Contraceptive Updates

Reference Manual for Doctors

December 2004

Department of Family Welfare
Ministry of Health and Family Welfare
Government of India

Preface

Increase in use of modern methods of contraception is resulting in substantive fertility decline. It has been estimated that around the world, over 600 million married women are using contraception. Although there are other direct factors-proportion of women married, post partum insusceptibility, infertility and induced abortion, none of these have changed as much as contraceptive use in past decades.

Quality of care in delivery of contraceptive services plays important influence on method acceptance, continuation and ultimately client satisfaction. Programmes are increasingly emphasizing importance on adhering to service delivery guidelines in provision of contraceptives. The need for evidence-based practice of family planning is acute and also as crucial as in other area of medicine.

The Government of India is planning to organize a series of "contraception updates" seminars for doctors in public and private health care system. A large pool of resource persons from medical colleges, training institutions and professional associations will be engaged as facilitators to conduct these seminars in the districts.

Present reference manual along with facilitators guide and CD will help in standardizing delivery of information in an organised manner in these seminars. I sincerely hope that resource faculty and seminar participants will immensely benefit from this publication. I thank UNFPA for providing necessary technical support in development of the resource material for these seminars.

December 2004

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CHAPTER 1

Introduction

1.1 Reproductive Rights

Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this freedom are:

1. The rights of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law,

2. The right of access to appropriate health-care services that will enable women to safely go through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.

In line with the above definition of reproductive health, reproductive health care is defined as the array of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems. It also includes sexual health, the purpose of which is the enhancement of life and personal relations, and not merely counselling and care related to reproduction and sexually transmitted diseases.

The International Conference on Population and Development (Cairo, 1994), endorsed a rights-based approach to reproductive and sexual health. This includes support for reproductive health services that protect a woman's general health and well-being, that allow for well-informed decisions, and are respectful of individual choices.

Also the Convention on Elimination of All Forms of Discrimination Against Women (CEDAW) General Recommendation 24: Women and Health (1999) affirms that access to health care, including reproductive health, is a basic right under [CEDAW] and is fundamental to women's health and equality. The recommendation says that states parties are responsible to "ensure the removal of all barriers to women's access to health services, education and information, including in the area of sexual and reproductive health," and to "prioritize the prevention of unwanted pregnancy through family planning and sex education and reduce maternal mortality rates through safe motherhood services and prenatal assistance." CEDAW is a treaty binding on 165 countries.

The International Planned Parenthood Federation (IPPF) recognizes and believes that the right to decide whether or when to have children is implied by the right that all persons have to decide freely and responsibly the number and spacing of their children and to have access to the information, education and means to enable them to exercise this right, and further recognizes that special protection should be accorded to women during a reasonable period before and after childbirth.

a. What Are Reproductive Rights?

Attaining the goals of sustainable, equitable development requires that individuals are able to exercise control over their reproductive lives. This includes the rights to:

- Reproductive health as a component of overall health, throughout the life cycle, for both men and women
- Reproductive decision-making, including voluntary choice of marriage, family formation and determination of the number, timing and spacing of one's children and the right to have access to the information and means needed to exercise voluntary choice
- Equality and equity for men and women, to enable individuals to make free and informed choices in all spheres of life, free from discrimination based on gender
- Reproductive security, including freedom from sexual violence and coercion, and the right to privacy.

b. Protecting Reproductive Rights

During the 1990s, a series of important United Nations conferences emphasized that the well being of individuals and respect for human rights should be central to all development strategies. Particular emphasis was given to reproductive rights as a cornerstone of development, and to the empowerment of women as being an important element in ensuring the exercise of these rights.

All major human rights treaties and consensus statements obligate countries to protect and promote rights that relate to reproductive health. Of all human rights documents, the Convention on Elimination of All Forms of Discrimination Against Women (CEDAW), provides the strongest legal support for the right to reproductive health per se. In Article 12, CEDAW guarantees non-discrimination in access to health care, including affordable services and information relating to family planning, pregnancy, and the post-natal period.

Reproductive Rights Provisions in CEDAW

Articles 10 (a) and 10(h) require state parties to take all necessary steps to eliminate discrimination against women in education, and to provide women equal access to educational materials and advice on family planning.

Article 11(2) requires state parties to undertake appropriate measures to prohibit dismissal of women workers on the grounds of pregnancy, to introduce maternity leave, to promote the development of a network of child care and to provide pregnant women with special protection from work that may be harmful.

Article 12 requires state parties to provide women with appropriate services where necessary during the ante and post-natal stages of pregnancy.

Article 12 (1) requires state parties to eliminate discrimination against women in the area of health care and to ensure that men and women have equal access to health care services, including family planning services.

Article 16 requires state parties to eliminate discrimination against women in all matters with regard to marriage and family relations.

Although non-binding, the International Conference on Population and Development, Programme of Action and the 1995 World Conference on Women (Beijing) Plateform for action are highly persuasive consensus statements that confirm the centrality of reproductive rights in advancing the health of populations and the status of women. Beijing in particular recognizes women's right to control their own sexuality and sexual relations and to decide upon these matters on an equal basis with men.

Similarly the IPPF(International Planned Parenthood Federation)Charter on Sexual and Reproductive Rights (http://content.ippf.org/output/ORG/files/6385.pdf) is based on twelve rights that are grounded in core international human rights instruments and additional rights that IPPF believes are implied by them. The Standards section draws heavily on documents that won international consensus at four key UN conferences, which took place between 1993 and 1995, namely the UN World Conference on Human Rights (Vienna, 1993); the UN International Conference on Population and Development (Cairo, 1994); the UN World Summit for Social Development (Copenhagen, 1995); and the UN Fourth World Conference on Women (Beijing, 1995). The Charter represents IPPF's response to the challenge of interpreting human rights language and applying it to sexual and reproductive health care issues.

1.2 Contraceptive Scenario in India

The current trends in family planning in India shows high level of knowledge among eligible couples, yet the acceptance remains low, especially for spacing methods. Female sterilization remains the most widely used family planning (FP) method in spite of efforts to popularise male sterilization. The current unmet need for family planning (1998-1999) is about 15.8 % of which the need for spacing is about 8.3 % and for limiting births is 7.5 %, which needs to be met through programmatic interventions. Poor access to and quality of family planning services are two important issues in catering to the unmet demand. Therefore, the trained family planning providers in both the public and private sectors need to be up-to-date with the recent developments in the contraceptive technology, so that they can provide high-quality family planning services to those who voluntarily want to accept contraception.

a. Background

Contraceptive use has been increasing in India over the last few decades. It is characterised by the predominance of non-reversible methods, limited use of male/couple-dependent methods, considerable levels of discontinuation, and negligible use of contraceptives among both married and unmarried adolescents.

According to official statistics out of the estimated 171 million eligible couples in India, 87 million eligible couples were effectively protected against conception by various contraceptive methods in 2000 (MOHFW 2003). However, at the same time, there is a substantial unmet need for contraception.

b. Ever use of family planning methods

- Although nearly all currently married women know at least one method of contraception, only 55 per cent have ever used a method, up from 47 per cent in NFHS-1 and 48.3 by 2000. Forty-nine per cent of currently married women have ever used a modern method, and 12 per cent have ever used a traditional method.
- Ever use of any method is higher in urban areas (67 per cent) than in rural areas (51 per cent).
- Ever use of both modern methods and traditional methods is also higher in urban areas.
- The most commonly used method is female sterilization, which has been adopted by 34.2 per cent of currently married women, compared to 1.9 per cent who have adopted male sterilization.
- Six to 8 per cent have ever used each modern spacing method (the pill, condom, or IUD).
- Ever use of each method of family planning is higher in urban than in rural areas, except for ever use of male sterilization, which shows almost no variation by place of residence.

- Ever use of IUDs and condoms is more than three times higher among urban women than among rural women. Ever use of any modern method increases with women's age up to age 35–39 (peaking at 67 per cent) and declines at an older age.

- The increase in contraceptive use up to 35–39 years reflects a life-cycle effect, with women increasingly adopting contraception as their fertility goals are met.

c. Current use

- The NFHS 2 data shows that current use of any method is considerably higher in urban areas (58 per cent) than in rural areas (45 per cent).

- Country-wide 89 per cent of current users are using a modern method.

- 34.2 per cent of currently married women are sterilized, accounting for 71 per cent of total current contraceptive prevalence.

- Only 1.9 per cent of currently married women reported that their husbands are sterilized.

- Female sterilization and male sterilization together account for 75 per cent of current contraceptive prevalence.

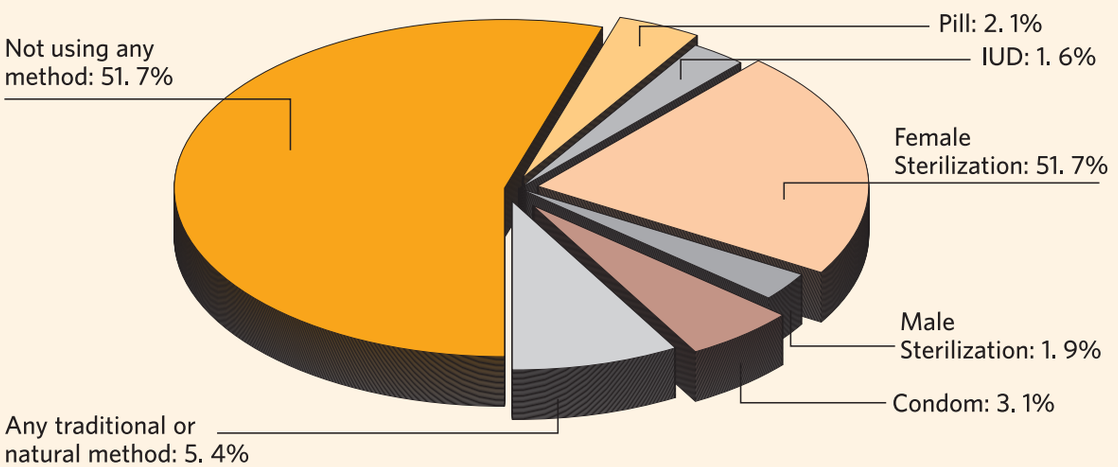
- By residence, female and male sterilization together account for 65 per cent of contraceptive prevalence in urban areas and 79 per cent in rural areas.

- Current use of all modern methods except male sterilization is higher in urban areas than in rural areas, and the gap for condoms is especially wide (urban use is more than four times rural use).

- By age, current contraceptive use increases from 8 per cent for women aged between 15–19 to a peak of 67 per cent for women aged between 35–39 and then decreases for older women. The pattern of variation by age is similar in urban areas and rural areas.

- Less than 7 per cent of currently married women are currently using any of the three spacing methods available through public systems.

Figure 1: Contraceptive Method Use by Married Women in India, 1999



National Family Health Survey -2 1999

- The share of female sterilization in contraceptive prevalence increased slightly from 67 to 71 per cent over the period. Since the share of male sterilization declined from 9 to 4 per cent, however, the share of female and male sterilization together remained almost the same in NFHS-1 and NFHS-2 at about 75 per cent.

- Current use of traditional methods increased slightly between the two surveys, from 4 per cent of currently married women in NFHS-1 to 5 per cent in NFHS-2.

d. Number of living children at first use of contraception

- Only 4 per cent of ever-married women began using contraception when they did not have any children (7 per cent of ever-married women who have ever used contraception).

- Another 10 per cent (19 per cent of ever users) began using when they had one living child.

- Although early use of contraception is rare, 39 per cent of ever-married women (73 per cent of ever users) began when they had three or fewer living children.

- Fifty-nine per cent of urban users and 44 per cent of rural users start using contraception when they have two or fewer children.

- Because of the dominance of sterilization in the contraceptive mix, women usually begin contraceptive use only after achieving their desired family size. Clearly, spacing methods need to be promoted if reductions are sought in the parity at which women first accept contraception.

e. Method-mix

- Nationally, NFHS–2 data show that sterilization accounted for 84 per cent of the contraceptive prevalence rate due to modern methods and 75 per cent of overall current contraceptive prevalence. The predominance of sterilization is observed in almost all states (see Table 1).

Table 1: Contraceptive prevalence

Contraceptive Prevalence Rate (CPR), 1999	48.3%
Pills	2.1%
IUD	1.6
Female sterilization	34.2
Male sterilization	1.9
Condom	3.1
Traditional or natural methods	5.4

- Use of male/couple-dependent methods: In India, gender inequalities favour men and they usually make sexual and reproductive health decisions. Data from NFHS–2, based on the responses of currently married women, show that one in ten currently married "couples" were using male/couple-dependent contraceptive methods (condoms, vasectomy, withdrawal and periodic abstinence) in 1998–99, which translates into 21 per cent of total current contraceptive prevalence.

- During the 1990s, according to survey data, condom use increased marginally from 2.4 per cent in 1992–93 to 3.1 per cent in 1998–99. Despite the introduction of "no-scalpel" vasectomy and campaigns to promote male involvement in family planning and reproductive health, the acceptance of vasectomy remained negligible, at 2 per cent of currently married couples nationally. In fact, during the 1990s the acceptance of vasectomy declined by 44 per cent nationally.

f. Contraceptive practice among the unmarried

- A review shows that 15–30 per cent of adolescent boys and up to 10 per cent of girls in India were sexually active before marriage (Jejeebhoy and Sebastian, 2003). However, studies indicate that a large majority of unmarried, sexually active adolescents do not use any contraceptive method. Those who report practicing contraception often use natural methods, which are more difficult for adolescents to use consistently and effectively because they require accurate knowledge of the reproductive cycle and active cooperation of the partner (Pachauri and Santhya 2002).

- The studies on premarital sexual behaviour among adolescent boys in India indicate that the vast majority had

engaged in unprotected sex, even with commercial sex workers (Jejeebhoy 1996). Among those who reported condom use, almost two-thirds mentioned prevention of pregnancy as the main reason for use, indicating that condom promotion efforts aimed at young men should stress the dual protection properties of condoms.

g. Sources of contraceptive methods

- Family planning methods and services in India are provided primarily through a network of government hospitals and urban family welfare centres in urban areas and Primary Health Centres (PHC) and sub-centres in rural areas. Family planning services are also provided by private hospitals and clinics, as well as non-governmental organizations (NGOs).In some states private sector providers are an important source of the family planning services.

- Modern spacing methods such as the IUD, pill, and condom are available through both the government/private sectors and the social marketing sector.

- The public medical sector is the source of contraception for 76 per cent of current users of modern methods, down from 79 per cent in NFHS-1. There are significant inter-state variations.

- The role of the private medical sector, including private hospitals or clinics, private doctors, private mobile clinics, private paramedics, *vaidyas*, *hakims*, homoeopaths, traditional birth attendants and pharmacies as the source for current users has increased marginally from 15 per cent in NFHS-1 to 17 per cent in NFHS-2.

- Five per cent of current users of spacing methods obtain their methods from other sources such as shops, friends, and relatives and 1 per cent from NGOs.

- Government/municipal hospitals are the main source (53 per cent) for female sterilization, followed by community health centres, rural hospitals, or Primary Health Centres (22 per cent), and private hospitals or clinics (12 per cent).

- Government hospitals, community health centres, and Primary Health Centres are the source for 75 per cent of male sterilizations.

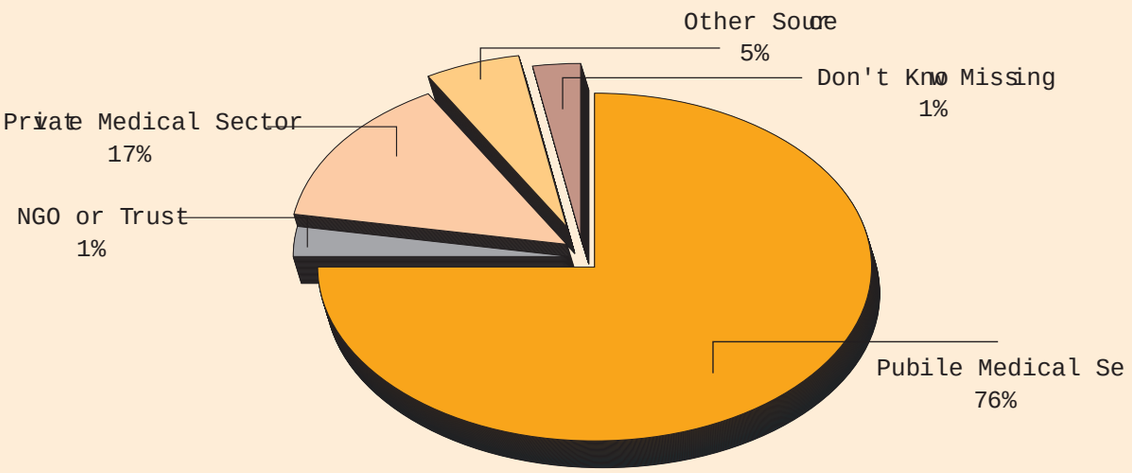
- In contrast, private shops and pharmacies/drug stores are the main source for condoms (68 per cent) and pills (62 per cent).

- Eighty-three per cent of rural users obtain their contraceptives from the public medical sector compared to 60 per cent of urban users.

- About one-quarter of female sterilizations, one-fifth of male sterilizations in urban areas as well as nearly one-third of IUD insertions in rural areas and more than half of IUD insertions in urban areas are performed in the private sector.

Figure 2

Sources of Family Planning Among Current Users of Modern Contraceptive Methods



h. Preferred future method of contraception

- According to NFHS 2 data, a large majority (65 per cent) of women who intend to use contraception say they intend to use female sterilization, up from 59 per cent in NFHS-1.
- The next most preferred method is the pill, which was the preference of 16 per cent of women, down from 19 per cent in NFHS-1.
- Less than 1 per cent of the women prefer that their husbands get sterilized, and 3 per cent each prefer to use the condom or IUD. Yet it is a very well known fact that male sterilisation is a more simple procedure when compared to female sterilisation.
- Among women who intend to use in the next 12 months, the pill is the spacing method mentioned most often (25 per cent), followed by the IUD and the condom (6 per cent each).
- Among women who intend to use a method within the next 12 months, a higher proportion of rural women than urban women refer the pill (28 per cent compared to 18 per cent), whereas a higher proportion of urban women than rural women prefer the condom (11 per cent compared to 5 per cent) and IUD (9 per cent compared to 5 per cent).

i. Reasons for discontinuation

- Among the women who were using a contraceptive method, overall four out of every five current users report having no problem with their method.

- The analysis of method-specific problems reveals that 75 per cent of sterilized women and 87 per cent of women whose husbands are sterilized report having no problem.

- The most common problems experienced by sterilized women are headache, body ache, or backache (13 per cent), abdominal pain (8 per cent), weakness or tiredness (7 per cent), and white discharge (4 per cent). Among women whose husbands are sterilized and who report problems with this method, the two most common complaints are headache, body ache, or backache and weakness or tiredness. These results point to a continuing need to strengthen post-operative care and counselling for sterilization acceptors.

- The two most common problems reported by pill users are weakness/tiredness and headache/body ache/ backache.

- Too much bleeding, abdominal pain, and headache/body ache/backache are reported as problems by 5 to 6 per cent of IUD users.

- Though the desire for a child was the main reason for discontinuation of contraception in about 30 per cent of cases, the fact that more than one-third reported method-related reasons such asm ethod failure, side effects and inconvenience, highlights the need for improved quality of services.

Table 2: REASON FOR STOPPING USE

Reason	Urban	Rural	Tatal
Method failed/got pregnant	3.6	4.7	4.3
Lack of sexual satisfaction	1.7	1.8	1.8
Creating menstrual problem	9.2	6.9	7.7
Creating healthproblem	14.4	12.7	13.3
Inconvenient to use	2.2	1.5	1.7
Hard to get method	0.5	1.9	1.4
Gained weight	0.3	0.1	0.2
Did not like the method	4.2	5.1	4.8
Wanted to have a child	29.8	29.2	29.4
Wanted to replace the dead child	0.6	0.5	0.5
Lack of privacy for use	0.8	0.7	0.7
Husband away	8.2	13.4	11.6
Cost to much	0.9	2.3	1.8
Others	23.2	18.3	20.0
Missing	0.4	0.9	0.8
Total percent	**100.0**	**100.0**	**100.0**

Source: NFHS - 2

- The data also shows that younger women between 15 and 24 years were more likely to discontinue using contraceptives than older women.

Unmet need for family planning

Currently married women who are not using any method of contraception but who do not want any more children or want to wait two or more years before having another child, are defined as having an unmet need for family planning. Current contraceptive users are said to have a met need for family planning. The total demand for family planning is the sum of the met need and the unmet need.

j. Magnitude of unmet need

- The NFHS–2 reports that nearly 16 per cent of currently married women have an unmet contraceptive need—8.3 per cent for spacing and 7.5 per cent for limiting.

- Thus, if all women who say they want to space or limit their births were to use family planning, the contraceptive prevalence rate would increase from 48 per cent to 64 per cent of currently married women.

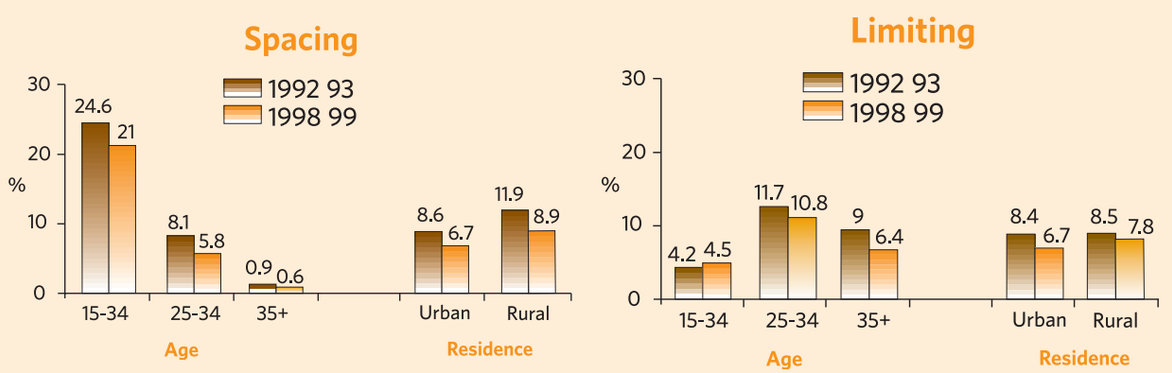
- Unmet need is much higher for women with one living child and for women with 6 or more living children (23 per cent) than for women with either no children (14 per cent) or two to five children (12–17 per cent).

- Among women with no children or one child, unmet need is almost exclusively for spacing.

- The proportion of unmet need that is for limiting rises from 47 per cent among women with two living children to 91 per cent among women with six or more living children.

- The trends in unmet need for spacing and limiting for different age groups, as shown in Figure 1, indicate that the decline was concentrated in the group of women 35 years and above and that the least decline was reflected in the younger age group.

Figure 3: Trends in unmet need for spacing and limiting



k. Barriers to meeting contraceptive needs

The following are some of the barriers in meeting contraceptive needs. All providers should be conscious of these issues while providing contraceptive services.

Limited knowledge

While general awareness of contraception is universal (99 per cent of currently married women in the reproductive age group were aware of at least one contraceptive method), there are still several grey areas where awareness is limited.

- Female sterilization is the most widely known method of contraception in India, followed by male sterilization. Overall, 98 per cent of currently married women know about female sterilization and 89 per cent know about male sterilization.

- The best-known spacing method is the pill, which is known by 80 per cent of currently married women, followed by the condom and IUD (71 per cent each). Although knowledge of these spacing methods is lower than knowledge of sterilization, the results indicate that knowledge of spacing methods has increased since NFHS-1.

- Seventy-five per cent of rural women know about the pill compared to 92 per cent of urban women. For IUDs and condoms, the corresponding proportions are 65 and 88 per cent.

- However, awareness of reversible (modern or natural) methods is relatively limited among both women and men.

- The awareness of specific reversible methods, which are more suitable for young women, is even more limited among younger women compared to older women. For example, only three-fifths of married adolescents were aware of condoms, compared to nearly three-fourths of women aged 20–34 years (Santhya and Jejeebhoy 2003). Also disturbing, particularly in the context of increasing premarital sexual experience among unmarried boys and girls, is the evidence from small-scale studies that a substantial proportion of unmarried boys and girls lack contraceptive knowledge (Bhende 1994; Kumar et al. 2000).

Table 3: Knowledge of contraceptive Methods

Percentage of currently married women who know any contracetive method by specific method and residence, India 1995-99

Method	Urban	Rural	Total
Any Method	99.7	95.7	99.0
Any Modern Metod	99.7	95.5	96.5
PIT	91.5	75.2	75.5
ILD	87.5	54.5	70.6
Condom	88.0	64.9	71.0
Female Sterlization	99.3	97.5	96.2
Male Sterlization	93.6	57.5	89.3
Any Additional Method	60.3	44.9	48.5
Rhylhnvmfe Period	56.7	41.0	45.1
Withdrawal	41.1	27.7	31.2
Other Method	**3.1**	**2.5**	**2.7**

Includes both modern and traditional methods and are not listed separetely.

Gender inequalities: Opposition from Husbands

- Nationally less than one in five currently married women reported discussing family planning with their husbands (IIPS and ORC Macro 2000).
- Studies also show that most men approve of contraception only after having a second or third child (Khan and Patel 1997), and that husbands' approval of a particular method is critical (Parveenet al. 1995).
- There have been some efforts to promote the use of male methods such as vasectomy and condoms, and initiatives to re-popularize vasectomy, including IEC campaigns and training of surgeons in "no-scalpel" vasectomy, have been launched in several states (MOHFW 1999). Though these efforts have proved successful in some districts in Andhra Pradesh, a similar change has not occurred in most other states (Planning Commission 2002).

Limited choice of methods

- The public sector essentially provides five contraceptive methods—two forms of tubectomy (laproscopy and minilap), vasectomy (including "no-scalpel" vasectomy), IUDs (Copper T 380), oral pills (combined) and condoms.

- Efforts to broaden the basket of choices have been under way, including clinical trials to assess the safety and efficacy of available methods such as estrogen-progestogen combination injectables, vaginal rings and long-acting IUDs, and the development of new methods of male and female fertility regulation.

- As part of expanding contraceptive choice, the government has introduced emergency contraceptive pills in the Reproductive and Child Health Programme.

- Methods that are perceived as less effective, including pessaries, spermicides and diaphragms, are either dropped or not introduced in the public programme or are given low priority by health workers.

- The recently introduced emergency contraceptive pills are currently available through medical officers only at the district, sub-district level and PHCs.

- Not only is access to a wider choice of methods limited, but providers also often do not assist women and men to exercise their right to contraceptive choice by offering them complete and accurate information about the variety of methods available. Nationally, for example, data from NFHS–2 shows that only 15 per cent of users of modern contraceptive methods who were motivated by providers, friends or others were informed about at least one alternative method.

- Evidence from a growing number of studies suggests that pre-acceptance counselling of clients on how the method works, what the expected side effects are and how to manage the side effects is typically lacking or limited in the Family Welfare Programme across the country (Foo and Koenig 2000).

- The data from NFHS–2 indicates that only 22 per cent of users of any modern method were informed of its possible side effects at the time of accepting the method (IIPS and ORC Macro 2000).

- Similarly, data from the Reproductive and Child Health Survey–1 report that only one-third of sterilization users (35 per cent), fewer than one-half of IUD users (46 per cent) and fewer than one fourth of pill users (23 per cent) were informed of the side effects before accepting the method.

- Even though most of the providers are trained to provide counselling for condoms, oral pills, IUDs and female sterilization, few providers informed clients how a method works, how to manage side effects and the danger signs that warrant medical attention.

Limited access to and availability of services

- Access to contraceptive methods has increased significantly, and only a negligible minority of women (4 per cent as per NFHS–2 data) perceived availability, accessibility or cost as major impediments to using contraception.

- A recent survey of health facilities across the country reports that most primary health centres were not adequately staffed: almost 10% were functioning without any doctor and 80 per cent did not have a female medical officer.

- The facility survey reveals that only 16 per cent of primary health centres had physicians trained in conducting

sterilization, and only two-thirds had at least one paramedical staff trained in IUDinsertion (IIPS 2001).

- While female health workers in many studies reported that they had received training in IUD insertion, the majority did not feel confident about actually inserting an IUD in field settings or showed little awareness of the precautions to be taken (Visaria 2000).

- Nationally, fewer than one in five non-institutional births was followed by a postpartum check-up. Among those who received a postpartum check-up, only 27 per cent of mothers received family planning advice, compared to 43 per cent receiving advice on breastfeeding and 46 per cent receiving advice on baby care. Only 14% mothers received advice about family planning during postpartum check-ups for first births, although these women are more likely to need advice on birth spacing and contraception.

- The health workers and other providers tend to overlook adolescents and young women until they are further advanced in their reproductive careers.

- Stock-outs and erratic supplies of reversible contraceptives make it unrealistic to expect providers to offer clients a choice of methods.

Poor quality of services

- The NFHS–2 data show that three in four sterilization users and two in five users of other modern methods received follow-up services (IIPS and ORC Macro 2000).

- Data from the Rapid household survey phase I & II, however, indicate that a much smaller percentage of women (only one in four) received a follow-up visit from a health worker after accepting the method—27 per cent in the case of sterilization, 13 per cent for IUD and 7 per cent for pills.

- In many states, fewer than one in ten women reported receiving a follow-up visit (IIPS 2001). It is commonly observed that auxiliary nurse-midwives do not maintain their registers adequately to follow-up users, and lack a clear idea of how many have continued/discontinued the method (Foo and Koenig 2000).

- The Reproductive and Child Health Programme emphasizes the need to assess client needs and perceptions, sensitize and orient health workers about the new ethos, involve the community including panchayati raj institutions in setting priorities and monitoring the quality of services, setting quality assurance guidelines and conducting refresher training for skill up gradation.

CHAPTER 2

Critical Components of Quality of Contraceptive Services

Components of Contraceptive Services

Delivery of care in accordance with the client's reproductive rights is fundamental to the quality of care. Clients should be offered a range of contraceptive methods and be empowered to select, switch and discontinue a method as per their needs. The quality elements include proper screening, provision of contraceptive services in adherence with guidelines, management of side effects and follow-up procedures for specific contraceptive methods. Other public health interventions that could be integrated while providing high-quality family planning services include screening and treatment of Reproductive tract Infections (RTIs), STIs, cervical cancers, anaemia, and promotion of breastfeeding.

Availability of skilled providers and appropriate supply chain management is critical for provision of quality family planning services. To provide contraceptive choices to the clients in a way that respects and protects their human rights, necessitates enabling clients to make informed choices themselves. Women's choices, however, are often imposed or limited by direct or indirect social, cultural and economic factors. Decision-making for contraceptive methods usually requires the need to make trade-offs among the different methods, with advantages and disadvantages of specific methods varying according to the individual circumstances, perception and interpretations.

Skilled providers

In order to ensure availability of high-quality family planning services, the service providers must be trained in providing family planning counselling to help clients make informed and voluntary decisions about their fertility. Counselling is a key element in quality of care and is also an important part of both initiation and follow-up visits and should respond to clients' needs, not only in contraception but also in relation to sexuality and the prevention of sexually transmitted infection (STIs), including the human immunodeficiency virus (HIV). In addition to counselling skills, the providers should have access to periodic updates on the recent advances in contraceptive technology and medical eligibility criteria. At the sites where sterilizations and intra-uterine device (IUD) services are provided, the providers should have necessary clinical skills for adhering to existing service delivery guidelines.

Physical infrastructure supplies and commodities

Adequate and appropriate equipment and supplies need to be maintained and held in stock (for example, contraceptive commodities, equipment and supplies for infection prevention procedures). The site readiness should include appropriate facilities for providing the services as well as management of the side effects. The sites providing family planning services must be equipped to meet the minimum standards or facility norms in order to ensure provision of proper FP services. These sites, besides having availability of appropriate instruments and equipment, must also be equipped with adequate and appropriate informative materials for clients in order to provide opportunities for making informed choice.

Method-specific counselling

Counselling is a key element of quality family planning services which allows the client to exercise informed choice, getting appropriate information about the correct and consistent use and successful continuation of the chosen contraceptive. Clients should be given adequate information in order to make an informed, voluntary choice of a contraceptive method. Information given to clients to help them make this choice should at least include understanding of the relative effectiveness of the method; correct use of the method; how it works; common side-effects; health risks and benefits of the method; signs and symptoms that would necessitate a return to the clinic; information on return to fertility after discontinuing method use; and information on STI protection. Providers should also keep in mind issues relating to gender-based violence linked to acceptance of contraceptives during counselling.

Adherence to service delivery standards and protocols

Service providers should have access to national service delivery guidelines and protocol to enable them to appropriately screen clients for conditions in which use of certain contraceptive methods would carry unacceptable health risks. These guidelines will also help providers to follow standard procedures for contraceptive provision and adhere to follow-up schedules.

Follow-up including management of side effects

For ensuring correct and consistent use of the chosen contraceptives, the clients should be given appropriate and adequate information about the follow-up schedules and management of side effects.

Issues for special consideration:

a. Return to fertility

The use of contraceptive methods, with the exception of male and female sterilization, does not result in an irreversible change in fertility. Return to fertility is immediate with all methods, with the exception of DMPA and NET-EN; the median delay in return to fertility with these methods is 9 and 6 months, respectively, from the date of the last injection, regardless of the duration of their use. Male and female sterilization should be regarded as permanent methods and should be emphasised during the counselling. The family planning counselling by trained providers must include a detailed instruction and information with clients about the return of fertility. In the long run, this helps in dispelling myths about various contraceptives and popularizes the methods.

b. STIs and contraception: Dual protection

While the development of international norms for contraceptive provision is essential for quality of care in services, the social and cultural context of each client must also be considered. In this regard, the problems of exposure to STIs, including HIV, deserves special consideration because of the importance of both preventing pregnancy and preventing transmission of infection. When a risk of STI/HIV transmission exists, it is important that health care providers highlight the importance of dual protection, either through the simultaneous use of condoms

with other methods or through the consistent and correct use of condoms alone for both pregnancy and disease prevention. Women and men seeking contraceptive advice must always be reminded of the importance of condom use for preventing the transmission of STI/HIV. Male and female condoms are proven to provide protection against STI/HIV when used consistently and correctly.

c. Adolescents

In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices. Age alone does not constitute a medical reason for denying any method to adolescents, although sterilization is rarely appropriate for this age group. While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents, (e.g., the use of progestrogen-only injectables by those below 18 years), these concerns must be balanced against the advantages of avoiding pregnancy and existing guidelines be adhered to. It is clear that many of the same issues regarding appropriate contraceptive use that apply to older clients apply to young people.

Social and behavioural issues are important considerations in the choice and use of contraceptive methods by adolescents. For example in some settings adolescents are also at increased risk of STIs, including HIV. While adolescents may choose to use any one of the contraceptive methods available in their communities, in some cases, using methods that do not require a daily regimen may be more appropriate. Adolescents, married or unmarried, have also been shown to be less tolerant of side-effects and therefore have high discontinuation rates. Method choice and use may also be influenced by factors such as sporadic patterns of intercourse and the need to conceal sexual activity and contraceptive use. For instance, sexually active adolescents who are unmarried have very different needs from those who are married and want to either postpone, space or limit pregnancy. Expanding the number of method choices offered can lead to improved satisfaction, increased acceptance and increased prevalence of contraceptive use. Proper education and counselling both before and at the time of method selection can help adolescents address their specific problems so that they can make informed and voluntary decisions.

d. Clients with special needs

Contraceptive provision to people with special needs requires additional consideration. Individuals with a physical disability represent such a group. Decisions on appropriate contraception must take into account the nature of the disability, the expressed desire of the individual and the nature of the method. Decisions must be based on informed choices. Similar considerations should be given to individuals who are mentally challenged or suffering from some serious mental illness.

If the nature of the condition does not allow for informed choice, contraceptives should be provided only after full discussion with all parties including guardians or care-givers. The reproductive rights of the individual must be considered in any such decision. Selected practice recommendations may need to be modified for clients with special needs; for example clients with mental disabilities may have difficulty remembering to take pills daily. Clients with physical disabilities may have difficulty obtaining supplies or otherwise accessing family planning services.

CHAPTER 3

Oral Contraceptive and Emergency Contraceptive Pills

3.1 Oral Contraceptive Pills

The Oral Contraceptive Pill (OCP) is one method of preventing pregnancy that can be controlled by a woman. OCPs are highly effective and can be taken for long time without any adverse effects, and there is quick return of fertility after discontinuation. OCPs are widely and easily available through primary healthcare providers, community-based volunteers, social marketing channels and also from commercial channels.

Checking medical eligibility before starting OCPs is desirable. Evidence over the years has shown that barring a few medical conditions most women can use OCPs. The healthcare providers must be well acquainted with the medical eligibility criteria for OCPs and be able to provide appropriate method-specific counselling for OCPs, thereby avoiding situations of missed pills and providing adequate support to the OCP users for increasing the use and continuation of this effective contraceptive method.

The low dose oral contraceptives are a safer and more easily available option for women for preventing unwanted pregnancy. Lower doses of hormones in the pills have reduced the circulatory disease risk of the pill. Taken correctly and consistently, the pill prevents pregnancy almost without fail. Pill users benefit in other ways too:

1. Protection from certain cancers.

2. Reducing menstrual bleeding, which in turn helps prevent iron deficiency (anaemia), which is common in developing countries.

In spite of these benefits, OCPs is one of the least used methods of contraception in India.

Oral contraceptives pills, commonly known as 'the pill,' are a widely accepted, safe, reliable, effective and reversible method of fertility control. The types of oral contraceptive pills are:-

Combined oral contraceptive pills

A. Monophasic pills

1. Standard dose pills
2. Low dose pills
3. Very low dose pills

B. Multiphasic pills

1. Triphasic pills
2. Biphasic pills

C. Progesterone only pills/minipills

Monophasic pills

The oestrogen used currently is ethinyl estradiol. The dose of estradiol in the pills was gradually lowered from 0.5mg to 0.3mg to the currently used dose of 0.2mg in the very low dose pills. The progesterone used initially was from the C-21 group e.g. Medroxyprogesterone acetate and megestrol, which were then abandoned due to suspected risk of breast cancer. Now there are two groups of progesterone in use:

- **Norethisterone group:** Norethisterone, norethynodrol, Norethysterone aceate, Ethinodiol diacetate
- **Norgestrel group:** d-Norgestrel, L-Norgestrel
- **Newer Progesterones:** Desogestrel gestodene, and norgestemate. They have contraceptive effect similar to other progesterones but have almost no androgenic or anabolic effect.

Multiphasic pills

These were developed with the aim of reducing the total monthly hormone intake while maintaining the efficacy.
Biphasic pills: EE- 0.035 mg constant

Low dose progesterone first 10 days
High dose progesterone next 11 days. These have higher failure rates and are not available in India.

Triphasic pills:

EE- 0.03mg + LNG 0.05mg for 6 days
EE- 0.03mg + LNG 0.075mg for 5 days
EE- 0.03mg + LNG 0.125mg for 10 day

These pills have fewer side effects like amenorrhoea, breakthrough bleeding and decreased incidence of acne. The drawbacks include errors in pill taking, increased failure and difficulty in postponing menstruation if required.

3.2 Combined Oral Contraceptive Pills (COCs)

a. Mechanism of action and effects

COCs have an effectiveness of 99.97% to 99.99%. The failure rate is 0.3% as commonly used and only 0.1% on correct and consistent use. The mechanism of action is as follows:

- Inhibition of ovulation by suppressing FSH and LH
- Alternation of endometrium to make it unsuitable for implantation even if the ovum is fertilized.
- Changes in cervical mucus, which make it hostile to the sperm

Important health benefits

Fertility-related benefits

- Prevention of pregnancy
- Offers protection against ectopic pregnancy

Menstrual benefits

- Menstrual cycle stabilization
- Lesser iron deficiency anaemia due to lighter menstrual cycles
- More regular menstrual cycles
- Less dysmenorrhea
- Less severe premenstrual symptoms

Protection from some cancers

- Protection against cancers e.g. endometrial and ovarian cancer
- Protection against benign diseases e.g. benign breast diseases like fibrocystic and fibroadenomatosis disease decreased by 50-70%

Other possible health benefits

- Protection against pelvic inflammatory diseases when compared to non-users
- Reduces risk of follicular cyst by 50% and corpus luteal cyst by 80%.
- Past contraceptive use protects women after they reach menopause where reduced risk of low bone mineral density was documented
- Reduction in acne

- Decreased incidence of rheumatoid arthritis

Side effects

- Nausea, vomiting, decreased appetite; usually subsides after 2 to 3 months of use
- Breakthrough bleeding - common with low dose progesterone pills due to low or absent estrogen.
- Oligo and ammenorrhoea seen due to lack of proliferation of endometrium, which can be treated with EE- 0.02 mg during the last 7 days of cycle. Common with women who had menstrual problems before starting oral contraceptive pills.
- Breast changes - oedema, heaviness and tenderness. This can be managed with reassurance and breast support.
- Vaginal discharge due to congestion and hypertrophy of cervical epithelium.
- Chloasma
- Weight gain in some cases due to estrogen and progesterone.
- Acne and oily skin.

b. Eligibility criteria for low dose combined contraceptive pills

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

- If they have no children
- Are fat or thin
- Are of any age, including adolescents and over 40
- Smoke cigarettes but are under 35
- Have just had an abortion or miscarriage

Also, women with following conditions can use low-dose combined oral contraceptives in any circumstances:

- Heavy, painful menstrual periods or iron deficiency anaemia (condition may improve)
- Irregular menstrual periods
- Benign breast disease
- Diabetes without vascular, kidney, eye or nerve disease
- Mild headaches
- Vericose veins
- Malaria
- Thyroid disease
- Pelvis inflammatory disease
- Endometriosis
- Benign ovarian tumour
- Uterine fibroids
- Past ectopic pregnancy
- Tuberculosis, unless taking Rifampicin

Women with the following conditions have an unacceptable health risks if COCs are used as contraceptives. **Hence, such women should not use COCs:**

- Breastfeeding women within 6 weeks of postpartum
- Women aged 35 + who smoke more than 15 cigarettes per day
- Multiple risk factors for arterial cardiovascular disease
- Having hypertension with systolic BP 140-159 and diastolic 90-99 and those having vascular disease.
- Women with a clear history of deep vein thrombosis (DVT), pulmonary thrombosis or current DVT or pulmonary thrombosis.
- Women having known thrombogenic mutations.
- Current history of ischemic heart disease or known hyperlipidaemias
- Those suffering from complicated pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis
- Migraine with aura
- Current breast cancer
- Diabetes with neuropathy, retinopathy, nephropathy and other vascular disease
- Acute hepatitis or severe cirrhosis of the liver or benign or malignant liver tumours

Important: Women having the above health conditions should be encouraged to use other appropriate contraceptives, rather than COCs.

Important clarifications and evidences regarding eligibility criteria

1. COC users who smoke were at increased risk of cardiovascular diseases, especially myocardial infarction, compared to those who did not smoke. There is an increase in the risk of myocardial infarction with the increasing number of cigarettes per day.

2. It is desirable to have blood pressure measurement taken before initiation of COC use. However, in the setting where the facility of blood pressure measurement is not available and/or risks due to pregnancy morbidity/ mortality are high, the women should not be denied use of COCs simply because their blood pressure cannot be measured.

3. In women having a history of high blood pressure, evaluation of cause and level of hypertension should be done as soon as possible. Among women with proven hypertension, COCs should not be used, unless other more appropriate methods are not available or not acceptable to the woman.

4. Among women with thrombogenic mutations, COC users had a 2 to 20 fold higher risk of thrombosis than non-users. Hence, COCs are not recommended in women having known thrombogenic mutations. However, COCs can be safely given to women with superficial venous thrombosis.

5. Among women with migraine, women who had aura had a higher risk of stroke than those without aura. Hence, in women above 35 years and those having migraine with aura, COCs are not to be recommended.

6. Women with depressive disorders can safely use COCs because the evidence suggests that COC use does not increase depressive symptoms.

7. In women with heavy or prolonged bleeding and unexplained vaginal bleeding, pregnancy or underlying pathological condition (such as pelvic malignancy),, COC use must be evaluated.

8. There is no increased risk of side-effects with COCs among women with dysmennoroea compared to women not using COCs. Rather, some COC users had a reduction in pain and bleeding. Therefore, in such cases COC could be safely used.

9. COCs can be safely used in women with trophoblast disease, benign breast disease, family history of cancer, women with pelvic inflammatory disease and STIs and HIV.

10. Women with diabetes and without non-vascular disease can generally use COC. But those women having diabetes with neuro/retinopathy and other vascular diseases, either cannot use COC or can use it only in s pecific conditions according to the assessment of the severity of the condition.

11. Women taking Rifampicin or certain anticonvulsants (phenytoin, carbamazepine, barbiturates, rimidone, topiramate, oxcarbazepine) should be prescribed COCs only if any other appropriate contraceptive is not available or acceptable. Although the interaction with these drugs with COCs is not harmful to the women, it is likely to reduce the effectiveness of COCs. Use of other contraceptives should be encouraged for the women who are long-term users of any of these drugs. Whether increasing the dose of the hormones in COCs is useful is still unclear.

12. The contraceptive effectiveness of COCs is not affected by the coadministration of most broad-spectrum antibiotics.

13. The COCs may cause a small increased risk of gall-bladder disease. There is also concern that COCs may worsen existing gall-bladder disease.

Chart 1: When to start combined oral contraceptives

Phase	Recommended Guidelines
Having a menstrual cycle	Within 5 days after the start of her menstrual bleeding.
In between 2 menstrual cycles	No additional contraceptive protection is needed.
Ammenorrhoea	Any day if she 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 next 7 days.
Breastfeeding	She can start COCs at any time, if she 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. If she is more than 6 months postpartum and ammenorrhoeic, she can start COCs as advised above. If she is more than 6 months postpartum and her menstrual cycles have returned, she can start COCs as advised for other women with menstrual cycles Women less than 6 weeks postpartum who are primarily breastfeeding should not use COCs. For women who are more than 6 weeks to 6 months postpartum and primarily breastfeeding, use of COCs is usually not recommended unless other more appropriate methods are unavailable or unacceptable
Switching to another hormonal method	Women using the hormonal method consistently and correctly, who are reasonably certain that they are not pregnant, can start COCs immediately. There is no need to wait for the next menstrual period. If her previous method was an injectable, she should start COCs when the repeat injection would have been given. No additional contraceptive protection is required.
Switching from non-hormonal method	She can start COCs within 5 days after the start of her menstrual bleeding. She can also start immediately or at any other time, if it reasonably certain that she is not pregnant. If it has been more than 5 days after the menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days
Switching from IUD (including hormonal)	She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is required. The IUD can be removed at that time. She can also start immediately or at any other time, if it reasonably certain that she is not pregnant. If she has been sexually active during this menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that IUD should be removed at the time of her next menstrual period.

d. Key steps while providing COCs

- An adequate number of pills must be provided. Running out of stock of pills is one of the major reasons for unintended pregnancy.
- Explain to the client how to use the pill
- If possible give her condoms to use as well:
  - Until she can start taking the pill
  - If she starts packet of pill late, if she misses the pill in a row or if she stops taking the pill for any other reason
  - If there is possibility of transmission of STIs/HIV
- Show her how to use condoms.
- Plan for return visit
- Invite the client to come back any time if she has any questions, problems or opts for another method

Explaining how to use the pill

1. Hand her at least 1 packet of the pill that she will use

2. Show her what kind of pill packet you are giving her, whether 21 pills or 28 pills. With the 28-pill packets, explain that the last 7 pills do not contain hormones. They are "reminder pills". Point out that they are different in colour from the first 21 pills. Explain that if she forgets to take the reminder pills she is still protected from pregnancy. However, if she forgets the active, hormonal pills, she risks pregnancy.

3. Show how to take the first pill from the packet.

4. Show how to follow the direction or arrows on the packet for the rest of the pills, one each day (first hormonal pills and then "reminder pills").

5. Give her instructions on how to start the first packet, then the next packet and what to do in case she misses a pill.

6. Ask her to repeat the most important instructions and show how she will take the pill, using the pill packet.

Give specific instructions

Starting the first packet

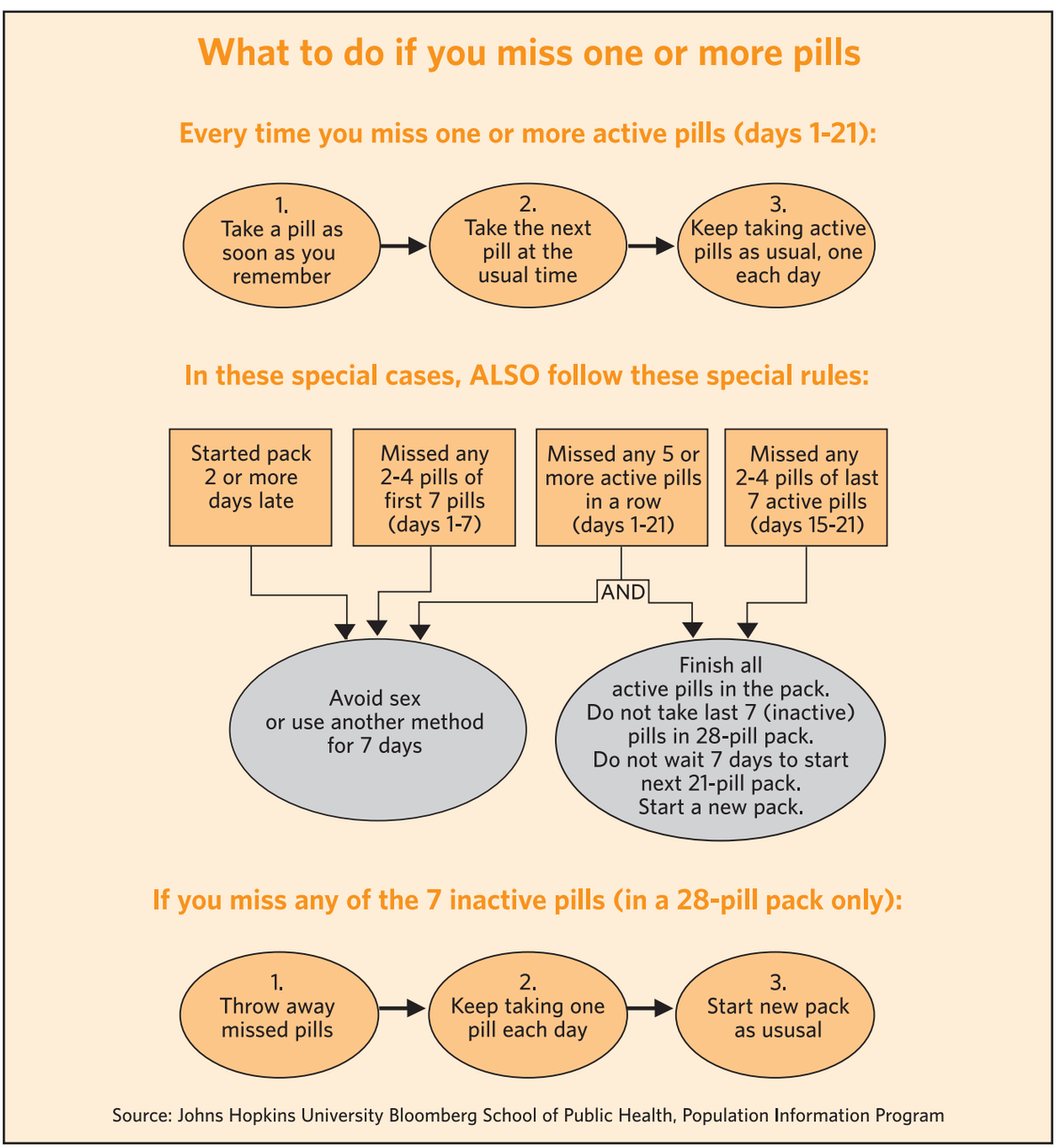
See chart 1 above for details on when to start.

- If she starts beyond day 5 after the start of her menstrual bleeding, she may have irregular menstrual bleeding for a few days.
- Taking the pill at the same (fixed) time of the day might help her to remember taking them.
- Starting the 28-pill packets: When she finishes one packet, she should take the first pill from the next packet on the very next day.
- 21-pill packets: After she takes the last pill from one packet, she should wait for 7 days and then take the first

pill from the next packet. She must not wait for more than 7 days between cycles of 21-pill packets.

- Give specific instructions about missed pills (See figure 4 below).
- Mention common side-effects - for instance, nausea, mild headaches, tender breasts, spotting between periods, irregular bleeding, moodiness etc. Explain that these side-effects are not signs of serious sickness. They usually become less or stop within 3 months after starting the combined oral contraceptives. Many women never have these side effects.

Figure 4
e. Dealing with some common problems of combined oral contraceptives



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

- Invite the client to come back if she has any problems in using the pill or has any complications. Let her know that she can switch to another contraceptive method any time she so wishes.

Chart 2: Common problems and remedies

Problems	Remedies
Common side-effects such as nausea, mild headaches, tender breasts, spotting between periods, irregular bleeding, moodiness	• Keep taking her pills. Skipping pills may make these side effects worse and also increases the risk of pregnancy • For spotting or irregular bleeding, she can try taking each pill at the same time of day. • Reassure her that these are not signs of more serious problems, and they usually disappear.
Vomiting (for any reasons) within 2 hours of taking an active (hormone) pill	• She should take another active pill
Severe diarrhoea and vomiting for more than 24 hours	• She should continue taking pills (if she can) despite her discomfort • If severe vomiting or diarrhoea continues for 2 or more days, she should follow the procedure for missed pills

- Describe the symptoms of problems that require medical attention. Serious complications of the pill are rare. It should be made clear that a woman should see a doctor or nurse or return to the clinic if she has any of the following symptoms or problems:

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

Follow-up

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

Helping clients at any routine return visit

1. Ask if the client has any questions or anything to discuss.

2. Ask the client about her experience with the method, whether she is satisfied, and whether she has any problems. Give her any information she needs and invite her to return again any time for help. If she has problems that cannot be resolved, help her choose another method.

3. If she has not developed any problems which prevent use of COCs, provide more supplies if needed. Plan for the next visit before she will need more pills.

Managing any problems

If the client reports any common side effects of low dose COCs:

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

Chart 3: How to deal with common problems

Problem	Remedies
Nausea	Suggest taking pills at night or with food
Minor headaches	Suggest taking ibuprofen, aspirin, paracetamol, or other non-steroidal anti-inflammatory drug
Amenorrhea (no monthly bleeding period) Common, not usually a sign of pregnancy	• Ask if she is having any bleeding at all. (She may just have a small stain on her underclothing and not recognize it as vaginal bleeding). If so, reassure her. • Ask if she is sure she has been taking the pill every day. If she has, reassure her that she is not likely to be pregnant. She should start the next packet of pills on time. If she is unsure • Ask her if she might have missed the 7-day break between the 21-day packets. This may have caused period. Reassure her that she is probably not pregnant. • Ask if she has missed 2 or more active hormone pills in a row. If so, assess whether or not she is pregnant. If she may be pregnant, tell her. Ask her to stop taking oral pills. Offer her condoms and/or spermicide. She can use them until her next period or until clear about whether or not she is pregnant. • Ask if she has recently stopped taking pills - If she is not pregnant, her periods may take a few months to return - Ask if she had irregular periods before she starting the COCs. If so, her periods may be irregular again after she stops the pills.
Spotting or bleeding between monthly periods over several months	• Ask if she has missed any pills. Explain that missing pills can cause bleeding between periods, even when taking pills every day) • Ask if she has had vomiting or diarrhoea.

Problem	Remedies
	• Ask if she is taking rifampicin or medicines for seizure, which may make COCs less effective. Encourage her to use condoms or spermicide.
Very bad headaches (migraines)	A woman who develops migraine while using COCs should switch to an alternative method. She should not choose a POP (progesterone only pill) method if she has blurred vision, brief loss of vision, sees flashing lights or has brief trouble in speaking or moving before, during or after the headaches.

3.3 Progesterone-Only Pills (POPs) - Minipills

There are not many contraceptive options available for a woman in India for preventing unwanted pregnancies and the threat of conceiving during lactational amenorrhoea remains one of the major problems. In such a situation Progesterone-only Pills are one of the best options available to a woman or couple, besides natural methods including the Lactational Amenorrhea Method (LAM). POPs do not affect the quality of breast milk and help in proper child nutrition, while preventing unwanted pregnancy. A success rate of 99.5% makes it an ideal option for breastfeeding mothers.

a. Mechanism of action and results

Progestin-only oral contraceptives (also known as mini-pills) are the best oral contraceptives for breastfeeding women, as they apparently do not reduce milk production. They also do not have any estrogen side-effects, unlike combined oral contraceptives. The POPs can also be used as emergency contraception after unprotected sex.

Products available:

There are several brands containing following progestin are available:
Norethindrone
Levonorgestrel
Norgestrel

Mechanism of action:

Thickening of cervical mucous
Suppression of ovulation
Involution of endometrium

Effectiveness

99.95% effective with correct and consistent use. Failure rate of only 0.5% in the first year in breastfeeding women. The failure rates are higher in younger women than in women over 40. These are most effective, when taken at about same time every day.

Advantages:

- Can be used by lactating mothers 6 weeks after childbirth. Quantity and quality of breast milk remains unaffected.
- No estrogen side-effects. Does not increase risk of estrogen-related complications such as heart attack or stroke.

- The client has to take 1 pill every day with no break, which is easier to remember than taking 21- day COCs.
- Can be very effective during breastfeeding.
- Even less risk of progestin-related side effects, such as acne and weight gain, than with COCs.
- May help prevent benign breast disease, endometrial and ovarian cancer and pelvic inflammatory disease

Disadvantages

- For women who are not breastfeeding, the common side effects are changes in menstrual bleeding including irregular periods, spotting or bleeding between periods and amenorrhea or missed periods, possibly for several months. A few women may have prolonged or heavy periods. Other less common side-effects include headaches and breast tenderness.
- POPs need to be taken at about the same time each day to work best. For women who are not breastfeeding, even taking a pill more than a few hours late increases the risk of pregnancy, and missing 2 or more pills increases the risk greatly.
- Does not prevent ectopic pregnancy.

b. Medical eligibility for POPs

In general, most women can use POPs safely and effectively. POP contraceptives can be used in any circumstances by women who:

- Are breastfeeding (starting as soon as 6 weeks after childbirth)
- Have no children
- Are fat or thin
- Are of any age, including adolescents and over 40
- Smoke
- Have just had an abortion or a miscarriage

Also, women with the following conditions can use POP contraceptives in any circumstances:

- Benign breast disease
- Heavy, painful menstrual periods or iron deficiency (anaemia)
- Irregular menstrual periods
- Diabetes without vascular, kidney, eye or nerve disease
- Mild headaches
- Vericose veins
- Malaria
- Sickle cell disease
- Thyroid disease

- Pelvis inflammatory disease
- Sexually transmitted disease
- Endometriosis
- Benign ovarian tumour
- Uterine fibroids
- Past ectopic pregnancy
- Epilepsy
- Tuberculosis unless taking Rifampin

c. Important clarification and evidences for medical eligibility of POPs

1. Studies have shown that among breastfeeding women less than 6 weeks postpartum, progesterone- only contraception did not affect breastfeeding performance and infant health and growth.

2. When multiple risk factors for arterial cardiovascular disease exist, cardiovascular disease may increase substantially, though this increase is substantially less than with COCs.

3. It is desirable to have blood pressure measurement taken before using POP. However, if the facility of blood pressure measurement is not available and/or risks due to pregnancy morbidity/mortality are high, women should not be denied use of POPs simply because their blood pressure cannot be measured.

4. Women with a history of deep vein thrombosis/pulmonary embolism can use POPs, but those with current disease should use POPs only if other more appropriate contraceptives are either unavailable or unacceptable to the client.

5. Women currently suffering from breast cancer have an unacceptable health risk by using POPs.

6. HIV/AIDS: Overall, evidence is inconsistent regarding whether there is any increased risk of HIV acquisition among POP users as compared to non-users.

7. Women taking Rifampicin or certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) should be prescribed POPs only if any other appropriate contraceptive is unavailable or unacceptable. Although the interaction of these drugs with COCs is not harmful to women, it is likely to reduce the effectiveness of POPs. Use of other contraceptives should be encouraged for the women who are long-term users of any of these drugs. Whether increasing the dose of the hormones in POPs is useful is still unclear. However, there is evidence that use of certain anti-convulsants decreases the effectiveness of POPs.

8. It is important to note that antiretroviral drugs (ARVs) have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data available suggests that the potential drug interaction between ARVs and hormonal contraceptives may alter the safety and effectiveness of both the hormonal contraceptives and ARVs. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended for preventing HIV transmission. This will also compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

Chart 4: When can a woman start POPs?

Women's situation	When to start
During menstrual cycle	She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraception is needed. She can also start POPs at any other time, if she is reasonably certain that she is not pregnant.
Amenorrhoeic	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 next 2 days.
Breastfeeding	She can start POPs 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. If she is more than 6 months postpartum and her menstrual cycle has returned, she can start POPs as advised for any other woman with a menstrual cycle. For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POPs is not recommended.
Switching from another hormonal method	She can start POPs immediately, if she has been using her hormonal method consistently and correctly, or if she is otherwise reasonably certain that she is not pregnant. There is no need to wait for the next menstrual period. If her previous method was an injectable, she should start POPs at the time when the repeat injection would have been given. No additional contraceptive protection is needed. She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
Switching from a non-hormonal method (other than IUD)	She can also start immediately or any other 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 next 2 days.

d. Explaining how to use POPs

Give specific instructions. The client should always take one pill every day. If not breastfeeding, it is best to take the pill at the same time each day if possible, as even taking a pill more than a few hours late increases the risk of pregnancy. Missing two or more pills in a row greatly increases the risk of pregnancy.

Starting the next packet

When the client finishes one packet, she should take the first pill from the next package on the very next day. All pills are active, hormonal pills. There is to be no gap between packets.

If a woman forgets one or more pills she should take one pill as soon as she remembers and then keep taking one pill every day as usual.

- A breastfeeding woman using progestin-only pills for extra protection is still protected if she misses the pill.
- If more than 3 hours taking a pill, a woman who is not breastfeeding or who is breastfeeding but whose menses have resumed should also use condoms or spermicide or else avoid sex for two days. She should also take last missed pill as soon as she can. Then she should keep taking one pill every day as usual.

Give advice on common problems. Describe the symptoms of problems that require medical attention. Serious complications of progestin-only pills are rare. Still a woman should see a doctor or nurse or return to the clinic if she has any problems. POPs may or may not cause the problems listed below:

- Extremely heavy bleeding.
- Any very bad headaches that start or become worse after she begins to take POPs.
- Skin or eyes become unusually yellow.
- Might be pregnant (for example, missed period after several regular cycles), especially if she also has signs of ectopic pregnancy - abdominal pain, tenderness, or faintness. A woman who develops these signs must seek care at once.

Pregnancies among POP users are few, especially during breastfeeding. When pregnancy occurs, however, as many as 1 in every 10 may occur outside the uterus. Ectopic pregnancy is life-threatening and requires treatment at once.

Following up POP users

Helping clients at any routine return visit

- Same as in COCs
- If the client has developed active liver disease, ask her to stop the pill and do not provide her with any further pill. Refer her to care and help her to choose a non-hormonal contraceptive.
- If she is taking medicine for seizures, rifampicin or griseofulvin, provide condoms or spermicide to use along with POPs. If she prefers, or if she is on long-term treatment, help her choose another effective contraceptive method.
- If she has developed breast cancer, discontinue the pills and help her choose another non-hormonal contraceptive.

It is important to note that if the client is dissatisfied with treatment and counselling, it is imperative that she be helped to choose another method of contraception, to ensure protection against pregnancy as per her wish.

Chart 5: How to manage problems

Problem	Plan of action
Amenorrhoea (or no monthly bleeding period) or irregular bleeding and spotting in a breastfeeding woman	• Reassure the woman that this is normal duringbreastfeeding, whether or not a woman is using progestin- only oral contraceptives. • Ask if she has been having regular monthly periods while taking POPs and then suddenly had no periods. She may have been ovulating. Rule out pregnancy. • If not likely that she is pregnant, tell the client that these bleeding patters are normal with POPs. They are not harmful. She is loosing less blood than she would if she were not using family planning. Explain to her that this can improve her health as it helps prevent anaemia.
Unexplained abnormal vaginal bleeding that suggests pregnancy or underlying medical condition	• She can continue using POP contraceptives while her condition is being evaluated. • Explain that POP contraceptives sometimes change the vaginal bleeding pattern, and that this is not harmful. • Evaluate and treat any underlying medical condition, including ectopic pregnancy, or refer her to care.
Heart disease due to blocked arteries (ischemic heart disease or stroke)	• A woman who has this condition can safely start using progestin-only contraceptives. If, however, the condition develops after she starts using them, she should switch to a method without hormones • Refer her to care as appropriate
Very bad headaches (migraines) with blurred vision	• A woman who gets migraines can safely start using progestin-only contraceptives. However, she should switch to a method without hormones if these headaches start or become worse after she begins using progestin-only oral contraceptives, more so if these headaches involve blurred vision, temporary loss of vision, seeing flashing lights or zigzag lines or difficulty in speaking or moving • Refer her to care as appropriate

3.4 Emergency Contraceptive Pills (ECPs)

Progestin-only OCPs containing the hormone levonergstrel can be used for emergency contraception. If the correct dose is started within 72 hours after unprotected intercourse, it reduces the chances of pregnancy. Emergency contraception has a special role for groups such as the adolescents and women who suffer from sexual violence. There is a need to increase access to ECPs by training healthcare providers and also by ensuring easy availability of ECPs.

a. What is Emergency Contraception?

It is method of contraception that is used to prevent pregnancy, also known as the "morning after pill" (although unlike its name the pill can be used any time in the day as per guidelines after exposure) or "postcoital contraception."

A woman who had an unprotected sex and wants to prevent pregnancy can use emergency contraception in the following circumstances:

- She did not expect to have sex and was not using any contraception
- Sex was forced upon her without her consent
- A condom broke or slipped
- She ran out of contraceptives, started a new packet of pills several days late, or missed three or more active pills in a row and did not use condoms or spermicide.
- She is late for a contraceptive injection – more than 2 weeks late for DMPA, more than 2 weeks for Norethindrone enanthate or more than 3 days late for a monthly injection such as Cyclofem or Mesigyna

To summarise, emergency contraception can be used in all those circumstances in which a woman has reason for concern that she may become pregnant.

b. Levonrgesterel only EC pills - A Dedicated Product

Several such dedicated commercial products are available in India. Emergency Contraceptive Pills containing levonorgesterol have been included in schedule K, which makes them over the counter drugs. A prescription is not needed for getting ECPs. In the national programme also, a dedicated product is available at the facilities. The current recommendation is that 1 pill of LNG 0.75 mg to be taken as soon as possible after unprotected coitus (within 72 hours), followed by another pill 12 hours later. This method has been found to be highly effective and has only mild and less frequent side effects compared to other combinations/regimen. In order to simplify the LNG regimen, a single dose of LNG 1.5 mg was tried in a WHO multicentric randomized trial. It has been found that within 120

hours of exposure to unprotected sex, a single dose of LNG 1.5 mg is as effective as 2 doses given 12 hours apart.

c. How ECPs work and how effective are they

Out of 100 women, if each has sex once in the second or third week of the menstrual cycle without using contraception, 8 women are likely to become pregnant. If all 100 women use progestin-only ECPs, only one is likely to become pregnant. These statistics show that while ECPs are appropriate in emergency situations, they are not as effective as the regular use of most modern contraceptives.

ECPs mainly stop ovulation (release of eggs from ovary) just as OCs taken daily do, but it is likely that there are other mechanisms involved too, such as:

- Inhibition or delay of ovulation
- Thickening of cervical mucus
- Direct inhibition of fertilization
- Histological and biochemical alteration in endometrium leading to impaired endometrial receptivity to implantation of the fertilized egg
- Alteration in transport of egg, sperm and embryo
- Interference with corpus luteum function and luteolysis

ECPs do not interrupt existing pregnancy. Any woman can use emergency oral contraception if she is not already pregnant.

d. The procedure

The ECPs should be taken as soon as possible after unprotected intercourse. The first dose should be taken within 72 hours of intercourse. It is important to note that emergency oral contraception should not be used in place of other family planning methods, but as its nomenclature suggests, it should be used only in the emergency situations described above.

1. Ask specific questions to determine the likelihood of pregnancy. If the client is clearly pregnant, do not provide Emergency Oral Contraceptives.

2. Explain what Emergency Oral Contraception is, its side-effects and effectiveness.

3. Provide the pills for Emergency Oral Contraception.

Make certain that the client does not want to become pregnant, but that she understands that there is still a chance of pregnancy even after using ECPs. Explain that the ECPs will not cause any harm to the foetus if it fails to

prevent pregnancy.

It is imperative that the client understands that the first tablet of Levonorgestrel 0.75 mg should be taken as early as possible, within 72 hours of the first act of sexual intercourse, and that the second tablet is taken within 12 hours of the first tablet. The timing of the second tablet is also important.

Explain that the pill can be taken with a sip of water and that nausea can be reduced if the pill is taken with milk or a snack. Explain that taking more than the two pills prescribed, DOES NOT increase its effectiveness, but rather increases the side-effects.

If willing, she should start another method immediately, such as condoms/spermicide, or she should avoid sex until she can start her preferred contraceptive method.

e. Advice on common problems

- Nausea: Suggest that the client eats something soon after taking the pills to reduce any nausea.
- Vomiting: If the woman vomits within two hours after taking the pills, she may take another dose. Otherwise she should not take any extra pills as this may increase nausea.
- Her next monthly period may start a few days earlier or later than expected. Reassure her that this is normal under the circumstances.
- Explain that ECPs do not protect against STIs or HIV.

Explain specific reasons to return to the healthcare provider

1. Advise her to return or see another health care provider if her next period is quite different from usual, especially if it is:
   - Unusually light bleeding (possible pregnancy)
   - Does not start within 4 weeks (possible pregnancy)
   - Unusually painful (possibly ectopic pregnancy - but emergency oral contraception does not cause ectopic pregnancy.)
2. Describe the symptoms of sexually transmitted diseases—for example, unusual vaginal discharge, pain or burning on urination. Advise her to see a health care provider if any of these symptoms occur.

If the woman is likely to have sex again, then counsel her to start using an effective contraceptive. Help her to do so or plan to do so. If she does not start any other method immediately, give her condoms or spermicide to use at least until she chooses another ongoing method of contraception.

f. Some FAQs about Emergency Contraception

Do ECPs cause abortion?

No. ECPs will not disrupt an established pregnancy. They are not effective once the process of implantation has begun.

Do any medical conditions rule out use of ECPs?

No medical conditions rule out ECPs. Medical conditions that rule out continuing use of oral contraceptives do not apply to ECPs. Furthermore, there is no suggested evidence that ECPs increase the risk of complications such as certain circulatory diseases, associated with ongoing oral contraceptive use.

After using ECPs, can a woman start an ongoing method of contraception?

ECPs do not provide continuing protection from pregnancy. Therefore, it is important to start an ongoing method of contraception after ECP use. Most methods can be started at once, for example:

- Condoms and spermicides: A woman who wants to start another method later, needs to use these methods before deciding on the best method of contraception for her.
- If a woman chooses to use oral contraceptives regularly, she should take the first pill on the next day after she finishes the ECPs. She should also use condoms for the next seven days.
- A woman who wants an IUD for ongoing contraception can have it inserted within five days of unprotected intercourse in place of taking ECPs.
- Injectables can be started within seven days after the beginning of the next menstrual cycle. The woman should use condoms until then.
- Couples who want to use a fertility awareness-based method such as periodic abstinence may need to abstain or use condoms at first and wait one or two cycles until the woman's menstrual cycle becomes regular.

All these guidelines also apply to switching to another method after regular use of oral contraceptives.

ECPs offer no protection against STIs. When indicated, as in case of rape, preventive STI treatment should also be considered.

g. Increasing access to ECPs

More women and more providers need to know about ECPs. Also, access to ECPs should be improved both for

women in general and for groups with special needs. decisions to include ECP as OTC drug.

Women: The public, and women in particular, need to know about ECPs and how to obtain them. Emergency contraception should be discussed with women at routine health care visits. Studies have shown that those who had correct information about ECPs, particularly about their ingredients and side-effects, had a more favourable attitude towards their use.

Providers: All health care providers should know about ECPs, including which pills to use, correct regimen and possible side-effects.

- Make access to ECPs easy
- Train a range of providers
- Remove unnecessary medical barriers to access
- Offer ECPs over the counter

Serve groups with special needs

Youth/adolescents: There are many reasons why it is adolescents that especially need ready access to ECPs. The psychological, social and health risks of an unwanted pregnancy are especially great for adolescents. At the same time, sexual activity among the youth tends to be more sporadic and less likely to be planned for than with adults, and young people are more likely to take risks. Furthermore, according to a US study adolescents tend to wait some time between starting sexual activity and seeking reproductive health care, including contraception. As family, schools and society at large often disapprove of adolescent sexual activity, more young people lack adequate and appropriate information on sexuality, family planning and reproductive health care. Not only can emergency contraception help prevent unwanted pregnancies and abortions in this vulnerable group, but also providing ECPs sometimes can create an opportunity for the health care provider to offer other reproductive health services and provide counselling on healthy sexual behaviour.

Women who risk sexual violence: Emergency contraception is a pressing need for many victims of sexual violence. Women abused by their husbands or boyfriends are often unable to negotiate timing or terms of sexual intercourse and use of contraceptives. A violent sexual partner may prevent a woman from using ongoing contraception, thus putting her at risk of an unintended pregnancy, which itself can perpetuate further violence from an abusive partner. Some women cannot discuss contraception with their partners for the fear that it would spark abuse. Thus, access to ECPs is especially critical for battered women. ECPs should be available where ever women may seek help for refuge, such as hospital emergency rooms, counselling centres and women's shelters

CHAPTER 4

Injectable Contraceptives: Progestin-Only Injectables (POIs)

Injectable Contraceptives: POIs

About 12 million couples throughout the world now use injectable contraceptives. Progestin-only injectables are the most widely used. DMPA (Depot Medroxyprogesterone acetate), provides three months of protection, and NET-EN (Norethidrone enanthate), provides protection for two months.

Throughout the world many women value injectables because they are highly effective, long lasting, reversible, convenient and can be used privately. Also, breastfeeding women who want to use a hormonal contraceptive can use progestin-only DMPA or NET-EN.

Women experience a variety of side-effects with injectables. Disruption of menstrual bleeding is common, which some women find troublesome. Good counselling helps women understand that frequent and irregular bleeding and amenorrhoea are not dangerous, and that many clients continue to use injectables despite irregularities in bleeding pattern.

The most widely-used and extensively studied progestin-only preparations are the three-monthly DMPA used by over 10 million women and two monthly NET-EN (norethidrone enanthate) used by over 1 million women. Both are highly effective, safe, long acting, reversible and convenient. An alternative injectable containing long-acting progesterone preparation with short action estrogen 25 mg DMPA + 15 mg estradiol cypionate (Cyclofem) and 50 mg NET-EN + 5 mg estrdiol valerate (Mesigyna) are currently available, which are given once a month and produce a menstruation-like pattern. The trials are currently taking place in India.

DMPA is currently approved and available in 106 countries and NET-EN in over 60 countries. It has been approved in India by the Drug Controller of India and is presently available through commercial channels, social marketing organisations and non-government organisations (NGOs).

a. How does it work?

Injectables inhibit ovulation by:

- preventing the LH surge and lowering FSH and LH.
- by thickening the cervical mucous and rendering the endometrium less suitable for implantation
- by hindering the rate of ovum transport.

Effectiveness: The reported first year failure rate of DMPA is 0.3%. The two-year pregnancy rate with NET-EN (given every 84 days) was 1.4 per 100 women in contrast to 0.4 women observed for DMPA and NET-EN (given every 60 days). Pregnancy rate with Mesigyna is 0.18 per 100 women years and nil for cyclofem.

Continuation rate: Markedly different between populations and centres. The continuation rate with DMPA at the end of one year has been in the range of 50 to 80%. Bleeding abnormalities account for 10-15% discontinuation rate

with both DMPA and NET-EN and an additional 11-12% of DMPA users and 7-8% NET-EN users discontinue due to amenorrhoea. For monthly injectables, the continuation rates range from 66-82% with 7% discontinuation for bleeding abnormalities and 2% for amenorrhoea.

b. The advantages and disadvantages of DMPA

Advantages:

- Very effective
- Confidential
- Long-term pregnancy protection, but reversible.
- No daily pill taking. Allows some flexibility in return visits. Clients can return as much as up to 2 weeks early (although this is not ideal) and up to 2 weeks late for next injection.
- Quantity and quality of breast milk not affected. Can be used by lactating mothers as soon as 6 weeks after childbirth.
- No estrogen side-effects. Does not increase the risk of estrogen-related complications, such as heart attack.
- Helps prevent ectopic pregnancies.
- Helps prevent uterine fibroids.
- May help prevent ovarian cancer.
- Special advantages in some women:
  - May help prevent iron-deficiency anaemia
  - May make seizures less frequent in women with epilepsy
  - Makes sickle cell crisis less frequent and less painful

Disadvantages:

- Common side effects:
  - Changes in menstrual bleeding are likely
  - Heavy bleeding can occur at first, but this is very rare.
  - Amenorrhoea is common with injectables, especially after the first year of use.
  - May cause weight gain.
- Delayed return of fertility (until level of DMPA in the body drops). About a 4-month longer wait before

pregnancy than for women who had been using combined oral contraceptives, IUDs, condoms or a vaginal method.

- May cause headaches, breast tenderness, moodiness, nausea, hair loss, less sex drive, and/or acne in some women.
- Does not protect against sexually transmitted diseases including HIV/AIDS.

c. Medical eligibility checklist

Most women can use DMPA. In general DMPA injectable contraceptive can be used safely and effectively under any circumstances by women who:

- Are breastfeeding (starting as soon as 6 weeks after childbirth)
- Smoke cigarettes
- Have no children
- Are any age, including adolescents, above 18 years and over 40. For women under 18 years there are theoretical concerns regarding hypo-oestrogenic effects of DMPA, including whether these women will achieve their peak bone mass. Similarly after 45 years there are theoretical concerns regarding hypo-oestrogenic concerns and whether these women will regain all lost bone mass after discontinuation
- Are fat or thin
- Have just had an abortion or miscarriage
- Changes in menstrual patterns associated with DMPA use have little effect on Hb status.

Also, women with these conditions can use DMPA under any circumstances:

- Benign breast disease
- Mild headaches
- Mild or moderate high blood pressure
- Iron deficiency anaemia
- Varicose veins
- Vulvular heart disease

- Irregular menstrual periods
- Malaria
- Sickle cell disease
- Thyroid disease
- Uterine fibroid
- Epilepsy
- Tuberculosis

c. Major clarifications on medical eligibility of DMPA

1. There is limited evidence showing decreased bone mineral density over time among adolescent DMPA users. No studies have examined whether DMPA use among adolescents affects peak bone mass level. However, older DMPA users had decreased bone mineral density compared to non-users. Also limited evidence found that women gained bone mass following discontinuation of DMPA prior to menopause. Furthermore, among perimenopausal women, there was no difference in bone mineral density between former DMPA users and never-users. The clinical implications are that findings on bone density to date do not warrant denying DMPA to any group of women. Providers may however give special consideration to women under the age of 16. Loss of bone mass at this age increases the risk of osteoporosis after menopause. Pregnancy at this age, however, can also affect bone mass. Thus, the benefits of an effective, reversible method such as DMPA to sexually active young women probably outweigh the risks.

2. Studies have shown that among breastfeeding women less than 6 week postpartum, progesterone-only contraceptives did not affect breastfeeding performance or infant growth and health.

3. Post-abortion use of NET-EN: Limited evidence suggests that there are no adverse side effects when NET-EN is initiated after a first trimester abortion.

4. Multiple risk factors for arterial cardiovascular disease: When multiple major risk factors exist, the risk of cardiovascular disease may increase substantially. The effects of DMPA and NET-EN may persist for some time after discontinuation. It is desirable to have blood pressure measurement taken before initiation of progesterone-only contraceptive (POCs) use. However, in some settings blood pressure measurements are unavailable. In many of these settings pregnancy-related morbidity and mortality risks are high, and POCs are one of the easily available contraceptive methods. In such settings, women should not be denied use of POCs simply because their blood pressure cannot be measured.

5. Limited evidence suggests that among women with hypertension, those who used DMPA or NET-EN had a small increased risk of cardiovascular complications compared to women who did not use these methods.

6. Deep venous thrombosis/pulmonary embolism: DMPA/NET-EN may increase the risk of venous thrombosis. However, this risk is much lower compared to COCs.

7. Current and history of ischemic heart disease: There is concern regarding hypo-estrogenic effects and reduced HDL levels, particularly among DMPA and NET-EN users. The effects of DMPA and NET-EN may persist for some time after discontinuation.

8. Unexplained vaginal bleeding: The DMPA and NET-EN may cause irregular bleeding which may mask the underlying pathology. This effect may persist some time after discontinuation.

9. Breast cancer: Breast cancer is hormone sensitive hence use of any DMPA/NET-EN may worsen the prognosis of the client.

10. A WHO study found that DMPA did not increase women's overall risk of breast cancer, invasive cervical cancer, liver cancer, or ovarian cancer and that it decreased the risk of endometrial cancer.

11. Pelvic inflammatory diseases or STIs: Whether hormonal injectables or COCs reduce the risk of PID among the women with STIs is not known, but they do not protect against HIV or lower genital tract STIs. Limited evidence suggests that there may be an increased risk of chlamydial cervicitis among DMPA users at high risk of STIs. For other STIs, there is either evidence of no association between DMPA use and STI acquisition or too limited evidence to draw any conclusions.

12. Risk of HIV: Overall, evidence is inconsistent regarding whether there is any increased risk of HIV acquisition among DMPA/NET-EN users when compared with non-users.

13. Effect on HIV-infected client: Studies are conflicting regarding whether there is an increased risk of HIV and herpes simplex virus shedding among HIV-infected women using DMPA.

14. Severe liver cirrhosis, active viral hepatitis, liver tumours: DMPA/NET-EN should be used only if other appropriate contraceptives are unavailable or unacceptable.

15. Woman undergoing antiretroviral (ARV) therapy: It is important to note that antiretroviral rugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. The limited data available suggest that potential drug interactions between many ARVs and protease inhibitors and hormonal contraceptives may alter the safety and effectiveness of both the hormonal contraceptive and the ARVs. It is not known whether the contraceptive effectiveness of DMPA and NET-EN would be compromised, as these methods provide a higher blood hormone level than progesterone-only contraceptives, as well as COCs. Thus, if a woman on ARV treatment decides to continue hormonal contraceptive use, the consistent use of condoms is recommended for preventing HIV transmission and may also compensate for possible reduction in the effectiveness of the hormonal contraceptives.

d. When can a woman start?

Chart 6: When to start on DMPA and NET-EN

Various situations	When to start injectable
Having menstrual cycles	• She can have the first progestogen-only injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. • She 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.
Amenorrhoea	• She 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.
Breastfeeding	• If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have her first injection at any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed. • If she is more than 6 weeks postpartum and her menstrual eriods have returned, she can have her first injection as advised for other women during menstrual cycle. * For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POIs is not usually recommended unless other more appropriate methods are unavailable or unacceptable.
Switching from another hormonal method	• She can have the first injection immediately, if she has been using her 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 progestogen-only injection when the repeat injection would have been given. No additional contraceptive protection is needed.

Various situations	When to start injectable
Switching from a non-hormonal method (other than IUD)	• She 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 hormonal)	• She can have the first injection within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time. • She can also start at any other time, if it is reasonably certain that she is not pregnant. If she has been sexually active in this 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 this 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.

e. Providing DMPA

A woman who chooses DMPA benefits from good counselling. A friendly provider who listens to a woman's concerns, answers her questions and gives clear, practical information about the side-effects, especially probable bleeding change including amenorrhoea, will facilitate the successful use of DMPA.

Follow these steps to provide DMPA:

- Explain how to use DMPA
- Give the injection
- Plan with the woman a return visit after 3 months for the next injection.
- Invite the client to come back any time she has questions or problems or requires another method.

Give specific instructions:

1. The client should try to come back on time for the next injection. She may come as much as up to 2 weeks earlier (although this is not ideal) or up to 2 weeks late. However, the woman should be encouraged to come back ON TIME (3 months after first injection) for the next injection.

2. If more than 2 weeks late for next injection, she should use condoms or spermicide or else avoid sex until the next injection.

3. She should come back no matter how late she is. The provider can ask questions to see if the client might be pregnant.

Give advice on common problems:

1. Mention the most common side effects, in particular changes in menstrual bleeding and possibly weight gain.

2. Explain about these side effects:

   - At first probably she will have bleeding at unexpected times. The amount of bleeding usually decreases over time. After 6 to 12 months of use, she probably will have little vaginal bleeding or none at all.

   - These changes are common, normal and not harmful. They do not mean that she is pregnant or sick or that the composition of her blood is changing. Little or no bleeding can in fact make some women healthier as this helps prevent anaemia.

   - She may gain weight. This also is common, normal and not harmful. Studies provide conflicting evidence regarding whether obese women are at increased risk of weight gain and bleeding problems with DMPA use inrelation to non-obese women. Many studies have shown that most users of injectables gain weight. On ana verage, DMPA users gain 1.5 kg to 2.0 kg in the first year. Some users may continue to gain weight the reafter at about the same rate. The range of weight change is wide. NET-EN users gained an average weight of 1.5 kg in a 1-year WHO trial.

- Advice on possible delay for return of fertility.

3. Invite the client to come back any time she needs more help with any problems or she requires a different method.

Explain specific reasons to see a nurse or doctor

Describe the symptoms of problems that require medical attention. Serious complications of DMPA are rare. Still a woman should see a doctor or nurse or return to the clinic if she has questions or problems or any of the following possible symptoms, which may or may not be caused by DMPA.

- Bothersome and extremely heavy bleeding (twice as long or twice as much as usual for her).
- Very bad headache that starts or becomes worse after taking DMPA.
- Skin or eyes become unusually yellow.

f. The injection

Equipment and supplies needed for the injection are:

- One dose of DMPA (150 mg)
- An antiseptic and cotton wool
- A 2 or 5 ml syringe and 21 to 23 gauge intramuscular needle. Syringe and needle should be sterile, or subjected to high-level disinfection.

Importance of proper injections

Careful injection technique ensures that the full dose is absorbed at the right rate and thus is fully effective

- With DMPA, providers need to shake vials to dissolve any sediment at the bottom, but they should not shake so vigorously that the liquid becomes frothy and difficult to draw into the syringe.
- With NET-EN, warming vials to body temperature thins the viscous solution and makes it easier to draw completely into the syringe.
- With all injectables, the injections should be given in the gluteal or deltoid muscle because absorption may be too slow if the provider injects it into the fat. In contrast, massaging the injection site accelerates the absorption and thus should be avoided.

To ensure that injections are carried out properly, follow these steps:

1. Wash hands and wear gloves.

2. Wash injection site with soap and water if needed and wipe with antiseptic, if available. Use a circular motion from the injection site outwards.

3. Shake vial gently, wipe top of vial and stopper with antiseptic and fill syringe with proper dose.

4. Insert sterile needle deep into the upper arm (deltoid muscle) or into buttocks (gluteal muscle, upper outer portion), and inject the contents of the syringe. For DMPA, the upper arm is more convenient.

5. DO NOT MASSAGE the injection site, and tell client not to massage or rub the site too. Explain that this could cause DMPA to be absorbed too fast.

6. Careful disposal of injections is very important. See chart no. 8 below.

Chart 7: How to process used injection equipment

Processing disposable equipment	Processing reusable equipment
DO decontaminate disposable needles and syringes by flushing them with 0.5% chlorine solution 3 times or soaking them in a chlorine solution for 10 minutes. DO dispose off disposable needles and syringes by placing them in puncture-proof container and then burning and/or burying the container when three-quarters full. DO NOT put disposable needles and syringes in the wastepaper basket after they have been contaminated. DO NOT recap disposable needles before disposal DO NOT bend or break needles before disposal.	DO process reusable needles and syringes appropriately: 1. Decontamination in 0.5% chlorine solutionfor 10 minutes 2. Cleaning with soap and water and rinsing 3 times with clean water. 3. Sterilization or high-level disinfection DO sterilize or use high-level disinfected containers in which reusable needles and syringes are stored. DO NOT high-level disinfect or sterilize equipment without decontamination and cleaning it first. DO NOT clean needles and syringes without taking them apart. DO NOT reuse disposable needles and syringes. DO NOT store sterilized or high-level disinfected needles and syringes in a container that has not been sterilized or high-level disinfected.

g. Follow up

Help the clients at the routine return visit and ask the following questions:

1. Ask if the client has any questions or anything to discuss.

2. Ask the client about her experience with the method, whether she is satisfied, and whether she has any problems. Give her any information or help that she needs and invite her to return any time she has questions or concerns. If she has problems that cannot be resolved, help her choose another method.

3. Ask about her bleeding pattern.

   - If the client has developed heart disease due to blocked arteries, stroke, blood clot (except superficial clots), breast cancer, severe high blood pressure, or active liver disease, help her to choose another method without hormones.

   - If the client has developed very bad headaches, help her manage it.

Plan for her next visit

If she has not developed any conditions necessitating discontinuation, and she wants to continue with this method, give her an injection and plan for the next visit in 3 months for DMPA.

Chart 8: When to have repeat progestogen-only injectables

The scenario	Suggestion
Reinjection interval	• Provide repeat DMPA injections every 3 months. • Provide repeat NET-EN injections every 2 months.
If client is early for an injection	• The repeat injection for DMPA and NET-EN can be given up to 2 weeks early.
If client is late for an injection	• The repeat injection for DMPA and NET-EN can be given up to 2 weeks late without requiring additional contraceptive protection. • If she is more than 2 weeks late for a DMPA or NET-EN repeat 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 appropriate.
Switching between DMPA and NET-EN	• Using DMPA and NET-EN injections interchangeably is not recommended. • If it becomes necessary to switch from one to the other, the switch should be made at the time the repeat injection would have been given.
For a repeat POI when the previous injectable type and/or timing of injection is unknown	• 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.

Chart 9: What to do if a woman has menstrual abnormalities or other common problems while using progesterone-only injectables?

If the woman has:	Suggestion
Amenorrhoea	• Amenorrhoea does not require any medical treatment. Counselling is sufficient. • If she still finds amenorrhoea unacceptable, discontinue the injectable, and help her choose another method.
Spotting or light bleeding	• Spotting or light bleeding is common during POI use, particularly in the first injection cycle, and is not harmful. • In women with persistent spotting or bleeding, or women with bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer her to care. • If STI or pelvic inflammatory disease (PID) is diagnosed, she can continue her injections while receiving treatment, and be counselled on condom use. • If no gynaecologic problems are found, and she finds the bleeding unacceptable, discontinue the injectable, and help her choose another method.
Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)	• Explain that heavy or prolonged bleeding is common in the first injection cycle. • If heavy or prolonged bleeding persists, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer her to care. • If the bleeding becomes a threat to the health of the woman, or it is not acceptable to her, discontinue the injectable. Help her choose another method. • To prevent anaemia, provide an iron supplement and/or encourage foods containing iron.

If the woman has:	Suggestion
Unexplained abnormal vaginal bleeding that suggests pregnancy or an underlying medical condition	• If her bleeding began after she started using DMPA, she can continue using it while her condition is being evaluated. • Explain that DMPA normally changes vaginal bleeding patterns and that usually these changes are not harmful. • Evaluate and treat any underlying medical condition, or refer her to care.
Very bad headaches (migraines) with blurred vision	• A woman who gets migraine headaches can safely start using DMPA. She should switch to a method without hormones, however, if these headaches start or become worse after she begins using DMPA and also if there is blurred vision, temporary loss of vision, seeing flashing lights or zigzag lines, or any trouble speaking or moving. • Refer her to care as appropriate.

g. Return to fertility in women using DMPA or NET-EN

Since DMPA is a long-acting contraceptive, it takes some time to wear off after the last injection. Re-establishment of menstruation after an injection of DMPA is delayed and difficult to predict. In pre-menopausal women it generally takes 6-8 months after the last injection for menstruation to become regular. No woman should use DMPA or NET-EN without knowing that there may be a delay in her becoming pregnant after stopping the contraceptive. In any case, providers need to make it clear that conception time cannot be predicted with certainty for any woman.

Providers must inform that pregnancy may be delayed by several months. If a woman wants to know how long she may have to wait, providers have several options for describing the typical delays:

- Time from last injection: Half of DMPA users become pregnant in the first nine months after the last injection.
- Time from when the next injection would have been given: Six months, on an average for DMPA
- Compared with other methods: DMPA users may have to wait 2-3 months longer on an average than former COC users.
- In a large US study of women who discontinued DMPA to become pregnant, data from 61% of them are available. Sixty-eight per cent of women who became pregnant conceived within 12 months, 83% conceived

within 15 months and 93% conceived within 18 months of the last injection. The median time to conception for those who do conceive is 10 months following the last injection.

- In a study in Thailand, 91% women of former DMPA users had conceived within 2 years after discontinuing compared to 93% of former IUD users and 95% of formers oral contraceptive users.

CHAPTER 5

Intrauterine Devices (IUDs)

5.1 What are IUDs?

The intrauterine devices (IUDs) offer almost complete protection from pregnancy. The newer IUDs have a longer life-span and are more effective. In practice the CuT-380A and other currently available IUDs such as CuT-220C, the Multiload-375, and the LNG-20 are more effective than oral contraceptives if used correctly and consistently, and are on par with injectables and voluntary sterilization. The hormone-releasing IUS, LNG-20 is one of the most effective IUDs, with just 0.3 pregnancies per 100 women after five years of use.

The providers of IUDs play a very crucial role in the increasing use of IUDs. The provider's good judgment, training and skills help ensure good counselling for clients, proper screening for medical eligibility, careful and gentle insertion using appropriate infection prevention techniques and adequate follow up support to the IUD users.

An intrauterine device is a small, flexible plastic frame, which often has copper wire or copper sleeves on it. It is inserted into the woman's uterus through her vagina.

Almost all brands of IUDs have one or two strings or threads, tied to them. The strings hang through the opening of the cervix into the vagina. The user can check that the IUD is in place by touching the strings. A provider can remove the IUD by pulling gently on the strings with forceps.

The different types of IUD now available are:

- *Copper-bearing IUDs:* Made of plastic with copper sleeves and/or copper wire on the plastic, such as TCu-380A, MLCu-375.

- *Hormone-releasing IUDs:* Made of plastic, steadily released small amounts of hormone progesterone or progestins such as levonorgestrol, LNG-20 and Progestasert.

Comparing IUDs: The second generation IUDs such as CuT-380A, CuT -220C, Nova T and Multiload 375 are much more effective and have fewer side effects than unmedicated IUDs. The copper IUDs currently available are similar in terms of effectiveness, side effects, expulsion and continuation rates.

The CuT-380A has been approved for use up to 10 years. It is now the most widely used IUD and one of the most effective methods of contraception ever developed. In the national programme also, CuT- 380 A is available.

Effectiveness: IUD is one of the most effective methods of contraception. Pregnancy rates for all major IUDs are less than one per 100 women per year. They are at least as effective as implants, injectable contraceptives

and voluntary male and female sterilization. In an ongoing international trial sponsored by WHO after 10 years of use, the cumulative pregnancy rate for CuT -380A was 2.1 per 100 women and for CuT-220C was 5.7. For the LNG-20 a pregnancy rate of 0.3 has been reported after 5 years.

Continuation: Women use IUDs longer than most other reversible contraceptive methods. A WHO study found 44% acceptors continuing to use the TCu-380A after 7 years. IUD continuation rates in clinical trials are as high or higher than implants and higher than oral contraceptives, condoms or diaphragms.

5.2 Copper-bearing IUDs

a. Mechanism of action, advantages and disadvantages

Copper-bearing IUDs work mainly by preventing the sperm and egg from meeting. The IUD makes it hard for sperm to move through the woman's reproductive tract, which reduces the ability of sperm to fertilize an egg, or it prevents the egg from implanting in the wall of the uterus.

Advantages:

- A single decision leads to effective long-term prevention of pregnancy.
- Long-lasting. The most widely used IUD — CuT-380A, lasts at least for 10 years.
- Very effective and also convenient, as the client does not have to remember anything once this is inserted.
- No interference with sex.
- No hormonal side effects of copper-bearing IUDs
- Immediately reversible. When women have their IUDs removed, they can become pregnant as quickly as women who have not used IUDs.
- Copper-bearing IUDs have no effect on quality or quantity of breast milk.
- Can be inserted immediately after childbirth or after induced abortion (if there is no evidence of infection.)
- Can be used through menopause (one year or so after the last menstrual cycle).
- Does not interfere with any medication.
- Helps prevent ectopic pregnancy (less risk of ectopic pregnancy than in women not using any contraceptive method)

Disadvantages

- Menstrual changes common in early months, but this is reduced after 3 months'
- Longer and heavy menstrual periods
- Bleeding or spotting between periods

- More cramps or pain during period.
- Some uncommon side effects:

  - Severe cramps and pain beyond first 3-5 days of insertion

  - Heavy menstrual bleeding or bleeding between periods, possibly contributing to anaemia. This is more likely with inert IUDs than with copper-bearing or hormonal IUDs

  - Rare possibility of perforation if not inserted properly

- Does not protect against sexually transmitted diseases (STDs) including HIV/AIDS. This is not a good method for women with recent STDs or with multiple sex partners (or who has a partner with multiple sex partners).

- Medical procedure, including pelvic examination is needed to insert IUD. Occasionally, a woman faints during the insertion procedure.

- Some pain and bleeding or spotting may occur immediately after IUD insertion, which disappears in a day or two.

- Client cannot stop IUD use on her own. A trained health care provider must remove the IUD from her.

- The IUD may come out of the uterus possibly without the woman knowing about it (more common when the IUD is inserted soon after childbirth).

- Does not protect against ectopic pregnancy.

- The woman should check the position of IUD strings from time to time. To do this, she must put her fingers into her vagina, which some women may not want to do.

b. Medical Eligibility Criteria

Many women can use copper-bearing IUDs. In general, women can use IUD safely and effectively. IUDs can be used in any circumstances by women who:

- Smoke
- Have just had an abortion or miscarriage (if there is no evidence of infection or risk of infection)
- Take antibiotics or anticonvulsants
- Are fat or thin
- Are e breast feeding

Also, women with these conditions can use IUDs in any circumstances:

- Benign breast disease
- Breast cancer

- Headaches
- High blood pressure
- Irregular vaginal bleeding (after evaluation)
- Blood clotting problems
- Varicose veins
- Heart disease (disease involving heart valve may require treatment with antibiotics before IUD
- History of stroke
- Diabetes
- Liver or gall bladder disease
- Malaria
- Thyroid disease
- Epilepsy
- Non-pelvic tuberculosis
- Past ectopic pregnancy
- Past pelvic surgery

c. Major evidences and clarifications relating to medical eligibility of copper-bearing IUDs

1. Postpartum: Evidence suggests that there is an increase in expulsion rates with delayed postpartum insertion compared to immediate insertion, and with immediate postpartum insertion compared to interval insertion.

2. Post-abortion insertion: There is no difference in risk of complications for immediate versus delayed insertion of an IUD after abortion. Expulsion was greater when an IUD was inserted following a first-trimester abortion.

3. Vulvular heart disease: In cases of vulvular heart disease, use of prophylactic antibiotics to prevent endocarditis are advised for insertion.

4. PID and continuation of IUD: To ensure continuation of IUD in cases of PID, treatment of PID should be done using appropriate antibiotics. There is usually no need for removal of the IUD if the client wishes to continue use. There is evidence that among IUD users treated for PID, there was no difference in clinical course if the IUD was removed or left in place.

5. STI and IUD: There is no evidence regarding whether IUD insertion among women with STI increases the risk of PID compared to no IUD insertion. Among women who have an IUD inserted, the absolute risk of subsequent PID was low among women with STI at the time of insertion but greater among women with no STI at the time of IUD insertion.

6. Increased risk of STIs and IUD complications: Using an algorithm to classify STI risk status among IUD users, one study reported that 11% of high risk women experienced IUD-related complications compared to 5% of those not classified as high risk.

7. HIV: Among IUD users, there is limited evidence showing no increased risk of overall complications of infection-

related complications when comparing HIV-infected women with non-infected women. Furthermore, IUD use among HIV-infected women was not associated with increased risk of transmission to sexual partner.

8. AIDS: IUD users with AIDS should be closely monitored for pelvic infection.

Chart 10: When to start an IUD

The scenario	When to start
Having menstrual cycle	● Any time during the menstrual cycle within first 12 days after the start of menstrual bleeding at her convenience (not just during menstrual cycle). No additionalcontraceptive protection is needed. Probability of anexisting pregnancy is extremely low before day 12 of menstrual cycle, based on extremely low risk of ovulation and five-day emergency contraception effect of the copper-based IUDs. These can be inserted any time during the cycle provided it is reasonably certain that she is not pregnant. ● During menstruation, possible advantages: - Pregnancy is ruled out - Insertion may be easy - Any minor bleeding caused by insertion is less likely to upset the client - Insertion may cause less pain Possible disadvantages during menstruation: - Pain from pelvic infection may be confused with pain of menstrual period. IUD should not be inserted if the woman has a pelvic infection. - May also be harder to identify other signs of infection
After childbirth After miscarriage or abortion When stopping another method	● During hospital stay after childbirth, if she has decided voluntarily in advance, the IUD is best inserted within 10 minutes after delivery of the placenta. Can be inserted any time within 24 hours after childbirth (special training is required for this procedure.)
After miscarriage or abortion	● If not immediately after childbirth, copper T IUDs such as TCu-380A can be inserted as early as 4 weeks after childbirth. For other IUDs insertion is recommended at least 6 weeks after childbirth.

The scenario	When to start
	• Immediate insertion if no infection present • If infection present, treat and help the client choose another effective method. After 3 months if no infection remains, re-infection is not likely, and if she is not pregnant, the IUD can be inserted.
When stopping another method	Immediate insertion

d. Providing the IUD

A woman who opts for IUD benefits from good counselling.

A provider who listens to a woman's concern, answers her questions, and gives clear, practical information about the side effects, especially probable bleeding changes and possible pain after insertion, will help the woman use the IUD with success and satisfaction.

All women who choose IUDs must have access to IUD removal. All family planning programmes that offer IUDs must have qualified staff to remove them, or they must set up convenient referral arrangements for removals.

Inserting the IUD

Learning IUD insertion takes training and practice under direct supervision. The following description of procedures is a summary and not a detailed instruction. All family planning providers should know about IUD insertion so that they can tell their clients about it.

Basic principles

The objective of IUD insertion is to place the IUD correctly while minimizing the woman's discomfort and risk of complications. Successful IUC insertion requires:

- ***Explaining the procedure*** to the client and responding to her questions and concerns. This helps the client relax, making insertion easier and less painful.

- ***Infection prevention procedure*** includes use of high-level disinfected instruments and cleaning of cervix with a water-based antiseptic such as chlohexidene gluconate or iodophor. This minimizes the chances of uterine infection following insertion. Particularly useful is the no-touch technique which includes loading sterile packaged IUDs in their inserters, while both IUD and inserter are still in the sterile packaging.

- ***Speculum examination and bimanual examination.*** The speculum examination should come first, to check for signs of genital tract infection. The bimanual examination determines the size, position, consistency, and mobility of the uterus and identifies any tenderness which might indicate infection. A retroverted uterus - that is bent backwards -requires special care during insertion.

- ***Sounding of uterus:*** It should be done slowly and gently to determine its depth and direction. This reduces the risk of uterine perforation, cervical laceration and other complications. As per national guidelines health workers should not insert IUD in the uterus less than 6 cm in depth. All such cases should be referred to medical officers.

- ***IUD placement high in the uterus:*** The IUD should be placed at the fundus of the uterus. This minimizes expulsions, accidental pregnancies and bleeding.

- ***Follow the manufacturer's instructions for insertion.*** Most IUDs are inserted by the withdrawal technique. The inserter tube, loaded with the IUD, is inserted to the depth indicated by sounding. Then the inserter tube is withdrawn while the inner plunger is held steady. This leaves the IUD in position. Then the plunger is withdrawn.

Key steps in procedure

1. The provider follows proper infection prevention procedures. Generally, the health care provider will insert a new, pre-sterilized IUD that is individually packed.

2. The 'No-Touch" technique is preferred. This includes:

   - Loading the IUD in the inserter while both parts are still in the sterile package

- Cleaning the cervix with antiseptic before IUD insertion
- Being careful not to touch the vaginal wall or speculum blades with the uterine sound or loaded IUD inserter
- Passing both uterine sound and IUD inserter only once through the cervical canal.

3. The woman is asked to tell the provider if she feels discomfort or pain at any time during the procedure. Ibuprofen may be given 30 minutes before insertion to reduce cramping and pain.

4. The health care provider conducts a careful pelvic examination (speculum and bi-manual) and checks the position of the uterus to make sure that the woman can use an IUD safely and effectively.

5. The provider carefully cleans the cervix and vagina several times with an antiseptic solution such as iodine.

6. Working slowly and gently, the provider inserts the IUD, following the manufacturers' instructions.

7. After the insertion, the provider asks the client how she feels. If she feels dizzy when sitting, suggests that she lie down quietly for 5 or 10 minutes. Any cramping probably will not last long.

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

An IUD can be inserted just after delivery of the placenta up to 48 hours after childbirth. It can be inserted both after vaginal delivery or caesarean delivery.

Explaining how to use the IUD

Follow this procedure:-

1. Plan with the client for a return visit in 3 to 6 weeks – for example, after a menstrual period - for check up and pelvic examination, to make sure that her IUD is still in place and that no infectionh as developed. The visit can be at any time convenient to the client when she is not menstruating. After this one return visit, no further routine visits are required.

2. Make sure she knows:
   - Exactly what kind of IUD she has and how it looks like
   - When to have IUD removed or replaced (for TCu-380A IUD, 10 years after insertion). Discuss how to remember the year to return. If she wants a new IUD, it can be inserted as soon as the old IUD is removed.
   - When she visits health care providers, she should tell them that she has an IUD.

Important: Provide the client with a written record of the month and year of IUD insertion and the month and year of when it should be removed.

Give specific instructions:

A woman who chooses an IUD should know what will happen during the insertion procedure. She also should understand that she can expect:

- Some cramping pain for first day or two after insertion. She can take some NSAIDs for this.
- Some vaginal discharge for a few weeks after insertion, which is normal.
- Heavier menstrual periods. Possible bleeding between menstrual periods, especially during the first few months after IUD insertion.
- Checking the IUD: Sometimes IUDs come out, especially in the first month or so after insertion or during a menstrual period. An IUD can come out without the woman knowing about it.

A woman should check that her IUD is in place:

- Once a week during the first month after insertion
- After noticing any possible symptoms of serious problems.
- After a menstrual period, from time to time. IUDs are more likely to be dislodged with menstrual blood.

To check her IUD, a woman should:-

- Wash her hands
- Sit in the squatting position
- Insert 1 or 2 fingers in her vagina as far as she can until she feels the strings. She should return to the health care provider if she thinks the IUD might be out of place.
- Wash hands again

Important:

1. She should not pull the strings, as the IUD may be dislodged.
2. After postpartum insertion, the strings do not always come down through the cervix.

e. Explain specific reasons to see a health care provider

Describe the specific symptoms of serious problems that require medical attention. Serious complications of IUD are rare. Still a woman should see a doctor or nurse if she has any of these symptoms or more serious problems, which may or may not be caused by the IUD.

- Missed menstrual cycle which could lead to confusion about pregnancy, especially if she also has symptoms of ectopic pregnancy, abnormal vaginal bleeding, abdominal pain or abdominal tenderness and fainting. A woman who develops these symptoms must seek care at once.

- If she thinks that she might have been exposed to sexually transmitted infections, or has HIV/AIDS.

- When checking her IUD strings, feels that the IUD might be out of place. For example, she finds:

  1. Strings missing or strings seen shorter or longer

  2. Something harder in her vagina at the cervix. It may be part of the IUD.

  3. Increasing or severe pain in the lower abdomen, especially if there is also fever and/or bleeding between menstrual periods (signs and symptoms of PID).

Other reasons to return to the clinic:-

- Her sex partner feels the IUD strings during sex and this bothers him. At the clinic she can have the strings cut shorter.

- Heavy or prolonged bleeding that bothers the client.

- Copper-bearing or hormonal IUD has reached the end of its effectiveness, and she needs it removed or replaced.

- She wants the IUD to be removed for any reason.

- She has questions.

- She wants to opt for another family planning method.

Follow-up

Helping clients at the routine return visit (3 to 6 weeks after IUD insertion)

- Conduct a pelvic examination as appropriate

- Definitely conduct a pelvic examination if you suspect:

  - Pelvic inflammatory disease or sexually transmitted infection
  - The IUD is out of place

Ask questions:

1. Ask if the client has any questions or anything to discuss.

2. Ask the client about her experience with the IUD, whether she is satisfied and whether she has any problems. Give her any information or help that she needs and invite her to return again any time she has questions or concerns. If she has problems that cannot be resolved, help her to choose another method.

3. Remind her of the reasons for returning

4. Remind her how long her IUD will keep working and when it should be removed.

5. Ask if she has had any health problems since her last visit.

- If she has developed any condition that means she should not use an IUD, take out the IUD. Help her choose another method.

- She may be able to keep using the IUD, however if she has developed:-

1) Unexplained vaginal bleeding that may suggest pregnancy (possible abortion) or an underlying medical condition or

2) cervical, endometrial, or ovarian cancer. Manage the problems as described below.

Managing any problems

If the client reports common side effects of IUDs, such as menstrual changes:-

1. Do not dismiss the woman's concerns or take them lightly.

2. If the woman is worried but wants to continue the method, reassure and counsel her about side effects

3. If the woman is not satisfied after treatment and counselling, ask her if she wants the IUD removed. If so, remove the IUD or refer for removal even if her problems with the IUD would not harm her health. If she wants a new method, help her choose one.

f. Removing the IUD

Possible reasons for removal**:-**

- The client's request for removal.
  Providers must not refuse or delay when the client asks to have her IUD removed, whatever her reason, whether personal or medical.

- Any side effects that make client want her IUD removed, including pain.

- Any medical reason for removal:
  - Pregnancy
  - Acute PID
  - Perforation of uterus

- IUD has come out of place (partial expulsion)

- When the effective lifespan of a copper-bearing or hormonal IUD is finished.

- When the woman reaches menopause (at least 1 year after her last period).

To remove the IUD:

- Removing the IUD is usually simple. It can be done any time throughout the menstrual cycle. Removal may be somewhat easier during menstruation, when the cervix is dilated.

- Proper infection-prevention procedures are followed.

- The health care provider pulls the IUD strings slowly and gently with forceps.

- If removal is not easy, the provider may dilate the cervix using a uterine sound or alligator forceps or refer the client to a specially trained provider.

Chart 11: How to manage any problems

Problems	Actions
Irregular bleeding, or heavy bleeding (prolonged bleeding = more than 8 days. Heavy bleeding = twice as long or twice as much as usual for her) Unexplained abnormal vaginal bleeding that suggests pregnancy or an underlying medical condition Lower abdominal pain that suggests pelvic inflammatory disease (PID)	*Evidence of infection or other abnormalities:* ● Conduct a pelvic examination to look for cervical disease, ectopic pregnancy, or PID. Refer to care if appropriate. ● She can continue using her IUD while her condition is being evaluated. *If there is no evidence of infection or other abnormalities,* less than 3 months since IUD insertion and bleeding is within normal and expected range, then: ● Reassure her that changes in menstrual bleeding are normal and will probably lesson over time. ● Suggest that she eat more food containing iron if possible. If possible, give her iron tablets. ● Ask if she wants to keep her IUD: - If she does want to retain, ask her to return in about 3 months for another check-up.

Problems	Actions
	- If she does not want to retain the IUD help her choose another method. *No evidence of infection or other abnormalities more than 3 months since IUD insertion* ● If the client wishes or if the bleeding or pain is severe, remove the IUD and help her choose another method. ● If an abnormal condition is causing irregular or heavy bleeding, treat or refer to care. ● If there is very heavy bleeding, check for signs of severe anaemia—pale under fingernails and inside eyelids. If found: - Recommend IUD removal and help her choose another method. - Give her enough iron supplements for 3 months
Unexplained abnormal vaginal bleeding that suggests pregnancy or an underlying medical condition	● She can continue using her IUD while her condition is being evaluated. ● Evaluate and treat her underlying medical problem, or refer her to care
Lower abdominal pain that suggests pelvic inflammatory disease (PID)	Take history and perform abdominal and pelvic examinations. If pelvic examination is not possible, do an external genital exam. If one or more of the following is found, refer to a capable provider at once: ● Missed a menstrual period, her period is late, or she is pregnant ● Recently gave birth or had an abortion ● Pain or tenderness when pressure is put on the abdomen during examination.

Problems	Actions
	• Vaginal bleeding • A pelvic mass Diagnose as PID if she has one or more of the following (the more conditions she has, the stronger the diagnosis) • Oral temperature of 38.3^{0}C (101^0 F) or higher • Abnormal vaginal or cervical discharge • Pain when moving the cervix during pelvic examination • Tenderness in the area of fallopian tube or ovary • Recent sex partner with urethral discharge or treated for gonorrhoea. *Note: Diagnosis may be difficult. PID signs and symptoms may be mild or absent. Also, the common signs and symptoms of PID often also occur with other abdominal conditions such as ectopic pregnancy or appendicitis.* 1. Treat or immediately refer her to treatment. Treat for gonorrhoea, Chlamydia, and trichomoniasis—all 3. 2. Remove the IUD if physical examination or laboratory tests point to PID (where PID management and follow-up are possible, some experienced clinicians may leave the IUD in place). If diagnosis is uncertain and follow-up is possible, treat with antibiotics without taking out the IUD, and watch carefully for results of treatment. If diagnosis is uncertain and follow-up is not possible, take out the IUD and start antibiotics. 3. Follow-up: If the woman does not improve in 2 or 3 days after starting the treatment, or if she develops a tubal abcess, she should be sent to hospital. 4. Otherwise, schedule another follow up for just after she has finished taking all her medicine. 5. Treat sex partners: Urge the client to have her sex partner or partners come for STD treatment.

Problems	Actions
	● Remove the IUD ● Diagnose and treat the STIs, or refer to care.
Pregnancy	**If copper-bearing IUD user is found to be pregnant** ● Exclude ectopic pregnancy. ● Explain that she is at risk of second trimester miscarriage, pre-term delivery and infection if the IUD is left in place. The removal of the IUD reduces these risks, although the procedure itself entails a small risk of miscarriage. - If she does not want to continue the pregnancy, and if therapeutic termination of pregnancy is legally available, inform her accordingly. - If she wishes to continue the pregnancy, make the risks clear to her. Advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever. **If the IUD strings are visible or can be retrieved safely from the cervical canal:** ● Advise her that it is best to remove the IUD. ● If the IUD is to be removed, remove it by pulling on the strings gently. ● Explain that if she chooses to keep the IUD, she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever. **The IUD strings are not visible and cannot be safely retrieved** ● Where ultrasound is available, it may be useful in determining the location of the IUD. If the IUD is not located, this may suggest that an expulsion of the IUD has occurred. ● If ultrasound is not possible or if the IUD is determined by ultrasound to be inside the uterus, make clear the risks and advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge or fever.

5.3 Levonorgestrel-20 IUD (LNG-20)

a. Introduction

LNG 20 is one of the newest forms of hormone-releasing IUDs. It contains 52 mg of levonorgestrel released at the rate of 20 micrograms per day and lasts for at least 5 years. It has been used for 10 years in Europe and is now considered to be an ideal method of contraception. Apart from preventing pregnancy, it also makes periods lighter, shorter and less painful. When it is removed, fertility returns immediately.

LNG 20 is particularly useful for 2 groups of women:

1) women who have been pregnant and do not want to any more children for the next few years and

2) women in their 30s and 40s who have completed their families and want a reliable long-term method of contraception which they can use and then forget about for 5 years at a time.

Effectiveness

The failure rate is so low that it can be compared to sterilization.It is unique method of contraception combining the main benefits of the pill - effective birth control - with the main appeal of sterilization, the “luxury” of not having to recall the contraception. It also has an advantage over copper IUD because it tends to make periods lighter and shorter which the copper IUD does not.

Mechanism

The LNG IUD consists of a plain Nova T device with a silastic reservoir attached to the vertical arm. The silastic reservoir is impregnated with levonorgestrel and is covered with a rate-limiting silastic membrane. The release rate of levonorgestrel is approximately 20 micrograms/24 hours for at least 5 years.

LNG 20 acts as a contraceptive in two ways: it makes the cervical mucous much thicker, preventing sperm from getting through and it also thins out the endometrium hampering implantation. In some women, it also prevents ovulation. This mechanism of LNG IUD appears to be at the level of endometrium, where the high dose of local progestogen causes deciduation, epithelial atrophy and direct vascular changes.

Advantages

- More effective than copper-bearing IUDs.
- Most IUDs make woman’s period heavier, however the LNG IUD actual makes periods lighter than usual.

- Pelvic infection is less common with LNG IUD than copper-bearing IUDs.
- The Dominican Republic study found that women who use LNG -20 for more than 3 years were significantly less likely to have low serum ferritin or hematocrit than either women not using IUDs or women using unmedicated or copper-bearing IUDs.
- The studies have shown that the LNG-20 has had a lower ectopic pregnancy rate than most copper IUDs.

Disadvantages:

- It is costlier than copper-bearing IUDs.
- Can cause irregular bleeding or spotting in the first six months of use.
- Not suitable for women who are at risk of sexually transmitted infections or ectopic pregnancy.

b. Major evidences and clarifications:

Most of the medical eligibility criteria for copper-bearing IUDs and LNG IUD are similar. However, LNG IUD is a hormonal IUD. The following are some of the major clarifications and additional eligibility criteria:

1. In cases of cardiovascular disease and high blood pressure, there is some effect of hormone of LNG IUD. Hence, though it can be used, it is definitely not as safe as copper-bearing IUDs.
2. In women with current deep vein thrombosis/pulmonary embolism, current history and migraine with aura of ischemic heart disease, the LNG IUD should be used only if other appropriate methods of contraception are unavailable or unacceptable.
3. There are evidences that LNG IUD use among women with endometriosis decreased dysmenorrhoea and pelvic pain.
4. Among women with heavy or prolonged bleeding, LNG IUD is beneficial in treating menorrhagia.
5. Among women with fibroids, there were no adverse health events with LNG IUD use and there was a decrease in symptoms and size of fibroids for some women.
6. Due to presence of hormone, LNG IUD is not found suitable for women with current breast cancer. Even in women with a past history of breast cancer, LNG IUD should be used only if other appropriate methods of contraception are unavailable or unacceptable.
7. Due to hormone present in the LNG IUD in women with liver–related diseases it should be used only if other appropriate methods of contraception are either unavailable or unacceptable

When LNG IUD is inserted

LNG IUD is inserted within a week of the beginning of a period - this helps to reduce the chance of expulsion and irregular bleeding. It may be inserted immediately after a medical termination of pregnancy, but should be deferred until 6 weeks after the delivery of a baby.

The hormone effect on the uterine endometrium is reversed within a month and normal periods and fertility returns. The LNG IUD lasts for 5 years and if required, a new one could be inserted at the same time the old one is removed.

CHAPTER 6

Sterilization

6.1 Male Sterilization

Despite the development of many new contraceptive methods over the last 15 years, sterilization is the most widely used in the world, in developing and developed countries alike. Couples and individuals around the world choose sterilization because they want to limit or end childbearing, rather than space future births. The method requires no action on the part of the user beyond selection of the initial surgical procedure. It produces minimum side effects, while generally offering a lifetime of contraceptive protection. Hence, quality sterilization services will always be a crucial component of any comprehensive family planning service.

Vasectomy, especially no-scalpel vasectomy (NSV), is one of the safest and most effective contraceptive methods, with very low complication rates and failure rates thought to be in the range of 2 to 4 per 1000. While potential physiological effects and long-term effects of vasectomy have been studied extensively over the past few decades, research has offered reassurance that this method has no serious long-term negative affect on men's physical and mental health. There is little evidence for a causal association between prostate cancer and vasectomy and experts after reviewing available evidence have concluded that no change was necessary in the practice of vasectomy.

a. What is vasectomy?

Vasectomy, a method of male sterilization, is a simple, minor surgical procedure that takes 5-15 minutes to perform, after 5-10 minutes of pre-operative preparation and administration of local anaesthesia. It is one of the safest and most effective family planning methods and is one of the few contraceptive options available to men. Failure rates are commonly quoted to be between 0.2% and 0.4%.

A small opening is made in the man's scrotum and the vas deferens on either side is closed off. This keeps sperms out of the semen. The man can still have erections and ejaculate semen, but his semen no longer makes a woman pregnant because it has no sperm in it.

It is a very effective and permanent method, which is commonly used, with 0.15 pregnancies per 100 men in the first year after the procedure. For this method to be effective, correct use is essential. Correct use means using condoms or another effective family planning method consistently for at least the first 3 months or until the sperm completely disappears from the semen.

Advantages

- Very effective
- Permanent. A small, quick procedure leads to lifelong, safe and very effective family planning.
- Nothing to remember except to use condoms or another family planning method for at least 3 months.

- Does not affect the man's ability to have sex.
- Increased sexual enjoyment because no need to worry about pregnancy.
- No supplies to get, no repeated clinic visits required.
- No apparent long-term health risks.
- Compared to voluntary female sterilization, vasectomy is:
  - Probably slightly more effective
  - Slightly safer
  - Easier to perform
  - If there is a charge, often less expensive
  - Can be tested for effectiveness at any time.

Even if pregnancy occurs it is less likely to be ectopic than if there is a pregnancy in a woman who has been sterilized.

Disadvantages:

- Common minor short-term complications of surgery:
  - Usually uncomfortable for 2 or 3 days.
  - Pain in scrotum, swelling and bruising
  - Brief feeling of faintness after the procedure
- Uncommon complications of surgery:
  - Bleeding or infection at the incision site or inside the incision.
  - Blood clots in the scrotum.
- Requires minor surgery by a trained provider.
- Not immediately effective. The couple must use another contraceptive method for at least the first 3 months after the surgery, or until sperms are cleared from semen. ?During this period, the man should resume sexual activity, but he or his partner will need to use additional contraceptive protection.? Semen analysis, where available, can confirm contraceptive effectiveness after the 3–month waiting period.
- Reversal surgery is difficult, expensive, and not available in settings that are poor in resource. Success cannot be guaranteed. Men who may want to have more children in the future should choose a different method.
- No protection against STIs including HIV.

b. Medical eligibility

Most men can have a vasectomy. Most men who want a vasectomy can have safe and effective procedures in

routine settings. This includes men of any age, who have no children, who have sickle cell disease or hereditary anaemia; or who are HIV positive or at high risk of HIV or other STIs (however, vasectomy does not prevent a man from passing HIV or other STIs to others).

DELAY the vasectomy and refer the client to treatment if he has:

- Active sexually transmitted infection
- Inflamed (swollen and tender) tip of penis, ducts or testicles
- Scrotal skin infection or mass in the scrotum
- Acute systemic infection or significant gastroenteritis
- Filariasis or elephantitis

If he has any of the following, refer him to a centre with experienced staff and equipment that can handle potential problems:

- Hernia in the groin (provider if able, can perform vasectomy at the same time as repairing hernia. If this is not possible, the hernia should be repaired first)

- Undescended testicles on both sides
- Current AIDS-related illness
- Coagulation disorders

If he has any of the following, use CAUTION:

- previous scrotal surgery or injury

- Large varicocoel or hydrocoele (swollen veins or membranes in the spermatic cord or testes, causing swollen scrotum)

- Undescended testicles on one side only (vasectomy is performed on the normal side only. Then if any sperm remains in the semen after 3 months, vasectomy must be performed on the other side too.

- If he has diabetes.

A man considering vasectomy needs good counselling.

c. Requirements for a safe procedure

Essential elements of quality sterilization include counselling, client assessment and screening, informed consent, infection prevention, selection of appropriate procedures, safe anaesthesia regimens and post-operative care and instructions.

Counselling: Since vasectomy is intended to be a permanent method of contraception, it should be provided only to men who have decided on their own that they do not want children any more. Clients should be counselled about other available methods of contraception before deciding on sterilization.

Client assessment: Vasectomy is a safe and simple procedure when undertaken with proper screening. Prior to vasectomy, a medical history should be taken and a limited physical examination should be done including genital examination; the penis, scrotum and the inguinal region should be inspected visually; and the scrotum should be palpated. Laboratory tests should not be routine but should be reserved for specific cases in which the provider suspects a condition that would make it necessary to make extra preparation.

Informed consent: The surgeon should verify that the client has signed the informed consent form before beginning the procedure. Although the purpose of signing the form is to document informed consent, the principle focus should be on confirming that the client has made an informed choice of vasectomy as a contraceptive method.

Infection prevention: Strict adherence to infection prevention practices all the times (before, during and after) is also crucial to the safety of the procedure. Proper aseptic technique is essential to preventing both immediate and long-term infectious morbidity and mortality. Inadequate infection prevention practices can lead to surgical site infections, tetanus and infections such as HIV and hepatitis B, hepatitis C. Shaving or clipping the hair at the operation site is no longer recommended. *Shaving of the scrotum is no longer recommended, as this significantly increases the chance of surgical-site infection.*

Anaesthesia: Good anaesthesia is essential for a pain-free vasectomy. The purpose of anaesthesia is to ensure that the client is free from pain and discomfort during the operation. Both, conventional and no scalpel vasectomy are done under local anaesthesia. Pre-medication is commonly not required. Use of regional or general anaesthesia is rarely needed and increases the risk and costs of the procedure. However, general anaesthesia may be necessary when there are scrotal abnormalities (such as large varicocele, large hydrocoele or chryptorchidism) or when vasectomy is performed along with another surgical procedure. Men who need modest sedation (e.g. those who are extremely nervous) may be given a small dose of an oral tranquilizer, such as diazepam.

Instructions to the client: Men undergoing vasectomy should receive clear instructions about post-operative care, the anticipated side effects, action to be take if complications occur, sites where they can access emergency care, the need for post-operative semen analysis and the time and place for making a follow-up visit.

The vasectomy procedure

Learning to perform vasectomy takes training and practice under direct supervision. This description is a summary and not a detailed instruction. All family planning providers should understand these procedures and be able to discuss them with clients, both men and women.

1. The provider uses proper infection prevention procedures at all times.

2. The man receives an injection of local anaesthetic in his scrotum to prevent pain. He stays awake throughout the procedure.

3. The health care provider feels the skin of the scrotum to find each tube (vas deferens). The provider makes a small incision in the skin with a scalpel or else uses a special instrument to make a puncture (the no-scalpel technique).

4. The provider lifts each vas out of the incision. Most providers cut each vas and tie one or both ends with thread. Some close off the vas with heat or a clip. The incision may be sewn shut or just covered with an adhesive bandage. Some providers also use facial transposition for better results. With fascial transposition, the fascial sheath (the thin layer that surround the vas) is sutured over one end of the cut vas. fascial interposition places a tissue between two cut ends of vas.

Ligation without division and division alone are not recommended, as the potential for failure due to recanalization is more.

5. The man may feel faint briefly after the procedure. If possible, he should rest for 15-30 minutes.

6. The man receives instructions on how to care for the wound. If his partner is not using an effective contraceptive, he must be given and use condoms until sperm are cleared from his system. For 3 months he should resume sexual activity, but he or his partner will need to use additional contraceptive protection.? Semen analysis, should be advised to confirm contraceptive effectiveness after the 3–month waiting period.

7. He can leave the clinic within a few hours, often in less than 1 hour.

Preliminary results from randomized controlled trials found that use of fascial interposition with ligation and excision of vas during vasectomy lead to more rapid decrease in sperm count than when ligation and excision were used alone.

d. Explaining self-care

Before the procedure, the man should:

- Bathe thoroughly, especially cleaning the genital area and upper inner thighs.
- Wear clean and loose fitting clothing.
- Not take any medicines for 24 hours prior to the procedure, unless the heath care provider performing the procedure tells him to do so.

After the procedure, the man should*:*

- If possible, put a cold compresses on the scrotum for 4 hours to lessen swelling. He will have some discomfort, swelling, and bruising which should stop in 2-3 days.
- Rest for 2 days. He should not do any heavy work or vigorous exercise for a few days.
- Keep the incision clean and dry for 2-3 days. He can use a towel to wipe his body clean but should not soak in water.

- Wear snug underwear or pants for 2-3 days to help support the scrotum. This will lessen swelling, bleeding and pain.

- Take paracetamol or another safe, locally available pain-relief medication as needed. He should not take aspirin or ibuprofen, which slow blood clotting.

- Use condoms or another effective family planning method for 3 months after the procedure.

He can have sex within 2-3 days after the procedure if he is not uncomfortable, but he needs to use condoms. He can expect his sexual performance to be unchanged. Vasectomy does not affect man's ability to have sex.

In most cases, using good surgical technique to minimize the trauma and limit bleeding, practicing aseptic techniques, and giving clients good post-operative instructions, can prevent bleeding, hematoma, and infection.

e. Explain specific reasons to see a doctor or health care provider

A man who has undergone vasectomy should return to the clinic for a follow-up and for any of these reasons:

As per the national guidelines for vasectomy:

- A health worker should visit all clients who undergo a vasectomy within 48 hours.

- First follow-up: seven days after the surgery, the client should go for removal of stitches (in cases of conventional vasectomy), to have the wound examined and to have his questions answered.

- Second follow-up: the client should undergo semen analysis after three months.

- Emergency follow-up: this can be done at any time after the surgery if:

  - His wife misses her menstrual period or thinks she is pregnant.
  - He has questions or problems of any kind.
  - If he has high fever (greater than 38^{0}C) in the first 4 weeks and especially in the first week, or
  - If he has bleeding or pus from the wound, or
  - If he has pain, heat, swelling, or redness at an incision that becomes worse or does not stop (signs of infection)

If the clinic cannot be reached quickly, he should go to another doctor or health care provider at once.

Helping the client at any routine return visit

Follow-up within 7 days or at least within 2 weeks is strongly recommended. A heath care provider checks the site for any signs of complications, and removes any stitches. This can be done in the clinic, in the client's home (by a trained provider), or at any other health centre. No man should be denied vasectomy, however, because follow up would not be possible.

A man may want to come back to have his semen examined, if feasible, at least 3 months after the vasectomy. This microscopic examination can make sure his semen contains no sperms, or that his vasectomy is working.

At any routine visit ask questions:

1. Ask if the client has any questions or anything to discuss.

2. Ask the client about his experience with vasectomy, whether he is satisfied or whether he has any problems. Give him any information or help that he needs, and invite him to return any time he has questions or problems.

f. Managing any problems

During recovery and healing, if a man experiences strong pain, heat, swelling or redness at or around the incision, he should come back to the clinic. If this happens, a heath care provider should check for clots, pus, infection or abscess.

Chart 12: How to manage problems

Problem	Provide treatment
Pain	Check for blood clots in the scrotum. ● Small, uninfected blood clots require rest and pain-relief medication such as paracetamol ● Large blood clots may need to be surgically drained ● Infected blood clots require antibiotics and hospitalization
Infection (Pus, heat, pain or redness caused by bacteria or other germs)	● Clean site with soap and water or antiseptic ● Give 7 to 10 day course of antibiotics
Abscess	● Clean site with antiseptic ● Incise and drain abscess ● Perform wound care ● If significant skin infection involved, give 7 to 10 day course of antibiotics
Fear of impotence	In counselling before the procedure, the health care provider should assure the client that vasectomy does not physically change sexual desire, functioning or pleasure. This information can be repeated at any follow-up visits.

FAQs on vasectomy

1. Will vasectomy makes a man lose his sexual ability? Will it make him weak or fat?

No. After vasectomy, a man will look and feel the same as before. He can have sex same as before. He may find that the sex is better since he is free from worry about making his partner pregnant. He can work as hard as before. His erections and ejaculation of semen will be the same. Vasectomy is not castration. Vasectomy does not harm the testicles which are organs that produce male hormones.

2. Will the vasectomy stop working after a time?

Generally, no. Vasectomy is permanent. In rare cases the tubes grow back together, but this is very unlikely.

3. Can a man have his vasectomy reversed if he decides that he wants another child?

Surgery to reverse vasectomy is possible. It does not always lead to pregnancy, however. The procedure is difficult, expensive and hard to access. Vasectomy should be considered permanent. People who may want more children should consider another method.

The available evidence suggests that men who underwent vasectomy at a young age were more likely to have the procedure reversed than older men.

4. Is it better for a man to have a vasectomy or for a woman to be sterilised?

Each couple must decide for themselves which method is best for them. Both are very effective, safe and permanent methods for couples who decide they do not want any more children. However, vasectomy is simpler and safer to perform than female sterilisation. It is less expensive and slightly more effective. Ideally, a couple should consider both methods. If both are acceptable to the couple, vasectomy should be preferred for medical reasons.

5. Does vasectomy increase the risk of prostate cancer?

No. The evidence is that vasectomy does not increase the risk of prostate cancer or heart disease.

6. How can providers help a man decide about vasectomy?

- Provide clear, complete information about vasectomy and other family planning methods.
- Discuss thoroughly his feelings about having children and ending his fertility.
- If possible, arrange for him to talk with men who have already had vasectomies.

7. Can a person at high risk of HIV or infected HIV undergo vasectomy?

Yes. Generally, no routine screening is required. Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures. The use of condom is recommended following sterilization.

8. Is vasectomy possible in a person with cryptorchidism?

If the cryptochidism is bilateral, and fertility has been demonstrated, extensive surgery will be required to locate the vas. If the criptorchidism is unilateral, and fertility has been demonstrated, vasectomy may be performed on the normal side and semen analysis performed as per routine. If the man continues to have a persistent presence of sperms, more extensive surgery may be required to locate the other vas.

6.2 Female Sterilization

Even though tubal sterilization usually involves abdominal surgery, female sterilization is one of the safest operative procedures. Complications are rare and occur in fewer than 1% of all female sterilization procedures. Moreover, the likelihood of failure is very low, at less than 2%, even 10 years after the surgery.

There are two broad elements in the performance of female sterilization: the means of reaching the fallopian tubes, and the methods used to occlude the tubes. The selection of a procedure is determined by such factors as the timing of sterilization in relationship to the pregnancy; the need for other gynaecological procedures; the women's health; the provider's training, expertise and experience; the cost and logistics of maintaining equipment; and the availability of backup services.

Female sterilization results in few long-term side effects. The overall risk of ectopic pregnancy is low. Perceived alteration of women's menstrual flow, length, or pain following tubal sterilization (referred to as the post-sterilization syndrome), have been debated and studied, but research carried out in the United States has shown no strong evidence for the existence of such a syndrome.

a. Introduction to female sterilization

Female sterilization is the most commonly used method of family planning and more than 180 million couples worldwide have chosen it as their contraceptive method. It is a relatively simple procedure that involves permanently blocking the fallopian tubes to prevent fertilization.

Female sterilization procedures can be grouped into two broad categories: procedures for reaching the fallopian tubes (primarily abdominal approaches such as minilaparotomy, laparoscopy and laparotomy), and methods for occluding the fallopian tubes (mainly ligation and excision, mechanical devices such as clips or rings, and electrocoagulation).

About 2-6% sterilized women in developed countries and 0.2% women in developing countries are estimated to seek information about reversal, but the actual rate may be substantially higher. In developing countries especially, women's potential interest in restoration of fertility is probably greatly underestimated, given the inaccessibility of such services and the corresponding lack of knowledge about them.

How does it work?

In female sterilization, both fallopian tubes of a woman which carry eggs from the ovaries to the uterus are blocked or cut off. With the tubes blocked, the woman's eggs cannot meet the man's sperm. The woman continues to have menstrual periods.

Chart 13: Approaches to the fallopian tubes, surgical procedures, timing of procedure, and related occlusion techniques

Approach	Surgical procedure and timing	Occlusion techniques
Abdominal	Minilaparotomy (postpartum, postabortion, or interval)	• Ligation and excision • Mechanical devices (clips, rings)
	Laparoscopy (interval only, contraindicated in postpartum)	• Mechanical devices (clips, rings) • Electrocoagulation (Unipolar, bipolar)
	Laparotomy (in conjunction with other surgery—e.g., caesarean section, salpingectomy, ovarian cystectomy)	• Ligation and excision • Mechanical devices (clips, rings)
Transvaginal (NO LONGER RECOMMENDED)	Colpotomy	• Ligation and excision • Mechanical devices (clips, rings)
	Culdoscopy	• Mechanical devices (clips, rings) • Electrocoagulation (Unipolar, bipolar)
Transcervical* (experimental)	Hysteroscopy (interval only)	• Physical occlusion (plug) • Chemical agents (e.g., quinacrine)

** Transcervical approaches for tubal occlusion have been studied for several years, but to date none of these methods have been found to be completely safe and effective enough for implementation into routine service delivery.*

Effectiveness

In the first year after the procedure: 0.5 pregnancies per 100 women.
Within 10 years of the procedure: 1.8 pregnancies per 100 women
Effectiveness depends partly on how the tubes are blocked, but all pregnancy rates are very low.

Postpatum tubal ligation is one of the most effective female sterilization techniques. In the first year after the procedure there are 0.05 pregnancies per 100 women and within 10 years after the procedure, 0.75 pregnancies per 100 women.

Advantages

- Very effective method of contraception
- Permanent. A single procedure leads to lifelong, safe, and very effective family planning.
- Nothing to remember (as in many other methods), no supplies needed, and no repeated clinic visits required.
- No interference with sex. Does not affect the woman's ability to have sex.
- No effect on breast feeding.
- No known side effect or health risks
- Minilaparotomy can be performed just after a woman gives birth.
- Helps protect against ovarian cancer.

Disadvantages

- Usually painful at first, but pain recedes after a day or two.
- Uncommon complications of surgery:

  1. Infection or bleeding at the incision
  2. Internal infection or bleeding
  3. Injury to internal organs
  4. Anaesthesia risk

- In the rare cases that pregnancy occurs, it is likely to be ectopic than in a woman who used no contraception.
- Requires physical examination and minor surgery by a specially trained provider.

- Compared to male sterilization, female sterilization is slightly more risky and often more expensive, if there is fee.
- Reversal surgery is difficult, expensive unavailable in most areas. Successful reversal is not guaranteed. Women who want to be pregnant in the future should choose a different method.
- No protection against STIs and HIV/AIDS.

b. Medical eligibility for female sterilization

In general, most women who want sterilization can have safe and effective procedures in routine settings. With proper counselling and informed consent, sterilization can be used in any circumstances by women who:

- Just gave birth (within 7 days)
- Are breastfeeding

Also, women with the following conditions can have sterilization in a routine setting in any circumstances:

- Mild pre-eclampsia
- Past ectopic pregnancy
- Benign ovarian tumours
- Irregular or heavy vaginal bleeding patterns, painful menstruation
- Vaginitis without purulent cervicitis
- Varicose veins
- HIV positive or high-risk of HIV or other STIs
- Malaria
- Non-pelvic tuberculosis
- Caesarean delivery (surgical delivery) at same time.

In the following conditions, use the instructions below:

1) Gynaecological/obstetrical conditions:

If the woman has any of the following, DELAY female sterilization and treat as appropriate or refer:

- Pregnancy
- Postpartum or second trimester abortion (7-42 days)
- Serious postpartum or post-abortion complications
- Unexplained vaginal bleeding that suggests a serious condition
- Severe pre-eclampsia, eclampsia
- Pelvic inflammatory disease within past 3 months
- Current STI
- Pelvic cancers
- Malignant trophoblast disease

If she has any of the following, REFER her to a centre with experienced staff and equipment that can handle potential problems:

- Fixed uterus due to previous surgery or infection
- Endometriosis
- Hernia (umbilical or abdominal wall)
- Postpartum uterine rupture or perforation or postabortion uterine perforation

If she has any of the following, use CAUTION:

- Past PID since last pregnancy
- Current breast cancer
- Uterine fibroid

2) Cardiovascular conditions

If she has the following, DELAY female sterilization:

- Acute heart disease due to blocked arteries
- Deep vein thrombosis or pulmonary embolism

If she has the following, REFER her to a centre with experienced staff and equipment that can handle potential problems:

- Moderate or severe high blood pressure (160/100 or higher)
- Vascular disease including diabetes-related
- Complicated vulvular disease

If she has any of the following, use CAUTION:

- Mild high blood pressure (140/90 – 155/99 mm)
- History of high blood pressure where blood pressure can be evaluated, or adequately controlled high blood pressure where blood pressure can be evaluated
- Past stroke or heart disease due to blocked arteries.
- Vulvular heart disease without complications.

3. Chronic disease conditions:

If she has any of the following, DELAY female sterilization:

- Gall bladder disease with symptoms
- Active viral hepatitis
- Severe iron deficiency anaemia (haemoglobin below 7g/dl)
- Acute lung disease (bronchitis or pneumonia)
- Systemic infection or severe gastroenteritis
- Abdominal skin infection

- Abdominal surgery for emergency or infection at time sterilization is desired, or major surgery with prolonged immobilization.

If she has any of the following, REFER her to a centre with experienced staff and equipment that can handle potential problems:

- Severe cirrhosis of liver
- Diabetes for more than 20 years
- Hyperthyroid
- Coagulation disorders
- Chronic lung disease
- Pelvic tuberculosis

If she has any of the following, use CAUTION:

- Epilepsy Or taking medicines for seizure
- Taking antibiotics or griseofulvin
- Diabetes with vascular disease
- Hypothyroid
- Mild cirrhosis of liver, liver tumours or schistosomiasis with liver fibrosis
- Moderate iron deficiency anaemia (haemoglobin 7-10 g/dl)
- Sickle cell disease
- Inherited anaemia
- Kidney disease
- Diaphragmatic hernia
- Severe lack of nutrition
- Obese (Is she extremely overweight?)
- Elective abdominal surgery at time sterilization is desired.

Be sure to explain the health benefits and risks and the side effects of the method that the client will use. Also, point out any conditions that would make the method inadvisable when relevant to the client.

c. Requirements for a safe procedure

Essential elements of quality sterilization include counselling, client assessment and screening, informed consent, infection prevention, selection of appropriate procedures, safe anaesthesia regimens and post-operative care and instructions.

Counselling: Since female sterilization is intended to be a permanent method of contraception, it should be provided only to women who have decided on their own that they do not want children any more. Clients should be counselled about all available methods of contraception before deciding on sterilization.

Client assessment: Pre-operative and client screening is performed to ensure every client's physical and emotional

fitness for the sterilization procedure, to assess client characteristics such as age and number and ages of living children, and rule out known and identifiable physical and medical risk factors. Client assessment consists of taking a history (medical and obstetrics and gynaecological history) and performing a physical examination (vital signs, heart, lungs, abdomen, and pelvic and speculum examination).

Laboratory tests: The recommended laboratory tests include tests to screen for anaemia and to rule out current pregnancy. To minimize the chances of pregnancy at the time of the procedure, sites should have criteria for being reasonably sure that a woman is not pregnant. For example, performing the procedure within 7 days of the menstrual period (in the follicular phase), within 7 days of abortion, within 7 days of term delivery or in women using reliable method of contraception.

Informed consent: The surgeon should verify that the client has signed the informed consent form before beginning the procedure. Although the purpose of signing the form is to document informed consent, the principle focus should be on confirming that the client has made an informed choice of tubal occlusion as a contraceptive method.

Infection prevention: Strict adherence to infection prevention practices all the time is also crucial to the safety of the procedure. Proper aseptic technique is essential to prevent both immediate and long-term infectious morbidity and mortality. Inadequate infection prevention practices can lead to surgical site infections, tetanus and infections such as HIV, hepatitis B and hepatitis C. Shaving or clipping the hair at the operation site is no longer recommended. Studies have clearly shown that shaving surgical sites significantly increases the chances of infection.

Anaesthesia: Client safety and satisfaction should be the primary considerations in the choice of anaesthesia regimen used in the performance of female sterilization procedures. The purpose of anaesthesia is to ensure that the client is free from pain and discomfort during the operation. Three choices of anaesthesia regimen—local, general, or regional can be used for female sterilization procedures. Each regimen has advantages and disadvantages, as well as risks and benefits. Factors to be considered in the choice of anaesthesia include the type of surgical technique, the skill of surgeon, the availability of appropriate drugs, and the safety and conformity of the client, and the ability of the surgeon to manage complications, should they occur. The presence of a provider skilled in administering regional and general anaesthesia is important if these regimens are being followed.

Instructions to accompanying persons: It is important for all clients and their accompanying family members to be provided with clear written and oral post-operative instructions, on post-operative wound care, venue for follow-up, warning signs and appropriate advice on restriction of activities following the surgery.

Key points about the long-term effects of female sterilization

- The absolute risk of ectopic pregnancy is lower among sterilized women than among other women, but when a pregnancy occurs, it is likely to be ectopic.
- The latest evidence questions the existence of post-sterilization syndrome.
- The likelihood that the woman will have a hysterectomy at some time following sterilization cannot be explained based on biological facts.
- Female sterilization has been shown to have a protective effect against ovarian cancer
- Female sterilization does not protect users against STIs or HIV infections

d. Providing female sterilization

Learning to perform female sterilization takes training and practice under direct supervision. This description is a summary and not a detailed instruction. All family planning providers should understand these procedures and be able to discuss with clients, both men and women.

The minilaparotomy procedure

This is a description of the interval procedure, used more than 6 weeks after childbirth. The postpartum procedure; used less than 7 days after childbirth is slightly different.

1. The provider uses proper infection prevention procedures.
2. The provider asks questions about the woman's past and current health and performs a physical examination and a pelvic examination. This step is to make sure that the surgery is done safely.
3. The woman usually receives light sedation (through pills or intravenous tube) to relax her. Local anaesthetic is injected in her abdomen just above the pubic hair line. She stays awake. A small incision (2-5 cm) is made in the anaesthetized area, which usually causes a little pain.
4. The uterus is raised and turned with an instrument (uterine elevator) to bring each of the 2 fallopian tubes under the incision. This may cause discomfort.
5. Each tube is tied and cut, or else closed with a clip or ring.
6. The incision is closed with stitches and covered with adhesive bandages.

7. The woman receives instructions on what to do after she leaves the clinic or hospital. She can usually leave in a few hours.

The laparoscopy procedure

1. The provider uses proper infection prevention procedures.

2. The provider asks questions about the woman's past and current health and performs a physical examination and a pelvic examination. This step is to make sure that the surgery is done safely.

3. The woman usually receives light sedation (through pills or an intravenous tube) to relax her. Local aesthetic is injected just under woman's navel. She stays awake. The doctor places a special needle into the woman's abdomen and, through the needle inflates the abdomen with gas or air. This raises the abdominal wall away from the organs inside.

4. The doctor makes a small incision (about 2 cm) just under the woman's navel and inserts a laparoscope, which is a special long thin tube containing lenses. Through the lenses the doctor can see inside the body and find the 2 fallopian tubes.

5. The doctor inserts an instrument through the laparoscope (or less commonly through a second incision) to close off the tubes. Each tube is closed with a clip or ring or by electrocoagulation.

6. After the tubes are closed, the instrument and laparoscope are removed, and the gas or air is let out of the woman's abdomen. The incision is closed with stitches and covered with adhesive bandages.

7. The woman receives instructions on what to do after she leaves the clinic or hospital. She usuallycan leave in a few hours.

Processing Laparoscopes

Surgical laparoscopes are delicate instruments and must be handled with great care, Laparoscopes and accessories should be sterilised or high-level disinfected using the chemical method by soaking in 2% Glutaraldehyde solution, so it does not damage rubber, plastics or lenscements, However, all the steps of decontamination and cleaning must be followed before putting the laparoscopes in chemical solution.

a) Decontamination: Immediately after use, gently wipe the laparoscope, fibreoptic light source and cable plastic tubing using a cloth soaked in 60-90% ethy 1 or isopropyl alcohol to remove all blood and organic material. As alcohol rapidly kills HBV and HIV, this step protect handlers against possible hepatitis B and AIDS infections.

b) Cleaning - Place the dissembled parts of the laparoscope in a basin of clean water. Wash all outer surfaces using a soft cotton cloth. Clean inner channels with a clean brush supplied in the laparoscopic kit.

C) High-level disinfection - Put a clean and dried, dissembled equipment in a basin of 2% glutaraldehyde for 20 minutes. The disinfectant must touch all the surface of the laparoscope to be effective. Rinse twice with HLD water (water boiled for 20 minutes and cooled) to remove all traces of the disinfectant.

d) Sterilisation - To sterilise, soak the clean and dried, dissembled laparoscope in 2% glutaraldehyde for 8-10 hours. Rinse twice with sterile water to completely remove all traces of the disinfectant and store in a sterile, covered container.

Standards of male and female sterilization: Division of Research studies & standards, Department of Family Welfare, Ministry of Health and Family Welfare, Government of India, October 1999

e. Explaining self-care for minilaparotomy or laparoscopy

Before the procedure, the woman should:-

- Not eat or drink anything for 8 hours before surgery;
- Not take any medication for 24 hours before surgery (unless the doctor performing the procedure tells her to do so);
- Bathe thoroughly the night before the procedure, especially her belly, genital area, and upper thighs;
- Wear a clean, loose fitting clothing to the health facility if possible;
- If possible, bring a relative to help her go home.

After the procedure, the woman should:

- Rest for 2 or 3 days and avoid heavy lifting for a week;
- Keep the incision clean and dry for 2-3 days;
- Be careful not to rub or irritate the incision for 1 week;
- Take paracetamol or another safe, locally available pain-relief medicine as needed. She should not take aspirin or ibuprofen which slow blood clotting.
- Not have sexual intercourse for at least one week. If pain lasts for more than one week, do not have sex until all pain is gone.

f. Specific reasons to see a doctor or nurse

A woman should return to the clinic for any of these reasons:

- For a follow-up, if possible, within 7 days or at least 2 weeks and to have stitches removed, if necessary. Follow-up can also be done at home or at any other suitable facility.
- She has questions or problems of any kind.
- Return at once if she has:
  - High fever (more than 38 degrees C) in the first weeks and especially in the first week or
  - Pus or bleeding from the wound, or
  - Pain, heat, swelling, or redness of the wound that becomes worse or does not stop (signs of infection), or
  - Abdominal pain, cramping, or tenderness that becomes worse or does not stop, or
  - Diarrhoea, or
  - Fainting or extreme dizziness

If the clinic cannot be reached quickly, she should go to another doctor at once.

- She thinks that she might be pregnant. First symptoms of pregnancy are:
  - Missed periods
  - Nausea, and
  - Breast tenderness

She should come to the clinic at once if she also has any one of the signs of possible ectopic pregnancy:

- Lower abdominal pain or tenderness on one side
- Abnormal or unusual vaginal bleeding, or
- Faintness (indicating shock)

Pregnancies among users of voluntary sterilization are few. But when pregnancy occurs, it is more likely to be ectopic than average pregnancy. Ectopic pregnancy is life-threatening. It requires immediate treatment.

Preventing failure following female sterilization

There are five common causes of female sterilization failure:-

1. An undetected luteal-phase pregnancy that was present at the time of sterilization
2. Surgical "occlusion" of a structure other than the fallopian tube (most often, the round ligament)
3. Incomplete or inadequate occlusion of the fallopian tube
4. Misplacement of the mechanical device
5. Development of tuboperitonoal fistula.

Given these common causes of failure, two methods can be used to prevent failures:-

1. The incidence of unintended pregnancy can be decreased by scheduling this procedure within the first 7-10 days of the start of a menstrual cycle.
2. The fallopian tubes can be identified properly by tracing it to the fimbrial end prior to occlusion.

Meticulous attention should be paid to technique, whichever method is used.

g. Following up

Help clients at any routine return visit. Follow-up within 7 days or at least 2 weeks is strongly recommended. A health care provider checks the site of the incision, looks for any sign of complications and removes any stitches. This can be done at the clinic, in the client's home, or at any other health centres.

Ask questions

Ask if the client has any questions or anything to discuss and if she is satisfied. Give her any information or help that she needs and invite her to return any time she has questions or concerns.

Possible complications

During recovery and healing, if a woman experiences a strong pain, heat, swelling, or redness around the incision, she should come back to the clinic. If this happens, a health care provider should check for infection or abscess.

Chart 14: Managing problems

Problem	Suggestion
Infection (pus, heat, pain or redness caused by bacteria or other germs)	1.Clean the site with soap and water or antiseptic 2.Give suitable oral antibiotics for 7 to 10 days
Abscess (a pocket of pus under the skin caused by infection)	1.Clean site with antibiotics 2.Incise and drain the abscess 3.Perform wound care 4.In significant skin infection involved, give oral antibiotics for 7-10 days.

FAQs on female sterilization

1. Will sterilization change a woman's monthly periods or make her menstrual bleeding stop?

No. Most studies find no major changes in bleeding patterns after female sterilization. A woman's menstrual bleeding pattern may, however, change if she was using a hormonal method or IUD before sterilization. Also, a woman's menstrual period usually becomes less regular as she gets older.

2. Isn't it easier for the woman and the health care provider to use general anaesthesia during female sterilization? Why use local anaesthesia?

Local anaesthesia is safer. After general anaesthesia, the woman usually feels nauseous. This does not happen after local anaesthesia.

Proper use of local anaesthesia removes the single greatest source of risk in the female sterilization procedure. When using local anaesthesia, however, providers must take care not to overdose with the sedative. They must also handle the woman gently and talk to her throughout the procedure. This helps her to stay calm. Sedatives can be avoided in many clients, especially with good counselling and a skilled provider.

CHAPTER 7

Condoms

7.1 Male Condoms

Condom is a simple but very effective method of contraception if used correctly and consistently. It holds a special place among the contraceptives due to the dual protection it provides both from unwanted pregnancy as well as sexually transmitted infections. It is one of the methods of contraception which ensures male involvement in preventing unwanted births. The higher failure rate of condoms is mostly due to its inappropriate use by the clients, which in turn is partly due to inadequate client instructions by the FP providers.

7.1 Introduction

- Condom is a sheath made to fit over a man's erect penis.
- Most condoms are made of latex rubber
- Some condoms are coated with a lubricant or with spermicide
- Condoms may be available in different size, shapes, colours and textures

Condoms help in preventing pregnancy as well as the spread of sexually transmitted infections If used correctly, they prevent sperm and ST infections entering the vagina, or organisms from the vagina from entering the penis.

a. How effective are condoms

- If the partners of 100 women start using condoms, with typical use there is likelihood of 14 of these women getting pregnant in the first year of use of condoms.
- With correct and consistent use every time, there are 3 pregnancies per 100 women in the first year of use.

Prevent transmission of sexually transmitted infections

- During sex, condoms are the best protection against catching STIs or transmitting STIs to one's partner. Condoms can stop sexual transmission of many diseases including HIV/AIDS, gonorrhoea, syphilis, Chlamydia, and trichomoniasis. Condoms probably protect somewhat, but not as well, against herpes, genital wart virus (HPV), and other diseases that can cause sores on the skin not covered by condoms.
- In general, studies show that condom users have about two-thirds as much risk of getting gonorrhoea, trichomoniasis or chlamydial infection as people who never use condoms. Condom users have less than half the risk of HIV infection, which may lead to AIDS. These studies, however, included some people who used condoms incorrectly or inconsistently.

- People who use condoms correctly and consistently face even less risk of disease. They reduce their risk of STDs to a very low level.

Advantages:

- Prevent STIs including HIV, as well as pregnancy, when used correctly and consistently with every act of sexual intercourse.
- Can be used soon after childbirth
- Safe. No hormonal side effects.
- Help prevent ectopic pregnancies
- Can be stopped at any time.
- Offer occasional contraception with no daily upkeep.
- Easy to keep at hand in case sex occurs unexpectedly.
- Can be used by men of any age.
- Can be used without seeing a healthcare provider first.
- Usually easy to obtain and sold at most places.
- Enables a man to take responsibility of preventing pregnancy and disease.
- Often help to prevent premature ejaculation.

Disadvantages

- Latex condoms may cause itching for a few people who are allergic to latex. Also, some people may be allergic to the lubricant on some brands of condoms.
- The couple must take the time to put the condom on the erect penis before sex.
- Small possibility that condom might slip off or break during sexual intercourse.
- If not properly stored or if used with oil-based lubricants, condoms can go weak and break.

Medical Eligibility

- Only one condition prevents use of condoms - severe allergy to latex rubber (severe redness, itching, swelling after condom use).
- If the client is at risk of STIs or HIV, she/he should continue to use condoms during sexual intercourse despite the allergy.
- In general, anyone can use condoms safely and effectively if not allergic to latex.

b. Providing condoms

A person who chooses condoms benefits from good counselling. At the same time, condoms should be made available widely, even where counselling may not be available.

Follow this procedure

1. Give each client a supply of 3 months of condoms, if possible. How often people have sex varies, therefore, ask the client how many condoms are needed and supply accordingly.
2. Also provide some spermicide, if available, in case the condom breaks.

Explain why using a condom every time is important

1. Just one unprotected act of sexual intercourse can lead to pregnancy or transmission of STIs.
2. Looking at a person cannot tell you if he/she has STIs. A person with STIs and HIV can look perfectly healthy.
3. A person cannot always tell if he or she has STI, including HIV.

Explaining how to use condoms

Whenever possible, show the client how to put on and take off a condom. Use a model, a stick or banana or 2 fingers to demonstrate putting on condom. Suggest to a new user that he practice putting on the condom by himself before he next has sexual intercourse.

Give the following specific instructions:

1. Put the condom on the erect penis before the penis touches the vagina:

- Hold the pack at its edge and open by tearing from a ribbed edge.
- Hold the condom so that the rolled rim is facing up, away from penis.

- Place the condom on the tip of penis.

- Unroll the condom all the way to the base of the penis. The condom should unroll easily. If it does not, it is probably backwards. If more condoms are available, throw this one away and use a new condom.

2. Most of the condoms are already lubricated; hence there is no need to apply any additional lubricant This may damage the condom.

3. After sexual intercourse (ejaculation), hold the rim of the condom to the base of the penis so it will not slip. The man should pull his penis out of the vagina before completely loosing his erection.

4. Move away from vagina and take off the condom without soiling semen on the vaginal opening.

5. Tie a knot at the rim of the condom. Dispose it off by burying or burning it. Do not leave it where children will find it. Do not use a male condom more than once.

If the condom breaks

- Immediately insert a spermicide into the vagina, if spermicide is available. If not, washing both penis and vagina with soap and water should reduce the risk of STIs and pregnancy.

- However, the best way would be to use emergency contraception pills to prevent pregnancy.

Tips for caring for condoms

1. Store condoms in cool, dark place, if possible. Excessive heat, light and humidity damage condoms.

2. Use lubricated, well packed condoms. Lubrication helps prevent tears.

3. Handle condoms carefully. Fingernail and rings can damage condoms.

4. Do not unroll condom before use. This may weaken them. Also, an unrolled condom is difficult to put on.

5. Do not use the condom if:

- The packet is torn or damaged.

- Have manufacturing date beyond expiry date or more than 5 years from the date of manufacture.

- If it is uneven or has changed colour.

- If it feels brittle, dry or very sticky.

Explain specific reasons to see a health care provider

Urge clients to return to a health care provider, if they or their sex partners:

- Have symptoms of STIs such as sores on the genitals, pain when urinating or a discharge.
- Have an allergic reaction to condoms (itching, rash, irritation).

Other specific reasons to return: Need more condoms, dissatisfied with condoms for any reasons, have any questions or problems.

Helping clients at any routine return visits

1. Ask if the client has any questions or anything to discuss.
2. Ask the client about his or her experience with condoms, whether the client is satisfied, and whether the client has any problems. Is the client able to use the condom correctly every time? Also, you can check if the client knows how to use a condom; ask the client to put a condom on a model or a stick. Give any information and advice that the client needs. If the client has problems that cannot be resolved, help the client choose another method of contraception.

Urge clients at risk of STIs including HIV to keep using condoms despite any dissatisfaction. Explain that only condoms protect against STIs during sex.

3. If clients are satisfied:

- Give them more condoms.
- Remind then to return if they or their partner have symptoms of STIs, or if they are dissatisfied with condoms.
- Invite then to return again at any time they have questions or concerns.

c. Managing any problems

If the client reports any problems with condoms:

1. Do not dismiss the client's concerns or take them lightly.
2. If the client is not satisfied after counselling, help the client think about the risk of STIs. If the client has or might get a STI, encourage continued condom use. If not, help the client choose another method if he or she wishes.

Chart 15: Solution to problems

Possible problems	Solutions
Condom or lubricant causes itching or rash on genitals	1. Suggest using water as a lubricant (if additional lubricant is desired) 2. If itching continues, clients should be assessed for infection (both partners) 3. If there is no infection and allergy to latex seems likely, help the client choose another method of contraception unless client is at risk of STIs. If the client is using lubricated condoms or condoms with spermicide:
Man cannot maintain an erection while putting on or using a condom	1. Recommend a dry condom one without spermicide (can use water as lubricant) 2. If the problem continues, help the client choose another method of contraception, unless the client is at risk of STIs For clients at risk of STIs including HIV, urge continued use of condoms despite discomfort. Explain that the only way to be reasonably sure of not getting STIs are: ● Using condoms every time you have sex, or, ● Having sex with only one partner who does not have STIs and does not have any other partners, or, ● Not having sex (abstinence)
Man cannot maintain an erection while putting on or using a condom	● Often due to embarrassment. Discuss how to make condom use more enjoyable and less embarrassing. If a woman put on condom for a man, this may make use more enjoyable. Explain that, with experience, more couples are less embarrassed. ● Suggest a small amount of water or water-based lubricant on the penis and extra lubricant on the outside. This may increase sensation and help maintain an erection.

7.2 Female Condom

The Female Condom (FC) is a viable option for women to protect themselves from pregnancy and STIs including HIV. Female condom is the only currently available method which woman can initiate and in some ways control, which provides dual protection from both unwanted pregnancy and STIs including HIV.

The female condom is a thin, soft, loose-fitting polyurethane plastic pouch-like device that lines the vagina. It has two flexible rings, an inner ring at the closed end, used to insert the device inside the vagina and hold it in place, and an outer ring which remains outside the vagina and covers the external genitalia. The device, being made of polyurethane, can be used with any type of lubricant without compromising its integrity. This is advantageous in countries where water-based lubricants are hard to find.

a. How effective is the female condom

Pregnancies per 100 women in the first year of use as commonly used is 21. If used correctly and consistently there are 5 pregnancies per 100 women.

Advantages:

- Female-controlled
- No medical condition limits use.
- More comfortable to men, less decrease in sensation than male latex condoms. As a result, sensitivity of male partner is not substantially reduced. It also offers ease of use by men with erectile dysfunction.
- Offers greater protection as it covers both internal and external genitalia.
- Stronger (polyurethane is 40% more stronger than latex), and therefore there is less frequent breakage (1% compared to 4% for male condoms)
- Longer shelf-life even under unfavourable storage conditions.
- CSWs found that the female condom allowed them to continue their job without interruption during menstruation (study from Guatemala and Mexico).

Disadvantages:

- Difficulties in insertion and removal. Some participants noted difficulties associated with insertion and removal

of the female condom, discomfort, messiness and inconvenience associated with use and movement of device during use.

- More expensive than male condoms.

How to use

Some time before the sex, the woman places the closed end of the female condom high in her vagina. The closed end contains a flexible, removable ring to help with insertion. A large flexible ring around the open end of the condom stays outside covering external genitalia.

Some evidences

1. A few cases of the penis slipping between the device and the woman's body and slippage and breakage of device have been reported.

2. In a study in Alabama, 25% of the women were unable to correctly insert the female condom in first use, the most common error being not pushing the inner ring high into vagina. 3% were never able to do so despite additional instructions and multiple efforts.

3. A study focused mainly on acceptability in 58 respondents from urban slums in Chennai and CSWs showed good acceptability in this group.

4. A social acceptability study by Hindustan Latex Family Planning Promotion Trust along with Female Health Foundation was conducted in the states of Andhra Pradesh, Kerala and Maharashtra, amongst 3 target groups, namely Female Sex Workers (FSWs), Men who have sex with men (MSM) and eligible couples. The study results show that almost all of the target respondents used female condoms consistently over the study period of 2 months, Usage levels were above 90% in all 3 categories. While the usage level by the FSWs was almost uniform during this period (and even increased), there was slight decrease in usage levels among MSMs and eligible couples. While majority of the FSWs reported the insertion process to be easy, the MSMs largely reported it to be difficult. The percentage of among all three groups saying insertion was difficult dropped over time and after 2-3 times of practice.

Female condom reuse

The female condom is approved for a single use only, but re-use has been reported in several countries. WHO, UNAIDS and USAID among others have conducted studies to investigate the safety of disinfection, washing, drying, storage and re-lubrication, followed by re-use, and WHO has convened two technical consultations to review data from these studies.

WHO recommends use of a new male or female condom for every act of intercourse, where there is a risk of unintended pregnancy and/or STI/HIV infection. Recognizing the urgent need for risk-reduction strategies for women who cannot or do not access new condoms, WHO has developed a draft protocol for the safe handling and preparation of used female condoms intended for re-use. WHO does not recommend or promote re-use, but will make available the protocol, together with guidelines on programmatic issues, to programme managers who intend to evaluate its feasibility and application in local settings. WHO's information update on re-use is available on-line at

www.who.int/reproductive-health/rtis/reuse.en.html

b. Disposal of female condoms

The proper removal and disposal of female condoms should be included with the packaging of FC as well in introductory training programmes:

FC does not need to be removed immediately after a man's ejaculation, like the male condom. But it should be taken out before the woman stands up to avoid the semen spilling out.

The outer ring should be twisted to seal the condom so that no semen comes out.

FC can be pulled out and wrapped in the package it came in and/or in tissue.

FC should be disposed of in waste containers and not in the toilet.

Also, since in many countries women dispose of sanitary napkins in a clean and private way, the same procedures can be promoted for the disposal of FC.

CHAPTER 8

Lactational Amenorrhoea Method (LAM)

Lactational Amenorrhoea Method (LAM)

Lactational Amenorrhoea Method (LAM) is the use of breastfeeding as a temporary family planning method. It provides natural protection against pregnancy and encourages the starting of another method at the proper time.

In addition to the prevention of pregnancy, LAM makes sure that the baby gets needed nutrients and protection from disease provided by breast milk.

a. How effective is LAM?

LAM stops ovulation (release of eggs from ovaries) because breastfeeding changes the rate of release of natural hormones.

Effective as commonly used: 2 pregnancies per 100 women in the first 6 months after childbirth.

Very effective when used correctly and consistently: 0.5 pregnancies per 100 women in the first 6 months after childbirth.

Correct and consistent use means

The following three conditions need to be met to ensure the correct use of this method:-

1. The baby gets at least 85% of his or her feeding as breast milk. And the mother breastfeeds often, both day and night
2. The mother's menstrual periods have not returned
3. The baby is less than 6 month old.

If any of these conditions is not true, the woman should:

- Use another method for effective family planning, one that does not interfere with breastfeeding
- Keep breastfeeding her baby, if possible, even while starting to give the other baby food.

Advantages of LAM

- Effectively prevents pregnancy at least 6 months and maybe longer if a woman keeps breastfeeding often, day and night.

- Encourages the best breastfeeding patterns.
- Can be used immediately after childbirth
- No need for any precaution at the time of sexual intercourse
- No direct cost for family planning or for feeding the baby.
- No supplies or procedure required to prevent pregnancy.
- No hormonal side effects.
- Counselling on LAM encourages starting a follow on method at the proper time.
- Breastfeeding practices required by LAM have other health benefits for mother and baby:
  - Provides the healthiest food for the baby
  - Protects the baby from life-threatening diarrhoea.
  - Helps protect the baby from diseases like measles and pneumonia by passing the mother's immunities to the baby.
  - Helps develop close bondage between mother and baby.

Disadvantages

- Effectiveness after 6 months is not certain
- Frequent breastfeeding may be inconvenient or difficult for some women, especially working mothers
- No protection against STIs including HIV
- If the mother has HIV, there is a small chance that breast milk will pass HIV to the baby.

b. Medical Eligibility for LAM

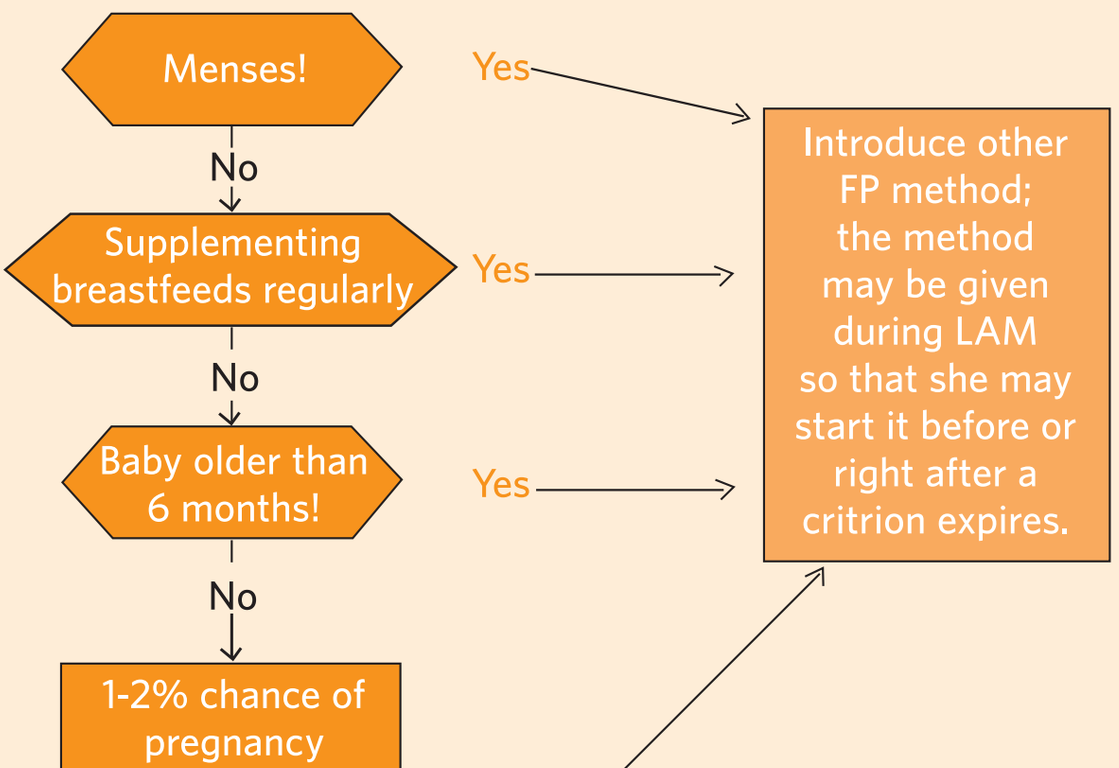
A woman can use LAM after childbirth, if:-

- Her baby is less than 6 months old
- After last childbirth her menstrual period has not returned

- She is breastfeeding day and night, (at least 8-10 times a day, at least once in 4 hours) and at least once at night (night feeding regularly not more than 6 hours apart), and at least 85% of her baby's feeding should be from breastfed milk.

Figure 5: The Lactational Amenorrhea Method (LAM)

The Lactational Amenorrher Method (LAM) is presented as an algorithim, below.



When response changes to YES ...

A dapted from; Labbok M, Cooney K, Coly S. Guidelines: bre astfeeding, family planning, and the Lactati Onal Amenorrhea Method-- LAM. Washington, DC: Institute for Reproductive Health, 1994

In general most women CAN use LAM safely and effectively. LAM can be used in any circumstances by women who:

- Smoke
- Are young or old
- Are fat or thin

The only conditions that limit use of LAM are conditions that make breastfeeding difficult or that rule out breastfeeding.

c. Starting LAM

Start breastfeeding as soon as possible after the baby is born

2. In the first few days after childbirth, breast milk contains substances very important to the baby's health.

3. Early and frequent breastfeeding helps the mother produce enough milk to keep her baby well-fed and healthy. It also ensures effective protection from pregnancy.

Providing LAM

A woman who chooses LAM benefits from good counselling.

A provider who listens to a woman's concerns, answers her questions, and gives clear, practical information about LAM, especially how to breastfeed properly and when to start a follow-up contraceptive method, will help the woman use LAM with success and satisfaction.

Explaining how to use LAM

Give specific instructions:

1. Breastfeed often: An ideal pattern is at least 8-10 times a day including at least once at night. No daytime feedings regularly more than 4 hours apart and no night feedings regularly more than 6 hours apart.

2. Breastfeed properly: Counsel her on breastfeeding technique and diet.

3. Start other foods when the baby is 6 months old. Breastfeed before giving other food, if possible. If the baby's hunger is satisfied first by breast milk, this will help ensure good nutrition and will encourage breast milk production.

The babies may breastfeed less after starting to eat other foods. Therefore, LAM may no longer be as effective. An additional family planning method is recommended in such a situation.

4. Her menstrual period returns (bleeding in the first 56 days, or 8 weeks, after childbirth is not considered menstrual bleeding)

   OR

5. She stops fully or nearly fully breastfeeding.

   OR

6. Her baby is 6 months old (about the time when the baby starts sitting up)

   OR

7. She no longer wants to rely on LAM for family planning

Give her another method now that she can start later, when needed. For example, if she has no condition that would prevent using progestin-only oral contraceptives, she can be given these pills along with instructions for taking them.

LAM has three criteria:-

- Amenorrhea, defined as the absence of the menses. Menses return is defined as the first two sequential days of bleeding or spotting which may occur after two months postpartum.

- Fully or nearly fully breastfeeding, includes exclusive breastfeeding, almost exclusive breastfeeding, and nearly fully breastfeeding, day and night, on demand by the infant.Efficacy and duration of LAM are enhanced with more intense breastfeeding patterns, especially during the earlier weeks and months.

- Less than six months post partum

CHAPTER 9

Fertility Awareness-Based Methods: Standard Days Method (SDM)

The Standard Days Method (SDM)

"Fertility Awareness" means that a woman learns how to tell when the fertile time of her menstrual cycle starts and ends. The fertile time is the time when she can get pregnant. The Standard Days Method involves identifying the fertile days during each menstrual cycle. Women with menstrual cycles ranging between 26 and 32 days can prevent pregnancy by avoiding unprotected sexual intercourse on days 8 to 19.

The Standard Days Method (SDM) is a new natural family planning method for women with menstrual cycles ranging between 26 and 32 days. This method involves identifying the fertile days during each menstrual cycle. Women with menstrual cycles ranging between 26 and 32 days can prevent pregnancy by avoiding unprotected sexual intercourse on days 8 to 19.

Most women using the SDM use a device called cycle beads - a string of colour-coded beads that help women identify the days of their cycles when they can become pregnant and the days when pregnancy is very unlikely. The white beads, which represent the end of the cycle, indicate the time when the woman has a high probability of becoming pregnant if she has unprotected sexual intercourse.

a. How to use SDM

- On the day that your menstrual period starts, hold the Cycle Beads and move the rubber ring onto the first red bead.
- Each day, move the rubber ring onto the next bead, moving in the direction of the arrow.
- Avoid sexual intercourse or unprotected sexual intercourse on the days when the rubber ring is on any of the white beads.

Return to your health care provider or facility if:

- You are not happy with the method.
- You think you are pregnant.
- You want information about or want to start using another family planning method.
- You think there is any chance you may have been exposed to HIV infection or any other sexually transmitted infection (STI).

b. FAQ of SDM:

What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?

Advise her that the method may not be appropriate for her because of a higher risk of pregnancy. Help her consider another method.

The expert working group concluded that the probability of pregnancy is increased when the menstrual cycle is outside the 26-32 day range, even if unprotected intercourse is avoided between days 8-19.

What is the initial provision of SDM for women whose menstrual cycles are within the 26-32 day range?

Provide another method of contraception for protection on days 8 to 19 if she desires. Give supplies in advance.

What advice is there for SDM users who have unprotected intercourse between days 8-19?

Advise the use of emergency contraception if appropriate.

c. New Evidence

Most women can learn to use the SDM in a single counselling session of about 20–30 minutes. A follow-up session after one cycle of use is helpful but not essential.

- Most women who choose the SDM have not used a modern family planning method before; others have been dissatisfied with other methods. Almost all women who choose the method do so because it is "natural" and does not have side effects.10 Follow-up interviews with both current and previous users found high levels of satisfaction with the method among women and their partners.

- Women who start using the SDM and then find it is not appropriate for them (because of cycle length or personal preference) are very likely to switch to another effective method, thus creating an entry point into family planning.

- Programmes report that SDM counselling presents an opportunity—and a comfortable context—to encourage and discuss condom use. Studies conducted in 6 countries found that more than half the people who use the SDM use condoms on fertile days.

CHAPTER 10

Centchroman

Centchroman

Introduction

Centchroman is a novel, nonsteroidal chemical that is marketed in India, where it was developed, as a once-a-week contraceptive pill. Based on limited studies, Centchroman appears to be a highly effective, safe and easy to use oral contraceptive. Also, because it is free of the side effects commonly associated with contraceptives containing both estrogen and progestin, Centchroman could become an extremely important new oral contraceptive.

Mechanism of Action

In humans, Centchroman behaves as a potent antiestrogen but also has weak estrogenic and antiprogestational actions. These effects are similar to those of the ovulation-inducing drug, clomiphene citrate. For example, it has been reported by Roy et al (1976) that Centchroman can induce ovulation when given chronically in daily doses of 15.30 or 60 mg for 10 to 20 days to women who are not ovulating. When only a single dose (30-60 mg) is given weekly to healthy, ovulating women for contraception, however, Centchroman does not alter basal or peak gonadotropin (FSH/LH) secretion or production of estradiol and progesterone (Roy et al 1976). In addition, it does not block ovulation. At this dosage and frequency of administration the only remaining reproductive endocrine effects of the drug are:

To slightly increase the transport of the zygtoe through the oviducts

To accelerate balstocyst formation, and

To suppress uterine endometrial proliferation and decidualization.

Apparently, the combined effect of these actions is capable of creating sufficient asynchrony between the developing zygote and endometrial maturation to prevent implantation.

Effects of Centchroman

Reports from Phase III clinical trials suggest Pearl Index of 2.84 as a weekly regimen and on a twice weekly/weekly regimen. Compared with typical use effectiveness for COC, effectiveness for Centchroman is encouraging.

Of the 37 women who withdrew from the second trial in order to become pregnant, 23 (62%) conceived within 6 months of stopping Centchroman, 10 more during the next 6 months and 3 after 12 months. All told, 36 women (97%) conceived, and all reportedly delivered a normal baby. The only woman who did not become pregnant was reported to be 39 years old with five children (Centchroman 1991).

Side Effects

Centchroman is free from side effects, commonly associates with steroidal oral contraceptive like nausea, vomiting, weight gain and dizziness.

Annexure 1

Checklist to Rule Out Pregnancy: Instructions for Use

Goal of the Checklist Tool:

Family planning providers should always rule out pregnancy when providing hormonal methods or IUDs. However, pregnancy tests may not be available in all clinics or affordable for all clients. In such cases, this checklist provides workers with an easy-to-use tool to help non-menstruating clients safely initiate their method of choice. The checklist is based on criteria for ruling out pregnancy recognized by the World Health Organization (WHO) (United States Agency for International Development, 1997). Tests of the checklist's effectiveness in family planning clinics showed that the tool was more than 99% effective at ruling out pregnancy (Stanback J et. Al, 1999).

Using the Checklist

The checklist is used to rule out pregnancy if no pregnancy tests are available. The provider simply asks the client each of the six questions (or includes them in history-taking). If the client answers "Yes" to any one question, and has no signs or symptoms of pregnancy, then she can safely be provided with her method of choice. It is very important that the provider trusts what the client says. For example, if the client says her menstrual period started within the past seven days, the provider should accept the client's word.

Pregnancy cannot always be ruled out. In these cases, the woman may go for a pregnancy test elsewhere, or use a temporary barrier method while awaiting her menses. If a pill client chooses to wait for her menses, she should be given the option of carrying home a cycle of pills to initiate when her menses returns.

Adapting the Checklist

Some programmes may choose to adapt the checklist to their own unique situations. For example, since a provider does not need to continue asking questions once a client answers "yes", a programme can re-order the checklist questions to reflect locally common reasons that exclude pregnancy. However, programmes should take care to ensure that the meaning of the original questions remains unchanged when adapting or translating the checklist.

How to be reasonably sure a client is not pregnant

Ask the client the following questions:-

1. Have you abstained from menstrual intercourse since your last menses?

2. Have you given birth in the last 4 weeks?

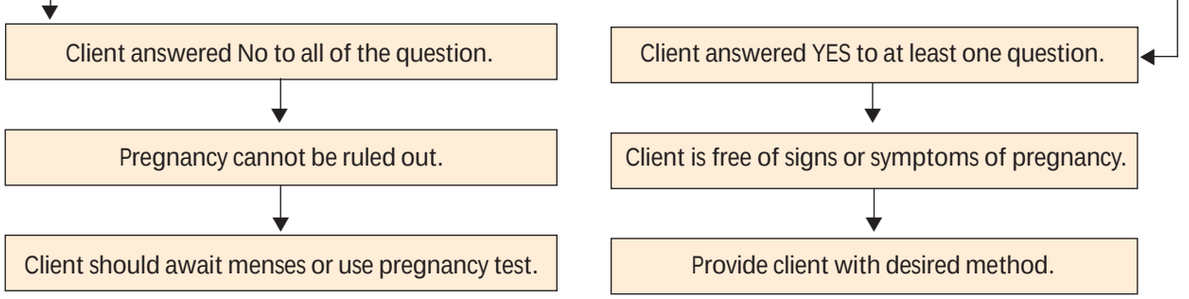
3. Did your last menstrual period start within the past 7 days?

4. Have you had a miscarriage or abortion in the past 7 days?

5. Have you been using a reliable contraceptive method correctly and consistently?

If the client answers YES to any question, proceed to the first box directly below the YES column.

NO		YES
	1. Are you less than 6 months postpartum *and* fully breastfeeding and free from menstrual bleeding since you had your child?	
	2. Have you abstained from sexual intercourse since your last menses?	
	3. Have you given birth in the last 4 weeks?	
	4. Did your last menstrual period start within the past 7 days?	
	5. Have you had a miscarriage or abortion in the past 7 days?	
	6. Have you been using reliable contraceptive method consistently and correctly?	



Annexure 2

Useful Websites on Contraceptives:

1. www. who.int
2. www. fhi.org
3. www. rho.org
4. www. engenderhealth.org
5. www. contraceptive.org
6. www. hsph.harvard.edu
7. www. irh.org
8. www. ihuccp.org
9. www. path.org
10. www. rhtp.org
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