorine compounds available in powder (calcium hypochlorite or chlorinated lime) or tablet form (sodium dichloroisocyanurate). The World Health Organization (WHO) recommends that chlorine solutions should be replaced daily, or more often if necessary, because they lose potency rapidly over time or after exposure to light.

Making a chlorine solution from bleach powder:

To prepare a chlorine solution use the following formula:

$$\frac{\% \text{ chlorine desired}}{\% \text{ chlorine in powder}} \times 1000 = \text{grams of powder per litre of water.}$$

Examples:

To make a 0.5% chlorine solution from calcium hypochlorite powder (bleach) that contains 35% available chlorine:

$$\frac{0.5}{35} \times 1000 = 0.0143 \times 1000 = 14.3$$

Thus, dissolve 14.3 grams of calcium hypochlorite powder in 1 litre of water.

To make a 0.1% chlorine solution from calcium hypochlorite powder (bleach) that contains 35% available chlorine:

$$\frac{0.1}{35} \times 1000 = 0.0029 \times 1000 = 2.9$$

Thus, dissolve 2.9 grams of calcium hypochlorite powder in 1 litre of water.

Preparation of a dilute chlorine solution from liquid bleach:

To prepare a dilute chlorine solution, use the following formula to determine the parts of water needed for each part of concentrated chlorine solution (liquid bleach):

$$\frac{\% \text{ chlorine in concentrate}}{\% \text{ chlorine desired}} - 1 = \frac{\text{number parts of water needed}}{\text{per part concentrate}}$$

Example: To make a 0.5% solution from a 3.5% concentrate

$$\frac{3.5}{0.5} - 1 = 7 - 1 = 6$$

Thus, add 6 parts water to 1 part concentrated chlorine solution (see also Table 15.1).

Table 15.1—How to prepare 0.5% chlorine solution from liquid bleach (sodium hypochlorite)		
Example of brand of bleach — Country	Chlorine % available	0.5% dilution
ACE—Turkey, Eau de Javel—France (15° chlorum) ¹	5	1 part bleach to 9 parts water
Lejia—Peru	10	1 part bleach to 19 parts water
JK—Kenya, Robin Bleach—Nepal	3.5	1 part bleach to 6 parts water
Blanqueador Cloro —Mexico	6	1 part bleach to 11 parts water
Lavandina—Bolivia	8	1 part bleach to 15 parts water
Extrait de Javel—France (48° chlorum) ¹	15	1 part bleach to 29 parts water

¹Where concentrations of active chlorine are expressed in chlorum, convert to per cent as follows: 1° chlorum roughly equals 0.3% active chlorine; therefore multiply the degrees of chlorum by 0.3 to give % active chlorine.

4.2 Cleaning

Cleaning instruments and other items before sterilization and disinfection procedures is crucial because it removes organic material which can:

- Entrap micro-organisms in a residue that may protect them against sterilization or disinfection procedures.
- Partially inactivate chemical disinfectants and sterilants, rendering them less effective.

How to clean

Clean instruments and large surfaces with detergent and water. Water alone is not effective in removing proteins, oils and grease. Use a liquid or powdered detergent which can easily dissolve in water. Avoid the use of soap, or detergents which contain soap, as fatty acids contained in soap react with the minerals in hard water and form residue which is difficult to remove. Do not use abrasives (e.g., Vim or Comet) because they may damage instruments.

- Wear rubber (household or utility) gloves and, if possible, eye protection.
- Clean instruments with detergent and water using a brush. This should be done under the surface of the water to prevent infectious material from becoming airborne through splashing. Pay particular attention to instruments with teeth, joints or screws.
- Rinse thoroughly with water to remove detergent residue which can interfere with chemical disinfection or sterilization.
- Dry by air or with a clean towel. (Water from wet instruments will dilute chemicals used for sterilization or disinfection.) Drying is not necessary for instruments which are to be boiled.

4.3 High-level disinfection (HLD)

High-level disinfection (HLD), if carried out properly, destroys bacteria, viruses, fungi and parasites, but does not reliably eliminate bacterial endospores; it makes objects safe to touch broken skin or intact mucous membrane. Sterilization is the preferred processing method for items that will make contact with the bloodstream or tissues beneath the skin. When sterilization is not possible, HLD is the only acceptable alternative. HLD can be achieved by two techniques: *boiling and chemical (cold) disinfection*.

Boiling

- Decontaminate, clean and dry all items to be disinfected (see sections 4.1 and 4.2).
- Use a pot with a lid or an instruments boiler.
- Submerge all the instruments in water so that the water level is above the instruments. Open jointed instruments such as clamps and scissors. Disassemble items composed of more than one part. Make sure that any bowls and containers to be disinfected are full of water. Bowls should not be kept upside down as they may trap air which will not reach the required temperature to kill micro-organisms.
- Close the lid and apply heat.
- Boil for a minimum of 20 minutes; start timing when the water is at a rolling boil.
- Lower heat to keep water at a rolling boil because too vigorous boiling wastes fuel, evaporates the water and may damage equipment.
- Do not add anything to the container, including more water, once timing has begun.
- Immediately after boiling, remove items with sterilized or disinfected forceps. The instruments will air dry better if taken out of the hot water when they are still hot. Do not leave the items in the container with the lid open once the water has stopped boiling because, as the water cools down, the steam condenses and air and dust particles are drawn into the container, which may contaminate the instruments. After removing the instruments from the hot water, place them in a pan or dish which has also been boiled.
- For procedures such as male or female sterilization, insertion or removal of implants and IUD insertion, instruments can be used wet immediately after cooling, or air dried and stored in a covered, disinfected container for use within 24 hours.
- For procedures such as pelvic examination, instruments do not need to be sterile or disinfected at the time of being used. These instruments, however, should be sterilized or disinfected between cases. They should be stored and handled in the conditions required to keep them clean, but not necessarily sterile or disinfected. Air dry these items or dry them with a clean towel before use or storage. If the items are towel dried, the towel should be used only for this purpose and replaced every day, or sooner if necessary.

Use the same water throughout the day, adding only enough to keep the surface at least 1 inch (over 2 cm) above the equipment to be disinfected. Frequent draining and replacing of water increases the risk of mineral deposits.

Chemical disinfection

Selection of disinfectant

- Glutaraldehyde 2% (e.g., Cidex).
- Formaldehyde 8%.
- Chlorine 0.1% solution (boiled water should be used for dilution).

Although alcohols and iodophors are inexpensive and readily available, they should not be used as disinfectants. Alcohols do not kill some viruses and spores, and *Pseudomonas* has been known to multiply in iodophors. Hydrogen peroxide (6%) is a high-level disinfectant, but is highly corrosive and loses potency rapidly when exposed to heat and light.

Precautions

Take precautions while using the following:

- *Formaldehyde*: Do not dilute with chlorinated water because a carcinogen (bischloromethyl ether) can be produced.
- *Formaldehyde and glutaraldehyde*: The vapours of both these chemicals are toxic and cause irritation to the skin, eyes and respiratory tract. Always wear gloves and use them in a well-ventilated area. Formaldehyde is the more toxic.
- *Chlorine solutions*: These solutions can corrode metals. Always rinse promptly to avoid corrosion.

Procedures

- Wear thick household gloves.
- Decontaminate, clean and dry all items to be disinfected (see sections 4.1 and 4.2).

- Use a clean container with a lid. Open jointed instruments, such as scissors and forceps. Disassemble items composed of more than one part. Cover all items completely with the disinfectant solution.
- Soak in a glutaraldehyde, formaldehyde or chlorine 0.1% solution for 20 minutes.
- Remove, using disinfected forceps or gloves.
- Rinse well with sterile or boiled water.
- For procedures such as male or female sterilization, insertion or removal of implants, and IUD insertion, instruments can be used wet immediately after cooling, or air dried and stored in a covered disinfected container for use within 24 hours.
- For procedures such as pelvic examination, instruments do not need to be sterile or disinfected at the time of being used. These instruments, however, should be sterilized or disinfected between cases. They should be stored and handled in the conditions required to keep them clean, but not necessarily sterile or disinfected. Air dry these items or dry them with a clean towel before use or storage. If the items are towel dried, the towel should be used only for this purpose and replaced every day, or sooner if necessary.

Chemical disinfection of needles and syringes should be avoided because they are difficult to rinse effectively and chemical residues may interfere with the action of medications being injected.

Preparation and storage of solutions

- Formaldehyde is commercially available in 35%-40% solutions. One part of this solution should be diluted with 4 parts of boiled water to prepare a final solution which contains about 8% formaldehyde. Do not dilute with chlorinated water as a carcinogen (bischloromethyl ether) can be produced.
- Glutaraldehyde solutions are available as a 2% aqueous solution. Most need to be "activated" before use. Activation involves addition of a powder or a liquid supplied with the solution; this renders the solution alkaline. Instructions provided by the manufacturer should be followed.
- For guidance on the preparation of chlorine solution, please see section 4.1.

Replace chlorine solutions daily and formaldehyde and glutaraldehyde solutions every 2 weeks, or more frequently if they get diluted or become cloudy during use.

4.4 Sterilization

The sterilization process ensures that all micro-organisms, including bacterial endospores, are destroyed. Sterilization can be achieved by using heat (high-pressure steam or dry heat), or by using chemicals (“cold-sterilization”).

Another technique, practised in some countries, is gas sterilization using ethylene oxide (ETO). ETO may produce harmful effects in human beings. It is toxic, mutagenic, possibly carcinogenic, flammable and explosive. It is also an expensive process, and, therefore, its use is impractical for most SRH/family planning programmes.

A new technique using paraformaldehyde has recently been patented. Paraformaldehyde is vaporized by dry heat in an enclosed area to disinfect or sterilize objects. This process has been used for sterilizing laparoscopes. The gas is highly toxic, the heat makes it very expandable and it is difficult to ensure the conditions for safety in a clinical facility. Therefore, this method is not recommended.

Steam sterilization (autoclaving)

High-pressure saturated steam is generally the method of choice for sterilizing instruments and other items used in SRH/family planning and other health-care facilities. Sterilization by steam requires the following conditions:

- Adequate contact of steam with all surfaces of the items to be sterilized.
- Sufficiently high temperatures.
- Proper timing.

The two commonly used steam sterilizers are a gravity displacement autoclave and a pre-vacuum autoclave.

- *Gravity displacement autoclaves.* With this type of autoclave, water at the bottom of the sterilizer is heated and turned into steam. As steam is produced and fills the autoclave chamber, cool air is forced out from the chamber. It is important to remove all the air from the autoclave

chamber to achieve sterilization. There is a pressure cooker type sterilizer that can be used on a kerosene or electric burner. This has been used for immunization programmes, but has been modified for instruments to be used in family planning procedures such as IUD insertion and insertion and removal of implants.

- *Pre-vacuum sterilizers.* These use a vacuum pump system to rapidly remove the air from the autoclave chamber before steam is let in. This reduces the total cycle time and the chances of air pockets forming. Pre-vacuum sterilizers are more expensive and more complex to operate and maintain; they are normally used in large hospitals.

SRH/family planning clinics usually use gravity displacement autoclaves. The following guidelines apply only to gravity displacement autoclaves.

Preparation of items

To ensure correct operation, consult specific operating instructions supplied by the manufacturer.

- Decontaminate, clean and dry all items to be sterilized.
- Wrap the sharp edges and needle points in gauze. Keep instruments such as scissors, haemostats and artery forceps in the opened or unlocked position, and disassemble instruments composed of more than one part or sliding parts.
- Do not tie instruments together with rubber bands or any other means as this will prevent steam contact with all surfaces.

Wrapping

Instruments and other items can be sterilized either unwrapped or wrapped. If sterilizing instruments wrapped:

- Wrap clean instruments and other items in cotton cloth, double-thickness muslin (140 thread count), paper wrapper or newsprint before autoclaving.
- For sterilization the wrapper must:
 - Be large enough to completely enclose the items.
 - Be properly folded to secure the package contents.
 - Be loose enough to allow air removal and steam penetration.
 - Allow safe storage and aseptic presentation at the point of use.

- Place wrapped instrument sets in trays with mesh or perforated bottoms.
- When using drums for autoclaving, ensure that:
 - The drum is not overloaded.
 - Holes are in the open position.

Loading

- Do not overload. Leave sufficient space between items for efficient air removal, steam penetration and steam evacuation.
- Ensure that all items are dry before loading.
- Do not sterilize linens and gloves with hard items. They should be sterilized separately. If this is not possible, place linen and/or gloves on top shelves and hard items below. This prevents linen or gloves from becoming wet due to dripping of condensate (moisture) from hard items.
- Place trays containing packs of instruments in a way that will ensure even distribution of instruments and facilitate proper drainage. If the tray has holes in the bottom, place it flat on the shelf. If the tray does not have holes in the bottom, place it tilted on its side.
- Stand utensils, basins and treatment trays on their sides.
- Place linen packs so that the layers within are perpendicular to the shelf (not sitting flat, one on another) for more efficient air removal, steam penetration and evacuation for drying.
- Do not allow items to touch chamber walls where they could get in contact with condensate and become wet or get too hot and burn.
- Use sterilizable baskets to contain small items on sterilizer shelves/carts.
- Instruments sets should not exceed 8 kg (18 lb). Basin sets should not exceed 3 kg (7 lb). Linen packs should not exceed 30 x 30 x 50 cm (12 x 12 x 20 in) in size and should weigh no more than 5 kg (12 lb) in order to assure steam penetration of the pack.

Sterilization temperature, pressure and timing

- Sterilize at a temperature of 121°C (250°F) and at a pressure of 106 kPa (15 lb/in²) for 20 minutes for unwrapped items and 30 minutes for wrapped items. If using a mixed load, sterilize for 30 minutes. Start timing when required temperature and pressure have been reached.

- When time is complete, turn off heater and release the pressure valve. Wait until the pressure gauge reads zero (approximately 20 to 30 minutes) to prevent steam from escaping abruptly when opening the door and hurting the person performing the procedure.
- Open the door 12-14 cm (5-6 in), soon after the pressure gauge reads zero. Stand behind the door while opening it to prevent burning yourself with escaping steam.

If using a pressure-cooker type of autoclave, bring water to boil over an electric or kerosene burner until steam escapes from the pressure valve; turn down heat just enough to keep steam coming out of the pressure valve. Ensure that steam escapes only from the pressure valve and not from either the safety valve or from under the edge of the lid. Do not allow to boil dry.

Unloading

- Allow items to dry completely before removal, which may take at least 30 minutes after opening the door. Damp packs act like a wick, drawing in bacteria, viruses and fungi from the environment. Wrapped instruments are considered unacceptable if there are water droplets or visible moisture on the package exterior when removed from the autoclave chamber.
- Do not place sterile trays on cold surfaces or stack them one upon another until they are completely cool because condensation may occur beneath or between them. Place them on surfaces padded with paper or fabric.

Wrapped items can be stored for up to 7 days, provided that they are kept dry. Unwrapped items must be used immediately, or placed in a closed sterile container for use within 7 days, but they should be used within 24 hours once the container is opened again.

Dry heat sterilization

A commercial sterilizer with a fan is recommended for carrying out dry heat sterilization, but it can be done in an ordinary household oven using electricity or another fuel source. Dry heat sterilization is ideal for reusable needles and syringes as it does not dull sharp points and edges as much as autoclaving. It is good in humid climates as it eliminates “wet

pack” problems. Dry sterilization can be an option for metal or glass items. It should not be used for linen, plastic or rubber as these can burn or melt.

- Decontaminate, clean and dry all instruments to be sterilized.
- If necessary, wrap instruments in cotton muslin or aluminium foil. Take care that the temperature in the oven does not exceed 204°C (399°F) if you are using cotton muslin. If the temperature cannot be carefully controlled, do not use muslin.
- Sterilize at 170°C (340°F) for 1 hour. Start timing once the oven has reached the temperature of 170°C. (Total cycle-time is 2-21/2 hours, which includes placing instruments in the oven, heating to 170°C, timing for 1 hour and then cooling.)
- Sterilize at 160°C (320°F) for 2 hours (total cycle-time 3-31/2 hours) if sterilizing needles or other instruments with cutting edges, because higher temperatures tend to dull sharp edges.
- Remove packs after cooling and store for up to 7 days in covered sterilized containers (unwrapped items should be removed with sterile forceps/pickups and used immediately) or placed in a closed sterile container for use within 7 days, but they should be used within 24 hours once the container is opened again.

Chemical sterilization

Chemical sterilization is also called “cold sterilization”. Disinfectants such as 2% glutaraldehyde and 8% formaldehyde are used for chemical sterilization. When instruments are soaked for prolonged periods (10-24 hours) endospores are killed. **Warning: The vapours of both these chemicals are irritating to the skin, eyes and respiratory tract. Formaldehyde is more toxic, although less expensive, than glutaraldehyde. Both chemicals should be used in a well-ventilated area.**

Indications

- When steam or dry heat sterilization equipment is not available.
- When steam or dry heat sterilization would damage objects (e.g., laparoscope).

Procedures

- Wear thick household gloves.
- Decontaminate, clean and dry all items to be sterilized.
- Use a clean container with a lid. Open jointed items, such as scissors and forceps, and disassemble items composed of more than one part. Cover the items completely with the solution.
- Soak the items in 2% glutaraldehyde solution for at least 10 hours or in 8% formaldehyde for 24 hours.
- Remove objects from the solution with sterile forceps/pickups.
- Rinse well with sterile water as both chemicals leave a residue on treated instruments. Do not use boiled water, since it does not reliably inactivate endospores and can recontaminate sterile instruments.
- For procedures such as male or female sterilization, insertion or removal of implants and IUD insertion, instruments can be used wet immediately after cooling, or air dried and stored in a covered disinfected container for use within 24 hours.
- For procedures such as pelvic examination, instruments do not need to be sterile or disinfected at the time of being used. These instruments, however, should be sterilized or disinfected between cases. They should be stored and handled in the conditions required to keep them clean, but not necessarily sterile or disinfected. Air dry these items or dry them with a clean towel before use or storage. If the items are towel dried, the towel should be used only for this purpose and replaced every day, or sooner if necessary.

5 Processing of individual items

5.1 Pelvic examination tabletop or other large surface areas

- Wash with detergent and water every day. Make sure that no organic material remains.
- Whenever there is any spill of body fluids (e.g., blood) decontaminate and clean between clients by wiping with a cloth soaked with 0.5% chlorine solution and wash.

5.2 Linens for surgical procedures (caps, masks, gowns and drapes)

- Wear gloves to handle soil linen.
- Decontaminate by soaking all items in a decontaminant solution (see section 4.1).
- Wash with detergent and water.
- Air or machine dry.

No further action is necessary for caps and masks.

- Check surgical gowns and drapes wraps for holes after they are completely dry. If there are holes, the item should be repaired before use or discarded.
- Wrap the linen using two double thickness wraps of muslin cloth (140 thread count) or two wraps of paper (newsprint). **Packs should not exceed 30 x 30 x 50 cm (12 x 12 x 20 in) in size and weigh no more than 5 kg (12 lb) in order to allow proper steam penetration.** Alternatively, linen can be placed unwrapped in an autoclaving drum.
- Sterilize by autoclaving.
- Linen wrapped in muslin or paper, or linen autoclaved inside a drum without a wrapping, can be kept for 1 week. However, once a drum containing unwrapped linen is opened, the material inside should be used within 24 hours. Store sterile linen in a dry place, free from dust and insects, preferably in a cabinet or in a container. In order to protect linen, do not store it near areas that are frequently mopped or near a sink.

If linen becomes wet or has not been used within 1 week, it should be autoclaved again.

5.3 Gloves (rubber or plastic)

For surgical procedures

It is best to use sterile gloves for any invasive procedure (e.g., sterilization or insertion/removal of implants). If sterile gloves are not available, high-level disinfected gloves are the only acceptable alternative.

Do not use powder when putting on sterile or high-level disinfected gloves, as the tiny powder granules (talc) may fall into the insertion/incision site and cause a fibrous reaction.

For non-invasive procedures

Sterile or disinfected gloves are not necessary to perform non-invasive procedures (e.g., pelvic examination or the no-touch technique for IUD insertion or removal). New, non-sterile, single-use (disposable) gloves are adequate. However, **if using reusable gloves, sterilization or HLD is required between clients to prevent cross-infection**. These gloves can then be stored in a way which will keep them clean, but not necessarily sterile or disinfected.

Processing reusable gloves

- Decontaminate by soaking in 0.5% chlorine solution.
- Wash with detergent and water.
- Rinse with clean water and check for holes by filling the gloves with water and looking for leaks.

Sterilization

The most practical way to sterilize gloves is by autoclaving.

- Dry the gloves inside and outside and fold the cuffs out so that sterilized gloves can be put on without contamination. Put gauze inside each glove and under the fold of the cuff to allow steam to contact all surfaces during sterilization and also to prevent surfaces from adhering to each other.
- Pack the gloves in a double-thickness muslin (140 thread count) or paper wrapper, or newsprint. If a drum is used, do not pack too many gloves in it.
- Steam sterilize according to instructions provided in section 4.4.
- Do not use gloves for 24-48 hours after sterilization, to allow them to regain their elasticity before use.

High-level disinfection (HLD)

HLD can be done by boiling.

- After boiling, remove gloves with disinfected forceps and shake off excess water. Never leave boiled gloves in water which has stopped boiling. As water cools down and steam condenses, air and dust particles may be drawn into the container and contaminate the gloves.
- Place the gloves in a disinfected container. Cover and allow to cool before using.
- Use disinfected forceps to remove gloves from the container.
- For invasive procedures, use wet gloves immediately. Do not store them, as it is difficult to avoid contamination while drying.
- Gloves which will be used for non-invasive procedures and do not need to remain disinfected can be dried with a clean towel used only for this purpose and replaced every day, or sooner if necessary. These gloves can be stored in a clean container.

5.4 Instruments for pelvic examination

For pelvic examination, instruments do not need to be sterile or disinfected at the time of being used. These instruments, however, should be sterilized or disinfected between cases.

- Decontaminate and clean (see sections 4.1 and 4.2).
- Sterilize or disinfect (see sections 4.3 and 4.4). If disinfection is used, dry instruments before use or storage.
- Handle and store in the conditions required to keep the instruments clean, but not necessarily sterile or disinfected.

5.5 Instruments for male and female sterilization (except laparoscope), insertion and removal of implants and IUD insertion

- Decontaminate and clean (see sections 4.1 and 4.2).
- Sterilization is recommended (see section 4.4).
- If sterilization is not possible, high-level disinfection by boiling or by a chemical method is the only acceptable alternative (see section 4.3). If instruments are disinfected, use them wet immediately after cooling, or air dry and store them in a covered disinfected container for use within 24 hours.

5.6 Endoscopes (laparoscopes)

Clean endoscopic equipment immediately after use.

- Wearing utility gloves, disassemble and place all the parts in a basin of clean water and mild non-abrasive detergent. Wash all outer surfaces, using a soft cotton cloth. Clean inner channels with a cleaning brush supplied with the laparoscopic kit.
- Rinse thoroughly with water to remove detergent, which can interfere with chemical disinfection/sterilization.
- Dry by air or with a clean towel (water from wet instruments will dilute chemicals used for sterilization or disinfection).

After cleaning, the laparoscope can be either chemically disinfected or chemically sterilized. HLD is normally used between cases performed during the same day or working session. Sterilization is recommended at the end of the day or working session.

- Chemically disinfect by soaking for 20 minutes in 2% glutaraldehyde or 8% formaldehyde.
- Sterilize by soaking for 10 hours in 2% glutaraldehyde or 24 hours in 8% formaldehyde.

If sterilization is not possible at the end of the day, clean the laparoscope and wash the inner channel with alcohol to facilitate drying of the channel. Leave it until the day it will be used again, when it should be chemically disinfected before use.

5.7 Needles and syringes

Ideally, disposable needles and syringes should be used. These needles and syringes should not be reprocessed and used again. They should be properly discarded after a single use (see section 8.5).

However, some programmes may find it difficult to maintain a reliable supply of disposable syringes and needles, and have to rely on reusable ones.

Processing reusable syringes and reusable needles

- Wear utility gloves.
- Decontaminate immediately after use:
 - Fill assembled needles and syringes with 0.5% chlorine solution and soak them in the solution for 10 minutes;
 - Then rinse by flushing them 3 times with clean water.
- Disassemble, then wash with detergent and water, removing all particles.
- Rinse with water.
- Air or towel dry syringes and air dry needles before sterilization. If disinfection will be done by boiling, drying is not required.
- Sterilize glass syringes by dry heat or autoclave (for details see section 4.4).
- If sterilization is not possible, disinfect by boiling (for details see section 4.3).

5.8 Storage containers for instruments

- If a container is contaminated with blood or body fluids, decontaminate it by soaking in a 0.5% chlorine solution for 10 minutes and rinse immediately after decontamination.
- Wash with detergent and water, removing all particles.
- Sterilize by dry heat or autoclave, OR
- Disinfect:
 - Boil container and lid.
 - If container is too large to boil, chemically disinfect by filling it with 0.5% chlorine solution and soak for 20 minutes.
- Re-sterilize or re-disinfect weekly, when empty or contaminated.

5.9 Water

High-level disinfection (HLD)

Disinfected water can be prepared by boiling. It is best to filter water before boiling if the water is obviously dirty. Boiled water could be needed to rinse chemically HLD items.

6 Storage of sterilized or disinfected equipment

Sterilized or disinfected equipment should be stored in enclosed shelves or in covered containers to protect it from moisture, dust and debris. The storage area should be easily accessible, but away from circulation of contaminated material and individuals not related to the preparation or handling of equipment and materials. It should also be separate from the area where contaminated material is cleaned and prepared for sterilization or disinfection.

- Store when packs reach room temperature (usually takes about 1 hour).
- Do not place warm packages in plastic dust covers. Moisture will be trapped and remain there until opened.
- If the pack is dropped, tears or gets wet, consider it contaminated.
- Mark packs and containers used for storing sterile or disinfected items with the expiry date, a list of contents items and the name of the person who sterilized or disinfected the material. Store packs and sterile containers (drums) for up to 1 week.
- Store packs and containers (drums) containing sterile items off the floor.
- Re-process objects which have not been used within 1 week. Linen must be wet before autoclaving again, in order to restore moisture, because dried out fibres decrease the ability of the cloth to form a barrier to micro-organisms.
- If sterile or disinfected articles are dispensed from a central supply department to the service delivery areas of a large facility, or from one service facility to another, or if they are used in mobile clinics, cover all items properly during transport.
- Remove supplies from all shipping cartons and boxes before storing them with other sterile material or bringing them into the procedure room. Cardboard boxes shed dust and debris and may harbour insects.
- Use unwrapped items immediately or place them in a closed sterile/HLD container for use within 1 week. However, once the container is open, all the items in the container should be used within 24 hours or sterilized or given HLD again.

7 Care during procedures

7.1 Handwashing

Handwashing may be the single most important infection prevention procedure.

Indications

- Before and after examining a client, especially when touching mucous membrane.
- Before putting on sterile or high-level disinfected gloves for a surgical procedure (surgical handscrub).
- After removing gloves, as they may have invisible holes or tears.
- After handling contaminated objects, such as used (soiled) instruments (even though gloves should be used).
- When accidentally touching blood or other body fluids (e.g., when collecting laboratory specimens).

Staff giving injections should keep their hands clean, although handwashing between procedures is not always required.

Ensure that the following items are available:

- *Soap:* Use plain soap for routine handwashing. If bar soap is used, provide small bars and soap racks which drain. Micro-organisms multiply in moisture and standing water.
- *Clean running water:* If no running water is available, use a bucket with a tap or a bucket and pitcher. If the available water is not clean, filter the water through a cloth and/or boil it.
- *Drain for disposal of used water:* If a drain is not available, collect used water in a basin and discard in the toilet.
- *Clean, dry towels.*

For surgical handscrub, the following items are also required:

- Sterile towels.
- Stick or brush for cleaning fingernails.
- Soft brush or sponge for cleaning the skin.
- Antiseptic soap.

Technique

For non-surgical procedures (e.g., examination of a client, pelvic examination and insertion/removal of IUD):

- Wash hands briefly with plain soap for about 15-30 seconds; then rinse in a stream of water. Dry hands with a clean towel or air dry. Shared towels easily become contaminated.

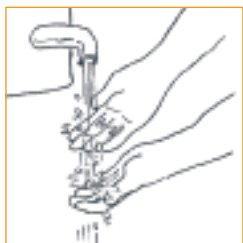
For surgical procedures (e.g., laparoscopy, minilaparotomy, vasectomy, or insertion and removal of implants):

- Remove all items of jewellery, including wristwatch.
- Wash hands with an antiseptic soap for 3 to 5 minutes:
 - Clean fingernails with a brush or stick.
 - Scrub hands with a soft brush or sponge. Begin at the fingertips, wash between all fingers and move towards the elbow.
 - Repeat for the second hand.
- Rinse each arm separately, fingertips first, holding hands above the level of the elbows to prevent water running down from the elbow to the hands.
- Dry hands with a sterile towel.
- After handwash has been completed, hold hands above the level of the waist.
- Repeat handwashing if hands touch any unsterile object before gloves are put on. However, if this happens while wearing gloves, just change the glove.

If antiseptic soap is not available, wash hands with plain soap and water, then rub hands for 2 minutes with an alcohol solution containing an emollient. Allow alcohol to dry for antiseptic effect. This procedure is particularly indicated for personnel with allergies to antiseptics or detergents.

The solution can be prepared by adding 2 ml of either glycerine, propylene glycol or sorbitol to 100 ml of 60%-90% alcohol.

Figure 15.2 Steps for non-surgical procedures



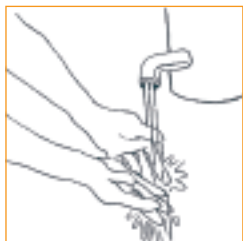
Wet hands with running water.



Rub hands together with soap and lather well. Make sure to rub all parts of your hands.



Vigorously weave fingers and thumbs together and slide them back and forth for 15-30 seconds (longer if hands are visibly soiled).



Rinse hands under a stream of clean, running water until all soap is gone.



Dry hands with a clean towel or allow hands to air-dry.

7.2 Gloving

Gloves should be worn by all staff prior to contact with blood and body fluids, either when dealing with a client or when handling contaminated equipment and material. Gloves may be made of latex or synthetic material such as vinyl. Vinyl examination gloves are weaker and tear more easily than latex, but are an acceptable alternative for non-invasive procedures when latex gloves are not available.

Indications

Sterile gloves: Sterile gloves are preferable for surgical procedures.

Disinfected gloves: Disinfected gloves can be used wet, soon after disinfection, for surgical procedures when sterile gloves are not available.

Non-sterile gloves: Clean non-sterile gloves are adequate for non-surgical procedures such as:

- IUD insertion (when no-touch technique is used).
- IUD removal.
- Pelvic examination.

Disposable non-sterile examination gloves or reusable gloves can be used. If reusable gloves are used for the above procedures, it is necessary to sterilize/disinfect them between clients to prevent cross-infection, although they do not need to remain sterile/disinfected at the time of use.

For details of disinfection and sterilization procedures see sections 4.3 and 4.4.

Utility gloves

These thick rubber gloves are specially made to resist frequent and rough use. They are normally inexpensive and often used in household duties.

Indications

- Handling used instruments (e.g., during decontamination, transportation and cleaning).
- Cleaning spills of blood or body fluids.
- Handling waste material.

Do not use gloves which are cracked, peeling or have detectable holes or tears.

Figure 15.3 Steps for putting on surgical gloves



Prepare a large, clean, dry area for opening the package of gloves. Either open the outer glove package and then perform a surgical scrub, or perform a surgical scrub and ask someone else to open the package of gloves for you.



Open the inner glove wrapper, exposing the cuffed gloves with the palms up.



Pick up the first glove by the cuff, touching only the inside portion of the cuff (the inside is the side that will be touching your skin when the glove is on).



While holding the cuff in one hand, slip your other hand into the glove. (Pointing the fingers toward the floor will keep the fingers open). Be careful not to touch anything, and hold the gloves above your waist level.



Pick up the second glove by sliding the fingers of the gloved hand under the cuff of the second glove. Be careful not to contaminate the gloved hand with the ungloved hand as the second glove is being put on.



Put the second glove on the ungloved hand by maintaining a steady pull through the cuff. Adjust the fingers and cuffs until the gloves fit comfortably.

7.3 Injection procedures

- Wash hands thoroughly with soap and water.
- Use a single-use (disposable) needle and syringe as a first choice. If this is not possible, a reusable syringe and needle can be used provided these have been properly sterilized or disinfected by boiling.
- If using a boiled needle and syringe, remove the needle and syringe from the covered container with dry, disinfected forceps/pickups.
- Always change the needle and syringe for each client. Changing only the needle, and not the syringe, between clients can result in transmission of infection (hepatitis B, HIV and others).
- Use a single-dose vial, whenever possible. If using a multi-dose vial:
 - Avoid the practice of leaving one needle inserted in the vial cap for multiple uses. This dangerous practice provides a direct route for micro-organisms to enter the vial and contaminate the fluid between each use.
 - Wipe the top of the vial with a cotton swab soaked in 60%-90% alcohol and allow to dry before extracting each dose.
- Draw the fluid into the syringe. Use the same needle you will use for the injection.

8 Environment

It is important to reduce the level of microbial growth and contamination in the clinic, especially in the following areas:

- *Procedure areas*: where clients are examined, IUDs are inserted/removed, implants are inserted/removed and vasectomies are performed.
- *Surgical areas*: where minilaparotomy, laparoscopy and other ambulatory surgical procedures are performed.
- *Work areas*: where instruments, linen, gloves and other equipment are cleaned, disinfected or sterilized and stored.

This can be accomplished by:

- Keeping these areas clean.
- Minimizing traffic flow.
- Handling and disposing of waste properly.

8.1 Cleaning of activity areas

Detergent and water are required for cleaning most activity areas.

For operating theatres and areas where heavy contamination is expected, such as toilets, and for sites with blood and body fluid spills, a disinfectant cleaning solution is also required.

A disinfectant cleaning solution can be made as follows:

- Add enough liquid detergent to a 0.5% chlorine solution to make a mild soapy solution.

Warning:—Do not use a cleaning solution or detergent which contains an acid (e.g., phosphoric acid), ammonia or ammonium chloride because, when mixed with a chlorine solution, these compounds produce gases which may result in temporary illness in exposed persons.

General guidelines

- Always wear utility gloves, especially for cleaning heavily contaminated areas such as toilets, and spills of blood and body fluids. If gloves are not available, use a plastic bag over the hand or keep hands out of direct contact.
- Frictional cleaning (scrubbing) is the best way to remove dirt and micro-organisms.
- Use a damp or wet cloth or mop for walls, floors and halls. Avoid dry sweeping as this will spread dust and micro-organisms into the air and onto clean surfaces.
- Use separate equipment (brushes, cloths) for surgical areas.
- Also use separate equipment (brushes, cloths) for areas which are likely to be contaminated (e.g., toilets).
- Change cleaning solutions when they are obviously dirty.
- Clean and dry mops and cloths between use.
- Wash from top to bottom, so that debris which falls on the floor will be cleaned up last.

Do not use disinfectant fogging (fumigation with formalin) to reduce microbial contamination of environmental surfaces such as walls, ceilings and floors. Fumigation with formalin or other chemicals is ineffective and results in release of toxic fumes. In addition, this practice is time consuming (it requires 24 hours), making working areas such as

operating theatres or treatment rooms unavailable. Scrubbing with soap and water is a safe, quick and effective way to reduce microbial contamination of these surfaces.

Cleaning of non-surgical areas

Walls, ceiling and furniture/equipment

For areas such as treatment and procedure rooms, laboratories etc., routine wiping of walls and ceiling with a damp cloth at least every month is adequate. Chairs, lamps, tabletops and counters should be wiped daily. Whenever soiled, or visibly dirty, any surface or furniture/equipment item should be cleaned with detergent and water. Use a disinfectant (0.5% chlorine solution) when contamination is expected, such as for blood spills.

Floors

Clean floors at least twice a day as needed with a damp mop, detergent and water. Use a disinfectant (0.5% chlorine solution) when contamination is expected, such as for blood spills.

Sinks

Use a disinfectant cleaning solution. Scrub daily or more often as needed with a separate cloth or brush. Rinse with water.

Toilets and latrines

Wear gloves. Clean daily or more often as needed with a disinfectant cleaning solution. Use a separate cloth or brush.

Waste containers

Wear gloves. Use disinfectant cleaning solutions. Scrub to remove soil and organic matter. Clean contaminated containers after each emptying. Clean non-contaminated waste containers at least once a week or more often if visibly soiled. Use a brush with a handle to prevent hand injury with any sharp materials which may have been left in the container.

Cleaning of operating room/theatre

Daily cleaning

At the beginning of each working day wipe all horizontal surfaces (tables, lights, trolleys etc.) with a damp cloth to remove dust which may have collected overnight.

At the end of each working day scrub all surfaces:

- Wipe any visible soil from walls and ceilings with a damp cloth, detergent and water.
- Wipe lamps, chairs, sinks, tabletops and counters with a damp cloth and disinfectant cleaning solution.
- Decontaminate operating tabletop with 0.5% chlorine solution. Clean sides, base and legs with a damp cloth and disinfectant cleaning solution.
- Clean floors with a damp mop, detergent and water.

Do not dry mop or sweep the operating room. This causes dust, debris and micro-organisms to rise and contaminate clean surfaces.

Between each client:

- Decontaminate operating table, instrument trolley and other potentially contaminated surfaces with cloth dampened with 0.5% chlorine solution and rinse with clean water.
- Clean spills with 0.5% chlorine solution. For large spills, flood area with 0.5% chlorine solution, mop up solution and then clean with detergent and water.

Cleaning of soiled and contaminated cleaning equipment

- Use utility gloves.

8.2 Traffic flow

Procedure areas

- Limit entry to only authorized personnel and clients at all times.
- Close doors and curtains during all procedures.

Surgical areas

- The operating theatre should be located away from areas of the clinic which are frequently passed through by staff and clients.
- Keep all doors closed in the surgical support area and operating theatre.

The operating theatre should be locked when not in use. Never use it as a store room.

- Limit entry to only authorized personnel and clients at all times.
- Whenever possible, arrange space so that personnel entering the surgical area enter via the clothes changing room.
- Personnel should wear surgical gown, cap, shoe covers or shoes not worn outside the surgical area.
- During surgical procedures, permit only those persons who are assisting with the procedure, and limit the number of trainees.
- Keep the number of people and movement to a minimum.

8.3 Processing area for instruments and other items

- Permit only authorized personnel.
- Separate the receiving/clean-up area from the clean work area by either a wall and door or a screen. If this is not possible, the receiving/clean-up area should be well away from the area where sterilization and disinfection are done.
- Dirty/unclean items should never cross paths with clean and fully processed items.

Equipment: Receiving/clean-up area

- A counter for receiving used (dirty/unclean) items.
- Ideally two sinks (one for cleaning and another for rinsing) with adequate water supply.
- A counter for placing cleaned items.

Equipment: Work area for sterilization and disinfection

- Large worktable.
- Shelves for holding clean and packaged items.
- Autoclave or hot air oven, boiler, and/or supplies for chemical disinfection/sterilization.

Note: See section 6 for guidelines on the storage of sterile or disinfected equipment.

8.4 Transport of clean, disinfected, sterile and soiled items

- Keep clean, disinfected and sterile supplies separate from soiled equipment and waste. (Do not transport or store together.)
- Transport disinfected and sterile instruments, equipment and linens to the procedure and operating rooms with a cover to prevent contamination.
 - If supplies are being delivered to the surgical area, the delivering person, standing outside, should pass them through the door to a person on the inside.
- Remove supplies from all shipping cartons and boxes before bringing them into a procedure room, operating theatre, the work area for sterilization and disinfection, or storage room. Shipping boxes shed dust, harbour insects and may contaminate these areas.
- Transport soiled (used) supplies and instruments to the receiving/clean-up area in covered, leak-proof decontamination buckets.

8.5 Waste disposal

Wastes from SRH/family planning and other health care facilities may be contaminated with organic material which may carry organisms potentially infectious to the persons who handle them and to the community at large. These contaminated wastes should be disposed of properly. Members of the community are at risk because disposed wastes may be accessible to the public, children who are playing may pick up wastes from disposal sites, or adults may use them or sell them.

Proper disposal of clinic wastes must be done to:

- Prevent spread of infection to personnel who handle the waste and to the local community.
- Protect those who handle wastes from accidental injury.
- Preserve an aesthetically pleasing environment.

Persons handling wastes should wear heavy-duty gloves.

Transport contaminated waste in covered, leak-proof waste containers to the disposal site. Contaminated clinic wastes should be incinerated (burned) and/or buried.

Incineration provides high temperatures and destroys micro-organisms and therefore, is the best method for disposal of contaminated wastes. Incineration also reduces the bulk of wastes. If incineration is not possible, all contaminated wastes must be buried to prevent scattering.

Do not pile contaminated wastes behind the clinic because this practice puts staff and members of the community at risk.

Handling waste containers

- Use non-corrosive washable containers (plastic or galvanized metal) with covers for contaminated wastes.
- Place waste containers in convenient places for users. Carrying waste from place to place increases the risk of infection for handlers.
- Equipment which is used to hold and transport wastes must not be used for any other purpose in the health care facility.
- Wash all waste containers with a disinfectant cleaning solution (0.5% chlorine solution) and rinse with water. Clean contaminated waste containers each time they are emptied and non-contaminated ones when visibly soiled.
- When possible, use separate containers for combustible and non-combustible waste. This prevents workers from having to handle and separate wastes by hand later.
 - *Combustible (burnable) wastes* include paper, cardboard and contaminated waste such as used dressings and gauze.
 - *Non-combustible (non-burnable) wastes* include glass, metals and plastics.
- Use heavy work gloves when handling wastes.
- Wash hands after handling wastes.

Disposal of sharp objects (needles, razors and scalpel blades)

Sharp objects are the most dangerous type of clinical waste and must be handled and disposed of with strict care.

- Wear thick, household gloves when handling used sharp objects.
- Dispose of all sharp items in a puncture-resistant container. Puncture-resistant containers can be made of easily available objects, such as heavy cardboard boxes, tin cans with lids, or heavy plastic bottles.

Trainers and programme supervisors should assist service providers in identifying suitable, locally available containers.

- Place the container close to the area where it will be used so that workers do not have to carry sharp items any unnecessary distance before disposal.
- Avoid accidental needlestick injuries. Do not recap, bend or break needles prior to disposal. Drop the disposable syringe with uncapped needle attached in the puncture-resistant container. (For guidance on re-processing of reusable syringes and disposal of disposable needles, see section 5.7.) Every effort should be made to provide puncture-resistant containers. However, if that is not possible, then recapping will be necessary. A one-handed recap method should be used as follows:
 - First, place cap horizontally on a hard, flat surface; then remove hand.
 - Next, with one hand, hold the syringe and “scoop-up” the cap with the needle.
 - Finally, when the cap covers the needle completely, press the tip of the cap against a hard surface to secure the cap on the needle.
- When the sharps container is three-quarters full, cap, plug or tape it tightly closed.
- Dispose of container when three-quarters full, ideally by incineration (burning).

When an incinerator is not available, the following method may be used:

- Use a small tin drum (like a bucket) as the puncture-resistant container. When the tin is half full, pour a small amount of fuel over the sharps and burn it. The plastic syringes melt, forming a plastic blob with the needles and other sharps inside. The blob can be easily removed and buried or thrown with precaution.

When plastic syringes are not disposed of inside the container (e.g., when only reusable syringes are used), place pieces of plastic (used bottles, catheters etc.) inside the container on top of the sharps so that a plastic blob can be formed when burning.

- If using plastic or cardboard puncture-resistant containers, place the closed container inside a large tin drum, pour fuel over the container and burn as described above.

Disposal of liquid and semi-solid contaminated wastes (blood, faeces, urine and other body fluids)

- Wear thick household (utility) gloves when handling and transporting wastes.
- Carefully dispose of faeces and urine in a flushable toilet/latrine. Blood and other liquid waste should be poured into a utility sink, a flushable toilet or a latrine. Avoid splashing.
- Decontaminate the sink/toilet with 0.5% chlorine solution.
- Wash the sink/toilet carefully and thoroughly with water to remove residual wastes. Avoid splashing.
- Decontaminate specimen container with an appropriate decontamination solution. such as 0.5% chlorine solution, by soaking for 10 minutes before washing.
- Wash hands after handling liquid wastes; decontaminate and wash gloves.

Disposal of solid wastes (used dressings and other items contaminated with blood and organic materials)

- Wear thick household (utility) gloves when handling and transporting wastes.
- Dispose of solid wastes in non-corrosive washable containers (plastic or galvanized metal) with tight-fitting covers.
- Collect the waste containers on a regular basis and transport the combustible wastes to the incinerator. If incineration is not available, bury. Bury non-combustible wastes.
- Using a disinfectant cleaning solution (see section 8.1), clean waste containers each time they are emptied.
- Wash hands after handling wastes; decontaminate and wash gloves.
- Burn or bury waste immediately before it can spread into the environment. Incineration is the best method to kill organisms.

Disposal of used chemical containers

Glass containers

Rinse glass containers thoroughly with water. Glass containers may be washed with detergent, rinsed and reused.

Plastic containers

Plastic containers which have held substances such as antiseptic or disinfectant solutions can be washed and reused as containers for disposal of sharp items.

Those which have contained irritant substances such as glutaraldehyde (e.g., Cidex or Sporidicin) should be disposed of by burning or burial. If that is not possible, they should be damaged in a way that will prevent them from being reused (e.g., break the bottom).

9 Prophylactic antibiotics

The routine use of prophylactic antibiotics for contraceptive sterilization, IUD insertion or insertion of implants is not necessary when recommended infection prevention practices are conscientiously followed. The inappropriate use of antibiotics increases the prevalence of antibiotic-resistant micro-organisms that can cause infection, and is costly.

However, there are some specific situations in which the use of prophylactic antibiotics may be indicated:

- Clients who are susceptible to infection, such as individuals who have diabetes mellitus or HIV infection, or who are receiving treatment with steroids.
- Clients at risk of bacterial endocarditis, such as individuals with structural heart conditions.

10 Management

Successful infection prevention in SRH/family planning and other health care facilities requires careful planning and efficient management. It includes:

- Administration.
- Provision of guidelines.
- Training.
- Monitoring and supervision.

10.1 Administration

Programme managers should ensure that a system is in place for the prevention of infection by:

- Making decisions about equipment and supplies which are required to maintain acceptable levels of safety. These decisions should take into consideration cost, training needs and logistical implications.
For example:
 - Appropriate selection of gloves, needles and syringes (disposable vs reusable) and provision of facilities for the processing of reusable material.
 - Provision of facilities for sterilization and/or disinfection of equipment and materials based on the type of procedures performed and the workload. Service delivery sites in which invasive procedures are routinely performed should have facilities for the sterilization of equipment, or access to such facilities.
- Ensuring availability of:
 - Clean fresh water.
 - Electricity and/or fuel.
 - Antiseptics and decontaminants.
 - Gloves (examination, surgical and/or utility).
- Ensuring that back-up staff are available and trained to replace staff who are on leave or temporarily incapacitated (e.g., staff in the operating theatre who are suffering from colds or other infections, staff responsible for sterilization procedures who have cuts or sores on their hands or forearms). Assigning other duties to incapacitated staff until they recover from their problem.
- Ensuring that routine procedures for cleaning (and decontamination, when appropriate) of the physical facilities (e.g., operating theatre and examination rooms) are in place and followed.
- Ensuring the proper use and maintenance of equipment, such as autoclaves.
- Ensuring proper disposal of contaminated material by:
 - Providing puncture-resistant containers for used disposable needles and other sharp materials.
 - Ensuring that there is a site and equipment for incineration and/or burial of contaminated material. If that is not possible, ensuring that the material is made safe by decontamination before disposal.

- Ensuring the safe removal/transportation of contaminated material to the disposal site.
- Ensuring that disposable materials (such as gloves, syringes and needles) are not used again.
- Carrying out any necessary repairs in the physical facilities which are necessary for preventing infection (e.g., repairing damp walls).
- Developing good communication with staff at all levels, sharing ideas and listening to their viewpoints.

10.2 Guidelines

Written policies and procedures should be established for infection prevention. These should be presented as guidelines in a language and format that facilitates their understanding by all relevant staff.

- Guidelines should be accessible to all members of the staff, and they should be discussed periodically.
- Relevant extracts of the guidelines can be provided to individuals performing specific tasks. Some of the information can be outlined in posters as reminders and located where the tasks are performed.
- Guidelines should be used or referred to during training and supervision activities.
- Regular reviews should be conducted to ensure the adequacy of the recommended infection prevention practices, and to address any staff concerns about them.

10.3 Training

Training of health care staff is important to help them to understand the risk of infection both to themselves and to clients, and the role that protective barriers and prior infection prevention practices can play in preventing the transmission of infection. It is possible to ensure proper work habits related to infection prevention if staff understand the reason for, and importance of, the procedures.

Training should include pre-service training for new employees and in-service training for current staff.

Pre-service training

The training programme should be developed after identifying the needs of the participants and of the programme. It should include:

- *General aspects of infection prevention for all new clinical staff.* The following topics should be covered:
 - The mechanisms of infection transmission in a clinical environment.
 - The role of each staff member in preventing transmission of infection.
 - Methods to minimize disease transmission. Emphasis should be given to knowledge about the transmission of HIV/HBV infection. Without sufficient information, staff are more likely to take preventable risks (e.g., not adequately decontaminating, cleaning and sterilizing reusable needles and syringes) or excessive precautions (e.g., washing hands after shaking hands with people believed to be HIV-infected).
- *Specific aspects of infection prevention for staff according to job description.* For example, staff who will decontaminate and sterilize equipment should be taught these procedures; staff who will insert IUDs need training in aseptic technique.

At the end of the training period, the trainer should assess the performance of each trainee until he or she achieves the training objective.

In-service training

In-service training should be provided for the following purposes:

- Refresher training to provide general reminders of the importance of and procedures for maintaining an infection-free environment.
- Update training to introduce and discuss changes in policies and practices (e.g., if new equipment is introduced, a training session for those individuals who will be using it is essential).
- Training in response to needs identified during monitoring and supervision.

10.4 Monitoring and supervision

Regular monitoring of infection prevention processes is important to determine areas which need to be improved. To monitor performance:

- Spot check to determine if infection prevention guidelines are being followed. When discrepancies or problems are noted, supervisors should be able to provide guidance or assistance with solving problems.
- Observe the conditions and adequacy of physical facilities, and note whether the necessary equipment and supplies are available and are being used properly.

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ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ARVs	Antiretroviral drugs
BBT	Basal body temperature
BMI	Body mass index
BP	Blood pressure
BSE	Breast self-examination
CBS	Community-based services
CICs	Combined injectable contraceptives
CIN	Cervical intraepithelial neoplasia
COCs	Combined oral contraceptives
D&C	Dilatation and curettage
D&E	Dilatation and evacuation
DMPA	Depot medroxyprogesterone acetate
DVT	Deep vein thrombosis
ECPs	Emergency contraceptive pills
FSH	Follicle stimulating hormone
Hb	Haemoglobin
HBV	Hepatitis B virus
HCG	Human chorionic gonadotrophin
HIV	Human immunodeficiency virus
HLD	High-level disinfection
HPV	Human papillomavirus
HRT	Hormone replacement therapy
HSV	Herpes simplex virus
IUD	Intrauterine device
LH	Luteinizing hormone
LMP	Last menstrual period
MEC	Medical eligibility criteria
MMM	Modified mucus method
MTCT	Mother-to-child transmission

N-9	Nonoxynol-9
NET-EN	Norethisterone oenanthate
OI	Opportunistic infections
PE	Pulmonary embolism
PEP	Post exposure prophylaxis
PID	Pelvic inflammatory disease
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
POIs	Progestogen-only injectable contraceptives
POPs	Progestogen-only pills
RPR	Rapid plasma reagin
RTIs	Reproductive tract infections
SDM	Standard days method
SRH	Sexual and reproductive health
STIs	Sexually transmitted infections
STM	Sympto-thermal method
UTI	Urinary tract infection
VCT	Voluntary testing and counselling
VDRL	Venereal Disease Research Laboratory Slide Test
WHO	World Health Organization

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The International Planned Parenthood Federation (IPPF) is a global network of 149 Member Associations working in 182 countries, and the world's foremost voluntary, non-governmental provider and advocate of sexual and reproductive health and rights.