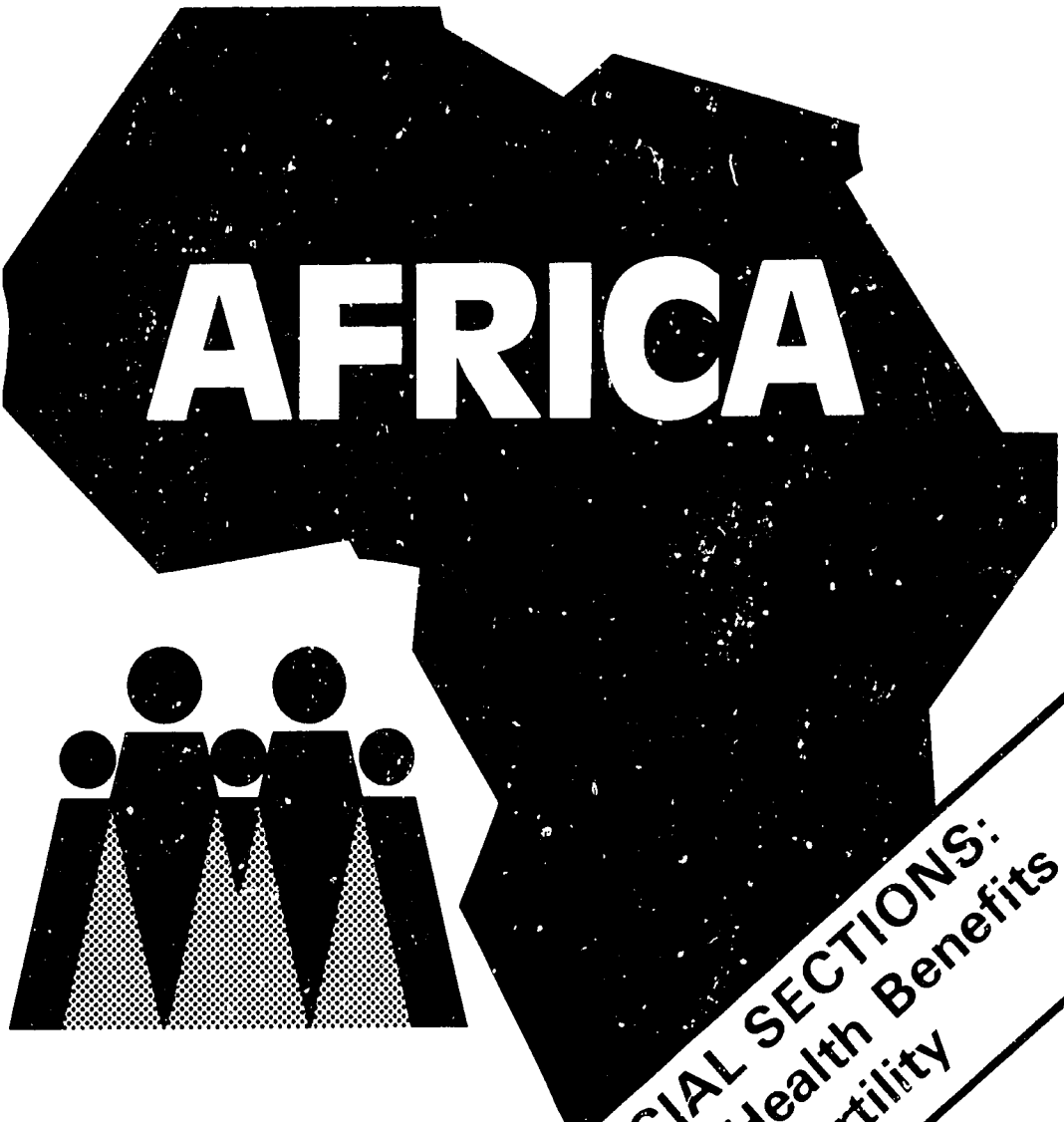


Family Planning Methods and Practice:



AFRICA



SPECIAL SECTIONS:
• Family Health Benefits
• Infertility

Family Planning Methods and Practice: Africa

1983

Centers for Disease Control (CDC)
Center for Health Promotion and Education
Division of Reproductive Health
Atlanta, Georgia 30333
United States of America

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Foreword

Family Planning Methods and Practice: Africa was written both for students of medicine, nursing, and midwifery, and their instructors. Health workers, program managers, policymakers, and international organizations will also find this book useful. The individuals who prepared the book hope that this book will enhance the understanding and availability of family planning services within Africa.

The partnership of Africans and Americans is a natural one for preparing this book. The Americans bring to the book their experience from working on other similar books for American audiences and from providing family planning services in several different successful health care systems. The Africans, themselves engaged in research and service delivery, bring to the book the wealth of their experience, working in nations where traditional family planning methods have been used for centuries and where the health care systems are developing in response to the unique needs and challenges of Africa. Thus, *Family Planning Methods and Practice: Africa* is a compilation of documented scientific research, tried-and-true common knowledge, and opinion derived from the expertise of those who prepared it.

I am confident that *Family Planning Methods and Practice: Africa* will be useful to African health and family planning workers because it takes into account specific cultural and pragmatic factors that influence an individual's decisions to begin planning the birth of children, to use contraceptives, and to choose the most suitable contraceptive method. For example, traditions surrounding the naming of children frequently place pressure on couples to have as many children as they can have as soon as possible. By contrast, customs related to the inheritance of land in densely populated areas can, in fact, provide a strong incentive for couples to space and limit their children. In polygamous societies and in areas where husbands leave home to work as migrant laborers for extended periods of time, women may have intercourse infrequently or irregularly and therefore may choose temporary barrier methods over other methods.

The combination of cultural and biologic factors also needs to be considered when assessing the risks and benefits of contraceptive use among African women. Some cultural practices that influence the health risks associated with the use of some contraceptives for African women include their diet, smoking habits, and family composition.

Further considerations in choosing the best contraceptive method for an African woman should include her access to medical care in case of complications, her practice of breast-feeding, and the possibility that she may have the sickle cell gene which is found in approximately 20% of Africans in Sub-Saharan Africa. The interrelationship of sickle cell anemia with contraception is a subject that has not been adequately studied.

The patterns of disease to which women are exposed also may influence the choice of a contraceptive method. For example, malnutrition or malaria

and other infections that contribute to anemia might contraindicate the choice of a particular contraceptive.

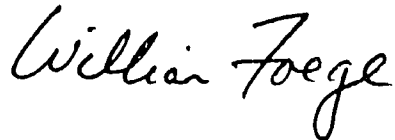
Further, differences in how people live—for example, water sources, transportation, housing, and literacy—are factors that in part determine the ease with which contraceptives can or cannot be used.

The types of health systems and the extent of their development influence the contraceptive methods available to African women. In several countries, maternal and child health centers are the primary sources of contraceptive delivery. In some countries, many family planning methods, including oral contraceptives, are available without formal medical supervision through pharmacists, patent medicine stores, and community-based distribution systems. Other countries are much more restrictive.

Traditionally, children are of great importance to couples throughout Africa because they are perceived by many as an affirmation of life, a sign of strength, and as an economic necessity. Yet, within African communities, there are large numbers of infertile or subfertile couples whose neighbors have many children. Therefore, this book not only provides guidance to help couples limit and space their children so that they have the number they desire when they want them, but also deals with the problem of the infertile couple.

In acknowledgment of the continued desire for large families by some, and in concern over the impact of infertility on others, African health professionals give careful emphasis to contraceptive methods that help couples space, rather than limit, children. As a result, "child spacing" is a phrase that is often used instead of "family planning." One of the limitations of this phrase, however, is that it does not include the concept of either delaying the first child in young adolescents until a girl is socially and medically ready to have a child or terminating childbearing for any of a number of medical reasons.

The underlying premise of both the Africans and Americans who developed this book is identical. Throughout the world, most couples desire to have children and to be part of a family. Family planning has been presented in this book as a *completely voluntary* decision and as an important service leading to *improved health*. *Family Planning Methods and Practice: Africa* upholds the very first principle of family planning which remains: "Voluntary family planning is an important health service."



William H. Foegen, M.D.
Assistant Surgeon General
Director, Centers for Disease Control

Preface

Family planning, until recently a very sensitive subject in black Africa, is now being increasingly accepted as a necessary ingredient of socioeconomic development. Many African leaders now accept family planning as an important health measure contributing to the health of mothers and children. They also accept it as an important contributor to any efforts aimed at the improvement in the status of women.

Unfortunately this understanding, expressed at the national levels and at least on two occasions by African parliamentarians at meetings in Nairobi and Yaoundé, is not being translated into appropriate education, information, and services which meet the needs of women and men in Africa.

In fact, of women of the fertile ages in Africa who need family planning, rather less than 10% use effective contraceptives for planning their families. Such services as exist are often available only to the urban elite or are governed by such unnecessary requirements as to make the services virtually unavailable, except to a small minority.

In 1974, after much debate in Bucharest, family planning was accepted as a human right of individuals and couples. Article 14(F) of the World Population Plan of Action states:

All couples and individuals have the basic right to decide freely and responsibly the number and spacing of their children and to have the information, education and means to do so; the responsibility of couples and individuals in the exercise of this right takes into account the needs of their living and future children, and their responsibilities towards the community.

This should be a clear mandate to family planners to stimulate the needed plans and programmes to enable rapid services to rural areas. In many countries there is a conspiracy of silence about these issues. Even doctors who should know the important contributions of family planning often hide behind archaic laws and practices and keep quiet. The time has come for all those interested in the health and welfare of children and their mothers and for the promotion of women's development to include family planning in the programmes they advocate.

Population dynamics need to be taught in schools and out of school. The meaning and implications of human sexuality knowledge should be given to everybody before they become biologically mature. Young people who are able to have children are old enough to be taught how to prevent having unplanned pregnancies.

These subjects should naturally be handled within social and cultural norms but should not necessarily be omitted because of them. It is necessary to remember that the Margaret Sangers, Marie Stopes, and Ottesen Jensens of the family planning movement had to face censure, prosecution, and even imprisonment for a cause they believed in. Such a fate hardly awaits any innovator in family planning today. Yet a lot of timidity is displayed over issues such as adolescent services, work among the unmarried,

and nonclinical services which will go a long way to meeting the needs of the majority of persons in rural areas and in the urban fringes.

Towards this end *Family Planning Methods and Practice: Africa* is a valuable aid. It seeks to put into the hands of all health workers an authoritative yet concise guide to family planning technology as it exists today. An African edition has been found necessary, both because there are environmental, social, and health conditions which do influence other approaches to family planning, and also to act as a stimulus for African health workers to monitor family planning technology in use under existing African conditions.

US/AID has been the generous sponsor of this publication as indeed it has been a supporter of many family planning programmes in Africa. Today, some African countries can really boast of good beginnings of programmes. US/AID supplies are a major source of commodities for many countries, saving them foreign exchange expenditure. Much still needs to be done.

The chances are that without foreign support many programmes will be less effective. Such assistance, however, should be sensitive to all of the really pressing problems of Africa, and it should not be used as an excuse for hectoring or for preaching the dogma of population explosion and control. Africans are accepting family planning as a human right and a health measure. That is enough for us now.

By
Fred T. Sai

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The Americans who helped to produce the book include **Michael E. Dalmat**, Dr. P.H., Public Health Advisor, Division of Reproductive Health, Centers for Disease Control, Atlanta, Georgia; **Deborah Kowal**, P.A., Editor, Contraceptive Technology Update, Atlanta, Georgia; **Felicia Hance Stewart**, M.D., Associate Medical Director, Planned Parenthood Association, Clinical Instructor in Obstetrics and Gynecology, University of California at Davis, School of Medicine, Davis, California; and **Gary K. Stewart**, M.D., M.P.H., F.A.C.O.G., Medical Director, Planned Parenthood Association of Sacramento, Clinical Assistant Professor in Obstetrics and Gynecology, University of California at Davis, School of Medicine, Davis, California.

In addition, more than 50 individuals representing 16 countries contributed to *Family Planning Methods and Practice: Africa* by reviewing and editing various chapters of the book (see list of contributors). The significant insights and technical contributions of seven individuals in particular have greatly enriched the book: Dr. Michael E. Kafrissen, Mr. Jeffrey M. Spieler, Dr. Kevin R. O'Reilly, Mr. Jay S. Friedman, and Drs. Carlos M. Huezo, David A. Grimes, and Herbert B. Peterson.

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Contributors

Ghana:	Fred T. Sai, M.D.	United States:	Willard Cates, Jr., M.D., M.P.H.
Kenya:	Irene Gathinji, M.D. John Githioni, M.D. Joseph Kanyi, M.D. Japheth Kimanzi Mati, M.B., Ch.B., M.D., F.R.C.O.G. Miriam Likimani, R.N. Francis M. Mburu, Ph. D. Lydia Muthara, R.N. Jeroen van Ginnekin, D.P.H.	(Continued)	Michael S. Dalmat, Dr.P.H. Sally Faith Dorfman, M.D., M.S.H.S.A. Jay S. Friedman, M.A. Dorothy R. Gilbert, C.N.M. Richard A. Goodman, M.D. David A. Grimes, M.D. Felicia J. Guest Richard J. Guidotti, M.D. Carolyn Boyd Hatcher, M.A.T. Robert A. Hatcher, M.D., M.P.H., F.A.A.P. Susan E. Holck, M.D. Douglas H. Huber, M.D. Carlos M. Huezo, M.D. Michael E. Kafrissen, M.D., M.S.P.H. Barbara L. Kennedy, R.N., C.N.M., M.P.H. Deborah Kowal, P.A. Wiley Henry Mosley, M.D., M.P.H. Kevin R. O'Reilly, Ph. D. Howard W. Ory, M.D., M.Sc. Bonnie R. Pedersen, M.P.H. Herbert B. Peterson, M.D. Terri Phillips Roger W. Roach, M.D. Judith B. Rooks, R.N., C.N.M. George L. Rubin, M.B.B.S. James D. Shelton, M.D. Mark E. Speckhard, M.D. Jeffrey M. Spieler, M.Sc. Felicia Hance Stewart, M.D. Gary K. Stewart, M.D., M.P.H. Jeanne B. Stillman Carl W. Tyler, Jr., M.D. Carole H. Tyson, Ph. D. Dallas Voran, M.S.W., M.A. Andrew T. Wiley, M.D., M.P.H. Sabwa A. Matanda, M.D. R.K. Galloway, R.N. Chisale Mhango, M.D.
Mali:	Moktar Diop, M.D. Mamadou Lamine Traore, M.D.		
Nigeria:	Grace Egun Delano, R.N., Nurse-Midwife Oladapo Alabi Ladipo, M.B. B.C.H., M.R.C.O.G. O. A. Osoba, M.D., B.C.H., M.R.C.O.G. Oyewale Tomori, D.V.M.		
Senegal:	Paul Correa, M.D.		
Tanzania:	Halidi Gongoro, M.D., M.P.H. E.E. Kiwelu, M.D. Nimrod A. Mandara, M.D. Rhodes Mwaikambo, M.D. Ezra Teri, M.D., M.P.H.		
Tunisia:	Samih Ben Fadhel, M.D., Ch.B.		
Uganda:	Wilson K. Kisubi, M.B., Ch. B, Dr. P.H.		
United Kingdom:	Ronald L. Kleinman, M.B., Ch. B., D.(Obstetrics) Pramilla Senanayake, M.B.B.S., D.T.P.H., Ph. D.		
United States:	L. Arden Almquist, M.D. Joseph T. Bayly, Th.M. Gary S. Berger, M.D., M.S.P.H. Nancy J. Binkin, M.D., M.P.H. Lewis P. Bird, Ph.D. Anthony F. Boni, M.A. Marianne C. Burkhart, M.P.H. Ronald T. Burkman, M.D. Nadine N. Burton, M.P.C.	Upper Volta: Zaire: Zambia:	

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*Giving birth is something in which mankind and animals are equal....
But rearing the young, and especially educating them for many years is something which is a unique gift and responsibility of man. It is for this reason that it is important for human beings to put emphasis on caring for children and the ability to look after them properly, rather than thinking only about the number of children and the ability to give birth. For it often happens that man's ability to give birth is greater than their ability to bring up the children in a proper manner.*

President Julius Nyerere, Tanzania
1969

SECTION I

AFRICAN CONTEXT

CHAPTER 1

HEALTH BENEFITS OF FAMILY PLANNING

In Africa, the average life expectancy at birth is 49 years, infant mortality averages 149 per 1,000 live births, maternal mortality is estimated to be between 110 and 647 deaths per 100,000 live births, and contraceptives are used by more than 15% of married women of reproductive age in only two countries. Clearly, the health benefits of family planning associated with child spacing and the use of specific methods can play a major role in protecting the lives of infants, children, women, and the family as a whole on this continent. (See Figure 1.1.)

In this chapter, we provide some fundamental answers to the question *"WHY IS FAMILY PLANNING IMPORTANT TO THE HEALTH OF THE FAMILY?"* The health benefits of family planning are obtained either as a result of child spacing or directly from the use of contraceptive methods. In both cases, all members of the family benefit.*

Three important factors associated with family planning influence the outcome of pregnancies: the survival, health, and development of children; the survival, health, and reproductive potential of childbearing women; and the general well-being of families. These include:

- interpregnancy interval (the amount of time that has passed between a current pregnancy and the previous pregnancy);
- maternal age (the age of the woman who is pregnant); and
- pregnancy or birth order (the number of previous pregnancies or births that the woman has experienced).

SURVIVAL AND HEALTH OF CHILDREN FETAL DEATHS

Fetal death rates tend to increase with birth order as shown in Figure 1.2 (3,4). Deaths per 1,000 deliveries in the last 2 months of pregnancy and during the first week following birth in Tientsin, China, more than quadrupled for women having their third or more delivery as compared with those having their first or second. Fetal death rates have also been shown to increase after the second and third pregnancies in numerous other developing countries (5).

The same study from Tientsin, China, and a study done in England and Wales demonstrate that fetal deaths are less likely to occur among pregnant women between the ages of 20-34 than among younger or older women as shown in Figure 1.3 (6).

*Many of the examples cited in this section come from two very useful publications:

MAINE, D. *Family Planning: Its Impact on the Health of Women and Children*. New York, The Center for Population and Family Health, Columbia University, 1981

OMRAN, A. R., STANDLEY, C. C. (Compilers) *Family Formation Patterns and Health, Further Studies*. Geneva, World Health Organization, 1981

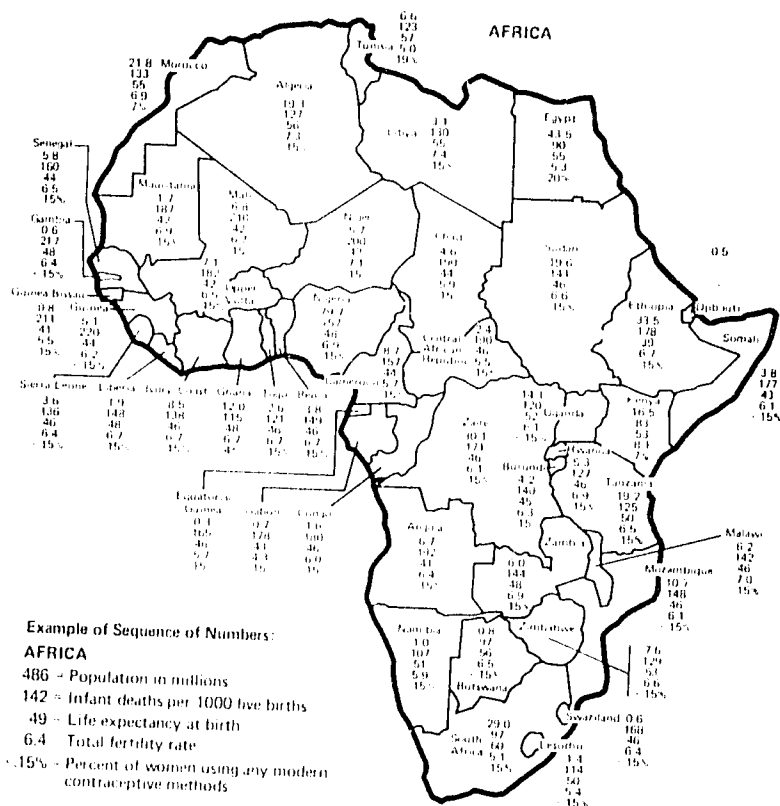


FIGURE 1.1 Population, infant mortality, life expectancy, fertility, and contraceptive use in Africa. (1,2)

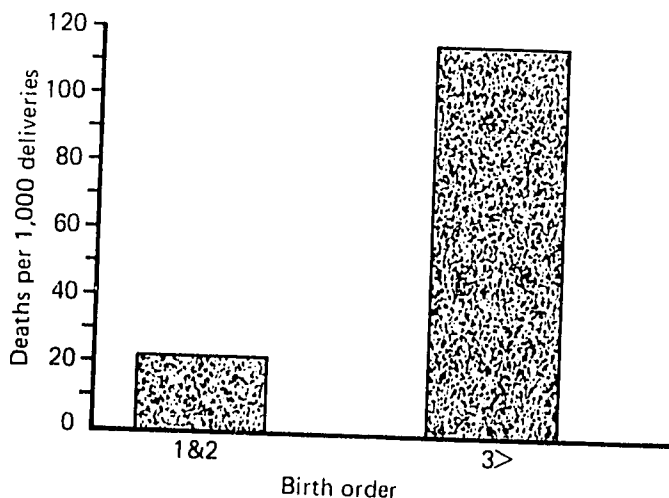


FIGURE 1.2 Fetal deaths during the last 2 months of pregnancy and deaths during the first week of life, by birth order. Tientsin, China, 1978.

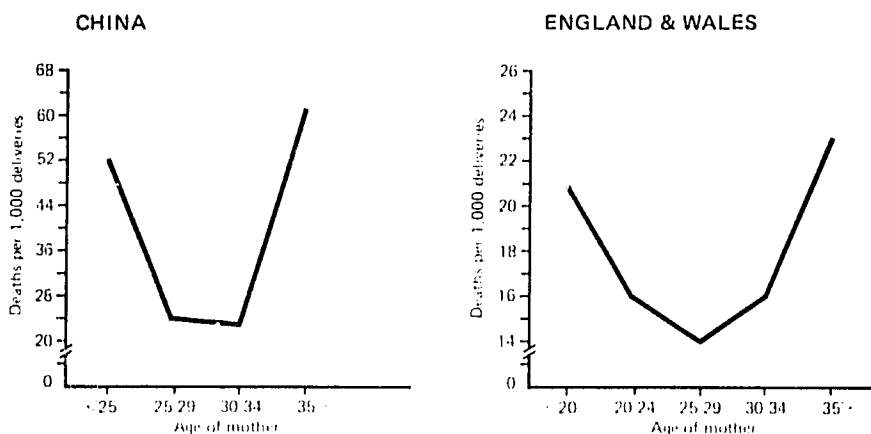


FIGURE 1.3 *Fetal deaths during the last 2 months of pregnancy and deaths during the first week of life, by age of mother. Tientsin, China, 1978, and England and Wales, 1977.*

As demonstrated in an international collaborative study conducted in Colombia, Egypt, Pakistan, and Syria, the proportion of pregnancies resulting in stillbirths and abortions (pregnancy wastage) tends to increase with the age of the pregnant woman and higher pregnancy order, and decreases with longer periods of time between pregnancies (interpregnancy interval) (7). These findings are illustrated in Figures 1.4-1.6.

BIRTH DEFECTS

Infants born to older women have a much greater risk of having birth defects than do children born to younger women. This relationship has been clearly established in the United States as shown in Figure 1.7 (8).

The risk of malformations increases rapidly for infants born to women in their late thirties. Specific defects that increase with maternal age include heart defects, cleft palate and lip, and Down's syndrome (or mongolism) (9).

INFANT MORTALITY

The likelihood of infants dying before their first birthday is far greater for infants born less than 1 year after the end of their mothers' last pregnancy than for infants born after a longer interval (10). This tragic association, based on experience in India, is shown in Figure 1.8.

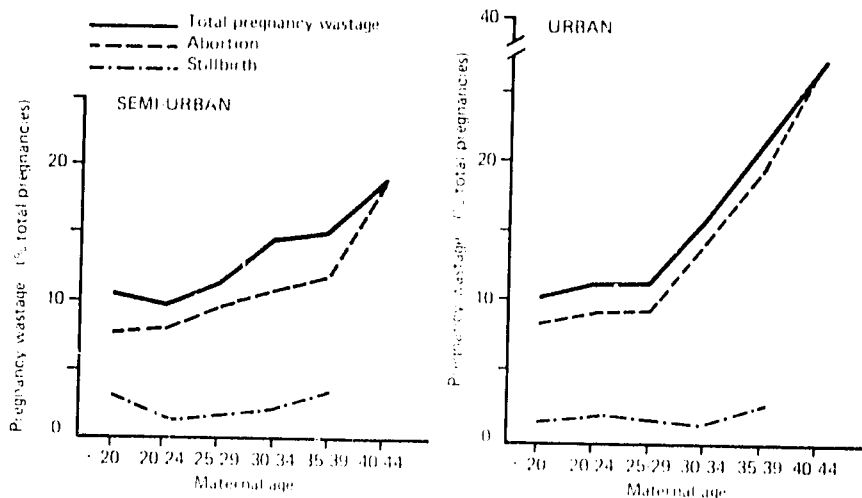


FIGURE 1.4 Pregnancy wastage by maternal age and residence. Semi-urban (Malir/Saudabad and Nazimabad/Paposhnagar) and urban (Karachi), Pakistan, 1975.

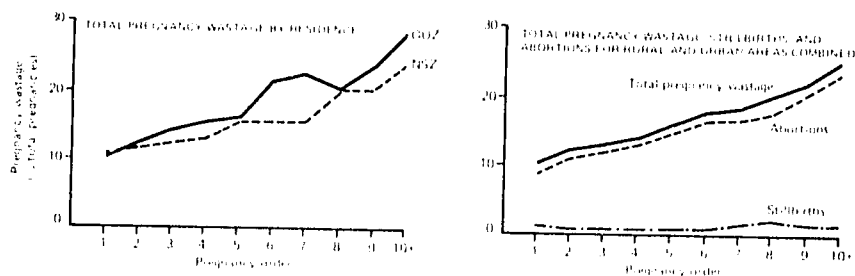


FIGURE 1.5 Pregnancy wastage by pregnancy order and residence. Old Urban Zone (OUZ) and New Settlement Zone (NSZ), Medellin, Colombia, 1975.

Infants born to women who already have had many births are also more likely to die in their first year than those born to women with fewer children. As in many other countries, after the third or fourth birth, the risk of infant death increased sharply in El Salvador, Chile, England, and Wales (6, 11). (See Figure 1.9.) In England and Wales, this pattern has remained stable over several decades, although infant deaths are less common than they used to be. Therefore, although improved living conditions and medical care greatly reduce the overall level of infant mortality, the effects of birth order remain (12).

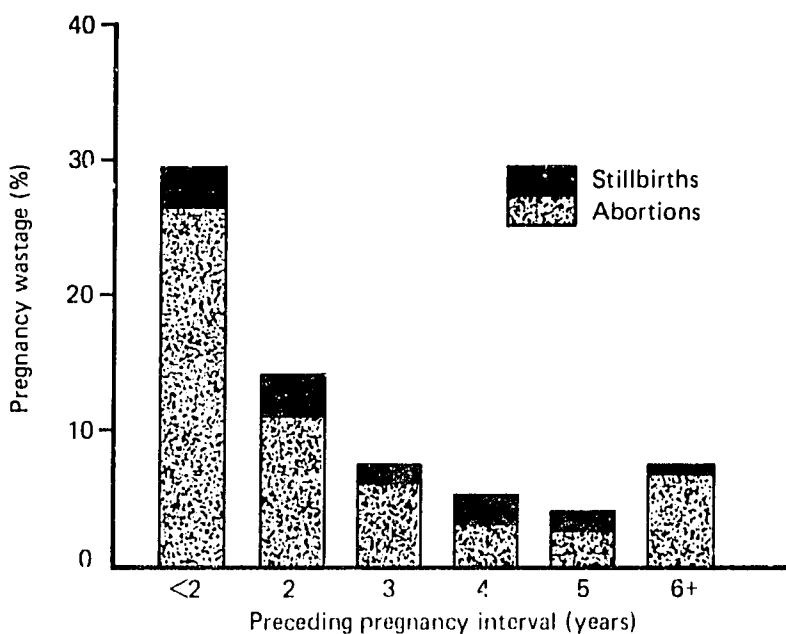


FIGURE 1.6 Pregnancy wastage by duration of preceding pregnancy interval. Assiut District and industrial Alexandria, Egypt, 1975.

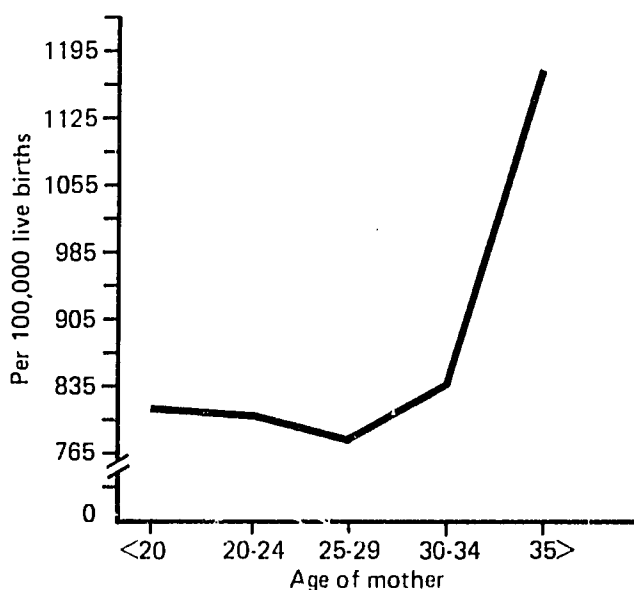


FIGURE 1.7 Infants born with malformations, by age of mother, United States, 1973-1974.

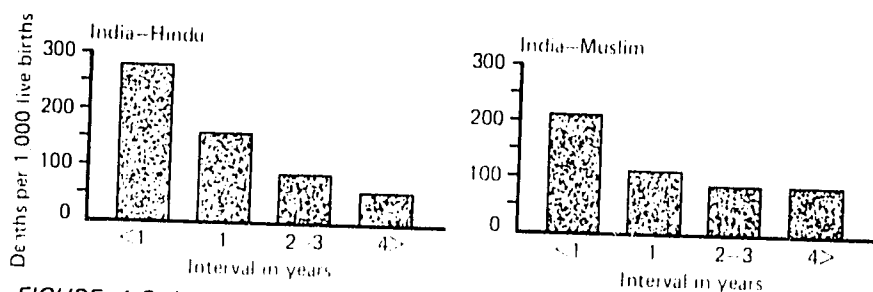


FIGURE 1.8 Infant deaths, by number of years between births, India, 1971-1975.

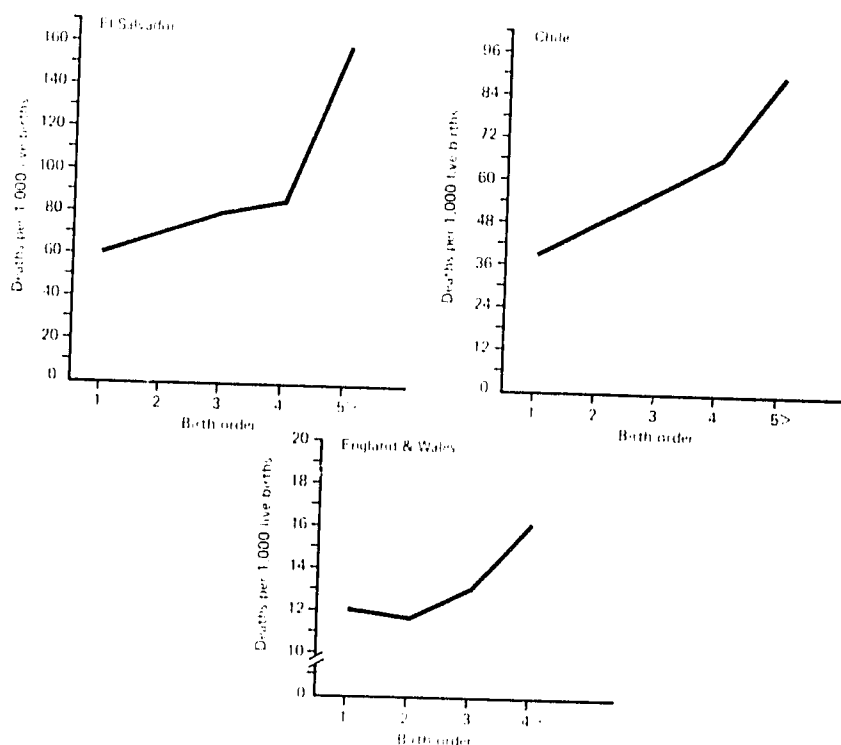


FIGURE 1.9 Infant deaths by birth order, El Salvador and Chile, 1968-1970, and England and Wales, 1977.

CHILD MORTALITY

The risk of childhood death posed by short birth intervals can continue through age 4 as evidenced in Figure 1.10, which is based on a study of three tribes in Kenya (13). When two children are separated by only a short birth interval, not only is the younger of the pair at risk, the older child's survival or health may be at risk as well. This has long been understood in some societies and has even found its way into the language via the word "kwashiorkor," a word from Ghana, which means "the child displaced from the breast too soon" because the mother is pregnant again (14).

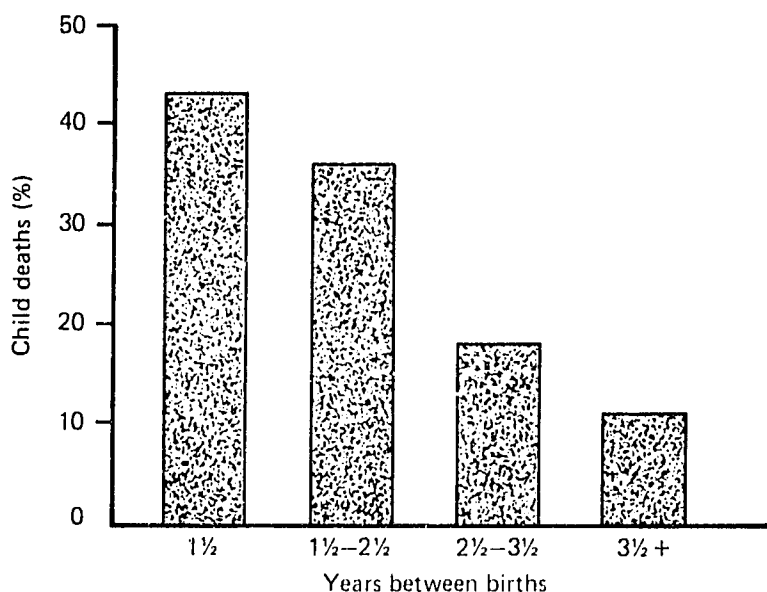


FIGURE 1.10 *Association between pregnancy spacing and child mortality (0-5 years of age) in Kenya—Msambweni, Kibondo, and Kasula Ethnic Groups.*

CHILD NUTRITION AND HEALTH

The effect of birth order on the survival and health of children is likely to be influenced heavily by nutrition, particularly in those African countries that suffer from recurrent drought. Children suffering from acute malnutrition (body wasting) or chronic malnutrition (stunting of their growth and development) are more susceptible to measles and respiratory and other infections and do not recover from parasitic infections and bouts of diarrhea as readily as well-nourished children (15). Consequently, mortality among malnourished children who become ill can be as much as 400 times greater than that for well-nourished children (15). For this reason, the results from a study conducted in India demonstrating the relationship between birth order and the daily consumption of calories and protein are of grave concern with respect to child survival and development. The study showed a rapid decline in the consumption of both proteins and calories for the third, fourth, and subsequent children born to a family (16). (See Figure 1.11.)

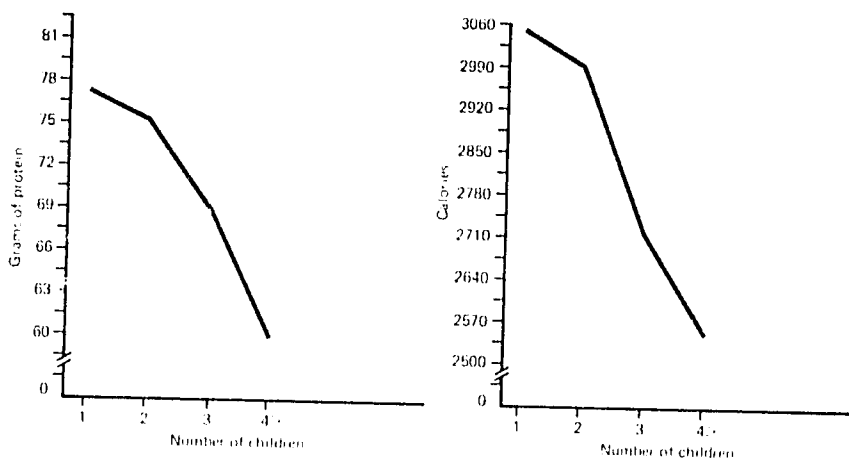


FIGURE 1.11 Amount of protein and calories consumed daily, per person, by number of children in the household, India, 1968.

CHILDREN'S INTELLIGENCE

A number of studies in various countries have examined the relationship between the intelligence of children, as measured through the use of IQ (intelligence quotient), and birth order and interval (7). The results of these studies are inconsistent and tenuous. They warrant continued investigation, however, as do other potential associations that link the full development of children with child spacing.

SURVIVAL AND HEALTH OF MOTHERS

BENEFITS OF CHILD SPACING

The death of a mother is one of the most traumatic events that can befall a family. The loss of the mother has an immense impact on the emotional well-being of the family members that survive her. It may also affect the physical health of her survivors since a third of African women earn a living and since women are directly involved in the hygiene and sanitation of children. Child spacing can protect a woman in significant ways. During the process of receiving family planning services, illnesses can be detected and treated early, which can reduce the likelihood of long-term debilitating problems. If family planning services are linked to other family health or maternal/child health services, high-risk pregnancies can be detected and referred for special assistance. Moreover, by spacing her children, a woman can avoid high-risk pregnancies. Finally, when a woman uses a contraceptive method effectively, she is less likely to resort to dangerous illegal abortions.

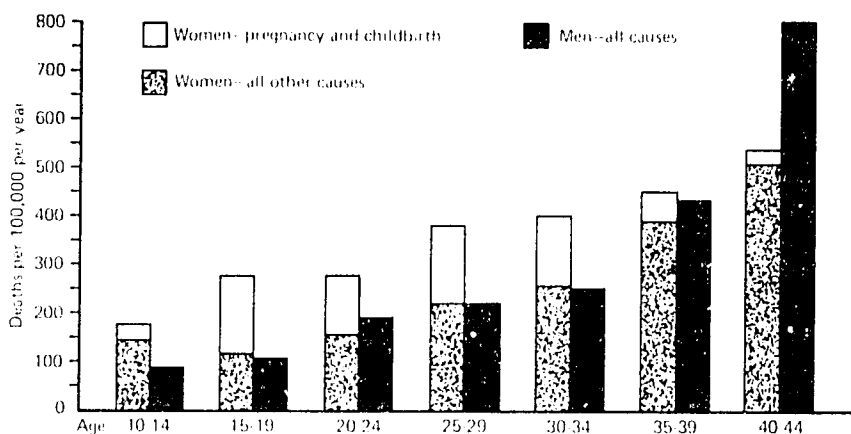


FIGURE 1.12 Deaths among women from pregnancy and childbirth and from all other causes, and deaths among men from all causes, by age, Matlab, Bangladesh, 1968-1970.

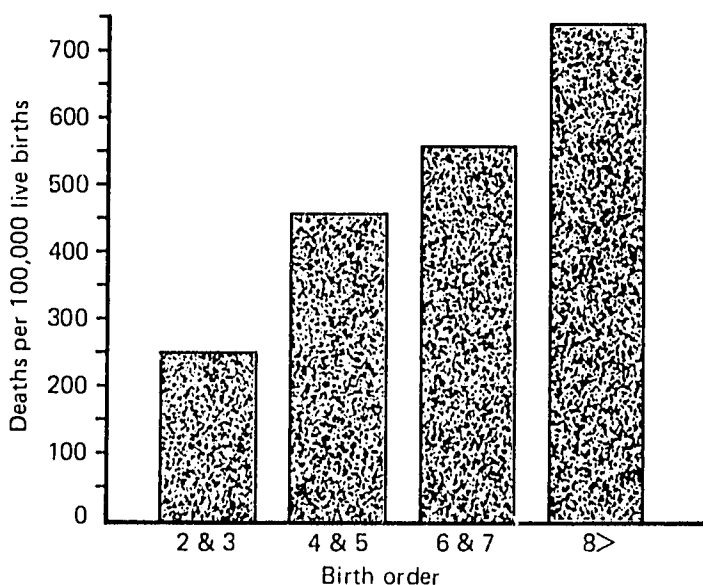


FIGURE 1.13 Maternal deaths, by birth order, Matlab, Bangladesh, 1968-1970.

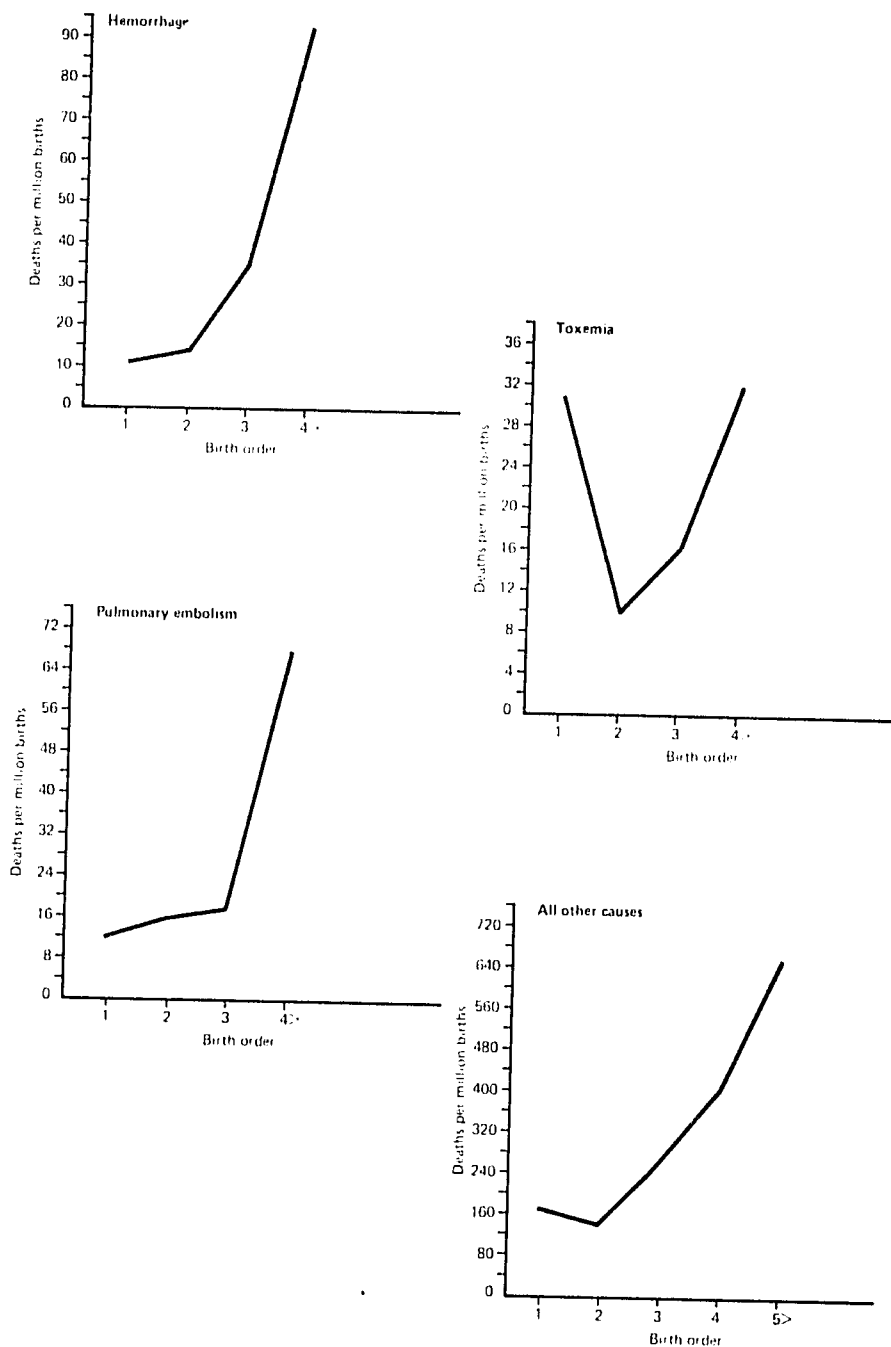


FIGURE 1.14 Maternal deaths, by cause and birth order, England and Wales, 1973-1975.

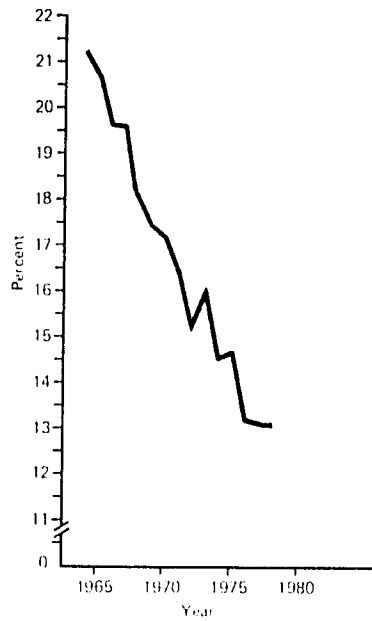


FIGURE 1.15 Maternal deaths due to abortion, Chile, 1964-1979.

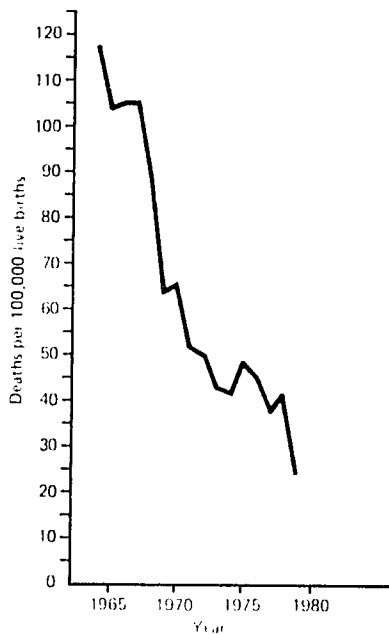


FIGURE 1.16 Percent of all oostetric hospitalizations attributable to abortion, Chile, 1964-1978.

According to the United Nations' Demographic Yearbook, 1978, for the eight African countries that provided information, between 110 and 647 women die for every 100,000 live births because of deliveries and complications of pregnancy, childbirth, and the puerperium (17).

These high rates of maternal mortality are partially attributed to a way of living that is common in developing countries: frequent pregnancies, prolonged lactation, heavy work, and local food customs (e.g., women eat with the children after the men have satisfied themselves). This combination produces a "continuous cumulative nutritional drain" on women; their bodies do not have time to replenish stores of vital nutrients (16,18). As a result, they are less able to combat infections associated with pregnancy, childbirth, incomplete abortions, puerperium, or everyday exposures to illness. In Figure 1.12, data from Matlab, Bangladesh, illustrate that women of childbearing age have a higher risk of dying than do men in the same age groups because of deaths related to pregnancy and childbirth (19). In fact, 40%-60% of all deaths among women between the ages of 15-34 are associated with reproduction.

Figure 1.13 from the same Bangladeshi study, conducted in 200 villages, shows that the risk of dying climbs steadily as the number of births increases.

Maternal deaths from the three major complications of pregnancy in England and Wales are shown in Figure 1.14 (20). Deaths from hemorrhage (uncontrolled bleeding) and from pulmonary embolism (blood clots in the lungs) are especially common among women having their fourth or subsequent birth (21). Toxemia (very high blood pressure during pregnancy that can lead to convulsions) is approximately equally high among first and fourth-and-later births, but is much lower among second and third births. In most parts of Africa, we suspect that the two leading causes of maternal deaths are hemorrhage and sepsis (infection often caused by retained placental tissue or manual intrauterine intervention).

Although not conclusively documented, a large proportion of maternal deaths related to pregnancy in Africa are probably associated with incomplete abortions, whether spontaneous, self-induced, or induced by a trained or untrained practitioner. In Kenyatta National Hospital (Nairobi, Kenya), one-fourth of all obstetric and gynecologic hospital admissions in 1981 involved cases of incomplete abortions (22). The major causes of maternal mortality related to abortion are hemorrhage, sepsis, and a spreading infection that affects the uterus, abdominal cavity, and overall body. These conditions, which are caused by retained fetal or placental tissue, can lead to septic shock and death. Medical colleagues from 12 African countries whom we consulted during the preparation of this book all consider abortion complications to be a major public health problem. Data from Chile suggest that prevention of abortions through effective contraception can dramatically reduce the number of maternal deaths attributable to abortion as well as the percent of all obstetric hospitalizations that are due to abortion (23-25). (See Figures 1.15 and 1.16.)

NONCONTRACEPTIVE BENEFITS OF FAMILY PLANNING METHODS

In Chapters 11 through 21, we have reviewed the health risks, contraceptive effectiveness, and some of the major health benefits of each of the family planning methods. To expand on the normal perspectives from which family planning is discussed, we have summarized some of the key noncontraceptive benefits of family planning methods in the rest of this chapter. They are important to keep in mind both for the benefit of the public and individual family planning users.

Oral contraceptives

In the United States alone, it has been estimated that over 50,000 hospitalizations—for conditions ranging from benign breast disease to cancers of the reproductive tract—are averted each year through the use of oral contraceptives (26). Eight diseases listed in Table 1.1 may be prevented by oral contraceptive use. For the first five—benign breast disease, ovarian cysts, iron-deficiency anemia, pelvic inflammatory disease (first episodes), and ectopic pregnancy—the Pill's protective effects are well documented. However, its effects on rheumatoid arthritis, endometrial cancer, and ovarian cancer need further confirmation.

*TABLE 1.1 Rate of hospitalization prevented annually by use of oral contraceptives per 100,000 Pill users, and estimated number of hospitalizations prevented annually, by specific disease, United States**

Disease	Rate	No.
Benign breast disease	235	20,000
Ovarian cysts	35	3,000
Iron-deficiency anemia**	320	27,200
Pelvic inflammatory disease (first episodes)		
Total episodes	600	51,000
Hospitalizations	156	13,300
Ectopic pregnancy	117	9,900
Rheumatoid arthritis**	32	2,700
Endometrial cancer	5	2,000
Ovarian cancer	4	1,700

*Except where noted, figures refer to hospitalizations prevented among the estimated 8.5 million current users of oral contraceptives in the United States.

**Episodes prevented regardless of whether hospitalizations occurred.
Based on an estimated 39 million U.S. women who have ever used oral contraceptives.

In those parts of Africa where endemic or acute drought conditions threaten the nutritional status of the populations, or where pelvic inflammatory disease, sexually transmitted infections, and infertility are prevalent (see Chapter 6), the value of the Pill in safeguarding the health of women should be weighed when deciding whether or not to use a contraceptive and when choosing a specific method.

Injectable contraceptives

In many African countries, before the public debates and newspaper articles appeared during the last few years on the controversies surrounding the use of Depo-Provera[™], several programs reported a growing demand for that and other injectable contraceptives since they are effective and simple to use. Providers and mothers are also in search of a method that does not interfere with lactation, a factor that is of paramount importance to the survival and growth and development of children. Most research has found that Depo-Provera[™] DOES NOT suppress milk production as do several other hormonal contraceptives (27). In fact, some studies report that Depo-Provera[™] increases milk volume and the duration of lactation for the majority of women (28-32). Study results have reported increased, unchanged, or decreased concentrations of lactose, protein, or lipids in human breast milk (29,30,33,34).

Further, the development of infrequent or scanty menstrual bleeding (oligomenorrhea) and the cessation of menses (secondary amenorrhea) during the use of Depo-Provera[™] may help to decrease the likelihood of iron-deficiency anemia among women of reproductive age who are prone to have this problem (35).

Condom, diaphragm, spermicides

The condom and diaphragm, if used correctly—particularly together with a spermicide—are highly effective in preventing the transmission of many sexually transmitted diseases (gonorrhea, syphilis, trichomoniasis, candidiasis, and herpes genitalis-types 1 and 2) (36-39). In addition, barrier methods have been shown to reduce the risk of pelvic inflammatory disease (PID) (40). These findings are of particular importance in areas that have high rates of sexually transmitted disease and PID, since untreated sexually transmitted infections can lead to PID, which can in turn cause infertility. (See Chapters 5 and 6.)

BENEFITS TO THE COUPLE

There are four specific ways in which a couple benefits from family planning. To begin with, both the man and woman can have more relaxed sexual relations when they are confident that intercourse will not lead to an unwanted or ill-timed pregnancy. In addition, through the effective use of

contraception, they can postpone having their first child or subsequent children to complete their education or vocational training. This freedom can make a significant difference in the economic future of the entire family because of improved employment opportunities. Further, if family planning leads to job security or a sound economic base, the couple can increase its sense of self-respect by being able to provide the type of education and home environment (shelter, food, clothing, recreation) that it elects for its children. Finally, if a couple provides a positive example to its children in terms of child spacing and takes the time to explain to them what family planning has meant to the couple and the family, the possibility is strong that the children themselves will plan their own reproductive lives and be spared the problems associated with an unplanned adolescent pregnancy.

SUMMARY

Child spacing or the timing of every birth, including the first and last, can improve the likelihood of survival and of good physical and emotional health for the entire family at all stages of life. The risks associated with fetal death, birth defects, infant mortality, child mortality, and nutritional depletion for women and children, which can lead to an increased risk of infection, maternal mortality, and unfulfilled family members, can all be reduced through effective family planning.

In the eyes of many, these health benefits provide the principal rationale for family planning programs. While we do not emphasize the point in this book, in addition to aiding individuals and families, family planning can benefit the community or society as a whole in at least three ways: (1) the health benefits to men, women, and children can result in a more productive labor force; (2) the number of unplanned pregnancies resulting in abortions can be reduced, thereby decreasing the proportion of hospital supplies and staff time used to treat women with incomplete, septic abortions; and (3) a basis for understanding how, where, and when the population will grow can emerge; thus, development plans can be made in relationship to the number of people to be served.

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CHAPTER 2

TRADITIONAL PRACTICES

Are you aware of any traditional approaches to regulating fertility? It is likely that you know of some practices based on your own professional experiences in family planning, your personal experiences, or the experiences of your family and friends. We have grouped traditional practices into two categories. One involves the intentional use of locally available plants and substances for the purpose of controlling fertility. The second group consists of behavior that may directly or indirectly affect fertility but is not necessarily practiced with the intention of spacing children.

Traditional practices have been used throughout history and are still in use today despite the availability of modern contraception. As a provider of family planning services, you must be aware that your users may be using a traditional practice. You need to assess the effectiveness and safety of these practices as well as their compatibility with the various modern methods of contraception available to you. In so doing, you will be more effective in helping your users to determine a course of family planning action and to stay with it.

WHAT ARE TRADITIONAL METHODS?

Historically, people have used many methods to control their fertility. Around the world, a large number of plants and other substances have been used to control fertility. While we are now beginning to realize how widespread traditional methods of contraception have been, the efficacy of many of the practices still needs to be determined. The use of these methods makes it evident that people believe in their ability to regulate their fertility and have seen a benefit in doing so for quite some time.

The rapid rate of modernization, urbanization, and social changes experienced in many African countries makes it difficult to determine how commonly traditional methods of fertility regulation are still used. Reports from earlier in this century indicated widespread use of these methods. More recent reports suggest their use continues, at least to some degree. How important these traditional practices are to you will depend to a large extent on where you provide family planning or other maternal and child health services. People working in urban clinics and hospitals will probably see fewer individuals who actively use traditional approaches to child spacing. On the other hand, health workers in rural settings are more likely to be providing services to women who frequently use traditional means to regulate their fertility.

PLANTS AND OTHER SUBSTANCES

Locally available plants have traditionally been used in a variety of ways to control fertility. The World Health Organization has been compiling information on the use of traditional contraceptives and abortifacients and has found references to the use of over 500 different plants and substances in Africa (1).

Plants are used in other ways as well. The oil of the seeds of *Buchholzia macrophylla* is said to have an estrogenic effect and has been used by women in Zaire to reduce menstrual flow (2). Many plants are used by women to stimulate the flow of breast milk. They are either drunk as teas, like *Osyris wightiana* in Kenya (3), or rubbed on the breasts like the pounded leaves of *Hibiscus surattensis* in Tanganyika (4). Other plants are used as spermicides (*Saponaria officinalis* or *Enterolobium cyclocarpum* (5), both used in Egypt), contraceptives (*Sphaeranthus cyathuloides* in Tanzania (3)), or labor-inducing agents (*Parinari excelsa* in Guinea (6)).

The active agents in most of these plants used to regulate fertility have not been identified. This fact, however, may not mean that they do not work. Laboratory experiments with some plants have shown them to be effective. *Combretodenron africanum*, used in the Ivory Coast, has been shown to have an anti-implantation effect in rats (7). The effects of *Saponaria officinalis*, used as a spermicide in Egypt, have also been demonstrated in controlled laboratory studies (5).

BEHAVIOR PATTERNS

Perhaps more important than traditional contraceptives and abortifacients are the cultural practices related to reproduction and sexuality that affect fertility. Post-partum abstinence associated with lactation is the most important of these practices in Africa.

Breast-feeding has a clinically demonstrated contraceptive effect, primarily before the menses return, as explained in Chapter 3. But its importance as a contraceptive is actually greater, since many cultures discourage sexual intercourse while the mother is breast-feeding. This may be practiced to space births so that each child will receive enough breast milk to survive, or because of the mistaken notion that semen pollutes breast milk.

Surveys indicate that lactation and post-partum abstinence are still important in their effect on fertility in some parts of Africa. A recent survey of fertility in Senegal, for example, revealed little use of modern contraception. Yet the levels of fertility were only about half of that projected for a population with an uninhibited fertility level (8). Lactation and post-partum abstinence, known to be practiced in Senegal, have apparently helped to keep birth intervals longer and fertility lower than would have otherwise been the case (9). A recent survey in Nigeria showed that about 80% of married couples knew of

some form of modern contraception but only 10% actually practiced any. The most prevalent method of fertility control was abstinence (10). Other surveys, for example, in Togo (11), Nigeria (12), and Zaire (13, 14), demonstrated the importance of post-partum abstinence for fertility regulation, particularly child spacing.

The impact of this practice on fertility was mathematically demonstrated in a recent study (15). The author concluded that prolonged post-partum abstinence is a powerful inhibitor of a population's fertility. He further suggested that fertility would rise 40% if post-partum abstinence were to decrease from current durations to a 1-year period.

Polygyny (the practice of having more than one wife, a form of polygamy), has also been important as a traditional means of controlling fertility. Polygyny can reinforce effects of the post-partum abstinence by providing the husband with another sexual partner or outlet, thereby decreasing the chances that the abstinence will be violated and sexual relations resumed prematurely (16).

In addition to abstinence after childbirth, and especially during breastfeeding, there are other culturally mandated periods of abstinence that affect fertility. The value placed on virginity in many areas prohibits the beginning of sexual activity until a girl is married. This is true for those living in the Kasai and Shaba regions of Zaire, for example (16). In some areas, women are supposed to abstain indefinitely from intercourse once they have become grandmothers. Thus, there are areas in Africa where abstinence shortens a woman's reproductive period at both ends of her reproductive life span, determining when she becomes sexually active as well as when she stops.

When sexual activity is permitted before marriage, it is usually in a limited form. Coitus interruptus (withdrawal), coitus inter crura ("between a skin" or separated by a garment), and coitus inter femora (between the thighs) are methods that, if correctly practiced, provide sexual release while reducing the likelihood of pregnancy.

Another practice that affects fertility and is commonly encountered in heavily Islamic areas of Africa is female circumcision. This procedure is performed in three basic ways with different levels of severity. Some of these procedures merely entail removing the prepuce of the clitoris and the posterior, larger parts of the labia minora. More extensive is the operation that removes the glans and the adjacent parts of the labia minora. This procedure is called "excision" or "reduction." The most extensive procedure is called "excision and infibulation." In this procedure, the whole clitoris, all of the labia minora, and part of the labia majora are surgically removed, and the vaginal opening is almost entirely closed. This procedure is still commonly practiced in Sudan, where it is called "pharaonic circumcision" (17).

These operations are rarely performed by medical personnel, and complications can be very severe. One of the significant long-term complications is the effect on a woman's sexual functioning. A study in Egypt compared

1,900 circumcised women with a similar group of uncircumcised women. Difficulty in penetrating or successfully completing intercourse or pain during coitus was reported by 50% of the circumcised women. Fifty-six percent of these women failed to achieve orgasm during intercourse. Perhaps because of these problems, 60% of the circumcised women experienced diminished coital frequency, three times less than the level found among the noncircumcised group (17). Consequently, female circumcision can have an important effect on fertility by limiting women's exposure to sexual intercourse.

Many of these practices, especially post-partum abstinence, were more important in the past than today. A recent Nigerian survey revealed a marked difference between wealthy urban women and poor urban or rural women in the duration of post-partum abstinence (18). Women of higher socioeconomic status tended to adopt modern contraceptives and to rely less on abstinence than did women of lower status. Recent anthropologic reports suggest that the stated duration of the period of abstinence has decreased noticeably with time (19). When the societies that practice a shorter (less than 1 year) period of post-partum abstinence are located on a map (Figure 2.1), three distinctive clusters are apparent. The first cluster stretches from Senegal to Somalia across the Sahel. Among these ethnic groups, the decline of taboos can be associated with the influence of Islam. While the Qur'an stipulates a 2-year period of abstinence, Islamic canon prescribes a post-partum period of only 40 days, or as long as the bleeding lasts. There are Moslem populations in the Sahel that maintain a longer taboo, however (from 2 months to 1 year), and even a larger cluster in portions of West Africa that has maintained the long period of abstinence. The impact of the Islamic canon appears to decrease the farther south one moves.

A second cluster of societies with shortened periods of post-partum abstinence is found in East Africa, although, in many of these societies, the longer period of abstinence is still adhered to by polygynists. The practice of coitus interruptus during lactation is widespread in many of these societies and may be the reason for the decline in the custom of post-partum abstinence. An additional factor in these societies is Christianity, which reduces the practice of polygyny (thereby opposing the separation of husband and wife after childbirth) and accelerates modernization through literacy.

The third cluster of societies with a shortened period of post-partum abstinence is in the Lacustrine area, where most of the societies engage in animal husbandry and regularly consume milk, decreasing the need to abstain from intercourse to protect lactation. In Rwanda and Burundi, intensive Christian influence may explain the decline in the abstinence practices of other societies. In Zaire, the period of abstinence has shrunk most along the lakes and in Central Zaire (among the Mongo) and least in the west and south. In Southern and Central Ghana, the period has shortened considerably, principally among Akan peoples (i.e., the Akuapem, Akyem, Kwahu, Ashanti, Brong, Fante, Nzima Sefwi, and Ga ethnic groups).

Figure 2.1 lists ethnic groups that appear from published reports to have maintained the long post-partum taboo. These ethnic groups are heavily concentrated in western Africa. An examination of these maps should give you an idea where you can expect to find traditional long periods of post-partum abstinence and where you can expect to see newer, shortened periods.

WHAT TO DO?

While traditional practices are slowly disappearing, there is ample evidence that some traditional forms of fertility regulation are still fairly common. As one who delivers family planning services, you must be able to determine if a woman is using a traditional method to regulate her fertility,

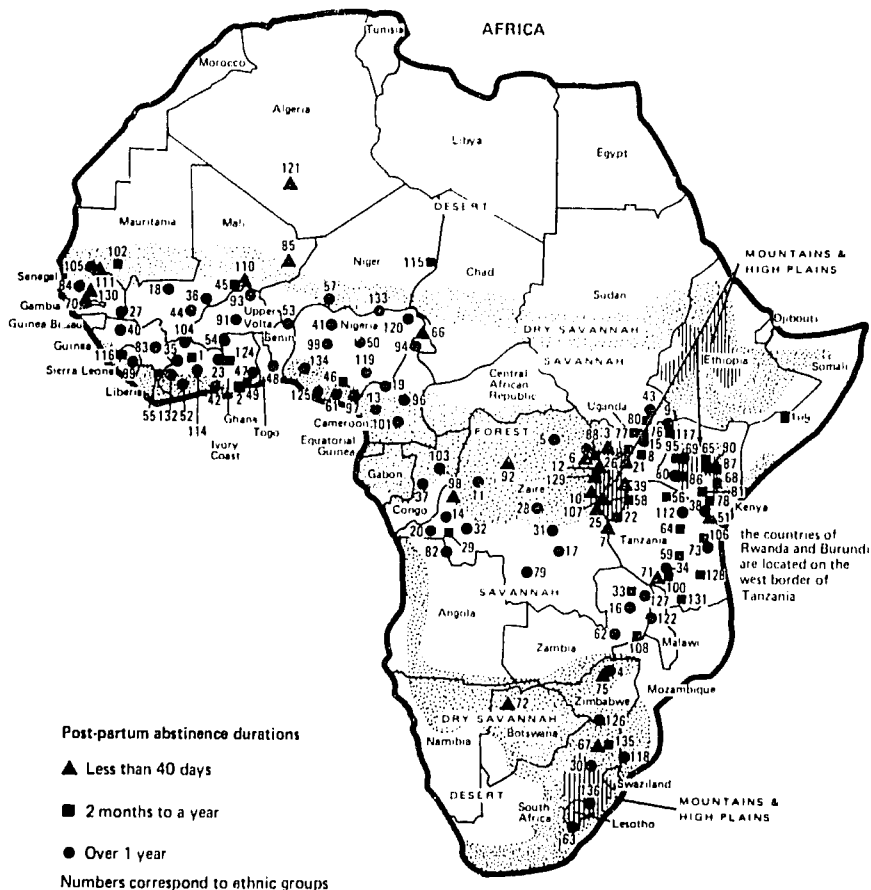


FIGURE 2.1 Patterns in post-partum abstinence among ethnic groups.

FIGURE 2.1 *Patterns in post-partum abstinence among ethnic groups—Continued*

ETHNIC GROUPS			
1. Agni	35. Bete	69. Kipsikis	103. Pomos
2. Akan	36. Bobo	70. Kissi	104. Senufo
3. Alur	37. Boumali	71. Konde	105. Serer
4. Ambo	38. Chaga	72. Kung bushmen	106. Shambaa
5. Azande	39. Chiga	73. Kwere	107. Shi
6. Babira	40. Coniagui	74. Lalia-Ngola	108. Shona
7. Bafulero	41. Dakakari	75. Lamba	109. Somali
8. Baganda	42. Dida	76. Lango	110. Songhai
9. Bagesu	43. Dinka	77. Lugbara	111. Soninke
10. Bahavu	44. Dioula	78. Luguru	112. Sukuma
11. Bahumbu	45. Dogon	79. Lunda	113. Suri/Bwa
12. Bahunde	46. Efik	80. Luo	114. Tagouana
13. Bakoko	47. Ewe	81. Maasai	115. Teda
14. Bakongo	48. Fon	82. Maiacas	116. Temne
15. Bakonjo	49. Ga	83. Malinke	117. Teso
16. Balala	50. Gbari	84. Mandinkas	118. Thonga
17. Baluba	51. Giriama	85. Maouri	119. Tiv
18. Bambara	52. Godie	86. Maragoli	120. Toupouri
19. Bamileke	53. Gourmantche	87. Mbeere	121. Tuareg
20. Bandibu	54. Grusi	88. Mbuti	122. Tumbuka
21. Banyankore	55. Guere	89. Mende	123. Tutsi
22. Banyarwanda	56. Gusii	90. Meru	124. Twi
23. Baoule	57. Hausa	91. Mole-Dagbani	125. Urhobo
24. Bapopoie	58. Haya	92. Mongo	126. Venda
25. Bashi	59. Hehe	93. Mossi	127. Wahenga
26. Bassabei	60. Hutu	94. Mukulehe	128. Wapogoro
27. Bassari	61. Ibibio	95. Nandi	129. Warega
28. Bassonge	62. Lla-Tonga	96. Ndiki	130. Wolof
29. Basuku	63. Kafir	97. Ngwa Igbo	131. Yao
30. Basuto	64. Kaguru	98. Ntombe	132. Yauoba
31. Batetla	65. Kamba	99. Nupe	133. Yaurawa
32. Bayaka	66. Kanuri	100. Nyakyusa	134. Yoruba
33. Bemba	67. Kgatla	101. Pahouin	135. Zezuro
34. Bena	68. Kikuyu	102. Peul (Toucouleur)	136. Zulu

whether she is using the method conscientiously and effectively, and whether use of the method is causing her any problems. Only when you have these facts will you be in a position to help her make decisions about family planning that she will be able to carry out with confidence.

The rest of this chapter is intended to help you examine your users' traditional practices and how they can affect the services that you can provide them. We will take you through a step-by-step approach that will enable you to get the information you need and to evaluate it, arriving at a method or combination of methods that will be suitable for your user.

The first step is to determine if your user is using a traditional form of fertility regulation. Answers to the following questions will give you some clues as to whether a woman does or does not make use of traditional methods and practices:

- Is she from an urban setting?
- Is her area strongly Islamic or strongly Christian?
- Does she appear to have adopted modern habits of dress, language, and bearing?
- Does she come from a cattle-raising ethnic group that consumes milk regularly?
- Is she in a monogamous marriage?

If the answers to all of these questions are "yes," it is likely that the woman is not a traditional family planner. In that case, you should suggest modern contraception. If, on the other hand, the answers to some of these questions are "no," the woman may be traditional in her fertility-related practices. Ask her directly if she uses any means to space her births. These questions may serve as a guideline:

- Do you breast-feed your children? How long do you breast-feed before you begin to supplement the child's diet? How long do you breast-feed before weaning the child completely?
- Do you abstain from sexual intercourse completely while you are breast-feeding? How long do you abstain? How long are you supposed to abstain?
- Do you use any means of contraception at all, especially methods that you have not received from a clinic or health professional?

If the answer to the first question in each series is "no," proceed with recommending modern contraception.

If the woman answers "yes," however, and she breast-feeds and abstains for a substantial period of time, the woman is probably a family planner, and modern contraception alone may not be the best course of action. Additional information is needed; specifically, you must determine how reliable this woman is in adhering to traditional family planning practices and how effective her method of choice is. Ask her if she has intentionally attempted to space her births. Use these questions as a guide to getting the further information you need:

- How many children do you have? How many do you want to have?
- How far apart are your children in age? How far apart should children be spaced?
- How long will it be before you want to have another child?

If the woman has more children than she intended or if her children are more closely spaced than she had desired, recommend a modern method of contraception. The traditional method she has used may have required long periods of sexual abstinence that she and her husband have found difficult. Modern contraception may be easier for her to use and will allow her greater

sexual activity. In this case, there may be indications that an IUD would be the safest choice, as it requires the least amount of user attention.

If the answers to these questions reveal the woman is managing to control her fertility to her satisfaction through the use of her traditional means, you need to investigate the safety of her method of choice. This step may be more difficult. If the woman is effectively spacing her births through a combination of breast-feeding and abstinence, there is nothing safer. If this is the case, the best course of action is probably to recommend a barrier method of contraception as a backup to her traditional practices. For example, you might recommend that the woman use foam or condoms just in case her resolve to abstain, or her husband's resolve, should weaken.

Completely replacing her traditional practice with a modern method of contraception may not be productive. In many places, particularly in rural areas, there are still difficulties encountered in maintaining a consistent supply of contraceptives. If you cannot guarantee that your user will be able to obtain the supplies she needs, you may be doing her a disservice by disrupting her traditional patterns and replacing them with at best spotty coverage with modern contraceptives. Furthermore, some types of oral contraceptives (the combination Pills) should be prescribed with caution for lactating women. If used improperly, they can decrease the milk yield and shorten the period of lactation (see Chapter 3). In cases where the period of sexual abstinence is directly related to breast-feeding, the improper use of a combination Pill could expose women to another pregnancy sooner than they would have been had they followed their traditional practice.

In the case of traditional contraceptives and abortifacients, however, it is very difficult to determine how safe they are for the user. There are many types in use and many different means of using them. Active agents have not been identified for many of these substances. The decision about the safety of these methods must be *yours*. There are no guidelines we can offer, though we can suggest that you question the woman about any side effects she may have experienced while using these methods. While this may require prompting and clever investigation, she will be your best source of information. If you have any doubt at all about the safety of her contraceptive, recommend a modern method.

In general, if a woman is willing to use a traditional contraceptive method, she may be willing to use a modern method, especially one that is analogous. For example, women who are accustomed to using traditional barrier methods that require vaginal insertion may be more willing to switch to a diaphragm or foam. Similarly, women who use traditional methods that are taken orally may be candidates for the Pill. Stressing the overall effects on her health may convince her to switch to a modern method.

Before you recommend such a switch, however, you should try to determine how receptive the woman is to changing her method and using modern contraception. If she is resistant to change, try to determine the source of

that resistance. Consider the following questions in each case:

- Will giving the woman contraception put her in disfavor with her husband? Is he aware that she is receiving care at your clinic?
- Will it open her to criticism from the other women in her group?
- Will she be in disfavor with her mother? her mother-in-law? her grandmother?
- Does she have the freedom to get to the clinic when she needs to, or is it difficult for her to leave her household?

If the woman appears to be socially free to use modern contraception, recommend that she do so. Even if not totally socially free, recommend that a woman adopt a method if she wants to space or limit the number of children she will have. However, in this case, your responsibility goes beyond providing contraceptive services. Counsel her about the pressures that she is encountering, reinforce her decision to use a modern method, and help her to develop good justifications for the use of her method. Assure her that she can contact the health clinic for further reassurance, for answers to questions, or for help in discussing with others their concerns about her use of the contraceptive. It is preferable to schedule a return visit, even if her method of choice does not require it, to check on her progress with contraception, and to help her with any problems—medical or social—that she may be having with its use.

As you can see, it is difficult to make comprehensive recommendations to all women regarding the use of traditional family planning methods. The preceding series of questions are intended to help you to arrive at a suitable solution. This means suitable for the woman so that she continues to use contraception effectively.

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CHAPTER 3

LACTATION

It is likely that even now, when considered on a global scale, more births are prevented by breast-feeding than by any other method of contraception.

Carl Djerassi
The Politics of Contraception, 1979

If we could develop contraceptives that promoted breast-feeding, they would increase the birth interval and reduce the infant mortality rate at the same time.

Dr. Roger Short
Royal Society of London — 1976

The majority of mothers in the world breast-feed their babies for at least 3 months. Breast-feeding, a very natural and effective process for providing a growing infant with high quality, no-cost nutrition, has two distinct advantages that will be described in this chapter:

1. Breast-feeding is a valuable means of fertility control.
2. Breast-feeding is often crucial to infant health and survival (1).

PREVALENCE

Traditionally, many African mothers have relied on breast-feeding as a method of delaying their next pregnancy. In addition, the period of breast-feeding, or lactation, is often accompanied by a period of abstinence. The husband might sleep in a separate dwelling or, if he is polygamous, with another wife.

The length of time that abstinence is practiced varies. Some mothers observe traditional customs that prohibit intercourse for a long period of time, measured by some activity of the child. For example, some cultures prohibit intercourse until a child can carry a bowl of food to the father, lift a three-legged stool, or walk steadily—usually at about 2 years of age.

With changing patterns of education, job opportunities for women, economic circumstances, and living conditions, however, abstinence, if done at all, is practiced for much shorter periods. In 1977, 90% of Nigerian women who were studied abstained for only 1 year (2). According to a recent report, the majority of Kenyan women stopped abstaining by 6 months after birth; about 50% stopped abstaining by 3 months (3). The unfortunate result of these changing practices of abstinence is that many breast-feeding mothers now rely on breast-feeding alone, without abstinence or modern contraceptives, to delay their next pregnancy.

Patterns of breast-feeding are also changing as Africa becomes more urbanized. Most mothers continue to breast-feed their infants for 1 to 2 years (2,4,5). Mothers in rural areas, however, tend to breast-feed for a longer time than mothers in urban areas. In a Nigerian study, for example, it was found that rural and poor urban mothers breast-feed their infants an average of 18 months. More affluent urban mothers, on the other hand, breast-feed their infants a much shorter period of time. Only 10% of the affluent urban mothers continued breast-feeding for 18 months (2).

Not only does the length of time a woman nurses her child differ between rural and urban mothers, but also other practices vary. The rural mother is more likely to practice "*full*" breast-feeding for a longer period, to carry her baby with her at all times as she goes about her daily activities, and to sleep with her baby at night so that the infant may feed on demand.

EFFECTIVENESS OF BREAST-FEEDING AS A CONTRACEPTIVE

How reliable is breast-feeding as a contraceptive? During the first month after delivery, the likelihood of pregnancy is low whether or not a mother breast-feeds her child since she is usually amenorrheic during this time. STUDIES HAVE SHOWN THAT AFTER MENSTRUATION RESUMES, THE RISK OF PREGNANCY IS SIMILAR WHETHER OR NOT A WOMAN BREAST-FEEDS (6,7). THIS SUGGESTS THAT THE PREGNANCY-PREVENTING PROPERTIES OF BREAST-FEEDING ARE PRIMARILY LIMITED TO THE AMENORRHEIC PERIOD (6).

However, there is no way of predicting when menstruation or ovulation will resume. After delivery, mothers take varying lengths of time to resume regular menstruation. In general, post-partum amenorrhea lasts longer in breast-feeding mothers than in nonbreast-feeding mothers. For most breast-feeding mothers, the duration of post-partum amenorrhea depends, in part, on the duration and frequency of breast-feeding; in different studies the duration ranges from 4 months to 24 months. For most nonbreast-feeding mothers, post-partum amenorrhea lasts about 2 months to 3 months (8).

But amenorrhea does not offer a completely reliable indication of the contraceptive effectiveness of breast-feeding. Nearly 80% of breast-feeding mothers ovulate before their first menstrual period (9). Ovulation may occur as early as 2 months after delivery. Anywhere from 3% to 7% of breast-feeding mothers will become pregnant before they have their first menstrual period (8).

On the other hand, breast-feeding does offer some protection against pregnancy. In areas where breast-feeding is prolonged, "expected" numbers of births do not occur. For example, a study in Rwanda showed that 50% of breast-feeding mothers became pregnant within 18 months after delivery compared with 50% of nonbreast-feeding mothers, who became pregnant by 4 months after delivery (10). In another study, only 5% of breast-feeding

mothers became pregnant within 9 months after delivery compared with 75% of nonbreast-feeding mothers; and 75% of breast-feeding mothers were still not pregnant 15 months after delivery (11).

Not only can pregnancy rates in a population be affected by breast-feeding or not breast-feeding, but also the rates can be affected by how breast-feeding is practiced. In Rwanda, urban mothers who breast-fed became pregnant 12 months to 16 months earlier than rural mothers who breast-fed (12). Among the factors that might explain the greater contraceptive effectiveness in rural women are:

- Less use of breast milk supplements
- More prolonged breast-feeding
- More breast-feeding on demand (around-the-clock)
- More simultaneous use of abstinence during breast-feeding

We emphasize, however, that while prolonged breast-feeding is a highly effective contraceptive when the entire population is taken into account, it may be a less reliable contraceptive for the individual woman. Since the time when menstruation will resume varies greatly, a woman does not know when the protection of lactational amenorrhea will end. Further, ovulation may occur before menstruation resumes (9,10). Thus, it is possible that a woman can become pregnant while she is breast-feeding. The most effective contraceptive effects of breast-feeding probably occur during the first 6 months when a woman is not supplementing the breast milk with other types of food. After 6 months, a woman would be wise to begin another contraceptive method to prevent pregnancy. Many experts encourage beginning appropriate contraceptive methods at the 6-week post-partum examination, or even after delivery. The woman who desires to have maximum protection against becoming pregnant while she is still breast-feeding her child should begin contraception as soon as permissible (9,11).

MECHANISM OF ACTION

THE PHYSIOLOGY OF LACTATION

Successful breast-feeding depends on perinatal practices. The sucking of the newborn infant causes two reflexes in the mother that lead to milk production and the prevention of pregnancy:

1. **Prolactin reflex:** As the baby sucks, impulses are sent from the areola of the nipple to the vagus nerve and then to the *anterior pituitary*. The anterior pituitary secretes the hormone prolactin, which stimulates glands in the breast to produce milk. It also produces a contraceptive action by decreasing the level of the leutinizing hormone necessary for maintaining the menstrual cycle (13). (See Figures 3.1 and 3.2.)
2. **Lact-down reflex:** As the baby sucks, impulses are sent from the areola to the vagus nerve and then to the *posterior pituitary*. The posterior

pituitary then releases the hormone oxytocin, which causes the muscle cells in the areola to contract and squeeze out milk. Oxytocin also helps the uterus contract to its normal condition. The mother's let-down reflex is also stimulated by seeing or hearing her baby. This reflex can be *inhibited*, however, by stress or anxiety, making nursing difficult.

Although prolactin has a contraceptive effect, lactation does not postpone menstruation or ovulation indefinitely. THE LONGER A MOTHER BREAST-FEEDS, THE MORE LIKELY SHE WILL BEGIN TO MENSTRUATE OR BECOME PREGNANT WHILE SHE CONTINUES TO BREAST-FEED. Moreover, a reduction from full breast-feeding to partial breast-feeding usually causes the menstrual cycle to resume (6).

MILK PRODUCTION IN THE BREASTS

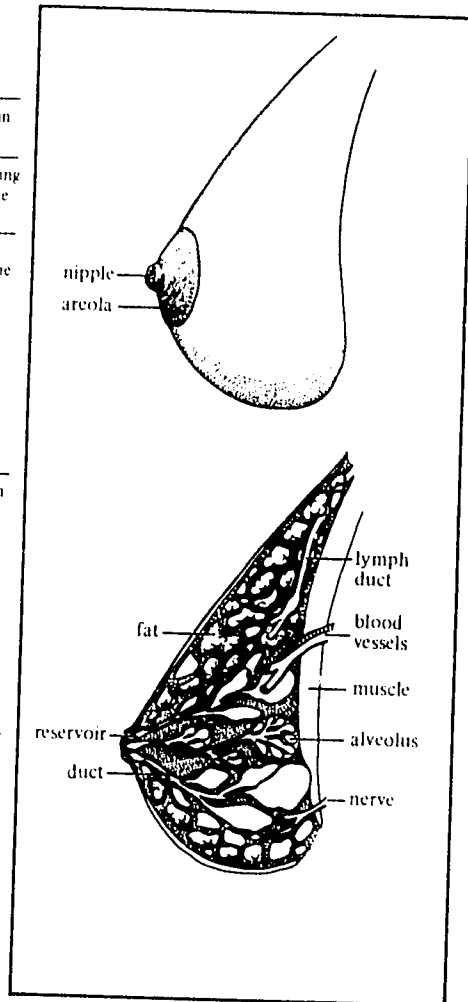
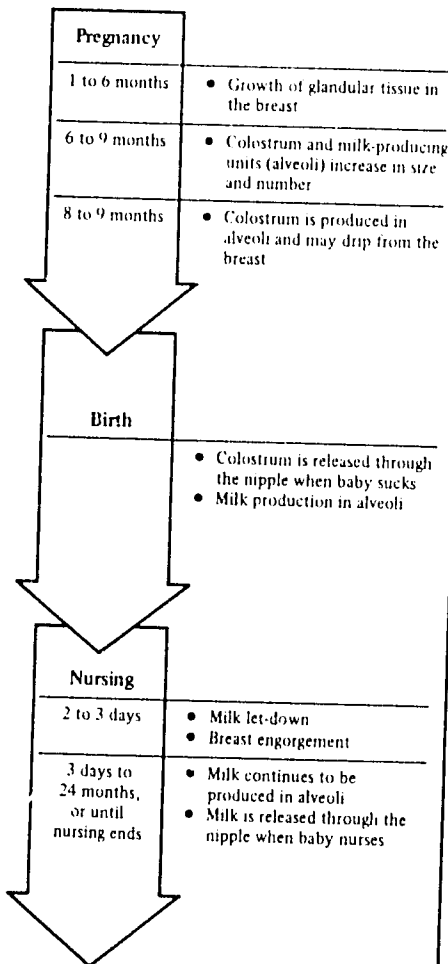


FIGURE 3.1 Anatomy of the breast and milk production in the breasts.

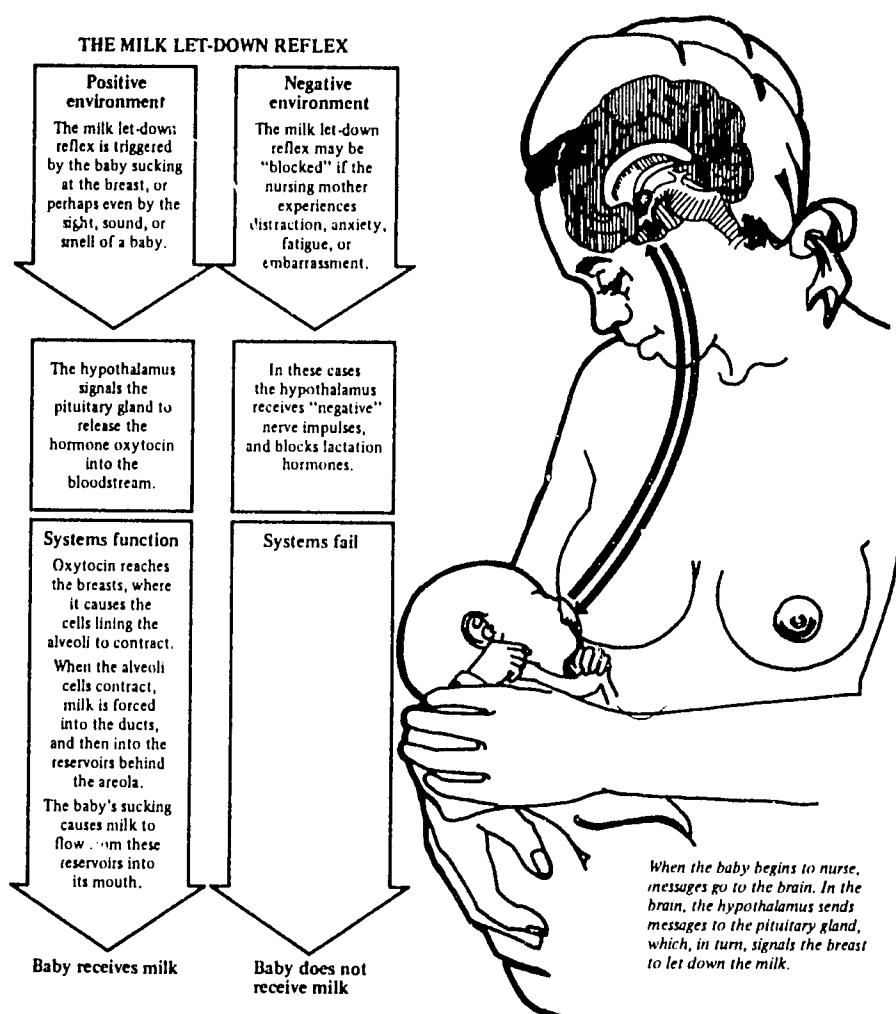


FIGURE 3.2 *Physiology of lactation and the milk let-down reflex.*

It is the frequency and duration of breast-feeding that most reduce the chance of pregnancy. The more frequent the stimulation of the breast by sucking (if, for example, the baby is nursed on demand and depends more on breast milk for its nutritional needs), the more intense will be the reflex stimulation of prolactin, which causes lactation to have a contraceptive effect. Stimulation of prolactin is greatest when the baby sucks frequently during both day and night.

PROVIDING CONTRACEPTIVES FOR THE BREAST-FEEDING MOTHER

Contraceptive counseling should begin in the antenatal period. Contraceptive use should begin either immediately after delivery or at the 6-week post-partum examination, depending upon which contraceptive method is chosen. In many cases, this may be one of the few times a woman has access to medical care. The contraceptive method chosen for a woman after child-birth should be one that does not interfere with the mother's ability to produce breast milk in sufficient quantity and quality. Contraceptives given at the 6-week post-partum examination or later are less likely to interfere with breast-feeding because lactation has already been fully established by that time. If a woman practices "full" breast-feeding (that is, frequent and prolonged), contraceptive use may be delayed until the baby's diet is supplemented—usually at 6 months.

Here are several contraceptive methods from which to choose (14, 15):

Abstinence, if practiced properly, is 100% effective in preventing pregnancy. If the mother chooses to remain abstinent while she is breast-feeding, this can be considered a suitable method of contraception. She should, however, be counseled about other contraceptive methods should she desire to resume having intercourse. Some mothers practice abstinence because they believe intercourse will harm their breast milk. Assure mothers that sexual relations will in no way harm their ability to breast-feed—unless they get pregnant. Having been educated in this manner, the mother can make an informed decision concerning the practice that best suits her.

Spermicides, such as foams, foaming tablets, creams, or jellies have no effect on breast-feeding. These can be used safely in the immediate post-partum period.

Barrier methods, such as the condom or diaphragm, have no effect on breast-feeding. Condoms may be used safely in the immediate post-partum period. However, the diaphragm cannot be fitted properly until the vaginal canal returns to its normal size and shape. Fitting may be performed at the 6-week post-partum examination, but the fit of the diaphragm should be checked periodically.

Inert IUD's, such as the Lippes Loop® or Saf-T-Coil®, probably do not affect breast-feeding, although some mothers experience mild uterine cramping when they breast-feed while an IUD is in place. In most cases, the cramping does not hinder the mother. Because of the high rate of expulsions of IUD's inserted immediately post partum, the 6-week post-partum examination is probably a better time to insert the IUD. Two new IUD's do appear to reduce the risk of expulsion after immediate post-partum insertion. The Delta T® and the Delta Loop® have sutures tied to their upper limbs; 1/2-cm ends of the sutures project downward at a 45° angle (16). If available, these IUD's may be inserted in the immediate post-partum period.

Medicated IUD's are also an acceptable choice of contraceptive for the breast-feeding mother. The copper on the Copper-T[™] or the Copper-7[™] does not appear to affect the quantity or quality of breast milk (17). The progesterone-containing IUD has only a small amount of progesterone, which is released slowly over 1 year. Progestins have little or no effect on breast-feeding. If available, progesterone-containing IUD's may be used safely. The disadvantage of the medicated IUD's, however, is that they need to be replaced every year, in the case of the progesterone-containing IUD, and every 3 years in the case of the copper-bearing IUD's. The best time to insert these IUD's is at the 6-week post-partum examination.

Tubal ligations are an excellent method for those mothers who have had all the children they want. In many African nations, tubal ligations are generally scheduled a month or two after delivery. However, tubal ligations can be performed immediately after delivery with no adverse effects on the mother.

POST-PARTUM TUBAL LIGATION AND USE OF ANESTHESIA

If you are considering performing a tubal ligation immediately after delivery, use a regional or local anesthetic if possible, instead of a general anesthetic. Many clinicians have observed that general anesthesia or heavy sedation during labor or immediately after delivery can be associated with problems in beginning successful breast-feeding. The sedatives carried in the breast milk may affect the infant's sucking response. A poor sucking response begins a vicious cycle of poor milk supply that again discourages the sucking response. The use of general anesthesia or heavy sedation during a post-partum tubal ligation may have the same effect.

Oral contraceptive Pills are frequently prescribed for breast-feeding African mothers. In a global survey of physician practices, estrogen-containing oral contraceptives were provided to lactating women by 63% or more of the responding physicians in developing nations and in less than 40% of the responding physicians in developed countries (18). The figure was highest in Africa (88%), and lowest for North America (26%). Many clinicians, however, are concerned that the oral contraceptive Pill will decrease the amount of milk the mother produces. In high doses, estrogen can suppress lactation and decrease milk supply. The dose of estrogen in oral contraceptive Pills *can* affect the milk supply, especially if the Pills are begun immediately after delivery or before lactation has been fully established (19). Lower-dose estrogen oral contraceptive Pills are believed to affect lactation less. Although research still needs to be done in Africa, based on available study results, many experts believe that the lower-dose oral contraceptive Pills

(30-35 mcg estrogen) are good contraceptive choices for breast-feeding mothers provided they are given *after the mother has begun breast-feeding successfully*.

Progesterone-only contraceptives may have little or no effect on lactation, according to studies. Some studies have shown that a decreased milk supply results from the use of progesterone-only contraceptives but that the quality of the milk is not affected. Other studies have shown an apparent reduction in the nutritional value of the milk, but this is compensated for by an increased milk supply (19,20). IN GENERAL, THE BEST HORMONAL CONTRACEPTIVE FOR BREAST-FEEDING MOTHERS IS ONE THAT HAS PROGESTERONE ONLY (SUCH AS THE MINI-PILL OR DEPO-PROVERA[®] IN A 150-MG INJECTION) AND THE LEAST POSSIBLE ESTROGENIC EFFECT (21). (See Figure 3.3.) BOTH OF THESE MAY BE GIVEN IMMEDIATELY POST PARTUM OR WHEN THE MOTHER RETURNS FOR HER 6-WEEK POST-PARTUM EXAMINATION. Although their numbers are small, in the global survey mentioned above, the percentage of African clinicians that received complaints of decreased milk supply from women using progestin-only Pills was significantly smaller (0%) than the percentage receiving complaints from women using combined Pills (32%) (18).

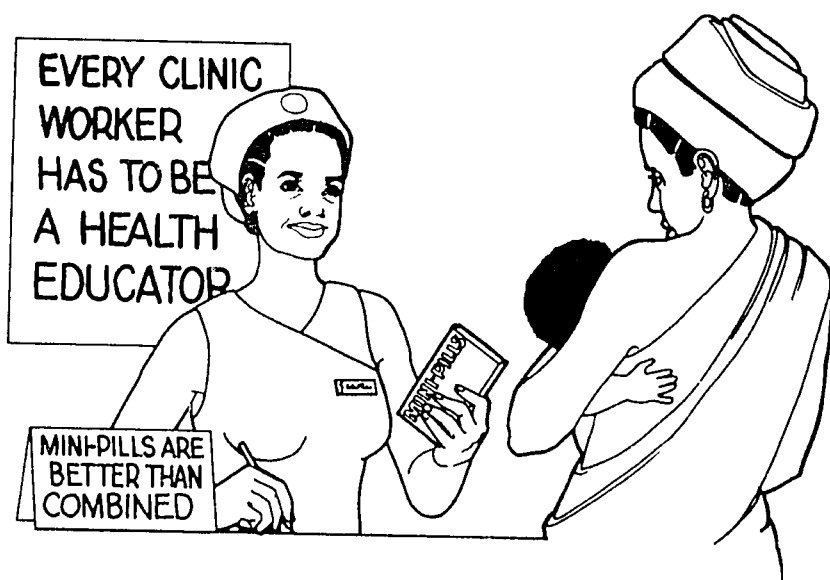


FIGURE 3.3 Progestin-only oral contraceptives appear to be a better contraceptive option than estrogen-containing combined Pills for the lactating woman.

How do hormonal contraceptives affect the nursing baby?

Experts are uncertain, although they surmise that Pills and injections present no hazard if they contain 2.5 mg or less of 19-nonprogesterone and 50 mcg or less of ethinylestradiol or if they contain 100 mcg or less of mestranol (22).

Little is known about the short- or long-term effects from exposure to oral contraceptive drugs during infancy. Breast enlargement in male and female infants has been reported when mothers had taken oral contraceptives with higher estrogen and progesterone doses than currently used. One study has shown that very little of the drugs actually passes through the mother's milk: about one-fifth to one-tenth of the d-norgestrel dose taken by the mother (20). Another study has shown that the amount of estradiol from a 50-mcg dose Pill has only a minimal transfer and that it does not exceed the transfer that occurs during physiologic conditions once the mother has resumed ovulation (23). Further research into the effects of hormones on breast-feeding infants is needed.

COMPLICATIONS OF BREAST-FEEDING

Breast-feeding is associated with relatively few complications although one, as noted previously, is the risk that a pregnancy can occur. The more commonly encountered complications for the mother involve the effects of breast-feeding on the breast. (See Table 3.1.) For the infant, it is diarrhea when fed breast milk, but not to the extent of bottle-fed babies.

Yet another complication of major concern, along with the risk of pregnancy, is the toll on the mother's nutritional health if she is suffering from an inadequate diet. For many mothers, the added demand that breast-feeding makes on her body can be met by her increasing the quality and quantity of the foods in her diet. For others, however, diet alone will not suffice.

The maternal depletion syndrome, in which a mother is literally drained of body nutrients by a rapid succession of pregnancies, is an extreme example of the need for child spacing. The mother's body has given so much of her nutrient stores to each developing fetus and nursing infant that she appears 20 or 30 years older than she actually is.

A more common nutritional complication of breast-feeding is anemia. Usually, anemia will occur during pregnancy by two mechanisms of action: (1) hemodilution associated with pregnancy results in a physiologic anemia

TABLE 3.1. Complications of breast-feeding and their management

BREAST-FEEDING PROBLEMS (24)		
PROBLEM	DESCRIPTION	SOLUTION
Sore breasts	Mother has pain in breasts while breast-feeding.	Reassure mother this is not unusual. The pain is related to a poorly functioning let-down response and will disappear within a few weeks.
Engorgement	Breasts overfull, discomfort.	Mother should breast-feed frequently. Mother and baby should not be separated in early weeks after birth since breasts fill more rapidly at this time.
Plugged duct	Caused by severe engorgement.	Mother should apply moist heat to breast and massage the breast beginning behind the plugged duct and moving toward the nipple. The baby should be breast-fed to help dislodge plug.
Leaking	Let-down occurs unexpectedly.	Mother should fold her arms over her chest and press firmly toward chest wall. She should apply pressure directly over nipples with finger or thumb.
Breast infection	Mastitis, breast infections usually interstitial and usually caused by staphylococcus. (Symptoms resemble influenza.)	Mother should continue breast-feeding; the infection will not harm baby. Moist heat should be applied to the breast, the mother should be urged to drink fluids and to rest in bed, and antibiotics appropriate for staph infection should be given.
Sore, cracked, fissured nipples	Caused by improper positioning, delayed feedings so baby is ravenous, allergy to lanolin, allergy to wool, nipples not kept dry.	The mother should rest her breast for several hours but not allow it to become overfull. She should change positions while nursing. The breasts should also be exposed to the sun for short intervals.
Thrush or moniliasis	Persistently sore nipples, inflammation of nipples and areola; baby has white patches in mouth.	Treat with nystatin or 1%-2% gentian violet, if severe. Treat with 1 tsp. baking soda in 1 cup water for mild cases. Treat any vaginal yeast infections.
Inadequate milk	Baby not gaining weight; sucking not of interest to baby for more than a few minutes at a time.	Encourage complete emptying of the breast. The more the mother nurses, the more milk that is produced. Discourage supplementing breast milk in the first few months.

(25) and (2) the demand the developing fetus makes on the mother's nutrient stores creates a genuine anemia. For example, the fetus and placenta require 360 mg of iron more than the 450 mg of iron usually required by the adult (25). When the anemic mother breast-feeds, the anemia may become more severe. If the mother's anemia is determined to be caused by an iron or folate deficiency, it can be treated with supplements.

However, the best approach to anemia is prevention. A properly balanced diet that includes adequate minerals, vitamins, and calories is essential. Both the mother and clinician should remember that maternal nutrition is aided by family planning. The practice of child spacing permits a woman to regain her strength and proper physical condition before beginning another pregnancy and period of breast-feeding.

NONCONTRACEPTIVE BENEFITS OF LACTATION

Family planning and nutrition go hand in hand. This is especially so for the breast-feeding mother and her child. Breast milk is the best source of nutrition and immunity for the growing infant. (See Figure 3.4.)

By preventing unplanned pregnancies, family planning helps prevent malnutrition in both the mother and the child. Family planning should begin even before childbearing is begun. Delaying the birth of the first child has several advantages. The future mother and father have more time to acquire



FIGURE 3.4 Breast-feeding is best.

economic stability, thereby insuring resources for a better food supply. Delaying the first pregnancy also serves to reduce the future mother's reproductive time span.

Increased intervals between births have several advantages also. The mother's nutrients are more fully replenished before the next pregnancy. Nutrition experts feel that an African mother may need 2 years to gain back the nutritional health she had before pregnancy.

Increased birth intervals also mean that the child will have the high-quality proteins and nutrients found in breast milk. A child who is weaned completely at too early an age or who receives supplements (before the age of 4 months or before clean, nutritious alternatives to breast milk can be provided) is in danger of having poor nutrition and poor defenses against diseases. High infant mortality also is related to weaning at too early an age (26). Studies have shown that, in many cases, early weaning is the result of another pregnancy that occurs while the mother is breast-feeding (4). Often this is because pregnancy reduces the mother's milk supply.

Hence, the wisdom of the proverb: "A second child will 'drink up' the first child" (27). A baby weaned before 5 or 6 months of age has a greater chance of dying. Therefore, it is preferable to delay full weaning until after 9 months or even later.

NUTRITION FOR THE BREAST-FED INFANT

Breast milk provides the new infant with adequate calories and protein for the first 6 months of life. Breast milk also offers the infant immunologic protection derived from the mother's antibodies carried in her milk. The breast-fed infant is less likely to suffer from diarrheal diseases (28). However, to be most protective, breast-feeding should continue for at least 1 year, if possible, and be given "on demand," that is whenever the baby is hungry.

For the mother who works away from the home, prolonged breast-feeding may not be possible. But she should try to nurse the infant at least twice a day and make certain her baby is getting good protein supplements. The excellent protein in breast milk complements and improves the quality of other foods given to the infant. If the working mother must give her baby bottled formulas, she needs to realize that the formulas must be prepared and mixed correctly. The right concentration must be made or else the baby will not receive enough calories or proteins for healthy growth.

Two serious conditions of nutrient deficiency are marasmus and kwashiorkor. These are two extremes of a syndrome. Infantile marasmus is often caused by too early weaning from breast milk with the substitution of grossly inadequate bottle feedings. As the infant starves from inadequate calories and proteins, development of the brain, muscle and fat cells, bones, and supporting and visceral tissues ceases. The infant begins to look old with

hollowed temples and wrinkled skin hanging in folds from a loss of subcutaneous fat and potassium. The abdomen is usually scaphoid but can be distended if the child suffers from diarrhea and potassium deficiency.

The mortality from infantile marasmus can be as high as 100% if untreated. With early diagnosis and good management, however, this figure can be reduced to 10% (29). Treatment requires a cautious increase of calories and protein in feedings.

Kwashiorkor affects a child who is over 1 year of age. In general, the infant has been breast-fed successfully for 6 months to 18 months, but then is weaned to a diet that is generous in calories but deficient in proteins and nitrogen. These babies have severe protein losses in their liver, muscle, pancreas, and other organs. The condition is marked by muscular weakness, apathy, and irritability. Edema is usually present, either gross and generalized, or slight and localized to the eyelids and feet. The hair becomes sparse, brittle, and depigmented, turning to a grayish or reddish tint. Skin changes consist of erythema followed by hyperpigmentation, desquamation, depigmentation, and, sometimes, ulceration. The baby will frequently suffer from chronic diarrhea with small, greenish stools.

Babies sick enough to receive hospital attention may have a 10%-40% mortality rate. The deaths in the first 24 hours of hospitalization are caused by acute electrolyte disturbances or irreversible biochemical changes. Deaths in the next 10 days are caused by sepsis. Treatment requires restoration of kidney function and electrolyte balance, supplementary feedings, and treatment of infection (29).

It is even more crucial to realize, however, that for every case of marasmus or kwashiorkor, many other children suffer more moderate forms of malnutrition. A malnutrition problem of this magnitude and its close association with infant mortality can only be attacked with mass education programs; more widespread health services including immunization, child spacing, and oral rehydration therapy; general availability of protein sources; and economic development (29).

NUTRITION FOR THE BREAST-FEEDING MOTHER

The breast-feeding mother requires even more food than a pregnant mother. To have an adequate milk supply, a mother needs an adequate amount of food and water. If nothing else, the mother should have at least an extra potful of maize or rice or an equivalent staple each day (30). Although an adequately balanced diet is best, if protein sources are not readily available, then increased calories will help the mother retain her health. Ideally, the mother's diet should have not only increased calories and proteins, but also increased iron, calcium, and vitamins. Family planning can aid the mother's nutrition by preventing a rapid succession of pregnancies that can drain her nutrient stores.

USER INSTRUCTIONS (13,14,28)

The following instructions are intended to help mothers obtain the maximum benefits of breast-feeding and to make breast-feeding a positive experience:

- Use a method of contraception at the appropriate time if you do not want to become pregnant while you are breast-feeding.
- Breast-feed on demand frequently if you plan to rely on breast-feeding to prevent pregnancy. Remember that you can still get pregnant while you breast-feed, although the chance of that happening is low.
- Breast-feed until your child is 1 to 2 years of age.
- Add supplements to breast milk when your baby is 4 to 6 months of age. Good supplements include starchy household foods, sauces, soups, stews, and eggs.
- Gradually wean your child from breast milk to balanced foods. Protein requirements can be met by adding beans, peas, meat, eggs, and fish to the child's diet.
- Use fresh and clean drinking water; get immunizations and malaria prophylaxis to prevent disease.
- Conserve your energy by avoiding unnecessary work.
- Ask your clinician for nutrition advice, iron supplementation, anti-malaria pills, and vitamins, if necessary.
- Eat a balanced diet. Include green vegetables, peas, beans, and fruits. Increase the amount of food you eat. A nursing mother should have sufficient quantities of water and other liquids.

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CHAPTER 4

ADOLESCENT PREGNANCY

Pregnant adolescents suffer from more problems than pregnant adults. Both the medical and social risks of pregnancy are greater in the adolescent than in the woman over 20 years of age (1). Rates of prematurity, low-birth-weight babies, maternal and infant mortality, anemia, and pre-eclampsia are dramatically higher for adolescent mothers (2-7). Recent research indicates that although a large part of the excess morbidity and mortality is attributable to inadequate pre- and postnatal care received by adolescents rather than to the mother's age, per se, other factors are involved in the increased medical risks for adolescent mothers (8-9).

If the adolescent receives poorer pre- and postnatal care partly because she is unable to plan ahead for her pregnancy, she will probably also be unable to cope with a child. Adolescent parenthood may increase the incidence of child neglect, abuse, and infanticide, halt education for many young people, lead to potentially dangerous and illegal abortions, or may cause a young woman to be abandoned by her family in some traditional societies (10-14).

Family planning clinicians who have worked with adolescent mothers understand how much they need guidance and support. This chapter focuses on ways in which family planning helps reduce the problems that arise from adolescent pregnancy. Delaying the first pregnancy until a young woman is mature enough physically and socially to care for herself and her child is the first step in coping with a problem that is common not only in Africa, but throughout the world.

FERTILITY IN THE AFRICAN ADOLESCENT

While more accurate data are needed, family planners are beginning to realize that marriage at too early an age is quite common in Africa and pregnancy out-of-wedlock is also becoming a major concern (15-17).

Compared with women in the rest of the world, African women marry young. Marriage close to the age of menarche is common in many Islamic areas. According to recent data from 28 African countries, about 55% of women aged 15 to 19 years were married. (This average is based on figures ranging from 82% in Guinea, 81% in Niger, 79% in Mali, 74% in the Ivory Coast, 73% in Chad, 72% in Nigeria, to 32% in Ghana, 22% in Lesotho, 18% in Rwanda, 14% in Somalia, 14% in Botswana, and 12% in Burundi.) (17)

Young women often marry older men which can put pressure on the women to become pregnant during adolescence (7). Consequently, early marriage is generally accompanied with early fertility. In the 31 countries where data are available, fertility rates among women aged 15 to 19 years

are high, averaging 164 births annually per 1,000 women aged 15 to 19 (17). The countries of Sub-Saharan Africa (excluding Southern Africa and the islands off East Africa) have the highest levels of early childbearing of any region of the world, averaging 50% higher than other high-fertility regions (17).

These fertility rates reflect pregnancies occurring both within and outside of marriage. The breakdown of traditional social pressures and the loss of traditional methods of fertility control (see Chapter 2) have contributed to this problem. Traditionally, young boys or girls in many cultures were carefully instructed by an elder relative of the importance of delaying pregnancy until marriage. Premarital pregnancy often was a disgrace to the parents' families, the ethnic groups, and the young persons involved. In place of intercourse were other activities that permitted young people to explore intimate relationships. When lost traditions are not replaced by modern systems of support, adolescents have no guidance and can make serious mistakes. Table 4.1 contains suggestions for helping reduce the rate of adolescent pregnancies.

TABLE 4.1 Reducing the number of adolescent pregnancies

-
- a. Return to some of the traditional customs that discourage sexual intercourse before marriage.
 - b. Discourage betrothals and marriages among the very young.
 - c. Provide public education and dialogue on the implications of childbearing in very young and unmarried girls—dialogue in parliaments, national assemblies, regional and city governments, and among local community leaders, cell-block leaders, and village spokespersons.
 - d. Teach young people that the medical and social implications of adolescent pregnancies are serious. One thoughtful physician suggested teaching young people that sexual intercourse is potentially dangerous because of the social and medical effects adolescent pregnancy may have.
 - e. Teach sex education in schools and in churches.
-

WHAT CAN BE DONE?

The adolescent-pregnancy problem must be addressed directly. Leaders must come to acknowledge the problem where it exists and redirect the health and other social services to deal with it directly. Although it will never be *solved* by family planning alone, contraceptives might help.

Adolescents should be educated and motivated to assume the responsibility for their choices and actions. We believe that family planners should pro-

vide services to those adolescents who do choose to have sex. At the same time, family planners should make every effort to actively support and serve those adolescents who choose not to have sex. While contraceptives may not be required by sexually inactive adolescents, family planning education should be provided to all adolescents. When appropriate, family planning groups should develop programs that support the decision of young people to delay sexual activity. Parents and their children should learn about the importance of family planning within today's society, particularly for the purpose of postponing the first pregnancy of married and unmarried adolescents.

Withholding family planning services from adolescents from urban or rural communities does not lead to a decline in the number of adolescents having intercourse. Rather, the results are many more unwanted pregnancies, each bearing a tremendous social, educational, economic, and emotional cost. We believe that providing contraceptives to adolescents is part of the solution to the problem of adolescent pregnancy.

Some may argue that sex education and the availability of contraceptives have been responsible for the rise in the number of adolescent pregnancies. But research has not shown this to be true. One study from the United States found that adolescent girls who had not taken a sex education class had, over a 20-year period, more than 16 times as many out-of-wedlock births than those who had taken a course. The study also found that the adolescent boys who had not taken the course had about four times the divorce rate of those who had taken the course (18).

Family planning can serve adolescents by:

- Providing contraceptives to those who desire them.
- Educating adolescents about issues relating to family planning, including pregnancy, sexually transmitted diseases, abortions, and the health benefits of family planning.
- Reaching out to the community with family planning information.

PROVIDING CONTRACEPTIVES TO ADOLESCENTS

Many contraceptive methods are suitable for adolescents.

BARRIER METHODS. If the adolescent is taught how to use barrier methods correctly, they can be both safe and effective. (See Chapters 14 and 15 for more information.)

SPERMICIDES. Again, if the adolescent is taught how to use spermicides correctly, they can be both safe and effective. (See Chapter 16 for more information.)

WITHDRAWAL. Because of the high failure rate associated with this method, it is not highly recommended. Some traditional practices, however, do encourage the use of withdrawal. Certainly, using withdrawal is better than using no method of contraception. (See Chapter 18 for more information.)

INTRAUTERINE DEVICE. The small-sized intrauterine device (IUD), such as the Copper-7[®], can be used in the adolescent nulliparous woman. One disadvantage of this method is the increased risk of pelvic inflammatory disease. A young woman who desires children later needs to be made aware of the increased risks of developing such inflammatory diseases should she use an IUD. (See Chapter 13 for more information.)

ORAL CONTRACEPTIVES. The Pill does not harm a young woman's development or her ability to become pregnant in the future. Nonetheless, it is important that a young woman be given the Pill after she has begun to menstruate regularly. (See Chapters 10, 11, and 12 for more information.)

MINI-PILL. The Mini-Pill is a good choice for the adolescent girl who has reached a stable menstrual cycle. She should know that her periods may be scanty and that spotting may occur. (See Chapter 12 for more information.)

STERILIZATION: Neither tubal sterilization nor vasectomy is recommended for the adolescent, except in rare cases. (See Chapter 22 for more information.)

EXAMINING THE ADOLESCENT

Adolescent women do not have to wait until they are married to have a pelvic examination. This first pelvic examination should be performed very gently. In a healthy adolescent, a painless first examination is more important than a complete examination. The attitude the young woman develops as a result of her first examination may affect her attitude toward reproductive health care for the rest of her life.

Clinicians must be prepared to perform pelvic exams on young women who may never have had intercourse or even used a menstrual tampon. Supplies of small speculae, including the Peterson vaginal speculae, are essential. A gonorrhea culture may be obtained digitally. However, tell the adolescent ahead of time what will happen to her during the examination.

EDUCATING ADOLESCENTS

Educating adolescents involves just that—education, giving information, not rules. Adolescents value their freedom as much as adults do (19), and they will stop listening if they feel they are being lectured to. Do not cut yourself off from them by assuming an authoritarian tone. Gain trust by being sincere and unforced. Help adolescents sort out their complex, but normal emotions. Provide reassurance that their bodies, their fantasies, and their sexual feelings and actions are usually normal.

COMMON QUESTIONS ASKED BY ADOLESCENTS

- Am I normal?
- Should I have sexual intercourse?
- Should I use a method of contraception?
- What should I do about an unplanned pregnancy?
- How can I tell if I have an infection?

Many adolescents already have answers to these questions. Their answers, however, may not have been made on the basis of knowing all, or the correct information. For example, a girl may request oral contraceptives, but she may not have given serious thought to any of the other methods.

Patient and thorough counseling will help adolescents make sound decisions. Yet be certain to distinguish between *deciding* what is good for adolescents and *exploring* with them what may be a good decision *for them to make*.

If you are talking with unmarried adolescents, be sensitive to those who still have not made up their minds about sex. Providing contraceptives may be seen as encouraging or condoning sexual activity. Give adolescents support to make their own decisions about what is right for them. If they choose not to have sex, let them know the decision is right for them and that they should not be pressured by others into an act with which they do not feel comfortable. Let them know that society as a whole still values virginity at the time of marriage. On the other hand, when adolescents decide to have sex, let them know that they must be prepared to live with the consequences. Preventing an unplanned or unwanted pregnancy is an important responsibility that goes along with the decision to have sex, but there may be other offsetting consequences in certain cultures which are hard to avoid.

REACHING ADOLESCENTS

Regardless of your efforts, a family planning program cannot reach all of the adolescents in the community. Often, adolescents will not seek family planning services until they are concerned about a possible pregnancy. By organizing outreach educational programs, however, family planners can reach adolescents before the youth have made their decisions about sex.

Education about contraception, health care, anatomy, and physiology can be offered through schools, churches, and youth groups. Adolescents themselves can become effective educators within a community, if given the chance. Not only do adolescents need education and counseling, their parents do too.

If you are going to lead discussion groups, there are a few general rules to keep in mind:

- Prepare your own thoughts about sexuality, contraception, and family planning before leading group meetings. Find out in advance as much as you can about the group you will address. Find out what your listeners want to learn and focus on those subjects first.
- Investigate the facts and present them in an organized and interesting way.
- During the discussion, allow time for questions and comments from your listeners.
- Be flexible. If your listeners have many questions or comments, be ready to forget your prepared presentation and encourage the group's participation.
- Listen. The most important aspect of talking is listening.

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CHAPTER 5

INFERTILITY

Children are the cloth of the body. Without children you are naked.

Yoruba Saying (Nigeria)

ONE WOMAN'S THOUGHTS ON HER INFERTILITY

To live with infertility is . . .

"To feel guilty when your husband tells you, 'It doesn't really matter.'"

"To go to see a new baby and always have someone say, 'You'll be next.'"

"To ache."

"To cry."

"To joke about it. But mostly to live day by day . . . and leave a little room for hope."

INTRODUCTION

Fertility is important to all societies. Infertility has traditionally been a source of pain, anxiety, and shame. And the more important children are to the fabric of a given society, the more important it is for couples to be fertile, and the worse are the consequences if a couple is infertile. Families of four to eight living children are common and only intensify the anguish and pain of those who are unable to bear children (primary infertility) or those unable to have as many children as they would have liked (secondary infertility). African gynecologists are becoming convinced that infertility is a problem of such magnitude that it must be given a very high priority in the development of rational family planning programs (1). More and more reports on the causes and treatment of infertility in Africa are appearing in the literature (2-7). Further attention to this problem is an important service and research priority for Africa.

Economic and social motivation underscore the hardship imposed on a family by infertility. In most of Africa a man's wealth is measured, in part, by the number of children he has. Children are important as farm workers and as a source of support in old age for the parents. Male children also play an important role in certain ethnic groups where, for example, a grandchild is the only person who can replace his departed grandfather, particularly with re-

spect to the practice of certain rituals. Similarly, a woman's value to her husband may be determined by her ability to bear a healthy child who will contribute to the family. A woman may be divorced summarily for her inability to bear children (even if the man is the major cause of the problem).

GLOSSARY

The terminology surrounding the subject of infertility is inexact and therefore confusing. In this book, the term "infertility" is used to mean a woman's inability to conceive and bear a living child or a man's inability to produce a pregnancy.

The World Health Organization has subdivided the term, as it relates to couples, as follows (1):

PRIMARY INFERTILITY

The woman has never conceived despite living with a man, being exposed to the possibility of pregnancy, and wishing to become pregnant for at least 12 months.

SECONDARY INFERTILITY

The woman has previously conceived but is subsequently unable to conceive despite living with a man, being exposed to the possibility of pregnancy, and wishing to become pregnant for at least 12 months.

PREGNANCY WASTAGE

The woman is able to conceive but unable to produce a live birth.

SUBFERTILITY

The difficulty experienced by some couples, both of whom may have reduced fertility, in conceiving.

BACKGROUND

The joining of sperm and egg to eventually produce a human being is one of nature's miracles. There are so many steps and possible missteps in the intricate sequence that we should not be surprised to learn that a certain percentage of couples in every society is infertile.

In societies where unplanned and unwanted pregnancies are prevalent, and where family planning programs may publicize this fact, the dilemma of those who are infertile is particularly poignant. Moreover, the diagnosis and treatment of infertility are physically and emotionally arduous, and the outcome of treatment remains uncertain.

Throughout this chapter we will be stressing how important it is that couples who come to a family planning clinic for treatment of infertility receive sensitive support from nurses, physicians, lay counselors, and the infertility specialists who may ultimately be giving treatment.

EPIDEMIOLOGY OF INFERTILITY IN AFRICA

There is a recognized belt of subfertility and infertility in Africa extending from the West African countries of Senegal, Upper Volta, Mali, Niger, and Northern Nigeria through Cameroon, Gabon, Congo, Central African Republic, Zaire, and Southwest Sudan, to the East African countries of Uganda, Southwest Kenya, and Tanzania (8). It is important to remember, however, that infertility exists in other parts of Africa, although the prevalence is lower than in these areas.

It is ironic that infertility and subfertility are prevalent within the high-fertility zones of Africa. Family planning administrators have to recognize this feature so that they deal sensitively with issues pertaining to fertility control in areas where fertility enhancement is also needed. Cameroon is a good example of a country divided between high- and low-fertility zones. Table 5.1 shows fertility differential based on the percentage of childless women per given age groups in Cameroon (9). It can be seen that infertility is a problem in Central, South, and East Cameroon, but much less so in other areas.

An example of childlessness, probably as a result of pregnancy wastage, is found in Southwest Nigeria, where the average number of pregnancies recorded ranged between 5.03 and 6.50, but the number of live births achieved by women over 45 years old was a maximum of 4.93 (10).

TABLE 5.1 Percentage of childless women in various age groups in Cameroon, 1962-1964 (9)

Age group of mothers	Central, South, and East Cameroon (1962-1964)	North Cameroon (1962-1964)	North west and Southwest (1964)
15-19	72	73	56
20-24	29	27	10
25-29	28	20	7
30-34	30	19	6
35-39	33	17	8
40-44	29	13	7
45-49	29	11	7

Infertility is associated with marital instability. The divorce rate is high among infertile women. On the other hand, if there is marital instability, the in-

dividuals may have multiple sex partners and therefore have a higher risk of becoming infertile due to an increased likelihood of a sexually transmitted infection.

PRIMARY VERSUS SECONDARY INFERTILITY

Published clinical data seem to indicate differences in the relative incidences of primary and secondary infertility in Africa. Two studies from Kenya (11,12) suggested that these diagnoses are made in nearly equal proportions, unlike almost all reports from West Africa in which secondary infertility is diagnosed in nearly two-thirds of the cases (13,14,15). Generally speaking, the variations in the rates of primary and secondary infertility reflect differences in the pattern of underlying causes.

OCCURRENCE OF INFERTILITY

The amount of time that it takes for a couple to achieve a pregnancy when they are actively trying to do so varies widely. Delay in conception, in those not using any contraception, is influenced by the age of the mother. Table 5.2 shows the age of the female and length of time it would take her to conceive as found in a study of 1,128 women. By 6 months, 40-73% of the women studied had conceived (16). Fertility was shown to be lower in women over 35 years of age.

TABLE 5.2 Length of time women have unprotected intercourse before they become pregnant, by age (16)

Length of time with unprotected intercourse	Percentage Distribution by Age Group				
	20 (%)	20-24 (%)	25-29 (%)	30-34 (%)	35+ (%)
Less than 3 months	46	52	51	34	29
3-6 Months	21	21	18	14	11
6 Months- 1 year	18	13	11	14	11
1-2 years	12	9	8	9	2
2 or more years	3	5	12	29	47
Number of women included in study	(113)	(438)	(381)	(141)	(55)

This table can be simplified by looking at what happens to any 100 couples actively trying to conceive, as portrayed in Figure 5.1.

WHAT ARE THE ESSENTIALS OF FERTILITY?

For a union between a man and woman to be fertile, there must be a healthy ovum produced by the female, which must be fertilized by a healthy spermatozoon from the male.* The fertilized ovum must then be transmitted into a uterus that is capable of protecting it and providing the necessary nourishment.

Male infertility may result from faults in the following normal physiological functions:

1. Normal spermatogenesis.
2. Ability to transmit the spermatozoa to the partner's vagina. This is possible through:
 - a) Possession of the necessary sexual drive,
 - b) Ability to maintain an erection, and
 - c) Ability to achieve an adequate ejaculation.

Any faults in the following normal physiological properties may be responsible for infertility in the female:

1. Presence of ovulation.
2. A normal vagina for reception of spermatozoa.
3. Normal cervical mucus to allow passage of spermatozoa to the upper genital tract.
4. Healthy fallopian tubes to permit the meeting of the sperm and ovum and, after fertilization, to permit migration of the ovum to the uterus.
5. A healthy uterus to permit the implantation and development of the fertilized ovum until it is delivered as a baby.

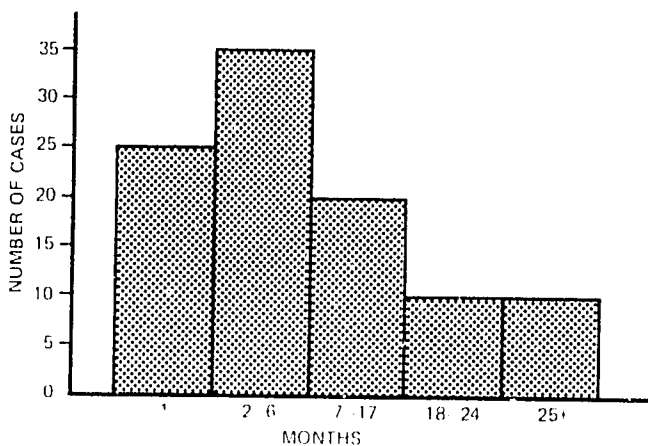


FIGURE 5.1 Occurrence of pregnancy in couples actively trying to conceive (all age groups) (17, 18)

*Incidentally, it is the male's sperm, not the female's ovum, that determines the sex of the offspring.

CAUSES OF INFERTILITY

Anything that can hinder or prevent either gametogenesis (egg or sperm formation) or fertilization can potentially prevent fertilization. Into this category fall such diverse conditions as undescended testicles, exposure to certain chemicals, and infrequent coitus.

The female factor has been more widely studied in Africa than the male factor because it is commonly assumed that the woman is primarily responsible for infertility. Factors associated with female infertility are presented in Figure 5.2.

FEMALE INFERTILITY

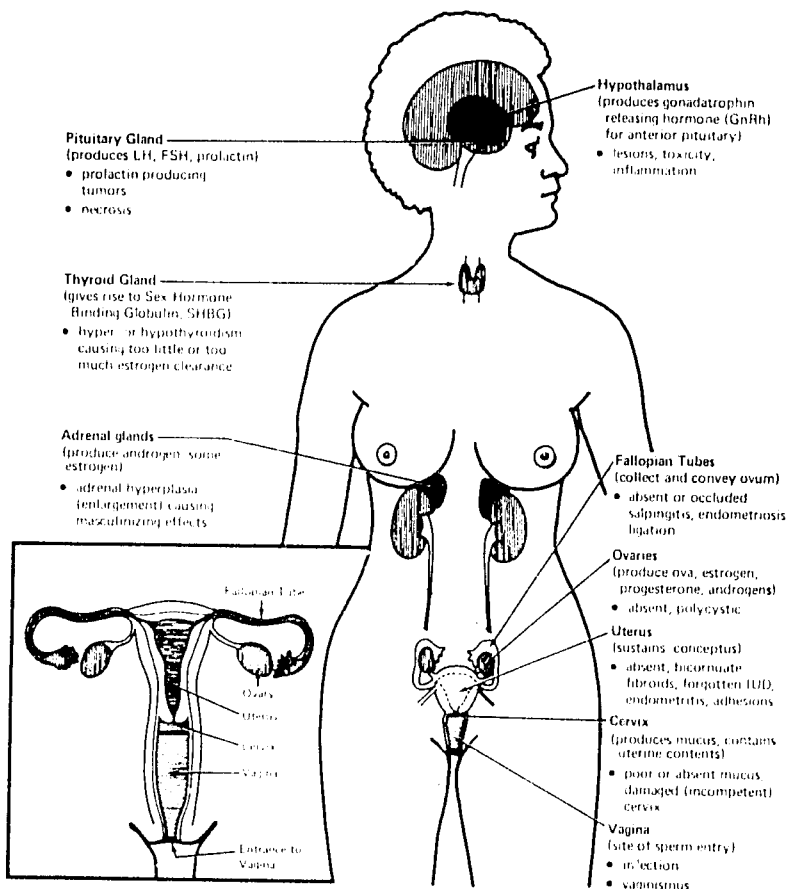


FIGURE 5.2 Causes of infertility in women.

In two laparoscopic studies conducted in Kenya, tubal occlusion was diagnosed in 73% of cases of primary and secondary infertility (12, 19). Tubal occlusion is presumably a consequence of pelvic inflammatory disease (PID) following sexually transmitted diseases, septic abortion, or puerperal sepsis. The infection has traditionally been attributed to *Neisseria gonorrhoeae* alone (20). In certain ethnic groups in Uganda, up to 50% of women are infertile as a result of the sequelae of gonococcal PID (21). It is becoming evident, however, that repeated episodes of PID may be caused by microorganisms other than *N. gonorrhoeae*, such as chlamydia (22, 23), although the initial episode may still be caused by *N. gonorrhoeae*.

If the preeminence of tubal occlusion reported in female infertility in the Kenyan studies holds true in other parts of Africa, ovulation disturbance (which exists in 30%-40% of cases in developed countries) plays a much less important role than normally expected. For instance, in 1970 investigators suspected anovulation (the suspension or cessation of the release of an egg) in only 2% of the cases in Kenya (11). But when the few patients with healthy tubes were analyzed, anovulation accounted for infertility in nearly 30% (12). Recent availability of better equipped laboratory facilities in some African countries will enable more accurate estimates of contribution of anovulation in female infertility.

The male factor, where studied, has been found to exist in 20%-40% of the couples. In a series of 173 semen analyses completed in Kenya, 14.5% were found to have azoospermia (lack of spermatozoa in the semen) (12). Table 5.3 presents the distribution of abnormal clinical findings for Nigeria (3).

TABLE 5.3 *Causes of male infertility from clinical findings in Nigeria (3)*

	Number of Cases	Percentage Distribution
Hypoplastic testes	26	58
Epididymal cyst	6	13
Cryptorchidism	4	9
Varicocele	3	7
Hydrocele	3	7
Inguinal operation	3	7
TOTAL	45	100

Of course, there are many different analyses of the different causes of infertility. Two studies from the United States and from Nigeria are summarized below. When an anatomic approach to the etiology of infertility is taken, the sites of dysfunction among infertile couples appear with approximately the frequencies listed in Table 5.4:

TABLE 5.4 Proportional distribution of causes of infertility in men and women: recent studies from the United States and Nigeria

Male infertility (24)	Female infertility		
		American data (18)	Nigerian data (3)
(%)	(%)	(%)	(%)
Varicocele (alone or in combination with other causes)	25	Tubal/peritoneal 30	66
Ductal obstruction	7	Ovarian 20	10
Other	68	Cervical 15	7
		Uterine 10	10
		Other 25	7

MALE INFERTILITY

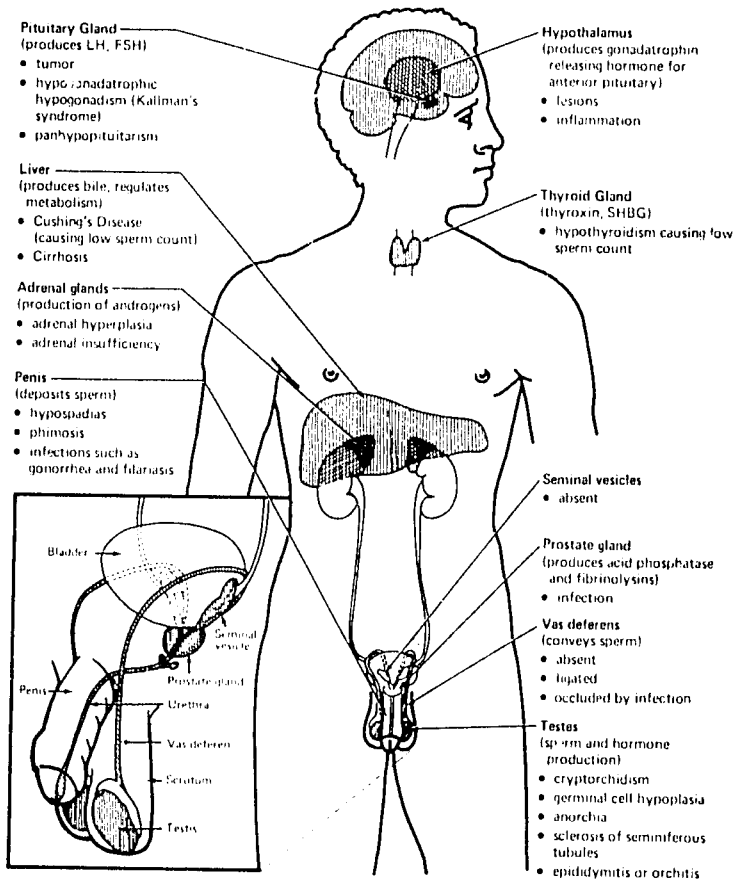


FIGURE 5.3 Causes of infertility in men.

Figures 5.2 and 5.3 depict the organ systems most commonly involved in infertility and briefly indicate their usual reproductive function and what may go wrong. It is estimated that in 30% of infertility cases, multiple contributors to infertility exist in one or both partners (25).

It should also be pointed out that although gonorrhea, filariasis, tuberculosis, a number of other infectious agents, trauma, and congenital anomalies can produce a number of anatomic changes in men and women, not all cases lead to infertility.

Certain patterns of sexual intercourse, marriage, and exposure to sexually transmissible infections are associated with primary infertility, secondary infertility, or lower birth rates for an entire culture. Arya, Taber, and Nsanze studied cultural patterns in two areas of Uganda in an effort to explain remarkably different birth rates in these two areas. Their findings summarized in Table 5.5 demonstrate that among women in the low-fertility area, lower abdominal pain, cervicitis, a tender pelvic mass, positive gonorrhea cultures, and positive laboratory tests (VDRL) are more common (26).

Nasah and Cox (15) reported vascular lesions, possibly filarial, in the testes of infertile males in the Cameroon. These lesions were seen in 40 of 41 males with severe oligospermia and consisted of massive subendothelial fibrinoid deposits in the small- and medium-sized vessels that led to testicular scarring. The investigators postulated that these deposits were a result of repeated formation and deposition of circulating antigen-antibody complexes. These antigens could be of various origins and, in two cases, parasitic elements were visible histologically. It is possible that other tropical diseases may play a role in male infertility in Africa.

The role of sexually transmitted diseases in male infertility has been discussed by Alausa and Osoba (27) and Arya, Taber, and Nsanze (26). They found that problems resulting from venereal infections contributed significantly to male infertility. Their findings are summarized in the following table.

TABLE 5.5 Infertility in two districts of Uganda

Characteristic Studied	Teso, Low Fertility District	Ankole, High Fertility District
Women	()	()
Married more than once	32.7	9.6
Never pregnant	19.7	2.2
Lower abdominal pains	25.0	8.9
Cervicitis	30.5	12.5
Tender mass	7.8	0.6
Gonorrhea identified	18.3	2.4
VDRL positive	25.3	12.6
Men		
Married	85.9	82.6
Polygamous	25.5	23.3
Never had child	24.8	3.7
Urethral discharge		
past	55.6	10.8
present	9.3	1.8
Epididymal thickening	27.9	4.3
Acute epididymoorchitis	2.2	0.6
Gonorrhea identified [†]	8.9	4.2
VDRL positive	38.8	15.5
Six or more children	20.2	50.0
Birth rate	37/1000	55/1000

There are a number of factors that increase the likelihood of infertility. These factors vary between geographic areas and ethnic groups resulting in different infertility rates as shown in Figure 5.4. Thus, the risk of infertility may also vary accordingly, even within a nation. These factors include:

- Malnutrition
- Prostitution
- Multiple sexual partners for either the man or the woman
- Failure to adequately treat infections when they occur
- Female circumcision
- Preference by women to delay childbearing until their late twenties
- Polygamy
- Rising divorce and remarriage rates
- Voluntary sterilization which couples later want reversed
- Restrictive laws governing abortion leading to high prevalence of septic abortion
- Infrequent intercourse
- Man and woman not living together
- Increasing age at marriage
- Septic abortions leading to infection
- Delayed diagnosis and treatment of pelvic inflammatory disease (PID)
- Infection with certain tropical diseases (malaria, filariasis, etc.)

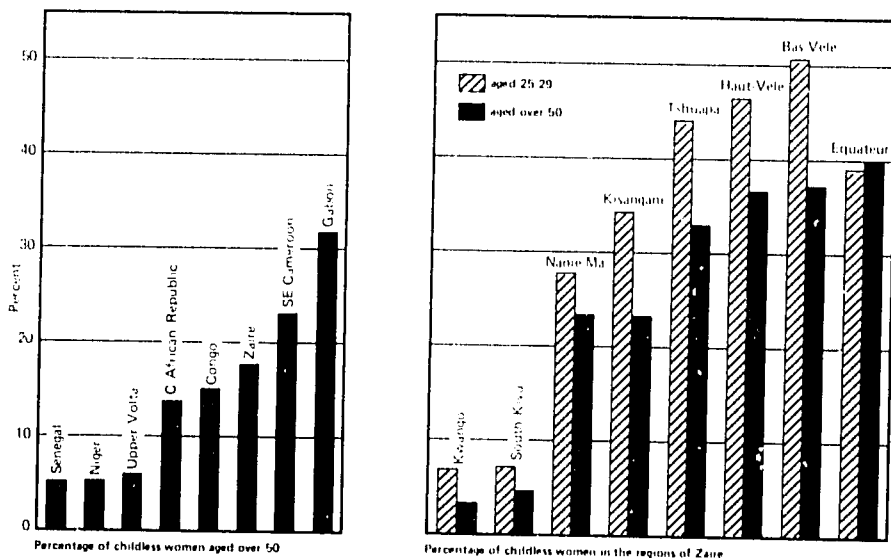


FIGURE 5.4 Infertility in eight nations in Africa and eight regions in Zaire. (28)

WHAT CAN FAMILY PLANNERS DO?

Many organizations involved with fertility control want to meet the challenge of infertility control. Yet, the diagnosis and treatment of infertility are often so complex that they must be referred to specializing obstetricians/gynecologists, urologists, and reproductive endocrinologists. Nevertheless, a definite role remains for family planners. The facilities available for investigation of infertility at a family planning clinic will vary from place to place, depending on the availability of resources. Some clinics can only refer an infertile couple to an appropriate center where investigations can begin. Some of the initial tests might include full blood count; urinalysis for sugar and protein; serological tests for syphilis; cervical, urethral, and rectal cultures for gonorrhoea; blood group and Rhesus factor; and a Pap smear. We **MUST** take a leading role in the area of **PREVENTION**. We *can* also help in the areas of **TRIAGE**,* **FERTILITY COUNSELING**, **HISTORY TAKING**, **EXAMINATION**, **FIRST TESTS FOR INFERTILITY**, **EDUCATION TO TREATMENT OPTIONS**, AND **DEALING WITH PERSONAL STRESS**.

PREVENTION

The family planning clinic provides an opportunity for healthy individuals to have access to medical examination. In the course of this, sexually transmitted diseases may be diagnosed and treated early. Certain family planning practices, such as the use of condoms, can also assist in reducing the spread of infections, such as gonorrhea, chlamydia, and trichomoniasis. On the other hand, contraceptives such as IUD's may increase the risk of infection, with consequent reduction in fertility. Family planners are not only in a unique position to advise men and women of such sequelae, but are also in a very fortunate one—that of being able to offer preventive health education. Some factors contributing to infertility are encountered daily by those caring for patients in family planning clinics. Listed below are some of these problems and the specific actions family planners might take to diminish the impact of each potential problem.

PELVIC INFLAMMATORY DISEASE

Pelvic inflammatory disease may lead to the occlusion or distortion of the fallopian tubes. Causes of pelvic infection include sexually transmitted

*Triage: If this clinic management technique is being used, usually a nurse will greet all patients, form a preliminary judgment as to the nature of each patient's problem, and refer the individual to the staff member best able to help the patient. In this way, the specialized skills of physicians, nurses, midwives, nutritionists, and others are put to optimal use, time is not wasted with repetitious questioning or services; and patient waiting time is minimized.

diseases and retained products of conception following childbirth, miscarriage, or incomplete abortion.

- ACTION:**
- Clinicians should be up to date in their knowledge of treatments.
 - Family planning health educators and administrators must begin or continue alliances with sex educators so that the consequences of untreated sexually transmitted diseases may be fully understood by young people.
 - They must work with educators to ensure that minors everywhere are receiving early and confidential treatment of all sexually transmitted diseases.
 - Family planners should be aware that of all the contraceptive options for a woman, oral contraceptives appear to have the greatest protective effect against PID (30). They should encourage sexually active youths to use condoms.

INTRAUTERINE DEVICES

The intrauterine device (IUD) is associated with an increased risk of contracting PID. The Food and Drug Administration in the United States advises that a 3- to 5-fold increase in risk of pelvic infection exists, and the International Planned Parenthood Federation suggests that a 1.5- to 4-fold increase in the risk of pelvic infection exists in IUD users compared with non-IUD users (29). Because of this association, family planners must take a number of factors into consideration when recommending the use of the IUD since PID may increase the risk of future infertility for the couple. (See Chapter 13.) Women wearing an IUD that is treated with a progestin seem to be less likely to develop PID than other IUD users.

- ACTION:**
- Be conservative in using IUD's for nulliparous women.
 - Do not use the IUD for women who may not understand or are concerned about risks to future fertility and who are at greater risk for sexually transmitted diseases and PID.
 - Urge further refinements in current IUD's.
(Specifically, tailless types need to be evaluated carefully and considered for use, particularly in areas where the incidence of gonorrhea is high.)
 - **DO NOT INSERT AN IUD IN A WOMAN WITH AN UNTREATED SEXUALLY TRANSMITTED DISEASE.**
 - In areas where the incidence of gonorrhea is high, consider giving antibiotic prophylaxis for one week after IUD insertion.

THE PILL

Oral contraceptive users are at less risk of developing PID than are either IUD users or those who use no birth control method at all. Decreased menstrual flow and myometrial activity, along with a less penetrable mucus, may exert a protective effect against PID in the Pill user (30).

Amenorrhea and temporary infertility following Pill use attributable to the oversuppression syndrome (post-Pill amenorrhea) do not appear to be serious threats to female fertility. The above symptoms are most commonly found in women who have irregular menses before beginning oral contraceptive therapy (31). This temporary condition is usually treatable.

- ACTION:**
- Educate patients to these aspects of the Pill.
 - Pills are probably as good a method as any in the prevention of PID and should be strongly considered as the contraceptive of choice for women hoping to have subsequent children.

STERILIZATION

The popularity of this method throughout the world continues to grow for both men and women. However, family planners in several parts of the world have expressed concern over the numbers of requests for sterilization reversal and over the uncertain prognosis and high cost of such procedures. In a recent survey of 100 female patients (32), the following breakdown of reasons for requesting reversal was obtained:

Change in marital status	63%
Death of child	17%
More children wanted (marital status same)	10%
Psychological reasons	6%
Other tragedy	4%

- ACTION:**
- Emphasize the permanence of the procedure and expose patients to information about the trend for requested reversals.
 - Do not sterilize childless adults unless there are extenuating circumstances.
 - Avoid using the term “tying the tubes” to describe sterilization procedures. It may sound overly simple and, by implication, reversible to some patients (32).

PROMPT RESPONSE TO THE INFERTILITY PROBLEM

It is critical that the first counselor whom the couple sees immediately try to sort out the facts of the case to determine what action needs to be taken to further investigate the problem. The couple should then be referred to the appropriate person(s) for diagnosis and treatment. Speed is of particular importance for couples when (33):

- a) the woman is over 30. Men and women reach peak physiologic fertility in their mid-twenties, after which fertility declines (more rapidly for the woman than for the man).
- b) the woman reports irregular menses. This could signal sporadic ovulation, a condition unlikely to improve spontaneously unless the woman is very young (an adolescent). It is also usually easy to treat. Irregular bleeding may be a symptom of a disease process, thus warranting a careful examination.
- c) there is a known history of disease such as mumps in the man or repeated miscarriages or PID in the woman, or when a major disability exists in either partner.

Time will not improve such problems, but will steadily diminish the couple's fertility, so a remedy should be sought promptly. A person's "sixth sense" that something is wrong should be heeded.

FERTILITY COUNSELING

Ways of living as diverse as occupation, diet, and even clothing are sometimes relevant to fertility. Couples experiencing difficulty in conceiving, or couples using contraception who plan to have children in the future, should learn which of their habits reduce or increase their fertility. Some examples include:

FERTILITY AWARENESS

Is the couple aware of the female fertility cycle and that sex with intent to produce a pregnancy must occur near the time of ovulation? Is the woman charting her basal body temperature or checking her cervical mucus?

SEXUAL INTERCOURSE

Failure to have intercourse at a time when fertilization would be possible (i.e., around ovulation) may be a cause of infertility. A couple should be encouraged to have relations frequently during the midcycle period, that is, about a week after the onset of menses to a week before the next, anticipated menses. Intercourse every other day, or even daily, should not be discouraged. Only in the case of the oligospermic (low-sperm-count) male should a buildup interval of 2 to 3 days between midcycle relations be recommended. Rigid schedules for the performance of intercourse are discouraged, as this may prove psychologically stressful and counterproductive to good sexual functioning (24,34).

LUBRICANTS

Couples may use some lubricants for their lubricating properties. However, since some are also spermicides, a couple that is actively trying to conceive may inadvertently be practicing contraception. One researcher recommends that couples use saliva as a lubricant when maximal fertility is sought (17).

DOUCHING

While douching is an unreliable method of birth control for couples of average fertility, it may, where fertility is marginal, manage to kill the very sperm that would have fertilized the ovum.

MEDICATIONS

A number of medications may affect male fertility by causing impotence, retrograde ejaculation, or by temporarily impairing spermatogenesis. Narcotics, tranquilizers (such as phenothiazides), monoamine oxidase inhibitors, and drugs such as guanethidine and methyldopa are in the former class, while amebicides, antimalarial drugs, nitrofurantoin, and methotrexate may affect sperm production (18,35). In utero exposure to DES (diethylstilbestrol) may or may not diminish the conceptive potential of females (36). It is claimed that rates of testicular cancer, sperm abnormalities, and undescended testicles are higher than usual for males so exposed to DES (35,37)

EXPOSURE TO IRRADIATION

This can affect male reproduction at several levels. The testicular germinal epithelium (enclosing the seminiferous tubules) may be reversibly or irreversibly incapacitated for sperm production, and chromosomal aberrations may occur (38).

ATHLETIC ACTIVITIES

Among other activities, long-distance running for women may bring on amenorrhea. Men who are in the habit of taking frequent hot showers or whirlpool treatments may be subjecting the scrotum to high enough temperatures to stop or greatly reduce sperm production (34).

TIGHT CLOTHING

Certain tight clothing (undergarments, tight pants) may have the same suppressive effect on sperm production as do hot showers because of high temperatures in the scrotal region (34,39).

OCCUPATION

Some occupations, for instance long-distance truck driving, may cause oligospermia or azospermia because of the heat exposure to males (39). In addition, some chemicals contained in cotton seeds and PCB's (polychlorinated biphenyl) may contribute to a low sperm count (40).

NUTRITION

Although it is thought that gross interference with conception does *not* occur until near starvation is experienced (41), poor nutritional status may exert a general debilitating effect that may indirectly hinder a couple's attempt to conceive. The opposite condition, obesity, may also lead to less frequent ovulation or to less frequent intercourse and thereby be a contributing factor to lessened fertility potential.

SMOKING/ALCOHOL

Smoking tobacco or drinking alcohol are being identified as causes of poor sperm quality in some cases (25). The evidence against marijuana is inconclusive, although it does appear to depress androgen levels (24). Smoking and alcohol can also have a negative effect on the developing fetus.

POLLUTION

Exposure to toxic fumes, pesticides, and lead are presently being examined on the suspicion that they cause or contribute to infertility (42).

MULTIPLE SEXUAL PARTNERS

Aside from the increased possibility of contracting a sexually transmitted disease, it is now known that some women may develop an immune response to sperm over time (sperm agglutinating antibodies) and that this is more likely to occur in women exposed to multiple partners. Regular use of foams, jellies, and condoms may prevent the development of sperm agglu-

tinating antibodies in a woman. The use of condoms in the infertile couple to avoid infertility is an apparent contradiction which needs careful explanation. (See Chapter 15.)

INFERTILITY - WHOSE PROBLEM?

Specialists claim that infertility is a shared problem. Males and females each separately account for about 40% of infertile unions and jointly are responsible for the remaining 20% (43).

Some clinicians advocate that the postcoital test (which involves a pelvic examination of the woman shortly after intercourse) precede the semen analysis (which requires that the man privately masturbate to produce a semen sample) because this ordering "avoids the stress associated with the semen analysis."

However, most clinicians recommend that semen analysis be the first diagnostic procedure in the infertility investigation. As one scientist has observed, "It is still all too common to find the wife subjected to an operative procedure before it was determined that her husband was azoospermic" (not producing any sperm) (24). Other workers have expressed concern over the "parallel but independent" routes which may be taken when the traditional woman-to-gynecologist and man-to-urologist separation occurs. They feel that lack of a coordinated treatment plan may slow the process and discourage the couple (44).

We hope that it will become a generally accepted principle in infertility investigation that the couple be dealt with as a unit and that at every stage of diagnosis and treatment of this unit, the least invasive procedures be used.

HISTORY TAKING, EXAMINATION, AND FIRST TESTS FOR INFERTILITY

After a preliminary explanation of the above areas, the interview with the counselor may lead into a full history-taking session. It is best to interview the man and woman separately at this point in case either feels that his or her history must be kept confidential from the other partner. Very complete fertility questionnaires have been developed by many medical schools that can be used in initiating an infertility evaluation in clinics and hospitals.

PHYSICAL EXAMINATION OF THE WOMAN

Visual evaluation of hair distribution and of body and breast development will be directed at detecting endocrinopathy or developmental deficiencies such as hypogonadism, adrenal hyperplasia, hypothyroidism, ovarian dysfunction, and hyperprolactinemia. A complete pelvic exam (palpation of

uterus and adnexae, speculum exam of vagina and cervix) should reveal whether uterine hypoplasia, adnexal tumors, or cervical lesions are present and should also indicate whether dyspareunia may be a problem (25).

PHYSICAL EXAMINATION OF THE MAN

Again, visual inspection of sexual characteristics to detect such endocrinopathies as hypogonadism or Klinefelter's syndrome (the genetic XXY anomaly often associated with infertility) is in order. The penile exam should be done to detect hyposadias (displacement of the urethral opening) or phimosis (constriction of the foreskin). The testicular exam detects atrophy, tumors, epididymal cysts, cryptorchidism (undescended testicles), vas thickening or absence, hydrocele (fluid accumulation in testes or along spermatic cord), or varicocele (dilatation of the veins of the spermatic cord in the scrotum) (25).

DIAGNOSTIC TESTS FOR INFERTILITY

The findings of the physical exam may indicate the direction for future investigations. However, it is often appropriate to begin with five basic diagnostic tests which, with some extra training, could be performed at selected family planning clinics. Ideally and where feasible, a lot of time and money can probably be saved if tubal patency is established fairly early in the workup because of the evidence of the high incidence of tubal occlusion in Africa. In many clinics this is done before hormonal assays and complicated cervical mucus studies are embarked on. Only those patients with patent tubes are passed on for further tests. Those with occluded tubes are assessed for tubal surgery, and only after successful treatment are they investigated further.

SEMEN ANALYSIS

This test can be done immediately unless the man has had coitus in the previous 2 days, in which case sperm count may be somewhat depleted. On the other hand, abstinence for more than 7 days will also introduce errors of interpretation because the concentration of round cells will have increased. The specimen of semen is collected by having the patient masturbate either at the laboratory (or not more than a 2-hour journey from it) into either a clean glass jar or into a polyethylene (not rubber) condom. The technician will be looking for directional motility in over 60% of sperm present, 40% normal morphology, and a count of at least 20 million sperm/ml. Except in azoospermia, the actual number of sperm is considered to be less critical than their apparent ability to move and their morphology.

BASAL BODY TEMPERATURE AND MUCUS

These important indicators of ovulation are fully discussed in Chapter 9. Again, this is a process the woman can begin immediately.

POSTCOITAL (SIMS-HUHNER) TEST

Within 2 to 4 hours after intercourse (with no douching afterward), the woman is examined and a cervical mucus-semen sample is collected. The mucus-semen sample is studied to note whether sperm are present in sufficient numbers and penetrating the mucus; also the spinnbarkeit (elasticity) and ferning of the mucus are observed to see whether they present the expected ovulatory qualities at midcycle.

ENDOMETRIAL BIOPSY

A postovulatory-phase biopsy (or premenstrual-phase biopsy) of the endometrial lining may indicate whether progesterone has been produced by the corpus luteum in the expected amount for the time of the cycle (under local anesthetic). If available, plasma progesterone levels may be determined, which may be less painful but as valuable diagnostically as endometrial biopsy. *Most* family planning clinics would *not* be able to perform endometrial biopsies.

TUBAL PATENCY TESTS

In some family planning clinics, tubal patency may be tested by tubal insufflation (Rubin test). In this test, a cannula is fixed in the cervical canal and carbon dioxide is gently introduced and allowed to flow through the fallopian tubes. Although this technique is not as reliable as hysterosalpingography or laparoscopy procedures which are only available in hospitals, the Rubin test can be a useful screening tool. If as a result of this test a patient is found to have patent tubes and she does not conceive for up to 6 months, she should be referred for further tests. In no case should tubal surgery be undertaken until hysterosalpingography and laparoscopy have been done. In some cases the Rubin test has been followed fairly closely by pregnancy and it has been suggested that this test may at times be therapeutic. At other times, the Rubin test may be harmful, causing a flare-up of a smouldering tubal infection.

It has been estimated that these five tests are capable of diagnosing 90% of infertility cases (18). Only the most sophisticated clinic will be able to perform tubal patency tests. The other tests could more readily be added to the services offered by a family planning clinic if resources are available. At the present time, it is rare for family planning clinics in Africa to offer any of the above five tests.

DEALING WITH PERSONAL STRESS

About 50% of couples who seek help for infertility may eventually report a pregnancy (many in the course of preliminary investigation) (18). However, within the group that does conceive, ectopic pregnancy, miscarriage, and perinatal mortality tend to surpass what would be expected in the general population. Therefore, of the original infertile population coming for treatment, just over half will eventually confront the reality of childlessness. The impact of this discovery sometimes damages a couple's relationship or an individual's self-esteem. Workers have noted typical reactions to infertility: surprise, denial, isolation, anger, guilt, grief, and, finally, resolution (39).

Family planning agencies may take an active and complementary role in helping infertile couples deal with personal stress. For very little extra expense or staff time, we can:

1. Provide full information on adoption, with names and addresses of local agencies, and we can get those agencies to assess waiting times, if any. Where adoption agencies do not exist, we can investigate for our patient the means of identifying and arranging for adoption.
2. Make referral for psychologic counseling if depression appears serious.

The rule of thumb to follow is to do that which might help the couple deal positively with their situation.

Family planners surely will do much more to help the infertile in the future. Assistance in diagnosis and, to some degree, treatment, dealing with personal stress, and prevention are all roles in which we can expand our involvement.

Confrontation with one's infertility is something that no counselor who has not personally faced it can easily imagine. Yet, when it comes to an emotion that we have not experienced personally and which we cannot fully understand, we can still offer respect and sensitivity.

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CHAPTER 6

SEXUALLY TRANSMITTED DISEASES

In addition to fertility control, family planning care can include the prevention and treatment of sexually transmitted diseases (STD). Why is the family planning clinic suited to treating STD's?

- The occurrence of an STD can have considerable medical and emotional consequences in people's lives: infertility, pain, marital disruption, hospitalization, and even death.
- Certain contraceptive methods can influence a person's likelihood of acquiring an STD.

STD's are a major cause of secondary infertility. (See Chapter 5.) An infection that invades the uterus or tubes can occlude the passage for sperm and ovum, thus preventing fertilization. Or, if fertilization does occur, the partially occluded passageway can lead to an ectopic pregnancy. STD's can also harm a developing fetus or a baby delivered through the birth canal of an infected woman.

In Africa, the consequences of STD's are major; and STD's, especially gonorrhea, have become endemic in many parts of Africa (1). In a study from central Africa, about 17% of women attending family planning clinics had gonorrheal infections; some had no symptoms of disease (2). In a study from Senegal, over 21% of the population was found to be serologically positive for syphilis or yaws (2). One survey in Zimbabwe found a crude rate of nearly 1,100 cases of syphilis per 100,000 population and about 2,100 cases of gonorrhea per 100,000 population (3). In some parts of Africa, chancroid is as common as gonorrhea. Other diseases that are quite common in other parts of the world may also be prevalent in Africa, although their prevalence is not well documented. Some estimates have placed the prevalence of trichomonas at 30%. About 60% of urethritis is probably caused by Chlamydia (2).

While some contraceptive methods help protect against STD, others may increase the risk of infection. In areas where STD's are prevalent, family planners need to be knowledgeable about the relationships between specific methods and infections. For example:

- Oral contraceptives may exert a protective effect against the development of pelvic inflammatory disease. (See Chapter 11.)
- Oral contraceptives may make a woman more prone to monilial infections. (See Chapter 11.)
- Barrier methods help decrease the transmission of many of the STD's. (See Chapters 5, 14, 15.)
- Spermicidal preparations such as foams have chemicals that may act against organisms such as *N. gonorrhoeae*, *T. pallidum*, *C. albicans*, *C. trachomatis*, *T. vaginalis* (4). (See Chapter 16.)

- The intrauterine device may increase the risk of pelvic inflammatory disease in a woman who has an STD. (See Chapter 13.)

By recognizing and treating STD's and by keeping these associations in mind when assisting a patient to choose a method, family planners can play a major role in preventing the spread of these infections while promoting the reproductive health of their patients.

For some of the most common STD's, associated symptoms, diagnosis, treatment, and patient instructions are summarized in Table 6.1.

SEVERAL POINTS TO CONSIDER IN THE MANAGEMENT OF SEXUALLY TRANSMISSIBLE INFECTIONS

1. While patients should be encouraged not to have sexual intercourse until their infection is cured, condoms should be provided just in case they are needed and should also be considered strongly for use after the infection is cured.
2. Patients should be urged to continue taking medications throughout the prescribed course of treatment even if symptoms subside or a menstrual period begins.
3. Often, patients have more than one sexually transmissible infection at a time.
4. Long-term use of broad-spectrum antibiotics such as ampicillin, tetracycline, and metronidazole (Flagyl[™]) often predispose a woman to monilia.
5. Whereas asymptomatic gonorrhea may be treated with a single dose of penicillin (or another drug), pelvic inflammatory disease caused by gonorrhea or any other organism should be treated for 7-10 days with antibiotics.

REMEMBER, TO PREVENT INFERTILITY, A SINGLE SHOT OF PENICILLIN IS INADEQUATE. TREATMENT FOR PELVIC INFLAMMATORY DISEASE SHOULD CONTINUE FOR 7-10 DAYS.

6. Patients should be advised to avoid iron, milk, and milk products for 1 hour before and 2 hours after ingesting tetracycline as these inhibit absorption of the drug.
7. Treatment of both partners is ESSENTIAL if a recurrence occurs and should usually be provided at the time of initial diagnosis.
8. Usually both partners must be treated. If one partner is treated by a clinician, it would be helpful to the couple if the other partner could be provided with a prescription simultaneously.
9. Always consider that there may be other sexual contacts who may *not* be treated.
10. Trichomoniasis may be responsible for some of the cases that show a Class II Pap smear reading. If this is the case, recheck the Pap smear 2 months after treatment.

TABLE 6.1 *Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases*

	Pelvic inflammatory disease	Gonorrhea	Chancroid
Symptoms	Abdominal, pelvic, back, and/or leg pain; fever or chills; vomiting; vaginal discharge often beginning on the last day of menstrual flow or shortly thereafter; prolonged menstrual bleeding or menorrhagia; bleeding after intercourse; dysuria; pain with intercourse.	May be totally asymptomatic in both sexes. Symptoms can include vaginal or penile discharge or pain; painful urination; tenderness of lymph nodes in groin; lower abdominal pain; fever; testicular pain in male and irregular and painful menses in female; pain with intercourse and postcoital bleeding may also occur.	Progression from initial vesicle-like pustule covered by a thin membrane to a sharply circumscribed ulcer with an irregular edge may take up to 2 weeks. The ulcer is soft and its base may be covered by a grey purulent exudate. Multiple lesions may occur. Lesions may be painful. Unilateral inguinal adenopathy occurs in 25%-50% of patients and suppurating bubos may develop. Destructive scarring may occur. In women ulcers occur most frequently on labia, clitoris, and vaginal introitus. In men, ulcers occur on penis and inside surface of foreskin. More common in uncircumcised men.
Diagnosis	BE SURE TO RULE OUT ECTOPIC PREGNANCY. Infectious agents associated with PID and endometritis are <i>N. gonorrhoeae</i> , <i>Chlamydia trachomatis</i> , <i>Bacteroides</i> , streptococci, peptostreptococcus, clostridia, staphylococci, <i>E. coli</i> , tuberculosis, schistosomiasis, filariasis, and occasionally actinomycosis. Some clinicians find the erythrocyte sedimentation rate (ESR) very useful. Patients with peritoneal signs or evidence of pelvic abscess should usually be hospitalized. Gram stain of endocervical secretions, gonorrhea culture on Thayer-Martin medium.	Gram stain, culture on Thayer-Martin medium. Because of the possibility of concomitant syphilis infection, each patient treated for a known gonorrheal infection should have a test for syphilis, if possible.	Chancroid is caused by <i>Hemophilus ducreyi</i> , a small pleomorphic gram-negative rod. Currently no available serologic test or skin test exists. Diagnosis is often made on basis of negative darkfield exam for spirochetes and response to sulfonamides. <i>H. ducreyi</i> is difficult to grow. When obtained from lesions, the organism is present in pairs and short chains.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Pelvic inflammatory disease	Gonorrhea	Chancroid
	Objective findings: lower abdominal pain or rebound tenderness, decreased bowel sounds, tenderness of uterus and/or adnexa, pain on movement of cervix, palpable mass or swelling, and/or a purulent vaginal discharge. The differential diagnosis includes ectopic pregnancy, endometriosis, ovarian cysts, neoplasms, mesenteric lymphadenitis, uterine leiomyomata, and appendicitis.		
Treatment	Tetracycline 0.5 gm orally four times a day for 10 days (not for pregnant patients); tetracycline should be given 1 hour before or 2 hours after meals. OR aqueous procaine penicillin G 4.8 million units I.M., ampicillin 3.5 gm, or amoxicillin 3.0 gm, each with 1.0 gm of probenecid (particularly if gonococcal infection is suspected). Either regimen is followed by ampicillin 0.5 gm or amoxicillin 0.5 gm orally four times a day for 10 days. Of the above approaches, tetracycline has the advantage of covering chlamydial infections. In general, IUD's should be removed if a woman develops PID. The IUD may be removed at the time PID is diagnosed, after 2 days of antibiotics, or following one menstrual period, depending on the clinical setting, the time of the cycle, and the days of the cycle when intercourse has occurred.	Tetracycline 0.5 gm orally every 6 hours for 5 days, or 3.5 gm of ampicillin or 3.0 gm of amoxicillin orally with 1 gm probenecid taken together. (Oral treatment is a precaution against anaphylaxis with parenteral penicillin.) If trained appropriate personnel are available 4.8 million units aqueous procaine penicillin (divided into 2 doses), given into two or more sites into the gluteal muscle, accompanied orally by 1.0 gm of probenecid should be given. NOTE: For nonpregnant penicillin-allergic individuals: 0.5 gm oral tetracycline every 6 hours for 5 days (as above) or 2 gm spectinomycin in a single injection. For pregnant penicillin-allergic persons: 2 gm spectinomycin in a single injection or cephalexin, 500 mg 4 times a day for 4 days. Treatment should include followup cultures and test for syphilis in 7-14 days.	Local cleansing and soaks for ulcer. Sulfonamides are the antibiotics of choice. Sulfisoxazole: 1 gm orally every 6 hours for 2 weeks. If this fails, continue the sulfa and add oral tetracycline, 500 mg every 6 hours. Kanamycin and gentamicin and parenteral cephalothin have also been used in resistant cases. Streptomycin also treats chancroid.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Pelvic inflammatory disease	Gonorrhea	Chancroid
Patient instructions	1. Use condoms until posttreatment cultures are negative for both partners. 2. Watch out for symptoms of yeast infection. 3. Avoid milk, milk products, and large amounts of any food for 1 hour before and 2 hours after ingestion of tetracycline, as milk inhibits tetracycline absorption. 4. Rest in bed until abdominal pain subsides. 5. ABSTAIN from sex at least 1 week. 6. Return to your clinician on the appointed date so that s he can make certain your infection is cured.	1. Get your partner treated. 2. Avoid intercourse completely until your clinician makes certain your infection is cured. If you do have intercourse, use condoms to prevent reinfection. 3. Be alert for symptoms of yeast infection if you take tetracycline or ampicillin. 4. Return to the clinic if you develop diarrhea while taking tetracycline or ampicillin.	1. Wash lesions carefully. 2. Continue antibiotics for the full 2 weeks. 3. Circumcision may be necessary after all lesions have completely healed. 4. Personal cleanliness is important both in treatment of active infection and in prevention of further infections.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Chlamydia	Syphilis	Trichomonas
Symptoms	Chlamydia can cause a range of problems including nonspecific urethritis, cystitis, purulent vaginal discharges, cervicitis, and pelvic inflammatory disease. Chlamydia trachomatis can cause conjunctivitis, urethritis, cervicitis, salpingitis, proctitis, and pneumonia of the newborn. Trachoma, another chlamydial infection, is not transmitted sexually.	PRIMARY (3 weeks after exposure): chancre is an indurated, painless, red-rimmed sore on the penis, anus, rectum, edge of vagina, cervix, or mouth—it will disappear 2-6 weeks later, even without treatment. SECONDARY (about 6 weeks after the healing of the primary infection): rash, especially on the palms of hands and soles of feet, fever, sore throat, headaches, arthralgia, sore mouth, anorexia, nausea, and/or inflamed eyes. These symptoms may disappear in 2-6 weeks even without treatment. Moist, broad-based, flat-topped growths (condylomata-lata) up to 2 cm in diameter may appear on the warm moist areas of the body. TERTIARY (10-20 years): heart disease, brain damage, spinal cord damage, blindness. One in four persons not treated for secondary syphilis will eventually suffer incapacity or death from the disease. Symptoms may be absent until tertiary damage occurs (latent syphilis). Congenital syphilis, a serious infection in newborns, occurs frequently if pregnant women with syphilis are not treated.	Frothy, thin, greenish-white, sometimes bubbly, vaginal discharge; intense vulvar itching, pain, and frequency of urination. The infection may be asymptomatic and usually is in males, although they may have occasional pain on urination and discharge from the urethral meatus.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Chlamydia	Syphilis	Trichomonas
Diagnosis	Chlamydia is an obligate intracellular bacteria. Usually diagnosis is one of exclusion since very few centers can provide techniques for culturing Chlamydia.	Dark field examination of fluid from chancre, VDRL (may not be positive until 2-3 weeks after appearance of chancre), and the fluorescent treponemal antibody absorption test (FTA-ABS); the treponema pallidum immobilization test (very few false positives) has been for the most part replaced by treponemal tests (microhemagglutination treponemal pallidum antibody test = MHA-TP, or TPHA, or the TRA-ABS test).	In females the appearance of discharge and punctate red petechiae on cervix is helpful but not diagnostic. Motile flagellated trichomonads appear on microscopic examination of saline wet mount. Culture. Pathologists can detect these organisms on a Pap smear. Often not necessary to treat asymptomatic women when organisms are found on a Pap smear. In males culture or wet smear of prostatic secretions may yield organisms, but identification of the trichomonad is difficult in males.
Treatment	Tetracycline 250-500 mg four times a day for 10-21 days is treatment of choice. <i>The sexual partner must be treated.</i> Erythromycin is also reported to be effective. Ampicillin is usually not effective.	Penicillin: 2.4 million units benzathine penicillin G for primary and secondary syphilis. The high short-term doses given for gonorrhea will prevent development of syphilis if given within 10 days of exposure, but will not cure syphilis that has progressed to the primary stage or beyond. Alternatives: 2.4 million units of benzathine penicillin weekly $\times$ 3 for early latent or tertiary syphilis. Or, for tertiary syphilis, penicillin G procaine 600,000 to 1.2 million units I.M. daily for 15 days, or tetracycline 30-40 gm p.o. over 10-15 days.	Metronidazole (Flagyl [®]) 2 gm p.o. (single dose) or 500 mg b.i.d. for 5 days. Provide condoms as part of treatment. Do not provide systemic metronidazole in first trimester of pregnancy—effects of metronidazole later in pregnancy or in nursing mothers is unknown. Metronidazole has been noted to produce leukopenia and allergic reactions. Metronidazole has been shown to be carcinogenic in mice and possibly carcinogenic in rats. Unnecessary use of this drug should be avoided.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Chlamydia	Syphilis	Trichomonas
Patient instructions	See instructions for cystitis, vaginitis, and or pelvic inflammatory disease.	1. Your partner(s) must receive treatment. 2. Use condoms during intercourse for a month.	1. Nausea, diarrhea, vomiting, dryness of the mouth, or a "tinny" (metallic) taste may occur. 2. Use condoms throughout treatment. Your partner must be treated for this infection. 3. It is not known what cancer-causing effects Flagyl® has on a pregnant woman or a developing fetus. 4. It is better to be treated, despite the potential problems caused by the drug, than to allow the infection to continue untreated. 5. Do not drink alcohol while you are being treated.
	Gardnerella Vaginalis	Monilia	Herpes Genitalis
Symptoms	Yellow to gray-green vaginal discharge, sometimes described as chalky white. May be thick or watery and may cause foul odor, pain on urination, vaginal itching, and or painful intercourse.	Thick, white cottage cheese-like discharge, itching, redness of external genitalia and sometimes upper thighs. Itching may be severe.	Multiple blister-like vulvar, cervical, or penile sores or ulcerations which are often contiguous ("herpes" means to "creep"); pain on intercourse, discharge, pain (may be very severe) and itching of vulva and perineum. Dysuria may be most prominent symptom.
Diagnosis	Short, rod-shaped bacteria on wet mount and stippled granular epithelial cells ("clue" cells). Addition of KOH to discharge containing vaginalis releases amines, causing a foul fishy odor. Gram stain may show numerous short, gram-negative bacilli. Lactobacilli are commonly absent in the presence of G. vaginalis. May be detected on Pap smear. May be cultured on thioglycolate broth or blood sugar culture.	Ten percent potassium hydroxide on discharge; Monilia is also easy to recognize on a gram stain. Look for hyphae and spores under microscope; your pathologist may note Monilia on Pap smear. Culture in Sabouraud's or Nickerson's medium.	Usually by clinical judgment. If confirmation desired, Pap smear from site(s) or lesion(s). Ask cytologist to look for intranuclear changes produced by herpes. Tissue culture may be taken, and immunologic diagnosis also possible, but difficult to obtain. Viral cultures (if available) give accurate results within 48 hours.

TABLE 6.1 *Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued*

	Gardnerella Vaginalis	Monilia	Herpes Genitalis
Treatment	Oral metronidazole 500 mg b.i.d. for 7 days for both partners. Ampicillin is a second approach. Use 500 mg q.i.d. for 7-10 days for patient and partner. Although sulfa suppositories have also been used in local treatment for 10-15 days, local agents are probably not very effective.	During examination, wash patient's vagina carefully, sponging with povidone-iodine if available. Nystatin vaginal suppositories once or twice a day for 15 days (longer for stubborn infections) or miconazole vaginal cream in a once-a-night application for 7-14 days. Steroid cream will diminish itching. Gentian violet suppositories once a day for 2 weeks or by direct application can also be used. Most women find it less messy to use suppositories at night only. A tampon may be used to keep vaginal suppositories in place. Boric acid (400 mg) in gelatin capsules have been used to treat Monilia.	No specific treatment exists. Analgesics can be used systemically. Keep lesions clean and dry. Avoid occlusive creams and ointments. Corticosteroids are contraindicated. Catheterization for urinary retention. Treatment of superinfections may be helpful.
Patient instructions	1. Partner(s) may be infected, so treatment of partner(s) is important. 2. Use treatment exactly as prescribed; take full amount prescribed. 3. Use condoms until treatment is completed and symptoms are no longer present.	1. Complete your prescription even if symptoms become less annoying. 2. Wear cotton underwear and avoid tight clothing. 3. Lose weight if you are overweight. 4. Ask for diabetes test if you have recurrent Monilia. 5. You may need to take medication throughout one or two complete menstrual cycles. 6. Consider using Monilia medication in the future if you are being treated for other infections with tetracycline or ampicillin. 7. White vinegar or commercially available douches may help prevent recurrences of yeast infections. Use 1 tablespoon of vinegar in a quart of warm water.	1. Keep area clean to prevent superinfection. 2. Wear loose underwear. 3. Urinate in a tub full of warm water while pouring warm water on vulva or penis if pain is severe. 4. You should be healed in 2-4 weeks. 5. If it is easy for you to get a Pap smear, you should have a Pap smear every year for the rest of your life. 6. Use condoms for at least 6 weeks and until the signs of infection are gone in both you and your partner. 7. Abstain from intercourse, or use condoms whenever there is any sign of a recurrence. (Often the first sign is a tingling sensation.) 8. Tell your clinician you have had herpes if you plan to carry a pregnancy to term because there is a risk of herpes infection in the newborn. Active herpes infections may be an indication for delivery by C-section.

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Condylomata Accuminata	Pubic Lice	Cystitis
Symptoms	Small (2mm) to large, dry, fungating, wart-like growths on the vulva, vagina, cervix, or penis. May cause pruritis and chronic discharge. Warts appear 1 to 3 months after exposure.	Itching and lice present in pubic hair.	Pain and burning on urination, frequent urination in very small amounts, cloudy foul-smelling urine, nocturia, lower abdominal pain, pain on manipulation of urethra, pain during intercourse, blood in urine.
Diagnosis	Appearance as given above. Be certain to differentiate between condylomata and secondary syphilis, which are flat moist lesions. A test for syphilis should be drawn.	Lice or eggs (nits) in pubic hair.	Bacteria on unspun urine, leukocytes on urinalysis, culture and sensitivities on clean-catch urine (particularly if there is recurrent infection or treatment failure), urethral irritation, bladder or trigone tenderness. NOTE: Check patient for back pain and fever. If present, may indicate pyelonephritis (also look for leukocyte casts in urine). Check for vaginitis (particularly gonorrhea, herpes, vaginalis, and trichomoniasis). Obtain clean-catch specimen to avoid contamination with vaginal discharge. Always think of PID when considering the diagnosis of cystitis.
Treatment	Apply 20%-25% podophyllin liquid or ointment to warts after protecting surrounding tissue with a lubricant jelly. Wash off in 4-6 hours. Reapply weekly leaving it on for progressively longer periods of time up to 24 hours. Often, three or more applications may be needed. Trichloroacetic acid or electrocoagulation is used for larger or resistant lesions. Huge masses may require surgical excision under local or general anesthesia. In some cases, plastic surgery under general anesthesia is necessary.	Gamma benzene hexachloride shampoo, lotion, or cream or other scabicide.	Two gm sulfisoxazole p.o. then 1 gm q.i.d. for 10-14 days. Some clinicians report excellent success following treatment of cystitis with just a single large dose of a variety of different antibiotics t.i.d. for 24-48 hours if the burning, pain, and sense of urgency are particularly troublesome. (Warn the patient to expect rust-colored urine.) Alternatives: Nitrofurantoin, ampicillin (which, when administered to pregnant women, may be associated with lowering of both plasma and urinary estriol values), or tetracycline. Other alternatives: combination of sulfa drugs, carbenicillin indanyl sodium, and metronidazole. Some clinicians recommend making the urine more acidic by increasing ascorbic acid intake (or intake of cranberry juice).

TABLE 6.1 Symptoms, diagnosis, treatment, and patient instructions for some common sexually transmitted diseases—Continued

	Condylomata Accuminata	Pubic Lice	Cystitis
Patient instructions	1. Wash the medicine off with soap and water after about 8 hours. 2. Your partner may need treatment. 3. Use condoms until all warts have disappeared. 4. Too much treatment may cause nausea, diarrhea, vomiting, stupor, or paralysis. For this reason, your clinician may only treat a portion of the warts if you have many.	1. Remove all lice and eggs that you can see. Wash with soap and water. Dry with a clean towel. 2. Massage lotion or cream on body from neck down. Include scalp if lice are present there. Leave medicine on overnight. 3. Boil clothing and linen. Lice can live in unlaundered clothes. Eggs can live 6 days and lice can live 24 hours after removal from the body. 4. Both you and your partner should receive treatment, which may need to be repeated after 24-48 hours.	1. Drink 10-15 glasses of water each day during treatment. Continue drinking 10-15 glasses of water a day if recurrent cystitis is a problem. 2. Complete taking the antibiotics, even if symptoms have gone away and you are feeling well. 3. Return for followup urinalysis 3-4 weeks after treatment is started (earlier if symptoms persist). Complete urologic evaluation may be necessary if recurrent infections occur. 4. Partner(s) must be treated if trichomoniasis or gonorrhea is cause of infection. 5. Until you feel better, avoid sexual intercourse. If cystitis is a recurrent problem, urinate and drink a glass of water following sexual intercourse. Avoid coitus if too painful. 6. If you are taking ampicillin or tetracycline, return to the clinic if you develop diarrhea. 7. If you are using the diaphragm as your method of birth control and you develop repeated bladder infections, consider the possibility that your diaphragm may be causing too much pressure against your urethra.

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SECTION II

**WHAT YOU NEED TO KNOW
TO USE CONTRACEPTIVES
EFFECTIVELY**

CHAPTER 7

THE MENSTRUAL CYCLE

A woman's fertility runs in cycles, unlike a man's fertility which is, for the most part, constant. An understanding of these cycles can help clinicians and users choose appropriate family planning methods and help individuals use these methods correctly. In each female cycle, hormones—the body's chemical messengers—stimulate changes in the body. These changes gradually build to a peak in which a mature egg ripens for fertilization. The lining of the uterus (endometrium) becomes a rich, nutritious bed in anticipation of a potential pregnancy. If the egg is fertilized by a spermatozoon during the cycle, a pregnancy develops. But if the egg is not fertilized, then the hormones gradually stop preparing the woman's body for pregnancy. When this happens, the nutritious lining of the womb sheds and the cycle begins again.

Understanding a woman's cycle of fertility, called the menstrual cycle, can help planning for a pregnancy, preventing one, and understanding and diagnosing many medical problems. Many of the contraceptives in this book work by interrupting one or more of the steps in the menstrual cycle necessary for creating a pregnancy.

PHYSIOLOGY

The menstrual cycle can be divided into three parts: the uterine cycle, the ovarian cycle, and the functions of certain organs in the brain (1). For simplicity, the description of the menstrual cycle in this chapter is based on a 28-day cycle, although a normal cycle may last anywhere from 21 to 35 days.

UTERINE CYCLE:

The beginning and the end of the uterine cycle are marked by the flow of menstrual blood, the shedding of the uterine lining. After 3 to 5 days when the blood flow stops, about one-third of the lining is left in the uterus, where it will begin to repair itself under the influence of estrogen and progesterone. This time of repair is called the follicular (or proliferative) phase. The follicular phase lasts until the middle of the cycle, when the hormones in the body cause the lining to be even further nourished by the increased stimulation from progesterone. This luteal (or secretory) phase begins at midcycle. The endometrial lining thickens, and its uterine glands and blood vessels branch and multiply.

If fertilization occurs, progesterone and subsequently human chorionic gonadotropin (HCG) continue to support the nutritious lining in support of the developing pregnancy. If fertilization does not occur, the hormones stop sup-

porting the lining. Blood vessels pinch off. Without support, the lining of the uterus sheds, creating the bleeding and signaling the beginning of the new menstrual cycle.

OVARIAN CYCLE:

The thickening and subsequent shedding of the endometrial lining seem simple enough. However, this action is controlled by the complex interplay of hormones. The key events that determine whether the uterine cycle will occur regularly (or if pregnancy will occur) revolve around ovulation—the releasing of a mature egg from the ovary.

Each of the two ovaries contains 300,000 to 400,000 follicles. Follicles are balls of cells with immature eggs in the center. In a woman's lifetime, about 300 to 500 eggs will mature. In one monthly cycle, about 10 to 20 follicles begin to grow under the influence of hormones. In most cases, only one of the follicles will mature fully and the others will degenerate. As the follicle matures, it secretes estrogen and progesterone, which cause the changes in the endometrial lining described above.

During the follicular phase, the egg matures within the developing follicle and moves to the surface of the ovary until it can float away as a free egg available for fertilization. (See Figure 7.1.) The release of an egg is called ovulation. Some women experience a cramping or a bloody discharge during ovulation. Many women will notice that the cervical mucus coming from their vagina increases and becomes slippery and more stretchable. (See Chapter 17.)

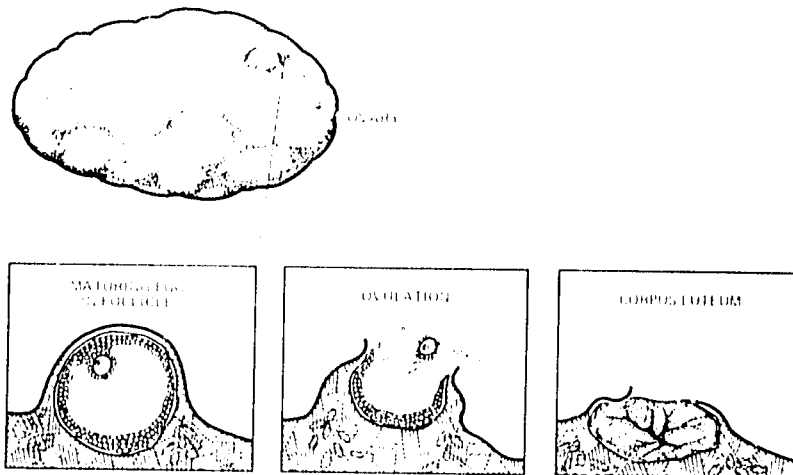


FIGURE 7.1 Changes in the ovary during the menstrual cycle. Maturation of the follicle occurs until ovulation occurs. Under the influence of luteinizing hormone (LH), the cells that line the fluid-filled follicle rearrange themselves into a cluster of cells called the corpus luteum.

The free egg begins its 6-12-day journey through the fallopian tube. Within a day after ovulation, the egg can be fertilized by sperm, which generally occurs in the outer third of the tube. After the egg is released, the follicle, now called a corpus luteum, secretes increasing amounts of progesterone and decreasing amounts of estrogen. The lining of the uterus enters the luteal (secretory) phase under the increased influence of progesterone. (See Figure 7.2.)

If fertilization occurs, the corpus luteum continues to release progesterone until the developing placenta begins to secrete its own hormone (HCG) to continue the support of the rich endometrial lining. If fertilization does not occur, the corpus luteum disintegrates into a white scar tissue called a corpus albicans and no longer secretes hormones. As the levels of hormones decline further, the endometrial lining is no longer supported, and menstrual bleeding begins.

FUNCTIONS OF THE BRAIN:

The complex interaction of hormones is controlled by organs in the brain: the hypothalamus and the pituitary. The hypothalamus is sensitive to changing levels of estrogen and progesterone. When the levels reach a certain point, the hypothalamus signals its messenger, the pituitary gland. The pituitary receives the signal and passes the message to the ovary, which responds as described below. (See Figure 7.2.)

When estrogen levels drop, as during the menstrual flow, the hypothalamus releases its signal—follicle-stimulating hormone releasing factor (FSH-RF)—to the pituitary. The releasing factor stimulates the pituitary to release follicle-stimulating hormone (FSH). Under the influence of FSH, the follicles in the ovary begin to grow. As one of the follicles reaches maturity, it secretes a burst of estrogen and some progesterone. Once again, the hypothalamus interprets the combined levels of estrogen and progesterone and signals the pituitary by releasing a second signal called luteinizing hormone releasing factor (LH-RF) in addition to more FSH-RF. In response to these signals, the pituitary releases both FSH and LH to stimulate the ovary. The peak levels of FSH and LH stimulate the follicle to release the mature egg. Ovulation occurs. Following ovulation, FSH drops back to baseline levels. But the LH continues, at lower levels, to stimulate the empty follicle (corpus luteum). As the corpus luteum begins secreting greater amounts of progesterone and lesser amounts of estrogen, LH slowly declines. If fertilization occurs, the placenta of the developing fetus secretes HCG to continue supporting the pregnancy. If fertilization does not occur, all hormone levels decline. In response to a return to the low levels of estrogen and progesterone, the hypothalamus releases FSH-RF to signal the pituitary, and the cycle begins again.

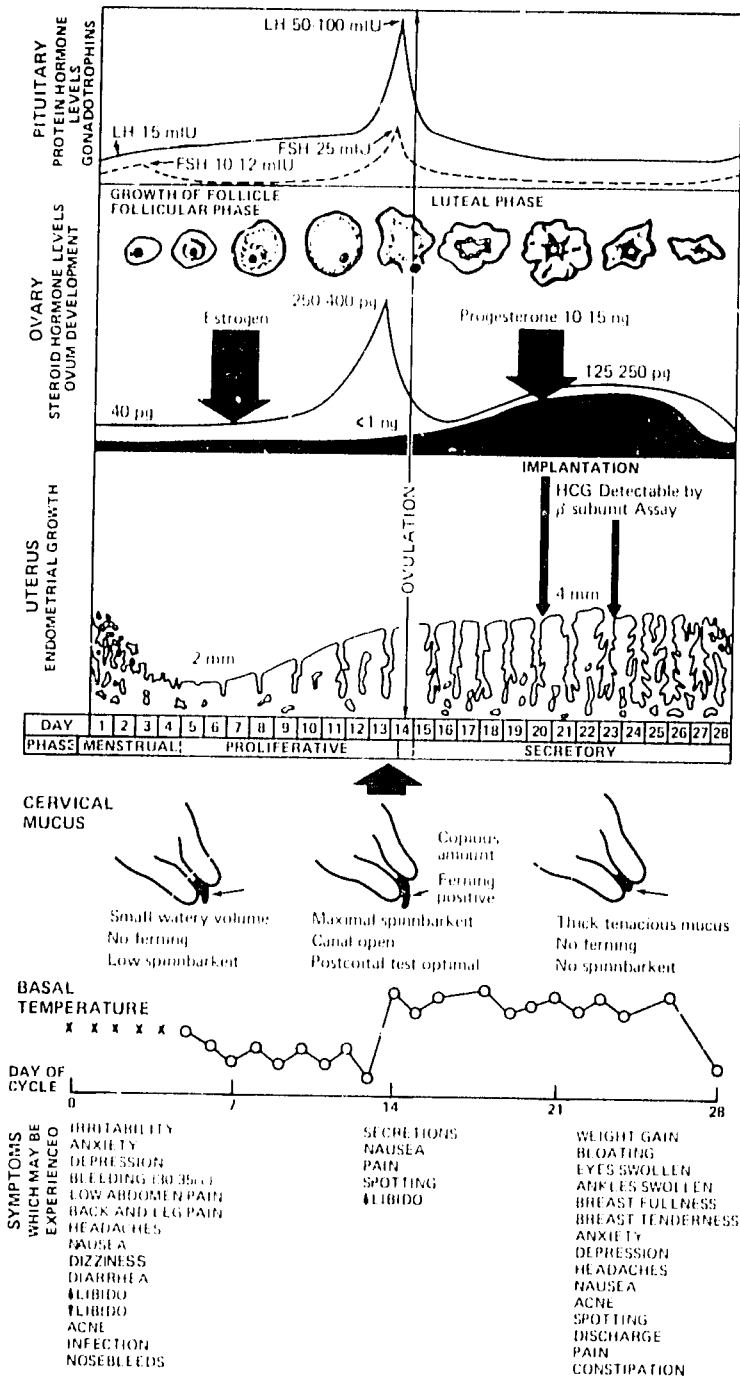


FIGURE 7.2 The menstrual cycle.

CHRONOLOGY

Below is a brief chronologic summary of the key activities associated with the menstrual cycle.

- Day 1: Menstruation begins. The lining of the uterus is shed because there is not enough hormone support to keep it in place.
- Day 5: Menstruation ends. Some women may have shorter or longer periods. The hypothalamus reads the low level of hormones and sends a message to the pituitary. The pituitary releases FSH to stimulate the ovary to start ripening an egg. The ovary releases mostly estrogen and some progesterone to help build up a new uterine lining.
- Day 14: Ovary releases an egg. (In longer or shorter cycles, ovulation may occur on another day, but almost always 14 days *before the next menstrual period*.) (See Figure 7.3.) Under the stimulation of LH and FSH peaks, the ovarian follicle releases the egg. The empty follicle (corpus luteum) secretes increasing amounts of progesterone and decreasing amounts of estrogen. If the egg is fertilized, the corpus luteum continues secreting increasing amounts of progesterone until the placenta produces sufficient quantities to sustain the pregnancy. If the egg is not fertilized, the events continue as follows.
- Day 26-28: Premenstrual time occurs. (This varies for women with shorter or longer cycles.) Levels of estrogen and progesterone drop. Many women experience premenstrual symptoms such as weight gain, breast tenderness, bloating, and acne.
- Day 1: Menstruation begins.

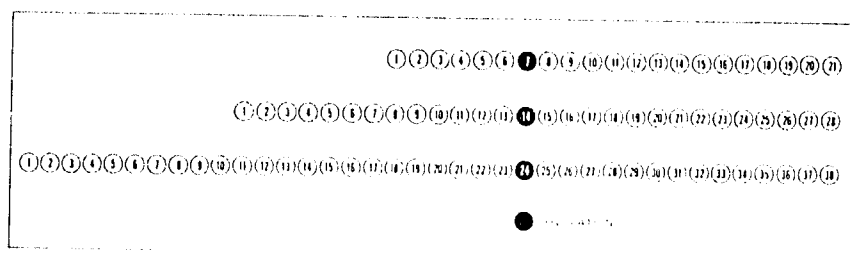


FIGURE 7.3 Timing of ovulation during the menstrual cycle. When a woman's cycle length varies, it is the phase before ovulation that changes in length. The number of cycle days after ovulation remains approximately the same—about 14 days.

MENSTRUAL HISTORY

Since many of the contraceptive methods described in later chapters affect the menstrual cycle, a good menstrual history will help both you and your patient choose the best method of contraception for her.

By asking your patient the questions listed below, you can help her develop her menstrual history.

How old were you when you started menstruating?

When was your last menstrual period?

How many days does your menstrual bleeding last?

Have you missed any periods?

Do you have cramping with your periods? How severe?

Have your menstrual periods become heavier recently?

Do you have bleeding between periods?

Do you experience any premenstrual depression,
headaches, anxiety, weight gain, ankle swelling,
breast tenderness or fullness?

Have your menstrual cycles changed since you started using
your present contraceptive?

COMMON QUESTIONS ABOUT THE MENSTRUAL CYCLE

Below are three questions that patients commonly ask about the menstrual cycle:

Question	Answer
Can you get pregnant when you have intercourse during your period?	Yes. While not common, it has happened. It is most likely to happen to a woman who has short menstrual cycles (18-25 days).
Can you get pregnant if you have never had a period?	Yes. A young woman can ovulate and become pregnant a couple of weeks before she would have had her first period.
Are women unclean when they have their periods?	No.

EFFECTS OF CONTRACEPTIVES ON THE MENSTRUAL CYCLE

Contraceptive methods can affect the menstrual cycle. They can alter the amount and duration of menstrual bleeding, the degree of premenstrual symptoms, flare-ups of acne, and intermenstrual bleeding. Perhaps the most important noncontraceptive effects are the influences on menstrual pain, or dysmenorrhea.

Menstrual pain is not uncommon. Since the use of hormonal contraceptives suppresses ovulation, many women using combined Pills, Mini-Pills, and long-acting progestin injections find relief from menstrual pain. IUD's are often associated with increased menstrual pain and bleeding. One IUD, however, the progestin-releasing IUD (Progestasert-T[®]), can suppress uterine contractions, thereby decreasing menstrual pain.

If a woman complains of menstrual pain, some of the following approaches may be used:

Mild menstrual pain	Severe pain
Vigorous physical exercise	Analgesics or narcotics
Lower back, leg, or calf massage	Diuretics
Lying with knees to chest	Prostaglandin inhibitors
One ounce of alcohol beverage	Birth control Pills
Hot drinks	Insertion of a progestin-elaborating IUD
Aspirin for several days before and during period	Dilatation and curettage
Rest	
Warm bath or shower	

AMENORRHEA

Amenorrhea—the failure to have a menstrual cycle—can have different causes. A woman may have primary amenorrhea due to abnormal physiology, or secondary amenorrhea in response to illness, drugs, stress or tumors, pregnancy, use of hormonal contraceptives, or menopause.

A woman who has not begun her menstrual cycle by age 17 should be evaluated by a specialist. A girl who has not developed breasts or female hair patterns by age 15 should also be evaluated.

If a woman once had periods but no longer has them, make certain that she is not pregnant. If she is not, check whether weight loss, depression, illness, or medications (including contraceptives) may be causing her amenorrhea. If none of these are the cause, and her periods do not resume with appropriate care, send her to a specialist for an evaluation.

An older woman, between the ages of 45 and 55, may have begun menopause. Menopause is the normal ending of a woman's cycle of fertility. However, a woman can still get pregnant in the early stages of menopause, because her cycle may merely be irregular before stopping completely. Advise the woman to use a contraceptive method until 6 months to 1 year after her periods have stopped.

ANEMIA

Most women of reproduction age have a borderline iron balance because of their monthly menstrual cycles. Heavy menstrual flow can result in anemia. However, in the malnourished woman, even normal flow may lead to anemia if the woman has no way of replacing the iron she has lost. The average blood flow during menstrual flow is about 30 ml. While women may vary in the amount of flow they have, various contraceptives can also affect the flow. An IUD usually makes a woman's menstrual flow heavier; thus, the IUD may not be an ideal choice for a woman prone to anemia. On the other hand, the oral contraceptive or Mini-Pill will decrease the blood flow in many women. Encourage all women in their childbearing years to consume iron either through the foods included in their diets or by taking supplements.

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CHAPTER 8

PREGNANCY TESTING

"Is this woman pregnant?" You may ask yourself this question often during the course of your work as a family planning professional. The answer is important for several reasons:

- You may wish to insert an IUD. However, inserting an IUD into the uterus of a pregnant woman can cause spontaneous abortion or sepsis. (See Chapter 13.)
- You may wish to administer medications. Giving some medications to a pregnant woman may affect her fetus.
- You should begin prenatal care if the woman is pregnant and planning to remain so. Advising a patient about how to keep herself and her developing baby healthy is a crucial part of family planning.
- You may want to determine why a patient has missed one or more periods. Finding out if a woman is pregnant is the first step in evaluating amenorrhea.
- You may want to know if an abortion (either spontaneous or induced) that a patient has undergone has truly terminated the pregnancy. (See Chapter 22.)
- You may be concerned that a patient may have an ectopic pregnancy. Detecting an ectopic pregnancy before it ruptures can save a woman's life.

DIAGNOSING A PREGNANCY

In the normal pregnancy, a thorough history and a complete physical examination are usually adequate to make the diagnosis of pregnancy. During the first 6 to 12 weeks of pregnancy, a woman may have the following signs: (1)

Missed periods	Weight gain
Breast tenderness or swelling	Mood changes
Nausea (morning sickness)	Changes in eating habits
Urinary frequency	Backaches

By the 12th week of pregnancy, the earlier signs of pregnancy may disappear or persist. New signs may appear:

Increase in breast size	Vaginal discharge
Increased facial pigmentation (mask of pregnancy, chloasma)	Fetal movements (beginning about the 18th or 20th week)
Protruding lower abdomen	Swelling or redness of gums
Darkening of nipples	

While most normal pregnancies can be diagnosed and managed without the use of pregnancy tests, certain situations such as those mentioned at the beginning of this chapter are best managed by combining a thorough history and physical examination with a laboratory test.

The more urgent reasons for using laboratory tests to detect pregnancy are to help rule out the following: (2-7)

ECTOPIC PREGNANCY

THREATENED OR INCOMPLETE ABORTION

TROPHOBLASTIC DISEASE

FETAL DEATH

PREGNANCY CONTINUED AFTER ATTEMPTED ABORTION

HUMAN CHORIONIC GONADOTROPIN

Today, most pregnancy tests work by detecting the presence of human chorionic gonadotropin (HCG), a hormone of pregnancy. In the normal pregnancy, human chorionic gonadotropin is secreted by the egg implanted in the endometrium (3). Soon after the fertilized egg implants in the endometrium, the very sensitive tests for pregnancy can detect HCG in the pregnant woman's blood (2). In another week or two, the less-sensitive* slide and urine tests can detect HCG in either the blood or the urine of the pregnant woman.

In the normal pregnancy, the HCG levels follow the pattern shown in Table 8.1.

Pregnancy tests work through an immunologic reaction to human chorionic gonadotropin. Since most of the commonly used slide and tube tests are indirect tests—that is, they inhibit agglutination—this chapter will describe the mechanism of action of these *indirect tests* only. Read the instructions that come with the test kit you use to determine what type of test you are using. (See Table 8.2.)

For performing the test, the technician adds an antibody to the patient's urine or serum specimen. After adding the antibody, the technician adds an indicator particle which becomes visible to the naked eye if it reacts with the antibody.

If the patient is pregnant, her urine or serum will contain HCG. When the antibody is added to her specimen, the gonadotropin will bind with the antibody. No antibody will be left to react with the indicator particle that is added. The specimen will, therefore, be clear because agglutination of the antibody and the indicator particle has been inhibited.

If the patient is not pregnant, her urine or serum will not contain HCG. Therefore, when the antibody is added to her specimen, it will not be bound

*The sensitivity of a pregnancy test refers to its ability to detect low levels of human chorionic gonadotropin.

but will remain free to react with the indicator particle. Thus, when the indicator particle is added, agglutination—or clumping—will form and be visible to the naked eye (8). (See Figure 8.1.)

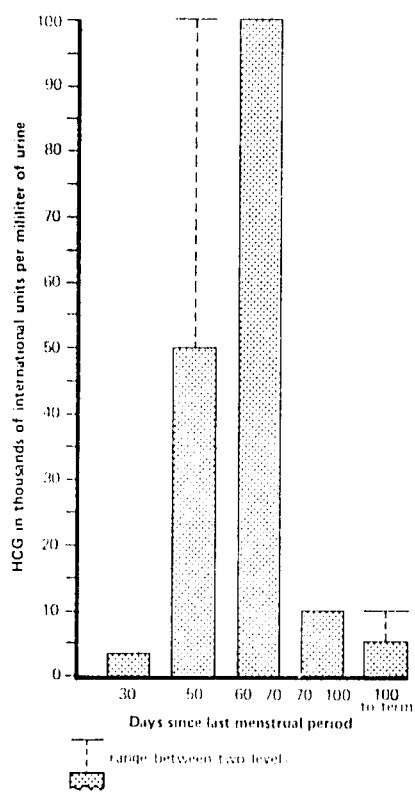
TYPES OF PREGNANCY TESTS

Three types of tests are commonly used to detect human chorionic gonadotropin during pregnancy: immunoassays (which include slide tests, tube tests, and the supersensitive tube tests), radioimmunoassays, and radioreceptorassays (2,4-7,9). (See Table 8.3.) Refer to Table 8.4 for a comparison of costs, sensitivity, and other requirements of tests produced by different manufacturers.

IMMUNOASSAYS (SEE ACCOMPANYING INSTRUCTIONS)

Two-minute slide tests are the most commonly used tests for screening. The tests are popular because they are rapid, easy to perform, inexpensive,

TABLE 8.1 Levels of human chorionic gonadotropin during the normal pregnancy



and convenient. They are, however, the least sensitive of the tests currently used: they do not detect pregnancy until 45 days after the last normal menstrual period.

Two-hour tube tests are somewhat more sensitive than the slide tests and are generally easier to read. On the other hand, the test materials are more expensive, and the test requires more time to produce results.

TABLE 8.2 *Instructions for performing the urine slide test for pregnancy (8)*

Specimen Collection

Have the patient collect a specimen of the first urine she voids in the morning.

Have the patient use a clean and well-rinsed glass or plastic container. Make certain no residue is left in the container.

Test the urine specimen within the same day it has been collected.

Performing the Test

Take a slide test card. There are circles on the card. Use one circle for one specimen.

Put 1 drop of urine from a pipette in the middle of a circle.

Add 1 drop of antiserum reagent to the urine. (Hold dropper perpendicular to the slide.)

Mix the urine and reagent with the applicator stick.

Rotate the card for a short time (30 seconds).

Add 1 drop of antigen reagent to urine and antiserum reagent mixture. (Hold dropper tip perpendicular to the card.)

Mix and spread the mixture over the entire circle.

Rotate the card for 2 minutes (no longer).

Observe for clumping (agglutination) while rotating the card.

In *most* tests, clumping means the test is **NEGATIVE**.

The absence of clumping means the test is **POSITIVE**.

(The direct agglutination tests react in an opposite manner.)

**CHECK THE INSTRUCTIONS ON THE SPECIFIC TEST
YOU ARE USING.**

SLIDE TEST FOR PREGNANCY

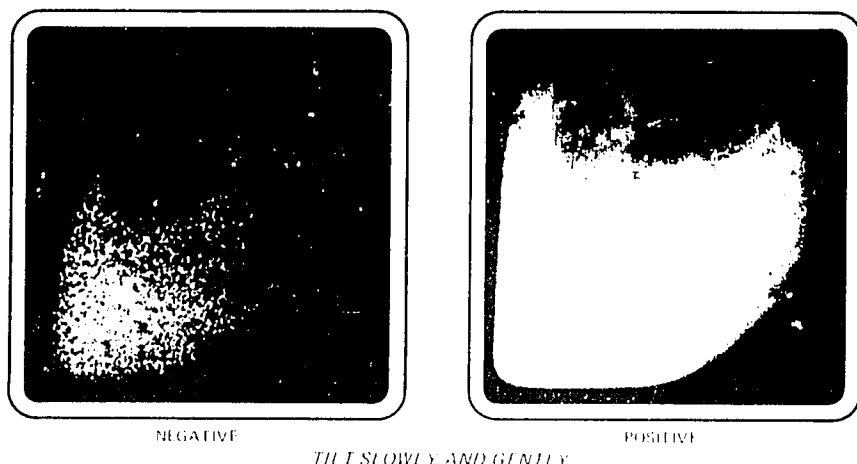


FIGURE 8.1 Interpreting the slide test for pregnancy. (10)

TABLE 8.3 Advantages and disadvantages of commonly used pregnancy tests (4,6)

Test	Advantages	Disadvantages
Slide test	- Convenient - Rapid - Centrifuging or filtering of specimen not necessary - Specific for HCG - Minimal drug interference	- Less sensitive than tube test or radioimmunoassay - High HCG levels needed for positive test (1.5-2.5 IU/ml) 90% accuracy only after 45 days has passed since last menstrual period - False-negative results on urine with high specific gravity - High technical error rate from improper mixing technique - Occasional false-positive results from proteinuria
Tube test	- Simple - More sensitive than slide test - Less technical error rate than with slide test	- Less sensitive than radioimmunoassay - High HCG levels needed for positive result (0.5-1 IU/ml) 90% accuracy only after 40 days has passed since last menstrual period - Significant proteinuria can produce atypical results - Vibration or jarring can cause inconclusive results in some tube tests

Newer, supersensitive tube tests work in the same way as the regular tube tests. These new tests, however, are much more sensitive and may be a suitable alternative, in some situations, for the highly sophisticated radioimmunoassays. These supersensitive tube tests may not be available in many areas.

RADIOIMMUNOASSAYS

Radioimmunoassay tests for pregnancy were developed within the past 10 years. Extremely sensitive, these tests can detect human chorionic gonadotropin within several days after fertilization has occurred. The use of these tests is limited by the availability of equipment and sustained funding and

TABLE 8.4 Costs, sensitivity, time, and refrigeration requirements for pregnancy tests (11)

	Cost per kit (tests in kit)	Sensitivity*	Time Required	Stability in Refrigerator
TUBE TESTS				
Pregnosticon Accu-				
spheres [®] (Organon)	\$1.46 (100)	750	2 hr	1 yr (RT)
Placentex [®] (Roche)	1.54 (100)	1000	90 min	18 mo
Gravindex [™] (Ortho)	1.09 (100)	500	90 min	1 yr
Beta-Stat [™] (Wampole)	1.78 (50)	200	1 hr	18 mo (RT)
Neocept [™] (Organon)	1.81 (50)	200	2 hr	1 yr
Sensi-Tex [™] (Roche)	1.75 (100)	250	90 min	7 mo
SLIDE TESTS				
Pregnosticon Dri Dot [†]	1.20 (100)	1500	2 min	2 yr
Pregnosis [™] (Roche)	.99 (100)	1500	2 min	2 yr
Pregnosticon Slide [™] (Organon)	.93 (100)	1500	2 min	1 yr
UCG Slide [™] (Wampole)	1.03 (100)	2000	2 min	18 mo
Pregnate [™] (Fisher Diag.)	1.16 (50)	2000	2 min	1 yr
Gravindex [®] (Ortho)	.96 (60)	3500	2 min	1yr
Beta Slide [®] (Wampole)	1.13 (100)	500	2 min	18 mo
Sensi-Slide [™] (Roche)	1.20 (50)	800	2 min	7 mo
SERUM TESTS				
Chorio Shure [™] (N.M.L.)	1.35 (100)	40	90 min	6-8 wks
Chorio Quant [™] (N.M.L.)	1.35 (100)	0-90	2.5-3 hr	6-8 wks
Beta Tec [™] (Wampole)	.72 (125)	30	1 hr	6 wks
R-hCG RIA [™] (Roche)	.95 (100)	6-50	1 hr	8 wks
HCG-Beta III [™] (Serono)	1.24 (125)	1	48 hr	.6 wks
HCG-Beta III [™] (Serono)	1.24 (125)	3	1 hr	6 wks
HCG-Beta III [™] (Serono)	1.24 (125)	35	30 min	6 wks
Preg Stat [™] (Serono)	1.26 (75)	25	1 hr	4 wks
Biocept-G [™] (Wampole)	1.92 (30)	200	1 hr	5 wks

*Milli-international units of HCG per liter of urine.

supplies. Radioimmunoassays require expensive, highly technologic equipment and costly, relatively unstable radiologic testing materials. Because of their sensitivity and accuracy, radioimmunoassays, where available, are the tests of choice for the diagnosis of certain complications of pregnancy, such as ectopic pregnancy or threatened or incomplete abortion. These tests are also capable of providing a quantitative measurement of human chorionic gonadotropin.

RADIORECEPTORASSAYS

Radioreceptorassays are similar to radioimmunoassays, although not as sensitive. Where radioimmunoassays have not been available, radioreceptorassays have been the tests of choice for women with complicated pregnancies. Some authorities suggest that the supersensitive tube tests, which have similar levels of sensitivity but are simpler to perform, replace some of the need for the radioreceptorassay.

(For further information about how these tests work, consult your local supplier.)

USING PREGNANCY TESTS

When you are called upon to confirm an uncomplicated normal pregnancy, the slide test is the test of choice (4,6). These tests can detect a pregnancy about 6 weeks after the last normal menstrual period (about 2 weeks after the first missed period). Most facilities use the slide test for screening when the physical examination is inconclusive or if the patient desires laboratory confirmation.

For pregnancies that are complicated, however, other tests are generally preferred, if available. For example, in an ectopic pregnancy, slide tests frequently (50% percent of the time) will yield a falsely negative result (7,12). Tube tests less frequently (15% to 35% of the time) yield a falsely negative result on an ectopic pregnancy (7). If available, the preferred tests include the radioimmunoassays, the radioreceptorassays, or the new supersensitive tube tests.

For many family planning facilities in Africa, the only available test is the slide test. If you are in a clinic that uses only the slide test, the following guidelines may be helpful for managing three of the more serious complications of pregnancy: ectopic pregnancy, threatened or incomplete abortion, and trophoblastic disease.

When the test is positive but the patient has no clinical signs of pregnancy, consider an ectopic pregnancy, trophoblastic disease, or a recent spontaneous abortion.

In many cases, the laboratory tests are used to *confirm* a clinical impression. Whenever the clinical impression and the laboratory test do not agree, BE SUSPICIOUS. Repeat the test. Refer the patient, if necessary. (See Table 8.5 for a list of reasons why false results may occur.)

TABLE 8.5 *False results from a test for pregnancy (13)*

When a pregnancy test produces a result that does not correspond with your clinical impression, consider the following possible explanations:

False negative:

Error in reading results of test

Test performed too early or too late in pregnancy

Urine specimen is too dilute (first morning specimen was not used)

Urine specimen has been stored too long at room temperature

Urine specimens are mislabeled (a patient's name is placed on another woman's specimen)

Too much antiserum is used

The patient is taking medication that interferes with the test

The patient has THREATENED ABORTION, MISSED ABORTION, ECTOPIC PREGNANCY

False positive

Error in reading results of test

Specimen container may have a detergent residue

Specimens may be mislabeled

Patient has proteinuria

Patient has hematuria

Patient may be ovulatory or menopausal

Patient may be taking medications —

psychotropic drugs such as phenothiazines, antidepressants, antiparkinsonian agents, anticonvulsants or *other drugs* such as aldomet, marijuana.

Patient may have the following conditions —

tubo-ovarian abscess

persistent corpus luteum cyst

post-partum period (should be negative after 10 days post partum)

undifferentiated lung cancer

ovarian teratoma

If the patient does not have acute abdominal pain but is amenorrheic and has a small and mobile uterus, repeat the test the next day to rule out a falsely positive result. If the test remains positive, consider that the patient may have either an early interuterine pregnancy or an ectopic pregnancy. Follow the patient closely for 2 weeks, and advise her to contact you if she has pain, feels weak, or has tenesmus, a frequent but unproductive urge to defecate (signs of ectopic pregnancy). If the patient has abdominal pain, refer her for surgical evaluation.

ECTOPIC PREGNANCY

REFER ALL WOMEN WITH ACUTE ABDOMINAL SYMPTOMS FOR SURGICAL EVALUATION. If the slide test for pregnancy is negative, do not be fooled into thinking the results are conclusive.

An ectopic pregnancy may present as a mass in the adnexa. (See Figure 8.2.) Although ectopic pregnancies secrete human chorionic gonadotropin, levels are generally lower than those found in normal pregnancies. For this reason, the pregnancy test may be negative, even though the patient is pregnant. On the other hand, the pregnancy test may be positive, but the patient may not have an enlarged uterus.

If the patient has an adnexal mass with either a positive or a negative pregnancy test or if she has a positive test but your clinical impression is different, refer the patient. Acute abdominal pain means the ectopic pregnancy may have ruptured, and the patient's life may be endangered. (See Figure 8.3.)

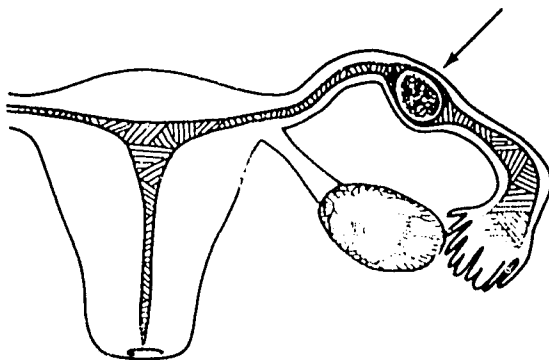


FIGURE 8.2 An ectopic pregnancy may present as a mass in the adnexa.

When the test is negative but the patient has clinical signs of pregnancy, consider an ectopic pregnancy, trophoblastic disease, a recent spontaneous abortion, or an early but normal pregnancy. Consider also that the urine specimen used may not have been a first morning specimen and may, therefore, have been too diluted. When adjusted to different levels of sensitivity, the diagnostic value of the test varies. (See Table 8.6.)

If the patient does not have abdominal pain, repeat the test in 2 weeks. By 2 weeks' time, the pregnancy should have advanced enough to produce higher levels of human chorionic gonadotropin. If the patient has abdominal pain, refer her for a surgical evaluation.

THREATENED OR INCOMPLETE ABORTION

The patient is having bleeding. Her pregnancy test had been positive but now is not. If she does not appear to have passed all tissue, refer her for an evaluation procedure.

Depending upon when you see the patient, she may have either a positive or negative pregnancy test. If abortion has occurred and is not just threatening to occur, it is important to make certain no products of conception are left in the uterus because this can lead to infection. Partially retained tissue may secrete human chorionic gonadotropin, sometimes in levels high enough to be detected, other times not.

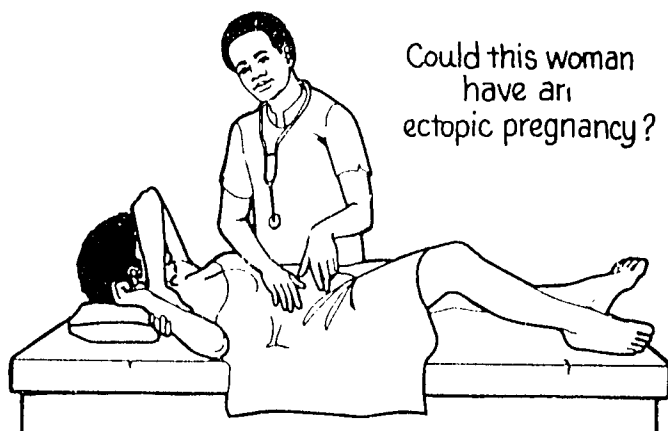


FIGURE 8.3 Detecting an ectopic pregnancy before it ruptures can save a woman's life.

When the test was initially positive but the patient is now bleeding, consider a threatened abortion. Obtain another test. If two morning urine specimens are negative, this may mean the patient has aborted, is carrying a dead fetus, or has an ectopic pregnancy.

TIPS FOR PERFORMING ANY PREGNANCY TESTS ACCURATELY

1. Have trained personnel perform the tests. Provide a supervised workshop where the workers can actually practice performing the tests. In your own facility, provide clear, posted instructions for the type of pregnancy tests you have chosen to use.
2. Instruct your patients how to obtain a good urine specimen. When possible, have them bring their first morning specimen in a clean, well-rinsed receptacle.
3. Label each urine specimen clearly. Do not separate the specimen from the reporting slip until results and names have been recorded. If possible, perform the test as soon as you receive the urine specimen.
4. Be certain that you have enough room in your testing area. Provide room for the actual testing, storing the materials, and for recording results in a clutter-free space.
5. Store tests appropriately. Many tests require refrigeration. Check the instructions supplied with the test. Make certain that you refrigerate the tests that require refrigeration and that you use tests before the expiration date stamped on the kit. (See Table 8.7 for other tips.)

TABLE 8.6 Uses of radioimmunoassay test adjusted to various levels of sensitivity

Test sensitivity	Capabilities and limitations
0.3 IU/ml	Picks up most ectopics and threatened abortions; many false positives
0.6 IU/ml	Picks up some ovulatory and menopausal FSH and LH, i.e., false positives
0.7 IU/ml	Best compromise level for a sensitive pregnancy test
1 IU/ml	Detects HCG as early as 4 to 7 days after missed period, but there are false negatives until day 14
5 IU/ml	Detects HCG as early as 7 to 10 days after missed period; if done too early, there may be false negatives; when properly done, false positives are rarely a problem with this test

TIPS FOR ORDERING PREGNANCY TESTS

1. Choose the type of test that has an expiration date stamped on the box and that has a distributor who will be available to replace faulty tests, to provide educational aids, and offer reasonable prices.
2. Determine what level of sensitivity you need for your purposes. Do not buy the more expensive and more sensitive tests if you do not usually require them at your facility.
3. Estimate the number of tests you will need before you order supplies. This should prevent your running out of tests when you need them or having tests expire because you cannot use them in time.

TABLE 8.7 How to get maximum accuracy from your pregnancy test (checklist of errors and corrections in performing pregnancy tests)

Errors	Corrections
Formation of layers	Mix well
Contamination of containers, work surface, pipette tips, reagents	Reevaluate technique used
Too many people using a kit	Give each person his or her own kit
Occasional testing	Have same person do the tests all the time
Patient error; someone else's urine	Sample given on the spot
Labeling error	Devise foolproof system

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CHAPTER 9

CHOOSING A CONTRACEPTIVE: EFFECTIVENESS, SAFETY, AND OTHER CONSIDERATIONS

Family planning decisions should be made on a completely voluntary basis, but also on the basis of thoroughly informed choice on the part of individuals and couples. A decision about childbearing cannot be called voluntary if individuals and couples have not been previously educated and informed about the meaning of family planning to their lives and the lives of their children and about the methods of family planning that are available.

Dr. Fred T. Sai

DEVELOPING A REPRODUCTIVE LIFE PLAN

This chapter is about choosing. It is a part of everything we do in life. Each society emphasizes helping young people and adults plan their lives. We often do not spend nearly enough time planning our families, so it should be no surprise that the family as an institution is being challenged in many areas of the world. In view of the importance of fertility, infertility, childbearing, and family, it might be wise for most of us to consider how we could help others, particularly adolescents, think clearly and creatively about their own *reproductive life plans*:

- When would I like to have a child? How many do I really want? Am I able to plan for a healthy, happy childhood for them?
- How should I space my children? Should I use a contraceptive?
- What contraceptive would be best for me? The most effective? The safest?

Every person, whether from a traditional or modern culture, already has at least a partially developed reproductive life plan. Cultural expectations about when to marry, when to bear children, and how many children to have can be strong and can form a person's future. In the process of accepting or challenging these expectations, one is actually forming a reproductive life plan. (See Figure 9.1.)

CHOOSING A CONTRACEPTIVE

If there were a perfect method of birth control, we would not need this chapter. A perfect contraceptive would be 100% effective, totally safe, available to everyone, inexpensive, completely without side effects, instantly

FIGURE 9.1 *Development of a reproductive life plan.*

QUESTIONS FOR USERS

The following questions are intended as aids in developing a reproductive life plan. They should be answered privately by the user alone, when possible. (Many of these questions can also aid men in developing a reproductive life plan.)

FOR UNMARRIED WOMEN WHO HAVE NOT YET HAD CHILDREN

1. Would I like to wait until I am married before having sexual intercourse?
2. At what age would I like to be married if I could get married whenever I wanted to?
3. Would I like to have children someday?
4. How old would I like to be when I have my first child?
5. How many children would I be happy having?
6. What are the things that I would like to achieve most in life, and by when?
7. Of all the things that I could do in life, probably the most important would be to accomplish this:
.....
.....
8. This life goal would affect (or be affected by) childbearing in the following ways:
.....
.....
9. How concerned would I be if I were to become pregnant before I was ready?
10. What would I do if I were to become pregnant before I wanted to have a (another) child?
11. How compatible is my life plan thus far with my religious beliefs, with what I personally feel God/Allah would want me to be doing, with what I personally feel is "right" or "wrong," and with what is expected of me by those who are important to me?

FOR MARRIED OR UNMARRIED WOMEN WITH CHILDREN

1. Would I like to have more children one day?
2. How many children would I be happy having?
3. What are the things that I would like to achieve most in life, and by when?
4. Of all the things that I could do in life, probably the most important would be to accomplish this:
.....
.....
5. This life goal would affect (or be affected by) childbearing in the following ways:
.....
.....
6. How old would I like to be when I have my last child?
7. How concerned would I be if I were to become pregnant again before I was ready?
8. What would I do if I were to become pregnant before I wanted to have a (another) child?
9. How compatible is my life plan thus far with my religious beliefs, with what I personally feel God/Allah would want me to be doing, with what I personally feel is "right" or "wrong," and with what is expected of me by those who are important to me?

reversible, and easy to use. It would not interfere with intercourse in any way and would require no advice or care from a clinician. There is no such method today, and, according to research experts, there are no likely prospects for the near future.

In the absence of a perfect method, two considerations rise to the top as the most important in the minds of couples considering contraceptives—*effectiveness* and *safety*.

EFFECTIVENESS

Patient questions about effectiveness

No one would bother with a contraceptive were it not felt to be effective. One hears many questions about effectiveness:

“Which is the most effective method?”

“Which do you think would be the most effective method for me?”

“Why did one doctor tell me diaphragms were 98% effective and another say they were 80% effective?”

“Can you get pregnant if you take your Pills every day?”

“Will the method I’m considering really work?”

Providing fair answers about effectiveness

“Will it work?” is the question asked first and most frequently about any birth control method. We suspect that those who ask “Will it work?” are in fact asking, “How well will it work for me?” Since this query cannot be answered for an individual woman, most clinicians feel it wise to provide two answers. They provide an effectiveness rate for women who use the method consistently and correctly (method effectiveness), and they provide a rate of effectiveness for typical users of the method (user-effectiveness). Different reliable researchers may report different effectiveness rates for the same method. This is largely caused by differences in how they conducted their studies and in the groups of women they studied. To avoid confusing users while still explaining to them both the method- and user-effectiveness of different methods, we suggest using Table 9.1. The rates reported in this table are widely accepted by researchers and clinicians. As these user-effectiveness rates were derived largely from studies conducted in developed countries where family planning and other services are relatively easily available, use these rates as guidelines—not as an absolute statement of the user-effectiveness in the geographic area you serve.

Predicting user-effectiveness for the individual user

The authors of *Contraceptive Technology* are aware that the effectiveness rates in Table 9.1 can vary. Method-effectiveness rates change along with

changes in the technology of contraceptives, such as lowering the amount of estrogen or progestin in Pills or adding copper or progesterone to an IUD. Actual user-effectiveness rates for any one method may vary for many reasons.

An individual's acceptance of a method is partially conditioned by his or her attitudes and the attitudes of others toward the method, and contraception in general. Figure 9.2 is included to help users establish their true feelings about methods under consideration.

TABLE 9.1 *First-year failure rates of birth control methods*

Method	Lowest Observed Failure Rate*	Failure Rate in Typical Users **
Chance (no method of birth control) (1)	70	70
Tubal ligation (2)	0.04	0.04
Vasectomy (3)	0.15	0.15
Injectable progestin (4, 5)	0.25	0.25
Combined birth control Pills (6-8)	0.5	2
Progestin-only Pill (9, 10)	1	2.5
IUD (6, 11, 12)	1.5	4
Condom (6, 7, 13)	2	10
Diaphragm (with spermicide) (6, 7, 14, 15)	2	13
Cervical cap (16)	2	13
Foam, creams, jellies, and vaginal suppositories (7, 17, 18)	3-5	15
Coitus interruptus (19)	16	23
Fertility awareness techniques (6, 7, 20, 21) (basal body temperature, mucus (22, 23) method, calendar, "rhythm," and douche (24-26))	2-20	20-30

* Designed to complete the sentence: "Of 100 women who start out the year using a given method, and who use it correctly and consistently, the number who will be pregnant by the end of the year will be ____."

**Designed to complete the sentence: "Of 100 typical users who start out the year using a given method, the number who will be pregnant by the end of the year will be ____."

FIGURE 9.2 Questions for individuals considering use of a specific method of birth control.

The following questions have been developed so that every “yes” response indicates to the potential user of a method of birth control a factor that might lower the effectiveness of a given method. When possible, users should be encouraged to answer these questions for themselves, in private. Or you may find it useful to select some of these questions to pose and discuss with them.

BACKGROUND: For each method of birth control there is a rate of failure or an estimated number of pregnancies that can be expected if that method is used perfectly. Since you will be using your method of birth control to avoid an unplanned pregnancy, you want to get just as low a pregnancy rate as possible. You want to be able to use your method **CORRECTLY** and **CONSISTENTLY**. Obviously, the rate of pregnancies, or failure rate, goes up if for any reason you don’t use the method or if you fail to use it exactly as it was designed to be used. The following questions were developed to help you decide if the method you are considering is a good choice or a poor choice for you.

METHOD OF BIRTH CONTROL YOU ARE CONSIDERING USING:

Have you had trouble with this method before?	Yes	No
If yes, what were the problems?		

PLEASE ASK YOURSELF THESE QUESTIONS	Yes	No
1. Am I afraid of using this method?		
2. Would I really rather <i>not</i> use this method?		
3. Will I have trouble remembering to use this method?		
4. Will I have trouble using this method correctly?		
5. Do I still have unanswered questions about this method?		
6. Does this method cost more than I can afford?		
7. Is this method known to have serious complications?		
8. Am I opposed to this method because of any religious or personal beliefs?		
9. Is my partner or others who are important to me opposed to this method?		
10. Am I using this method without my partner's knowledge?		
11. Will use of this method embarrass my partner or others who are important to me?		
12. Will use of this method embarrass me?		
13. Will I enjoy sex less because of this method?		
14. Will this method interfere with lovemaking?		
15. Has a midwife, nurse, or doctor ever told me not to use this method?		
16. Is there anything about my personality which would cause me not to use this method correctly?		
17. Will I be able to return to the clinic when I need to in order to continue using this method?		
18. Do I know what I should do if I have problems with the use of this method?		

TOTAL NUMBER OF YES ANSWERS: _____

When answering the questions in Figure 9.2, most persons will have several “yes” responses, indicating, unfortunately, that potential problems do lie in store for people using almost any method of birth control. If you have a number of “yes” responses, you may want to discuss some of these with your clinician, counselor, partner, or friend. This may help you to decide whether to use this method or how to use it to its maximum effectiveness. In general, the more “yes” answers you have, the less likely you are to use this method consistently and correctly.

SAFETY

Just as no contraceptive is 100% effective, no contraceptive is without risk. In fact, there are a variety of risks one might expose oneself to by using a method. First, there are the risks related to the inherent dangers of the *method*. How often might the method be associated with death, hospitalization, loss of fertility, hysterectomy, pain, infection of the genitourinary tract, etc.? Secondly, there are potential risks in terms of *inconvenience*. Does the method make sexual intercourse less pleasant or even unpleasant, is there great expense, lost time from work, or partner dissatisfaction or embarrassment associated with the method? Finally, there are risks associated with *pregnancy should the method fail* (or should the couple make a mistake using the method). How often does pregnancy occur? What are the dangers of pregnancy to this woman? Would pregnancy cause the family hardship? All too often, a method is classified as completely harmless because the inherent medical dangers of the method are minimal, while the inconveniences of the method and the very real risks associated with the pregnancies that can occur using the method are overlooked by the person considering the method.

Risks in everyday life

When it comes to death, the most serious risk of a contraceptive, the absolute level of risk is very low — indeed, so low that most people have little appreciation of the magnitude of risk involved. When we use the phrase, “it is a one in a million possibility,” we usually mean to imply that it almost *never* happens. But, of course, for that one person who suffers a complication, it is now a 100% reality, not a one in a million risk. Table 9.2 puts some of the risks of life in the United States into perspective. While it could not and should not be used to totally allay the concern of a woman choosing Pills, it helps a woman to compare the risks of Pills to other voluntary risks to which she exposes herself. Several of these risks are probably very different in Africa. For example, the risk of death from each pregnancy is 10 in 100,000 in the United States and is reportedly between 200 and 1,200 per 100,000 in Africa (27,28).

Contraindications

Some women are more likely than others to encounter problems with a specific method of birth control. Contraindications to the methods are an important consideration for a woman making a birth control choice. A contraindication is a medical condition that renders inadvisable or unsafe a course of treatment that might otherwise be recommended.

Clinicians usually rank contraindications on three levels:

1. *Absolute* contraindications: you *must not* try to use the method.
2. *Strong relative* contraindications: you will be *strongly advised* not to use the method. However, if other factors rule out the use of alternative methods, then this method would be acceptable if you are carefully followed for early signals of trouble.
3. *Other relative* contraindications: you may be able to try the method if you know that you may have problems with it and are willing to assume responsibility for seeking help the moment early danger signals appear.

Most of the serious complications of Pills and IUD's could be avoided by not giving the methods to women for whom they are contraindicated.

Using contraceptives cautiously—danger signals:

When helping a woman choose the method she can use safely as well as effectively, you must be able to teach the individual the danger signals of the method she is considering. If a danger signal does appear, the informed user can quickly seek help. This is particularly important should the method she is considering be the Pill or the IUD.

BY TEACHING WOMEN THE PILL AND IUD DANGER SIGNALS,
THE MOST SERIOUS CONTRACEPTIVE COMPLICATIONS CAN
BE PREVENTED

OTHER CONSIDERATIONS IN CHOOSING A METHOD

Pattern of sexual activity

Regarding their contraceptive choice, women and men should be and are influenced by the number of partners they have had and their frequency of intercourse. For example, a woman who has several partners might find condoms, foam, or a diaphragm relatively inconvenient even though they might be quite desirable in terms of preventing infection. Very infrequent intercourse might make a person not want to expose herself to the risks of Pills or an IUD. The risk of infection to a woman with a number of partners would make one advise against the IUD rather strongly.

Access to medical care

Because of high levels of method and user effectiveness—if users are properly screened for contraindications—the IUD and the Pill are both good choices for most women. (See Chapters 11 and 13.) Most complications resulting from either method are medically treatable. However, 70% of the population in Africa is rural, and at this point in the development of the health services of most countries, health facilities are not easily accessible for a large portion of women in their childbearing years. Consequently, trained health personnel are not readily available to treat complications from either contraceptives or from pregnancy or childbirth.

When weighing the pros and cons of providing Pills or IUD's in hard-to-reach areas, keep in mind that the risk of pregnancy-related mortality is very great in Africa, whereas the risk of mortality associated with the use of contraceptives has been found to be low in developed and developing countries alike. (See Table 9.2.)

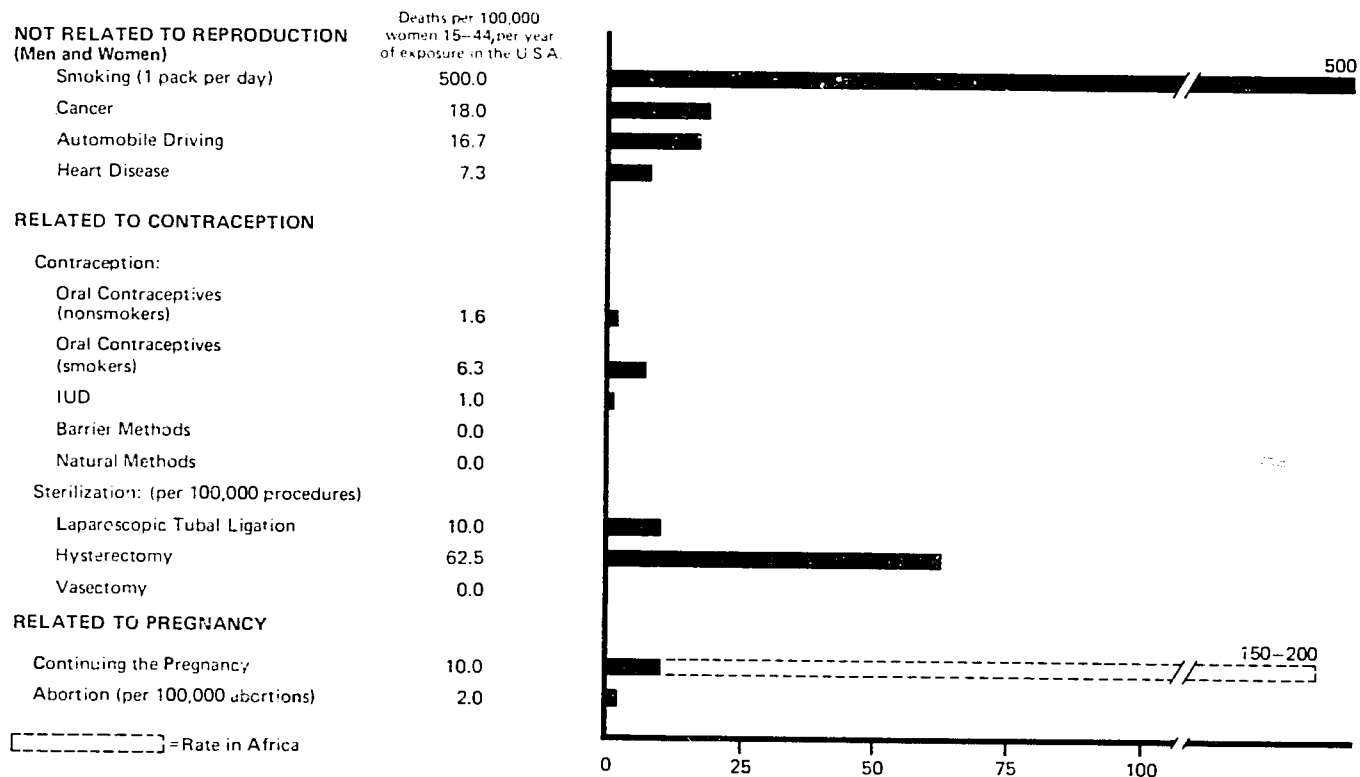
Even if a community-based distribution system has been established, the usefulness of the Pill for rural women is compromised *unless* the system provides for dependable resupply of oral contraceptives. Women are typically given one to three cycles of Pills to start with and are asked to return to replenish their supply. If upon return, packets of Pills are not available, these women will return home unprotected and will run the risk of becoming pregnant.

The IUD is an important contraceptive method for rural women if adequate screening is done and venereal diseases or other risk factors associated with pelvic inflammatory disease (PID) are not prevalent in the program area. The IUD is particularly convenient since the user usually needs to be motivated only once. However, the IUD should not be used indiscriminately because its use significantly increases the likelihood of PID. (See Chapter 13.) Therefore, strict criteria and thorough screening before the IUD is inserted are required. Given the limitations of both the Pill and the IUD, long-acting progestin injections may be a very attractive option to consider.

Cost of contraceptive

Most ministries of health in Africa do not charge for maternal and child health services, including family planning. Private physicians, clinics, and family planning associates customarily do charge for services. In both cases, women invest their time, loss of wages, and travel money in obtaining family planning services. A woman *should* be told in advance what her ongoing investment will be while using a particular method. If this will prove to be a major hardship, then an alternative contraceptive, or a means of obtaining the desired contraceptive without hardship, should be found.

TABLE 9.2 Putting into perspective the risks of mortality associated with contraceptive use (29,30)



Cooperation between men and women

Certain methods cannot be used over time without the man's cooperation. Condoms, foam, and often the diaphragm fit into this category. Fertility awareness methods, with attendant long periods of abstinence, require a stable relationship and mutual trust. Although IUD's, Pills, and injectable hormonal contraceptives can be used by a woman without a man's knowledge, it is more likely that she will continue to use the method effectively over time if the man is knowledgeable about family planning and the method and is supportive.

HOW EFFECTIVE ARE CONDOMS?
DOES THE ANSWER AN INDIVIDUAL RECEIVES
DEPEND ON WHICH PERSON IN YOUR CLINIC IS ASKED?

A woman's needs during the reproductive life

As a provider of services, you are accustomed to recommending a change in method if a woman develops side effects or if danger signals appear. In addition, you should expect, and in some cases encourage, women to use different contraceptive methods at different points in their reproductive life. For instance, if a young couple wants to postpone having their first child for a few years, a dependable temporary contraceptive like the Pill or diaphragm might be the method of choice. After the first child, the couple may choose to resume use of the same method or may decide to use a different one (condom and foam, natural methods) to space other children. If the parents reach a point where they are uncertain about having more children, a long-term method such as the IUD or an injectable contraceptive might be adopted. Once the couple decides that they do not want to have more children, either the man or the woman may elect to have a sterilization performed or to continue using (or use) an injectable method.

Choosing method for a program

Choosing the appropriate contraceptive methods to provide to women of different reproductive experiences and ages who live in ecologically and culturally different areas within a country is complex. Making appropriate decisions often involves seeking a compromise between:

- *The medically sound.* Prevalence of disease that contraindicates the use of a method, availability of adequate sanitation to permit the use of some methods, prevalence of marital arrangements that result in multi-

ple sex partners, risk of serious side effects and their relative importance, etc.

- *The practical* Method-specific continuation rates, cost of methods, transportation, shelf life, storage requirements, the need for sophisticated or costly equipment and supplies, complexity of training, etc.
- *The politically desirable*. Positions held about specific methods by influential interest groups, scientific opinion of international organizations and experts, other commitments that could limit the ability to develop an adequate delivery mechanism for a specific method, etc.

We can only recommend that those of you who are faced with making these decisions take into consideration some of the epidemiologic facts available in Table 9.2 and elsewhere in this book or other sources (relative risks, mortality and morbidity rates) so that the public health impact of your decisions is carefully weighed.

DEALING WITH METHOD FAILURES

What would your patient do were she to have a contraceptive failure?

If 1,000 women are using the Pill exactly as instructed, only 5 would be expected to become pregnant. Out of 1,000 perfect users of condoms or the diaphragm, 20 pregnancies would be expected. A woman who is totally uncomfortable with the possibility of a method failure might find the use of two contraceptives simultaneously (e.g., condoms and foam) an attractive option.

INFORMED CHOICE

The importance of informed choice in family planning has three bases: the pragmatic, the ethical, and the legal. Pragmatically, a user who thoroughly understands her/his contraceptive method may well be able to use it more safely and effectively. Ethically, every user has a right to have complete information about her/his method. The physician should provide adequate information in assisting the patient to reach a reasonable and informed decision about family planning medications and procedures.

At present, the whole subject of informed choice is not as widely debated and discussed in Africa as it is in America. However, it is of increasing interest to staff members working in hospital-based and large urban family planning clinics in Africa, and for this reason it is included in this book.

The Elements of an Informed Choice

The simple mnemonic, BRAIDED, may prove useful in remembering (1) what information needs to be provided to users and (2) some key points for the individual to consider in making a choice:

Benefits of the method (1).

Risks of the method (all major risks and all common minor risks) (1).

Alternatives to the method (including abstinence and no method) (1).

Inquiries about the method are the patient's right and responsibility at any and all times (2).

Decision to withdraw from using the method should be accepted by staff without disapproval.

Explanation of the method should cover how to use the method, what to expect, and what to do if there are danger signs (1).

Documentation of the above (2).

COMPETENCE TO CHOOSE

It is the responsibility of the health professional to ascertain that each person who obtains a family planning method has *sufficient information* on the proposed treatment and that this person is *competent to make a choice*. Sometimes it is very difficult to judge just who is and who is not competent to understand the information being provided about modern contraceptives.

The basic criteria for competence to choose are:

- Is the user capable of understanding the proposed method, the alternatives, and the risks?
- Is the user capable of balancing the pros and cons of alternatives and of arriving at a conclusion?

In some situations the individual's competence is quite difficult to evaluate. The very young adolescent, the mentally retarded, and the mentally ill user are examples of such situations. As difficult and uncomfortable as it may be to apply these criteria to specific cases, we must be prepared to do so since we are or may be called upon to sit in judgment. If there is any doubt about the competence of the person to choose to plan a family through the use of contraceptives, consult with other professionals to determine the appropriate course of action. This consultation must be in the person's record.

In America, a number of family planning programs have begun to use consent forms as an important part of patient education and now provide each patient with a copy of the form. These can reinforce what patients have already learned about the benefits, risks, and danger signs associated with a method.

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SECTION III

CONTRACEPTIVE TECHNOLOGY

CHAPTER 10

HORMONAL CONTRACEPTIVES: AN OVERVIEW*

Hormonal contraceptives are the most popular and most effective non-surgical methods of child spacing and fertility control in the world. In Africa where many women associate family planning with "birth control Pills," the Pill has become the most accepted contraceptive method. Unlike the IUD, the barrier methods, and the natural family planning methods, hormonal contraceptives have no traditional uses in history, since they are fairly new additions to the family planning field. Most of the serious work with hormonal contraceptive development began in the 1950's.

Hormonal contraceptives consist of synthetic compounds made to resemble actual hormones within a woman's body. These hormones, estrogen and progesterone, are essential for the functioning of the menstrual cycle (see Chapter 7) and, hence, for ovulation which is required for fertilization to occur. Early researchers believed that if they could interrupt the menstrual cycle with the synthetic compounds they could then prevent ovulation and implantation. (See Table 10.1.)

The first Pills marketed were combined ones, which contained both estrogen and progestin (or laboratory-produced progesterone). In the early 1960's, the combined Pills contained about 100 to 150 mcg (micrograms) estrogen and about 1 to 10 mg (milligrams) progestin. The Pills were extremely effective. But studies showed that the use of these Pills was associated with serious cardiovascular side effects in some women. Further, annoying minor side effects caused many women to stop using the Pills.

When it became clear that estrogen was the primary cause of the side effects, researchers began to lower the dose of estrogen in the Pills and to develop progestin-only contraceptives. (Refer to Chapters 11 and 12.) Today, the dose of estrogen in combined Pills is between one-third to one-fifth the dose in the earlier combined Pills. Most Pills provided to today's users contain only 30 to 50 mcg of estrogen and 1 mg or less of progestin. The progestin-only contraceptives include the Mini-Pill, long-acting progestin injections (such as Depo-Provera), plastic IUD's filled with progesterone, and progesterone-containing silastic capsules and cervical rings. (Refer to Chapter 12.) Although extensive studies still need to be conducted, some evidence suggests that the lower-dose combined Pills and the progestin-only contraceptives cause fewer side effects than the earlier Pills which have been studied.

*Specific references documenting the central points made in this overview that are available in Chapters 11 and 12 have not been reported in this chapter.

WHAT ARE SOME OF THE SIDE EFFECTS OF THE PILLS?

As with all the other methods, one risk is that of failure and the resulting risk of pregnancy. (Refer to Chapter 9, Table 9.2.) The most serious side effects, however, are cardiovascular. Yet, these effects (high blood pressure, blood clots, heart attack, and stroke) occur primarily in the woman who is older than 35 years and smokes or the woman who has an underlying disease that contraindicates the use of the Pill. For the rest of the female population, the risks of these serious complications are quite low. Moreover, the risk of death from any cause is lower in Pill users than in women who go through a full-term pregnancy and delivery. Some of the minor side effects from hormonal contraceptives include nausea, weight gain or bloating from water retention, and changes in menstrual bleeding.

WHAT ARE SOME OF THE BENEFITS OF THE PILLS?

These include an extremely high rate of effectiveness, relief from symptoms of the menstrual cycle, a decrease in iron-deficiency anemia associated with a heavy menstrual flow, some protection against the development of pelvic inflammatory disease, reduction in endometriosis, and a decrease in ovarian cysts, benign breast tumors, cancer of the uterus, and cancer of the ovary.

TABLE 10.1 How does the Pill prevent pregnancy?

Demonstrated mechanisms of action

OVULATION is inhibited. The hypothalamus cannot detect a pattern of change in estrogen levels and thus does not stimulate release of FSH and LH, which are required for the ovary to release an egg. Pills containing less than 50 mcg estrogen probably only suppress ovulation 95%-98% of the time.

***OVULATION** may be inhibited. Subtle changes in progesterone levels may modify the midcycle surge of FSH and LH to alter the hypothalamic-pituitary-ovarian axis.

***IMPLANTATION is inhibited.** High-dose estrogens work against the progestational effects on the uterus, alter the normal secretory development, and cause marked edema with areas of dense cellularity. This action has been shown with postcoital estrogens: ethinyl estradiol given in four to seven times the dose in combined Pills and DES in 500 to 2,000 times a comparable dose in combined Pills. Progestins may alter the FSH and LH peaks enough to decrease the progesterone released by the corpus luteum to prepare the endometrium for pregnancy. The decreased progesterone leads to a resting, atrophic lining.

***THICK, HOSTILE CERVICAL MUCUS** associated with the use of progestins hampers sperm transport. The cervical mucus is scanty but thick and cellular, with decreased ferning patterns and spinnbarkeit.

Theoretical mechanisms of action

***OVUM TRANSPORT** is accelerated by estrogen, as shown in animal studies. However, this is not known to be an important mechanism in preventing pregnancy. Ovum transport is slowed by progestins. Slowed transport may cause a partially degenerated ovum to implant in the uterus, resulting in a defective fetus. It may increase the risk of ectopic pregnancy.

***CAPACITATION is inhibited.** Capacitation, the activation of hydrolytic spermatic enzymes in the head of the sperm, is required for the sperm to penetrate the cells and macromolecules surrounding the ovum.

LUTEOLYSIS may occur. The degenerating corpus luteum cannot maintain normal serum progesterone levels required for normal implantation.

*The mechanisms of action of progestin-only methods have not been demonstrated. The items marked with asterisks are suggested mechanisms of action.

CHAPTER 11

COMBINED ORAL CONTRACEPTIVES: "THE PILL"

The most important contribution that the Pill, together with the various IUD's, has made worldwide is to teach people that reversible contraception can be completely separated from coitus by a method that for the first time permits the woman herself to decide whether and how to control her own fertility.

*Carl Djerassi
The Politics of Contraception, 1979*

HISTORY, MECHANISM OF ACTION, AND EFFECTIVENESS

HISTORY

The oral contraceptive Pill has been in use for about 20 years. As studies began to show an association between the use of oral contraceptives and certain side effects, researchers gradually reduced the dose of hormones, particularly estrogens. These lower-dose Pills have been shown to be safer than the earlier higher-dose Pills.

Oral contraceptive Pills are now used by some 50 million to 100 million women throughout the world. In many African countries, the Pill is the most popular method of contraception. Its effectiveness and relative safety have made the Pill not only an accepted, but often a preferred method of contraception for many women.

In this chapter, you will learn guidelines to help you reduce the risk of serious complications developing in Pill users. By not giving the Pill to women who have contraindications and by teaching users the Pill's "danger signals," you can help make the Pill an even safer method.

MECHANISM OF ACTION

How do combined oral contraceptives work? Estrogenic agents may have contraceptive effects by influencing normal patterns of ovulation, or ovum transport, implantation, or placental attachment.

The progestins also have a number of potential contraceptive effects. Normally, progesterone (pro=on behalf of; gestation=pregnancy) prepares the endometrium for implantation and maintains pregnancy. Progestation agents also may have several contraceptive effects. (See Chapter 10.)

EFFECTIVENESS

The Pill and injectable contraceptives have the highest effectiveness rate of all nonsurgical contraceptive methods. In theory, the effectiveness of the Pill should be close to 100%. However, the actual effectiveness rate is difficult to determine because many factors influence effectiveness. Does the woman use her Pills correctly and consistently? Does she have a reliable means of obtaining resupplies? Does the family planning program make it easy for patients to comply? Many pregnancies occur when women discontinue Pill use but fail to begin another method of contraception and therefore have unprotected intercourse. Although rare, pregnancies can also occur even though the woman has taken all of her Pills. The Royal College study reported that for every 300 women using the Pill in a given year, one pregnancy could be expected (1).

CONTRAINDICATIONS TO ESTROGEN-CONTAINING PILLS

Although the Pill is a safe contraceptive method, it is not appropriate for every woman.

Listed below are some of the contraindications to Pill use. When considering use of the Pill for women with strong relative contraindications (see Chapter 9), it is extremely important to weigh both its risks and benefits. Alternatives to the Pill must be considered by both the clinician and the patients.

CONTRAINDICATIONS TO COMBINED BIRTH CONTROL PILLS CONTAINING BOTH AN ESTROGEN AND A PROGESTIN

Absolute contraindications

1. Thromboembolic disorder (or history thereof)
2. Cerebrovascular accident (or history thereof)
3. Coronary artery disease (or history thereof)
4. Known impaired liver function at present time
5. Hepatic adenoma (or history thereof)
6. Malignancy of breast or reproductive system (or history thereof)
7. Known pregnancy

Strong relative contraindications

- *8. Severe headaches, particularly vascular or migraine
- *9. Hypertension with resting diastolic blood pressure of 90 or greater on three or more separate visits, or an accurate measurement of 110 or more on a single visit
- *10. Diabetes
11. Prediabetes or a strong family history of diabetes
- *12. Gallbladder disease, including cholecystectomy

13. Previous cholestasis during pregnancy, congenital hyperbilirubin (Gilbert's disease)
14. Mononucleosis, acute phase
- *15. Sickle cell disease (ss) or sickle C disease (sc)
- **16. Undiagnosed, abnormal vaginal bleeding
- *17. Elective surgery planned in next 4 weeks or major surgery requiring immobilization
18. Long-leg casts or major injury to lower leg
- *19. Over 40 years of age
- *20. History of heavy smoking and over age 35
21. Impaired liver function within past year

Other relative contraindications

- A. May contraindicate initiation of Pills:
 - *22. Termination of term pregnancy within past 10-14 days
 23. Weight gain of 10 pounds or more while on Pills
 - *24. Failure to have established regular menstrual cycles
 - *25. Patient with profile suggestive of anovulation and infertility problems: late onset of menses and very irregular menses
 - *26. Cardiac or renal disease (or history thereof)
 - *27. Conditions likely to make patient unreliable at following Pill instructions (mental retardation, major psychiatric problems, alcoholism, history of repeatedly taking Pills incorrectly)
 - *28. Lactation (oral contraceptives may be initiated after lactation is fully established)
- B. May initiate Pills for women with these problems and observe carefully for worsening or improvement of the problem:
 - *29. Depression
 - *30. Hypertension with resting diastolic blood pressure at a single visit of 90-99
 - *31. Chloasma or hair loss related to pregnancy (or history thereof)
 - *32. Asthma
 - *33. Epilepsy
 - *34. Uterine fibromyomata
 35. Acne
 - *36. Varicose veins
 37. History of hepatitis but results of liver function tests have been normal for at least 1 year.
- *Contraindication to estrogen-containing Pills, which may not be a contraindication to progestin-only Pills.
- **Several reviewers of this book strongly feel this should be listed as an absolute contraindication to Pill use. It remains here since we cannot in a simple, straightforward manner define "abnormal." If you, the clinician, feel that the patient's bleeding pattern is "abnormal," do not provide her with birth control Pills.

PROVISION OF COMBINED PILLS

HELPING A PATIENT CHOOSE THE APPROPRIATE PILL

Since Pills first became available, there have been numerous Pill preparations from which clinicians and patients can choose. The decision regarding which Pill to prescribe for a particular user is complex, since all Pills are not the same. This section is intended to help you make this decision.

Pills containing an estrogen and a progestin (combined Pills) may be an excellent initial contraceptive choice for healthy women early in their reproductive years, for post-partum women after they have stopped nursing their babies, and for women who have had a miscarriage or an induced abortion. Effective use of Pills and high Pill-continuation rates tend to occur when the Pill user is conscientious and can get thoughtful answers to questions and concerns about Pills; when family planning workers are supportive of this method; when supplies are available to users at the time of a followup visit; and when the user enjoys noncontraceptive effects of the Pill, such as a reduction of menstrual cramping or in heavy menses.

Assumptions

Once the patient and her clinician have decided that a combined Pill is the desired means of birth control and the various contraindications to Pills have been eliminated, the clinician must recommend a specific Pill.

The assumptions upon which the clinicians might make this recommendation are as follows:

1. The Pill provided should minimize the risk of the patient's developing major or minor side effects.
2. It is currently very difficult to predict which women will develop serious Pill-associated complications.
3. The estrogenic component of the Pill is responsible for most of the major Pill-associated complications and also for most of the minor side effects which can lead to discontinuing its use.
4. The progestin component of the Pill is responsible for some of the minor side effects that can lead to Pill discontinuation, but to a lesser degree than is the case with estrogens.
5. The cost and availability of oral contraceptives may be important to persons using, and to public family planning programs providing Pills.

Checklist For Use *Before* Dispensing Oral Contraceptives

Check the following (starting from the head and working down)

Head

- | | |
|---|--------|
| 1. Do you have severe headaches? | Yes/No |
| 2. Do you have problems with severe depression? | Yes/No |
| 3. Do you have seizures or convulsions or epilepsy? | Yes/No |

Chest

- | | |
|---|--------|
| 4. Do you ever have severe chest pain? | Yes/No |
| 5. Do you get very short of breath after walking or after light work? | Yes/No |
| 6. Have you ever had a lump in the breast? | Yes/No |
| 7. Are you nursing a baby who is under 6 weeks of age? | Yes/No |

Abdomen and Pelvis

- | | |
|---|--------|
| 8. Do you think you could be pregnant <i>now</i> ? | Yes/No |
| 9. Have you missed a period recently? | Yes/No |
| 10. Have you missed a period and then started bleeding? | Yes/No |
| 11. Do you have bleeding between periods or after sexual intercourse? | Yes/No |

Legs

- | | |
|---|--------|
| 12. Do you have severe leg pains or painful varicose veins? | Yes/No |
| 13. Do you have swelling or warmth (heat) in your legs? | Yes/No |
| 14. Have you ever had a clot in your legs? | Yes/No |

Other

- | | |
|---|--------|
| 15. Do you smoke? | Yes/No |
| 16. Are you over 35 years of age? | Yes/No |
| 17. Have you ever been treated for high blood pressure? | Yes/No |
| 18. Have you had any operation in the past 2 weeks? | Yes/No |
| 19. Have you ever had sugar in your urine? | Yes/No |
| 20. Do you have sickle cell disease? | Yes/No |

If all the above answers are "No," the woman may be given oral contraceptives.

If any are "Yes," it may be desirable for a woman to be seen by a doctor, nursing sister, or nurse. If you do decide to give oral contraceptives, you may need to arrange for the woman to be seen by a family planning worker within 2 months.

COMBINED PILLS AVAILABLE IN AFRICA

Table 11.1 lists the combined Pills currently available in Africa. The pyramid (Table 11.2) shows the relative estrogens and progestational strengths of various Pills.

TABLE 11.1 *Characteristics of combined oral contraceptives*

Proprietary Name	Manufacturer	No. of tablets	Estrogen	mg	Progestogen	mg
*Anovlar [®]	Schering	21	EE**	0.05	Norethisterone acetate***	4.0
*Brevicon [®]	Syntex	28	EE	0.035	Norethindrone	0.5
*Conovid-E [®]	Searle	20	Mestranol	0.10	Norethynodrel	2.5
*Demulen [®]	Searle	21 or 28	EE	0.05	Ethinodiol diacetate	1.0
Enavid E [®]	Searle	20	Mestranol	0.075	Norethynodrel	5.0
Eugynon 50 [®]	Schering	21 or 28	EE	0.05	Norgestrel	0.5
Gynovlar 21 [®]	Schering	21	EE	0.05	Norethisterone acetate	3.0
Loestrin 20 [®]	Parke, Davis	21	EE	0.02	Norethisterone acetate	1.0
*Lyndiol [®]	Organon	22	EE	0.05	Lynestrenol	2.5
Metrolen 50 [®]	Searle	2	Menstranol	0.10	Ethinodiol diacetate	2.0
*Microgynon 30 [®]	Schering	21 or 28	EE	0.03	Levonorgestrel	0.15
Minilyn [®]	Organon	22	EE	0.05	Lynestrenol	2.5
*Minovlar [®]	Schering	21 or 28	EE	0.05	Norethisterone acetate	1.0
*Neogynon [®]	Schering	21 or 28	EE	0.05	Levonorgestrel	0.25
*Nordiol [®]	Wyeth	21 or 28	EE	0.05	Levonorgestrel	0.25
*Nordette [®]	Wyeth	28	EE	0.03	Levonorgestrel	0.15
*Norminest [®]	Syntex	28	EE	0.035	Norethindrone	0.5
Norinyl-1/50 [®]	Syntex	21 or 28	Mestranol	0.05	Norethisterone	1.0
*Norlestrin [®]	Parke, Davis	21 or 28	EE	0.05	Norethisterone acetate	2.5
*Orlest [®]	Parke, Davis	21 or 28	EE	0.05	Norethisterone acetate	1.0
*Ortho-Novum 1/50 [®]	Ortho	21	Mestranol	0.05	Norethisterone	1.0
*Ortho-Novum 1/80 [®]	Ortho	21	Mestranol	0.08	Norethisterone	1.0
*Ortho-Novum 2 mg [®]	Ortho	21	Mestranol	0.10	Norethisterone	2.0
*Ovstate [®]	Organon	22 or 28	EE	0.05	Lynestrenol	1.0
*Ovral [®]	Wyeth	21 or 28	EE	0.05	Norgestrel	0.5
Ovran [®]	Wyeth	21	EE	0.05	Norgestrel	0.5
Ovranette [®]	Wyeth	21	EE	0.03	Levonorgestrel	0.15
Ovulen [®]	Searle	21 or 28	EE	0.05	Ethinodiol diacetate	1.0
*Ovulen [®]	Searle	21 or 28	Mestranol	0.10	Ethinodiol diacetate	1.0
Oxysmen 21 [®]	Ortho	21	E	0.035	Norethisterone	0.5

TABLE 11.1 Characteristics of combined oral contraceptives — Continued

Other oral contraceptives known to be available in Africa:

*Anacyclin 101 [®]	*Lyndiol 2.5 [®]	*Norlestrin 1 mg [®]
*Anacycline [®]	*Microgynon 50 [®]	*Norlestin Fe [®]
*Ermonil [®]	*Milli Anovlar [®]	*Norlestrin Fe 1 mg [®]
*Eugynon 0.25 [®]	*Neo-Prevision [®]	*Planor [®]
*Gyn-Anovlar [®]	*Non-Ovulen [®]	*Primovlar [®]
*Gynovlane [®]	*Noracycline [®]	*Regovar [®]
		*Stediril [®]
		*Yermonil [®]

*Known to be available in Africa

**EE = Ethinyl-estradiol

***Norethisterone = Norethindrone and Norethisterone acetate = Norethynodrel

TABLE 11.2. The relative potency of estrogens and progestins in currently available oral contraceptives.

PROGESTINS (mg)		ESTROGENS (mcg)	
.3	NORETHINDRONE .35 mg NOR OD [®] MICRONOR [®]		
2.2	NORGESTREL .075 mg DVRETTE [®]		
2	NORETHINDRONE ACETATE 1 mg LOESTRIN 1/20 [®] ZORANE 1/20 [®]	ETHINYL ESTRADIOL 20 mcg	1.7 1.8
1	NORETHINDRONE 1 mg ORTHO NOVUM 1/50 [®] NORINYL 1/50 [®]	MESTRANOL 50 mcg	1.0
9	NORGESTREL .30 mg Lo OVRAL [®]	ETHINYL ESTRADIOL 30 mcg	1.0 1.2
3	NORETHINDRONE ACETATE 1.5 mg LOESTRIN 1.5/30 [®] ZORANE 1.5/30 [®]	ETHINYL ESTRADIOL 30 mcg	1.0 1.2
.4	NORETHINDRONE 0.4 mg OVCON 35 [®]	ETHINYL ESTRADIOL 35 mcg	1.2 1.4
.5	NORETHINDRONE 0.5 mg MODICON/BREVICON [®]	ETHINYL ESTRADIOL 35 mcg	1.2 1.4
1	NORETHINDRONE 1 mg ORTHO NOVUM 1/80 [®] NORINYL 1/80 [®]	MESTRANOL 80 mcg	1.6
1	NORETHINDRONE 1.0 mg OVCON 50 [®]	ETHINYL ESTRADIOL 50 mcg	1.7 2
2	NORETHINDRONE ACETATE 1 mg NORLESTRIN 1 [®] ZORANE 1/50 [®]	ETHINYL ESTRADIOL 50 mcg	1.7 2
2	NORETHINDRONE 2 mg ORTHO NOVUM 2 mg [®] NORINYL 2 [®]	MESTRANOL 100 mcg	2
2.7	NORETHYNODREL 2.5 mg ENOVID E [®]	MESTRANOL 100 mcg	2
5	NORETHINDRONE ACETATE 2.5 mg NORLESTRIN 2.5 [®]	ETHINYL ESTRADIOL 50 mcg	1.7 2
15	NORGESTREL 0.5 mg OVRAL [®] EUGYNON [®]	ETHINYL ESTRADIOL 50 mcg	1.7 2
15	ETHYNODIOL DIACETATE 1 mg DEMULEN [®]	ETHINYL ESTRADIOL 50 mcg	1.7 2
15	ETHYNODIOL DIACETATE 1 mg OVULEN [®]	MESTRANOL 100 mcg	2

ESTROGENIC AND PROGESTATIONAL ACTIVITY OF PILLS

The relative estrogenic and progestational activity of various oral contraceptives is an incredibly complex subject. Table 11.2 is a pyramid adapted from a table developed by Heinen (2). It is admittedly simplistic in that it provides a picture of hormone strength for when the estrogen or the progestin is used alone. Actually, estrogens and progestins are used in combination when one provides combined birth control Pills. It is only when we provide Mini-Pills (progestin-only Pills) that we provide the progestins alone. None of the currently available contraceptive agents provides estrogens alone as an ongoing oral contraceptive. Several of the important qualifications of this are:

1. Progestins vary as to their inherent estrogenicity. For example, norethynodrel (in Enovid[®]) is a relatively strong estrogenic compound. Norgestrel (in Ovral[®]) has no estrogenic effect. The relative estrogenic potency of the various progestins is as follows (3):

Progestin	Estrogenic effect
Norethynodrel (Enovid [®])	2.08
Norethindrone (Norinyl [™] and Ortho Novum [™])	0.25
Norethindrone acetate (Norlestrin [®])	0.38
Ethinodiol diacetate (Demulen [™] and Ovulen [®])	0.86
Norgestrel (Ovral [®])	0.0

2. Progestins also vary as to their anti-estrogenic effects. Norethindrone acetate (in Norlestrin[®]) and norgestrel (in Ovral[®]) have strong anti-estrogenic effects, whereas norethynodrel (in Enovid[®]) has no anti-estrogenic effects, and ethinodiol diacetate (in Demulen[™] and Ovulen[®]) has relatively low anti-estrogenic effects. The relative anti-estrogenic effect of the various progestins is as follows (4):

Progestin	Anti-Estrogenic effect
Norethynodrel (Enovid [®])	0.0
Norethindrone (Norinyl [™] and Ortho Novum [™])	2.5
Norethindrone acetate (Norlestrin [®])	25.0
Ethinodiol diacetate (Demulen [®] and Ovulen [®])	1.0
Norgestrel (Ovral [®])	18.5

3. Progestins vary in their androgenic potency. Norethynodrel (in Enovid[®]) has no androgenic effect. Ethinodiol diacetate (in Demulen[®] and Ovulen[®]) has very low androgenic effect, while norgestrel (in Ovral[®]) has relatively

strong androgenic effect. The androgenic potency of the various progestins is as follows (5):

Progestin	Androgenic effect
Norethynodrel (Enovid [®])	.0
Norethindrone (Norinyl [®] and Ortho Novum [®])	1.6
Norethindrone acetate (Norlestrin [®])	2.5
Ethinodiol diacetate (Demulen [®] and Ovulen [®])	1.01
Norgestrel (Ovral [®])	7.6

4. In some women, endogenous estrogen production may be less suppressed, particularly as the dosage of exogenous estrogen is lowered. This means that in some women the total estrogen effect will be the result of estrogen from an oral contraceptive, in addition to endogenous ovarian estrogen.

5. Estrogens affect many different organ systems and produce a broad range of symptoms. Organ systems have different responses to different estrogens and to estrogens in combination with different progestins.

INITIAL PILL CHOICE

1. Avoid giving Pills to women who may be harmed by them. Look over the contraindications to estrogen-containing Pills in this chapter. There are now many alternatives women may be able to choose among if one of the contraindications to Pills exists. Women who have already made up their minds to use the Pill can often be encouraged to use the Mini-Pill if they have a contraindication to combined Pills.

2. Prescribe .05 mg or less of estrogen when initiating use of an estrogen-containing Pill. The use of .05-mg Pills seems to be associated with a minimum of troublesome breakthrough bleeding and missed menses. Most public family planning programs in both the United States and Africa use either Norinyl 1 + 50[®] or Ortho Novum 1/50[®] as their initial Pill of choice, although some programs are beginning to use more sub-50 Pills as their initial Pill of choice.

3. In general, we recommend giving three packets of Pills at the initial visit. Of the 30% to 50% of women who do not continue using the Pill after 1 year, many stop because they find visits for resupply inconvenient or because they were given a very small supply of Pills and ran out before they could obtain more.

CLINIC PROCEDURES IN MANAGEMENT OF PILL USERS

1. We recommend that six packets of Pills be provided after a woman has used the Pills for a year, if she is having no problems and wants to continue the Pills. After a woman has used the Pills for 2 years, we recommend that consideration be given to providing her with a full year's supply of Pills. Pill *discontinuation* is greatly *increased* if women have to *return repeatedly* for supplies.

2. The danger signals for Pills are the most important health education message to convey to women. These are described in Figure 11.1.

3. The storage of contraceptive supplies is discussed in Chapter 23.

SIDE EFFECTS AND COMPLICATIONS

The Pill affects virtually every organ system. (See Table 11.3.) Pill complications which become worse over time (see Table 11.4) deserve our constant attention as we provide Pills to more women who have used those Pills for periods of 5-15 years.

What are some of the risks of using the Pill? The most notable are cardiovascular side effects. Heart attack and stroke have been found to occur more often in women who use the Pill than in women who do not, according to studies in Britain and the United States (6-9). However, these cardiovascular side effects generally occur only in a small segment of Pill users. Women most at risk of developing cardiovascular side effects related to Pill use are those who have other characteristics that serve to increase their risk: they smoke, are over 35 years of age, or have other health problems such as hypertension, diabetes, or a history of heart or vascular disease.

Conversely, nonsmokers who are healthy and younger than 35 can use the Pill safely, with very little risk of developing serious complications (6). The Royal College of General Practitioners Contraception drug study, a cornerstone study of risks of the birth control Pill, showed that a woman using the Pill who is between 35 and 44 years of age had an excess annual risk of 1 in

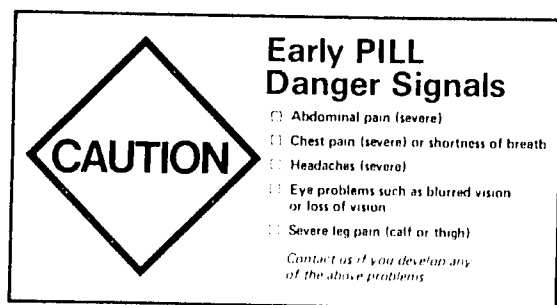


FIGURE 11.1 Early danger signals of the Pill.

2,000 if she smoked and 1 in 6,700 if she did not, but a woman younger than 35 years of age had an excess annual risk of only 1 in 10,000 if she smoked and 1 in 77,000 if she did not (6).

One might assume that African women have less risk of developing cardiovascular disease from using the Pill than do European or American women. The African woman is less likely to have the characteristics that would serve

TABLE 11.3 Side effects of the Pill

FAIRLY MINOR

Nausea (try taking the Pill with your evening meal if this is a problem; if you vomit within 2 hours of taking the Pill, take another one because your original Pill may have no effect).

Weight gain, fluid retention, breast fullness or tenderness.

Mild headaches (return to clinic if severe).

Spotting (bleeding) between periods.

Decreased menstrual flow (not always a nuisance).

Missed periods.

More problems with yeast infection, vaginal itching, or discharge.

Depression, mood changes, fatigue (return to clinic if severe).

Decreased sex drive (rare: women on the Pill often enjoy an increased libido).

Acne (again, more women notice a decrease in acne problems).

Chloasma, or the "mask of pregnancy" (skin darkens on upper lip, under eyes, or on forehead; sun may make it worse; it may become permanent).

SERIOUS

Gallbladder disease, with upper abdominal pain, indigestion and the development of gallstones.

Hypertension (high blood pressure attributable to Pills is usually reversible very quickly; but it can, if high enough, lead to permanent complications).

POSSIBLY LIFE-THREATENING

Blood clots in the legs, pelvis (lower abdomen), lungs, heart, or brain. Hardly anyone dies from blood clots without warnings. Signs of trouble—possibly serious—may be headaches, blurred vision or loss of vision, flashing lights, severe leg pains, severe chest pains, or shortness of breath. The risk of heart attack is increased, particularly in women over 40. This risk is highest in women over 40 who smoke.

Rupture of the capsule of the liver (a rare occurrence), extensive bleeding, and even death may be caused by benign tumors of the liver, which, although rare, are shown to be more common in women who use the Pill.

to increase her risks: she is less likely to smoke, more likely to get physical exercise, is less likely to be obese, and is less likely to have a diet high in cholesterol. The African woman's risk of death from using the Pill is probably about 1 per 100,000 Pill users. On the other hand, the risk of death from pregnancy is many times greater, generally between 200-1,200 per 100,000 births (10, 11).

Fortunately, most of the complications women have from taking birth control Pills are not serious. About 40% of Pill users do have side effects of one kind or another; however, the vast majority have only minor side effects.

The most serious complication of Pills can be minimized or avoided completely by following these steps:

1. Do not give the combined Pill to women for whom they are contraindicated.
2. Teach the individual the early Pill danger signals.
3. Be willing to use nonestrogen-containing Pills (Mini-Pills) or other contraceptive alternatives, when indicated.

Cardiovascular complications are less common among Pill users who are young, do not smoke, have normal weight, and do not have Type B blood. Over the past years, the authors of *Contraceptive Technology* have developed the accompanying TIME FRAMEWORK for the occurrence of Pill complications and the side effects by hormone etiology. (See Tables 11.4 and 11.5.) These tables have proven useful in teaching clinicians about possible problems from oral contraceptives.

MODIFICATION OF PILL DOSAGE

While your program may have fewer brands of Pills available than the full range discussed below, you can successfully assist Pill users in finding the formulation that they can best tolerate through the use of medium- (1+50), low- (1+35), and no-estrogen (Mini-) dosage Pills.

1. **Spotting, early or late.** From a medical point of view, spotting is generally *not* an ominous sign in young women and may usually be managed with a "watch-and-wait" approach for several months. Spotting can sometimes be controlled by having the patient take her Pill at exactly the same time each day. The .02 mg and .03 mg Pills appear to be associated with higher rates of breakthrough bleeding and/or spotting. Spotting is a potential problem with all the .05 mg Pills and sub-.05 mg Pills. After 2 or 3 months, one might try switching to Ovral[®], Norlestrin 2.5[™], or Demulen[™]. Rarely is it necessary to switch to a higher-estrogen Pill, such as Ortho Novum 1 + 80[™] or Norinyl 1 + 80[®].

TABLE 11.4 Time framework: The progression of Pill side effects over time

Worse in First 3 Months	Over Time: Steady-Constant	Worse Over Time	Worse After Discontinuing
1. Nausea plus dizziness 2. Thrombophlebitis (venous) leg veins *Pulmonary emboli *Pelvic vein thrombosis *Retinal vein thrombosis 3. Cyclic weight gain edema 4. Breast fullness, tenderness 5. Breakthrough bleeding 6. *Elevated serum lipid levels even to the extent of pancreatitis 7. *Abnormal glucose tolerance test 8. Contact lenses fail to fit because of fluid retention 9. Abdominal cramping 10. Suppression of lactation 11. Pregnancy if the user fails to understand correct use of oral contraceptives	1. Headaches during the 3 weeks that Pills are being taken 2. *Arterial thromboembolic events, blurred vision, stroke 3. Anxiety, fatigue, depression 4. Thyroid-function studies Elevated protein bound iodine Depressed T3 resin uptake 5. Susceptibility to amenorrhea after the Pill is discontinued 6. Decrease in libido 7. Autophonia, chronic dilatation of eustachian tubes rather than cyclic opening and closing 8. Acne	1. Headaches during week Pills are not taken 2. Weight gain 3. Monilial vaginitis 4. Periodic missed menses while on oral contraceptives 5. *Chloasma 6. *Myocardial infarction 7. Spider angiomas 8. Growth of myoma 9. Predisposition to gallbladder disease 10. Hirsutism 11. Decreased menstrual flow 12. Small uterus, pelvic relaxation cystocele, rectocele, atrophic vaginitis 13. Cystic breast changes 14. Photodermatitis - sunlight sensitivity with hypopigmentation 15. One form of hair loss (alopecia) 16. *Hypertension 17. *Focal hyperplasia of liver and hepatocellular adenomas	1. **Infertility, amenorrhea; hypothalamic and endometrial suppression and miscalculation of expected date of birth 2. One form of acne 3. Hair loss (alopecia) 4. Depression (in some women)

*May be irreversible or produce permanent damage.

**N.B. To avoid this complication in many patients desiring to be pregnant, discontinue Pills 3-6 months before desired pregnancy. Another possible way to avoid this problem is to avoid prescribing Pills for women with a history of very irregular menses.

TABLE 11.5 *Side effects from estrogen and progestin in oral contraceptives*

Estrogen Excess	Progestin Excess	Androgen Excess
1. Nausea, dizziness 2. Edema and abdominal or leg pain with cyclic weight gain, bloating 3. Leukorrhea 4. Increase in leiomyoma size 5. Chloasma 6. Uterine cramps 7. Irritability 8. Increased female fat deposits 9. Cervical ectropia 10. Contact lenses do not fit 11. Telanglectasia 12. Vascular type headache 13. Hypertension 14. Lactation suppression 15. Headaches while taking Pills 16. Cystic breast changes 17. Breast tenderness 18. Increased breast size (ductal and fatty tissue and fluid retention) 19. Thrombophlebitis 20. Cerebrovascular accidents 21. Myocardial infarction 22. Hepatic adenoma 23. Cyclic weight gain	1. Increased appetite and weight gain (noncyclic) 2. Tiredness and fatigue; feeling of weakness 3. Depressions and decrease in libido 4. Oily scalp, acne 5. Loss of hair 6. Cholestatic jaundice 7. Decreased length of menstrual flow 8. Hypertension 9. Headaches during week when Pills are not taken 10. Monilia vaginitis, cervicitis 11. Increase in breast size (aleolar tissue) 12. Breast tenderness 13. Decreased carbohydrate tolerance 14. Dilated leg veins 15. Pelvic congestion syndrome	1. Increased appetite and weight gain 2. Hirsutism 3. Acne 4. Oily skin, rash 5. Increased libido 6. Cholestatic jaundice 7. Pruritis

Estrogen Deficiency	Progestin Deficiency
1. Irritability, nervousness 2. Hot flushes, vasomotor symptoms 3. Uterine prolapse, pelvic relaxation symptoms 4. Early and midcycle spotting 5. Decreased amount of menstrual flow 6. No withdrawal bleeding 7. Decreased libido 8. Diminished breast size 9. Dry vaginal mucosa, atrophic vaginitis, and dyspareunia 10. Headaches 11. Depression	1. Breakthrough bleeding and spotting 2. Heavy menstrual flow late in the period and clots 3. Delayed onset of menses 4. Dysmenorrhea 5. Weight loss

As we provide women with lower and lower dose Pills in the interest of safety, we can predict and anticipate higher and higher rates of spotting and missed menses. We should warn women about these problems in advance. In general, however, spotting is *NOT* an ominous sign in young women and may usually be managed with a "watch-and-wait" approach for several months.

2. **Failure to have withdrawal bleeding; missed menses.** Initially, switch to a higher-progestin Pill such as Ovral[®], Demulen[®], or Norlestrin 2.5[®] or to a higher-estrogen Pill such as Norinyl 1 + 80[®] or Ortho Novum 1 + 80[®]. Try to avoid .1 mg Pills (estrogen-containing ones).
3. **Nausea.** Use 0-.05 mg of estrogen.
4. **Weight gain caused by fluid retention.** This type of weight gain is usually at its worst late in the cycle. Use 0-.05 mg of estrogen.
5. **Weight gain caused by increased appetite.** Consider using a low-androgen Pill, such as Micronor[®] or Nor-Q.D.[®], or another Pill relatively low in anabolic effects. Demulen[®] would be a good choice of the .05 mg Pills. (See section in this chapter on "Estrogenic and Progestational Activity of Pills" for relative androgenic strength of Pills.)
6. **Hypertension.** The association between hypertension and the use of oral contraceptives is not conclusively established or understood; neither is the role that progestin or estrogen may play (12,13). If a woman develops hypertension while using a combined Pill, suggest that she switch to the Mini-Pill (low-dose, progestin-only Pill) or a nonhormonal method. If she still is hypertensive while using the Mini-Pill, and if the risks associated with use of an alternative are less important than those associated with hypertension, recommend that she discontinue use of all hormonal contraceptives and switch to an alternative method. REMEMBER, PILL-INDUCED HYPERTENSION IS USUALLY REVERSIBLE.
7. **Oily skin or scalp; acne.** Provide a low-progestin, low-androgen Pill, preferably with .05 mg of estrogen. Initially use Demulen[®], Norinyl 1 + 50[®], or Ortho Novum 1 + 50[®]. Any Pill may cause acne to become worse, but this may be particularly bothersome with Ovral[®], which is the most androgenic of the .05 mg Pills. If acne does not improve, try Enovid-E[®] because of its very low androgenic effects. The high estrogenic content of Enovid-E[®] may also be helpful in improving acne.
8. **Hirsutism.** Use a low-androgen Pill with 50 mcg of estrogen or less: Demulen[®], Norinyl 1 + 50[®], Ortho Novum 1 + 50[®], Norlestrin 1[®], Zorane 1 + 50[®], Loestrin 1.5 + 30[®], Zorane 1 + 20[®], or Modicon[®].
9. **Depression.** This condition is complicated as depression may be attributable to high estrogen levels (fluid retention), to high progestin levels, or even to estrogen levels that are too low. Initially, try Norinyl 1 + 50[®] or Ortho Novum 1 + 50[®]. Depression may improve. If it becomes worse, consider switching to a no-estrogen Pill, such as Nor-Q.D.[®], Micronor[®], or Ovrette[®], or

to a .03-to .035 mg Pill, such as Brevicon[®], Lo-Ovral[®], Ovcon[®], or Modicon[®]. Some clinicians have noted that depression may be diminished by a dosage increase to greater than .05 mg of estrogen. Pill-induced depression has also been managed by treatment with vitamin B6, 25 mg/day. Depression can become much more severe or may be remarkably improved while using birth control Pills. Each Pill user must be questioned carefully.

Some women have used the Pill for years only to realize, after discontinuing it, just how depressed they had been while taking it. This is a potential justification for discontinuing the Pill for a "rest period" every 3 years or so. However, the authors feel that, in most instances, the risks of the "rest period" approach far exceed the benefits.

NONCONTRACEPTIVE BENEFITS

It is important to remember that women often experience benefits other than effective contraception from oral contraceptives. Several of these beneficial effects of birth control Pills, along with some adverse effects, are presented in the bar graph (see Figure 11.2) derived from the Royal College Study (1).

In this study, combined oral contraceptive users frequently experienced a relief of symptoms of their menstrual cycles. The Pill minimizes menstrual cramps, decreases the number of days of bleeding and the amount of blood loss, produces regular menstrual periods, and eliminates the pain of *mittelschmerz* in most instances. Also, iron-deficiency anemia is decreased in Pill users. Other women notice that their premenstrual tension, anxiety, or depression may be diminished while taking oral contraceptives. Extra Pills from a separate package may be taken to avoid menses on weekends, on vacations, or when menses are not wanted for whatever reason.

There is extensive evidence that the Pill provides a protective effect against pelvic inflammatory disease (PID). Users of the Pill are less likely to develop PID than users of all other contraceptive methods (14,15).

The symptoms of estrogen deficiency are often controlled by oral contraceptives. Women over age 35 are at greater risk of serious complications from use of oral contraceptives than younger women; therefore, women over age 35 should consider other combinations to remedy estrogen deficiency.

The Pill has been used in the treatment of such medical conditions as endometriosis and idiopathic thrombocytopenic purpura (ITP). In addition, there is a decreased incidence of functional ovarian cysts, rheumatoid arthritis, fibrocystic breast disease, and fibroadenomas of the breasts in women who use the Pill (16).

An acne condition is often improved in women taking oral contraceptives. Some women gain weight or notice an increase in their breast size while they are using the Pill (which can be either a beneficial or an adverse effect). Some

women and men experience an increased enjoyment of sexual intercourse, more probably because the fear of pregnancy is diminished.

USER INSTRUCTIONS

Patients should be instructed in the following way:

1. There are three satisfactory ways to start taking your Pills. You should use the approach suggested by your doctor, nurse, or clinic:

FIRST APPROACH:

TAKE THE FIRST PILL FROM YOUR FIRST PACK ON THE FIRST DAY YOU BEGIN BLEEDING DURING YOUR PERIOD

SECOND APPROACH:

START YOUR FIRST PACK ON THE FIRST SUNDAY (OR FRIDAY) AFTER YOUR PERIOD BEGINS. (See Figure 11.3.)

THIRD APPROACH:

START YOUR FIRST PACK ON THE FIFTH DAY AFTER YOU START YOUR MENSTRUAL PERIOD: THE FIRST DAY OF BLEEDING IS DAY 1.

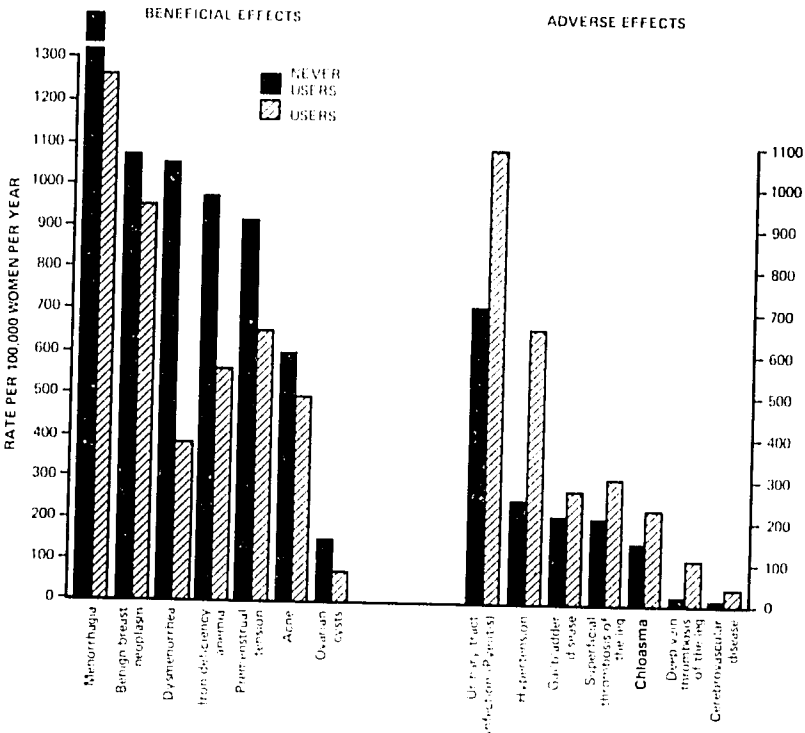


FIGURE 11.2 Comparison of the incidence of various conditions in current users of oral contraceptives.

Swallow one Pill a day until you finish the pack. If you are using a 21-day pack, stop for 1 week, and then start your new pack. If you are using a 28-Pill pack, begin a new pack immediately. (See Figure 11.4.)

2. Try to associate taking your Pill with some regularly scheduled activity like going to bed, eating a meal, or brushing your teeth. This may make it easier to remember. Pills work best if you take one about the same time every day in order to keep a relatively constant level of drug in your system. This is especially important if you have bleeding between periods.

3. Check your packet of Pills each morning to make sure you took your Pill the day before.

If you miss one Pill, take the forgotten one (yesterday's Pill) as soon as you remember it, and take today's Pill at the regular time. You probably won't get pregnant. Just to be sure, you could use your backup method. (See Figure 11.5.)

If you miss two Pills in a row, take two Pills as soon as you remember and two the next day. Here is an example: You forget your Pills on Saturday and Sunday evenings, but remember on Monday morning. What do you do? Take two Pills on Monday and two on Tuesday. You may have some spotting. Use another means of contraception until you finish that pack of Pills. (See Figure 11.6.)

If you miss three or more Pills in a row, ask yourself, "Am I a good Pill user?" The chances are great that your ovaries will produce an egg (you will ovulate) and that you may get pregnant. So start using a second method of birth control immediately. Throw away your old pack of Pills. Start a new packet the Sunday after you realize you have missed three or more Pills, even if you are bleeding. Use your second method of birth control while you are off Pills AND for the first 2 weeks that you are on your new pack of Pills. Consider using a method you can use more consistently, unless you are sure missing Pills will not become a habit. (See Figure 11.7.)

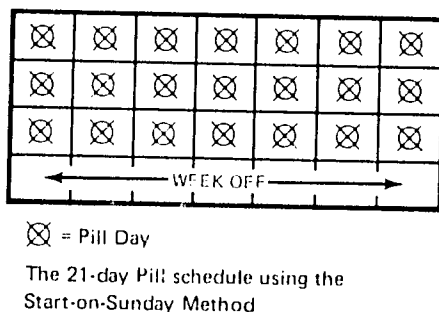


FIGURE 11.3 Start your first pack on the first Sunday (or Friday) after your period begins.

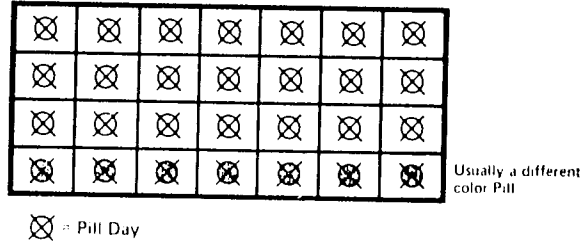


FIGURE 11.4 Twenty-eight-day combined birth control Pill package. There are no days without Pills.

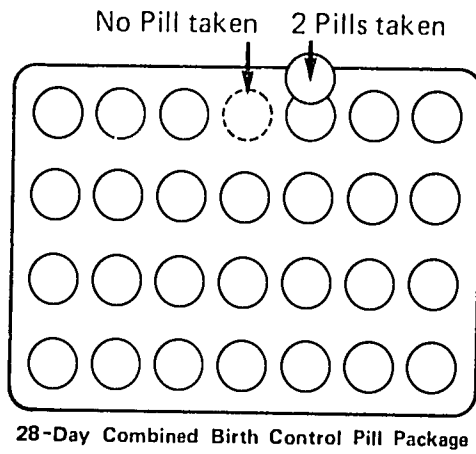


FIGURE 11.5 If you miss one Pill.

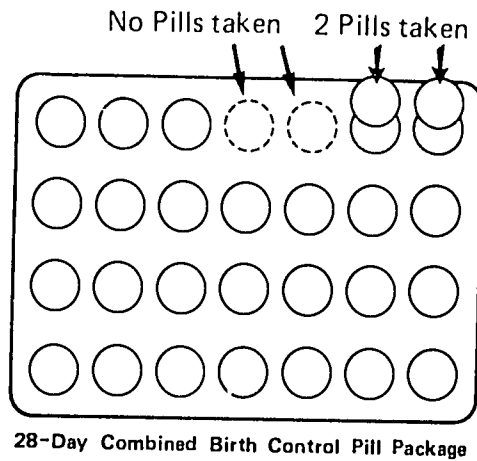


FIGURE 11.6 If you miss two Pills.

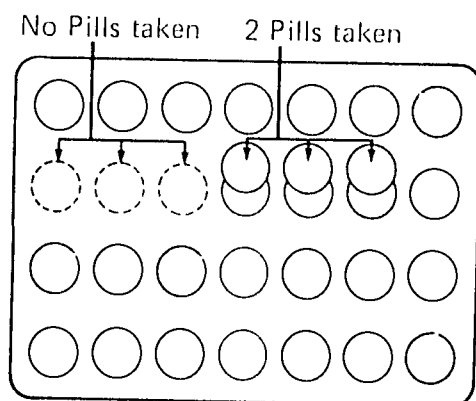
If you miss one or more Pills and skip a period, start using a method of birth control other than birth control Pills and contact your clinic to see about a pelvic examination or a pregnancy test to determine if you are pregnant. The family planning worker will help you determine when to start using the Pill again, if you have stopped.

If you miss no Pills but skip a period, you probably should not worry too much. You may be pregnant, but it is very unlikely. It is rather common for women taking birth control Pills to miss periods occasionally. If you are worried, call the clinic. You are fairly safe and can start a new package of Pills at the regularly scheduled time. (See Figure 11.8.)

4. Tell people you are using Pills whenever you are seen for any medical problems. (See Figure 11.9.)

WHEN YOU ARE SEEN BY A DOCTOR FOR OTHER PROBLEMS, BE SURE TO MENTION THAT YOU ARE USING BIRTH CONTROL PILLS. THIS IS PARTICULARLY IMPORTANT IF YOU ARE ADMITTED TO THE HOSPITAL.

5. The most important instruction of all is to contact the person who provided your Pills if you develop one of the five danger signals.

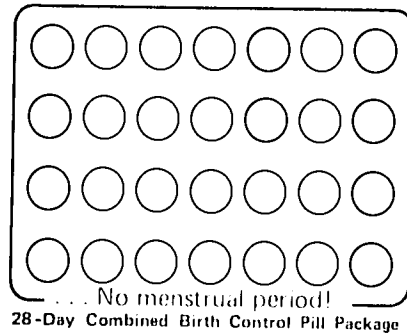


28-Day Combined Birth Control Pill Package

Three Pills missed. Extra Pills taken for next three days. Use of backup contraceptive strongly recommended for rest of that cycle (until next menstrual period starts).

ALTERNATIVE METHOD OF BIRTH CONTROL MIGHT BE BETTER THAN PILLS FOR PATIENT WHO MISSES THREE IN A ROW!!

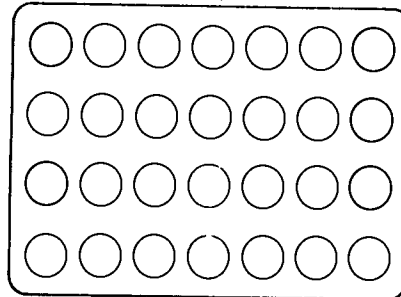
FIGURE 11.7 If you miss three or more Pills.



... assuming that no Pills were missed



start next package on schedule



28-Day Combined Birth Control Pill Package

Restart taking Pill on the same schedule even though period has not occurred.

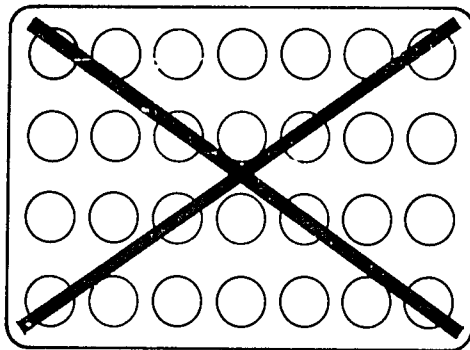
FIGURE 11.8 If you miss no Pills but skip a period.

6. Danger Signals : Which Aches and Pains May be Warnings of Serious Trouble?

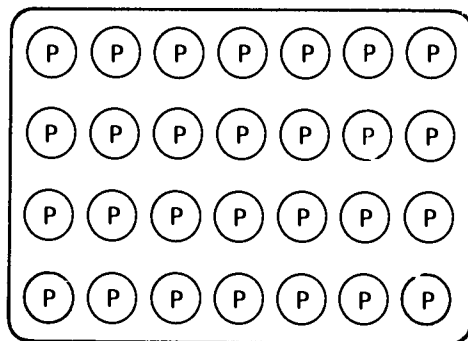
<i>Danger Signals</i>	<i>Possible Problem</i>
Abdominal pain (severe)	Gallbladder disease, hepatic adenoma, blood clot, pancreatitis
Chest pain (severe) or shortness of breath	Blood clot in lungs or myocardial infarction (heart attack)
Headaches (severe)	Stroke or hypertension or migraine headache
Eye problems: blurred vision, flashing lights, or blindness	Stroke or hypertension or temporary vascular problem of many possible sites
Severe leg pain (calf or thigh)	Blood clot in legs

These symptoms may mean serious trouble. Learn them well. Note that the first letter of each symptom spells out the word "ACHES."

These symptoms have been experienced by some women for weeks or even months before they sought help. Do not ignore these problems. Do not wait to see if these problems go away. Call the clinic or your doctor immediately and explain your problem. You should be seen in the family planning clinic or in the emergency room right away. Using birth control Pills can



28-Day Combined Birth Control Pill Package
Pills NOT ADVISED because of
PLANNED ELECTIVE SURGERY
WITHIN ONE MONTH

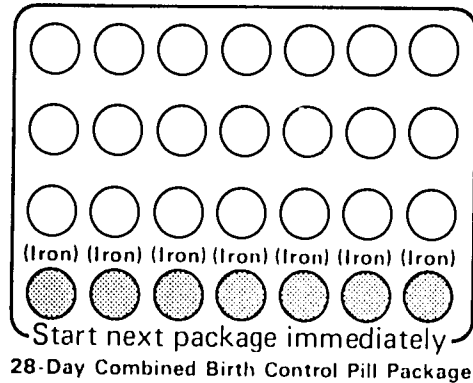


Progestin-Only Pill or Mini-Pill Package
MINI-PILL MAY BE USED the
month prior to elective surgery

FIGURE 11.9 Inform your doctor that you are taking the Pill whenever you receive care for medical problems.

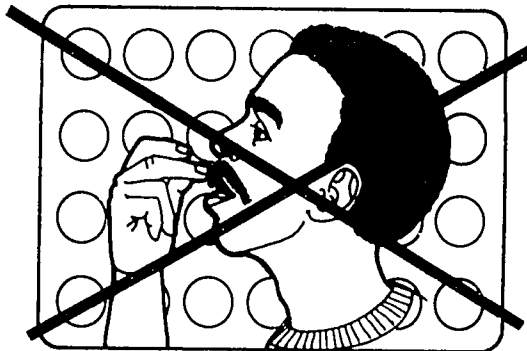
be made safer if you use them wisely and if you seek help early when problems arise.

7. Other variations in taking Pills are explained in Figures 11.10-12.



Iron added to final seven Pills. An excellent nutritional advantage.

FIGURE 11.10 Adding iron supplements.



28-Day Combined Birth Control Pill Package

NO! NO! NO! None of our current Pills are for men. Not at the time of sexual intercourse, not for the entire month, not at any time. We hope one day there will be Pills for men. Now there are no hormonal Pills for men.

FIGURE 11.11 Pills are not for men.

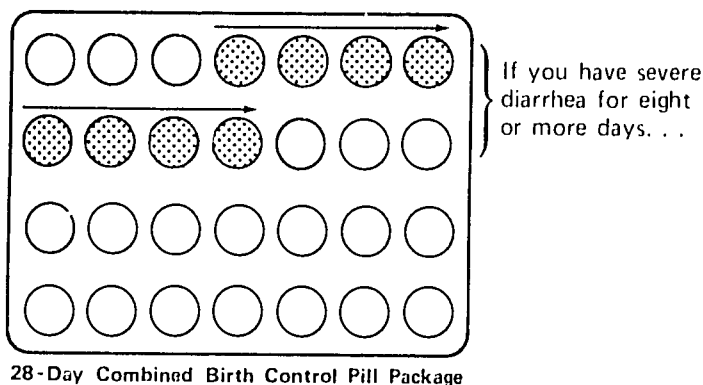


FIGURE 11.12 *If you ever have diarrhea for 8 consecutive days while taking the Pill, the diarrhea may reduce the contraceptive effect; use a backup contraceptive to ensure protection.*

ENCOURAGING CONTINUED USE OF THE PILL

Generally, anywhere from 30% to 70% of women who start combined Pills will still be using them after 1 year. Groups having low continuation rates include adolescents and women who were provided only a single pack of Pills. Most women who discontinue the Pills do so for nonmedical reasons, that is, not because they have developed a complication or major side effect.

In writing this edition of *Contraceptive Technology*, we solicited suggestions as to how continued use of the Pill might be increased. Among the suggestions we received are the following:

1. Develop community-based distribution systems that would provide Pills to women in their own homes; continue followup in homes.
2. When Pills are provided in clinics, followup may be done through a community-based distribution system. Pills can be brought to the user's home every 1 to 3 months.
3. Eliminate the need for so many revisits to the clinic by providing 6 to 12 packages of Pills to a woman who has used the Pills for a year or more and is having no problems.
4. Consider making Pills a nonprescription drug available to women through pharmacies and patent-medicine practitioners.
5. Make Pills available through a broad range of health and nonhealth agencies, including agricultural extension agencies, clinics at places of work (factories, cooperatives, offices), Maternal-Child Health/Family Planning Clinics, hospitals, private physicians, nurses, midwives, and school health programs.
6. Provide better counseling so that patients really understand how to take the Pills and what problems they are to watch out for.
7. Provide educational materials for distribution in community-based and commercial sales delivery systems.

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CHAPTER 12

CONTRACEPTIVE INJECTIONS AND OTHER PROGESTIN-ONLY CONTRACEPTIVES

Up to 10 million women have used the drug Depo-Provera® (DMPA) at some time, and more than one and a quarter million use it at present. It is registered as a therapeutic agent in the treatment of cancer in nearly all countries, and as a contraceptive agent in more than 80 developed and developing countries.

International Planned Parenthood Federation, 1980

PROGESTIN INJECTIONS

HISTORY, MECHANISM OF ACTION, AND EFFECTIVENESS

History and mechanism of action

Contraceptive injections of long-acting progestins are now being used in at least 80 countries throughout the world, including several countries in Africa (1-3). The most commonly used injectable progestins are medroxy-progesterone acetate (Depo-Provera™ or DMPA) and norethindron-^onanthate (NET). Just like the progestins in combined Pills, the progestins in the injectables prevent pregnancy by suppressing ovulation, inducing a thin, atrophic endometrial lining, and producing a thick cervical mucus that is difficult for sperm to penetrate.

While the many benefits of injectable progestins have gained them popularity and acceptance among providers and users, the possible side effects have raised some concern. People who encourage the use of injectables find the method is well accepted by users and enjoys high continuation rates, high effectiveness rates, and low complication rates. People who discourage the use of injectables believe the method needs further study to document its safety.

The use of injectable progestins has been effective and popular in a number of African countries. Reasons given by users and family planning workers for the great popularity of injectables were convenience, privacy afforded by the method, and the traditional belief that injections have a greater effect than oral medications (1). Higher continuation rates are associated with less frequent visits to the provider. This was shown in a 1978 study comparing the use of 150-mg DMPA given to 500 women every 3 months with the use of 450 mg given to 500 women every 6 months. At 6 months, the continuation rates were higher in women choosing the 6-month regimen, 73.2% vs 57%. However, amenorrhea, headaches, and a bloated abdomen were more frequent in women using the 6-month regimen.

Effectiveness

A number of studies of DMPA have shown that for every 400 women who use DMPA in a year, one will become pregnant (4). One of the reasons DMPA injections are so effective is that each 150-mg injection actually provides more than 3 months' protection. Thus, a woman using "the shot" as her contraceptive has a 4- to 6-week "grace period" during which she can be late for her next shot but probably still be protected. The pregnancy rate for NET is somewhat higher than for DMPA. Further, study evidence suggests that the contraceptive effect of NET lasts for *less* than three months (5).

ADVANTAGES AND DISADVANTAGES OF CONTRACEPTIVE INJECTIONS

For your own country and population, you should weigh the advantages and disadvantages of using the injectables. The following chart summarizes several reports of the pros and cons of injectable progestins (6,7). These will be described in detail later in the chapter.

ADVANTAGES:

- does not have the serious complications associated with estrogen-containing Pills
- highly effective
- long-acting; need be provided only at 3- or 6-month intervals
- effectiveness continues even if user is late in obtaining next injection
- offers privacy to user; need not be kept at home
- may produce amenorrhea; may help decrease anemia
- acceptable to women who prefer injections to oral medications
- does not suppress lactation

DISADVANTAGES:

- may produce amenorrhea; some women may want reassurance from menstrual flow that they are not pregnant and are still capable of becoming pregnant
- delays the return of fertility
- may cause menstrual irregularities
- studies on animals suggest injectables may affect a fetus if used during pregnancy and may be associated with cancer of the endometrium and breast

The United States Food and Drug Administration (FDA) has not yet approved DMPA for general use in the United States. This has caused some concern and touched upon the political sensitivities of certain African countries that have used the drug. The FDA gave four reasons for not approving the use of DMPA in America: DMPA produces breast tumors in beagles; it may be teratogenic if used during pregnancy; there was no evidence that DMPA was needed in America since sterilization is widely available; and the use of supplemental estrogens to control bleeding could be hazardous (8).

CONTRAINDICATIONS

The absolute contraindications to combined oral contraceptives have historically been applied to contraceptive injections. (See Chapters 9 and 11.) However, unlike the Pill, progestin-only injections have never had a documented association with increased risk of thromboembolic disease. (See Chapter 11 for the list of contraindications for both combined oral contraceptives and progesterone-only contraceptives.)

LONG-ACTING PROGESTIN INJECTIONS MAY PRODUCE
IRREGULAR MENSTRUAL BLEEDING PATTERNS.
THEREFORE, UNDIAGNOSED ABNORMAL GENITAL BLEEDING
NEEDS TO BE EVALUATED CAREFULLY
BEFORE PROGESTIN CONTRACEPTIVES ARE USED.

While it does not appear that women have extensive post-DMPA infertility problems, return of fertility does appear to be delayed until the effects of the injected progestin have elapsed (9-10). Thus, some programs choose not to provide injectable contraceptives to women planning to become pregnant in the future. Others provide injectables to women who have three or more children.

PROVISION

Contraceptive injections are especially useful in the following situations:

1. When a woman desires no more children but does not want to be sterilized.
2. When a woman is approaching menopause but does not want to be sterilized. (Older women are at greater risk of developing complications with the use of the combined Pill, a commonly available alternative method, than are younger women.)

WOMEN OVER 35 ARE AT A GREATER RISK OF DEVELOPING
CARDIOVASCULAR COMPLICATIONS IF THEY TAKE
COMBINED PILLS. YOU SHOULD CONSIDER INJECTABLE
CONTRACEPTIVES FOR THIS AGE GROUP.

3. When a woman wants a safe, effective method for a short period of time before she is sterilized: for example, if she is a post-partum patient who is unable to schedule tubal ligation for several months.
4. When a woman is living under conditions where personal hygiene is difficult. Injectable contraceptives are advantageous from both a hygienic and from a contraceptive standpoint.
5. When a woman has received a rubella vaccination and must be protected against pregnancy for 3 months.
6. When a woman has sickle cell disease and she is not a good candidate for a combined Pill.
7. When an alternative means of contraception is needed for a woman who has become pregnant while attempting to use another method or who has experienced complications with other methods.
8. When a woman has a particularly high risk of developing cardiovascular complications from estrogen-containing birth control Pills.
9. When a woman has developed estrogen-related complications while taking combined oral contraceptives, and a nonhormonal approach to birth control is not satisfactory for her. Such complications of oral contraceptives include:
 - high blood pressure
 - headaches
 - leg pain
 - chloasma

The settings in which injectable contraceptives are *least* likely to be considered are as follows:

1. When a woman has never been pregnant or is an adolescent. This is because return of fertility may be delayed. In the long run, however, return of fertility is excellent.
2. When a woman does not like receiving injections. Women who faint or have had repeated vaso-vagal reactions when they received injections of other medications are not candidates for injectable contraceptives.
3. When a woman has a history of breast cancer or a strong family history of this disease.

4. When a woman has a history of a breast mass (this is a consideration, but not an absolute contraindication, to use of DMPA).
5. When a woman has had an abnormal glucose tolerance test, with a history of gestational diabetes or with a strong family history of adult-onset diabetes.
6. When a woman has menorrhagia or metrorrhagia.

SIDE EFFECTS AND COMPLICATIONS

To our knowledge, women using injectable contraceptives are *not* exposed to an increased risk of any lethal complication, although definitive long-term studies are not available at this time.

**EXCESSIVE ENDOMETRIAL BLEEDING AND AMENORRHEA
ARE THE MOST FREQUENT REASONS
FOR DISCONTINUING DMPA.**

Women using injectable contraceptives may have breakthrough bleeding. If a woman is bothered by this, the bleeding can be managed by giving her 1 or 2 cycles of an oral contraceptive. However, usually this is not necessary, nor is the provision of any other exogenous estrogen. Occasionally, women using injectable contraceptives bleed extensively. If a woman is experiencing numerous days of bleeding each month, check to see if she is anemic. Consider discontinuing DMPA or treating the woman with iron if her hematocrit drops 5 points or more.

**AMENORRHEA IS TO BE EXPECTED AFTER
9-12 MONTHS OF USING DMPA.**

Many women consider amenorrhea a desirable effect of DMPA; others clearly do not. Amenorrhea was the most common reason for discontinuing DMPA (14.1%) among 400 women provided this contraceptive in Ibadan, Nigeria (11). Pregnancy may result if a woman in her forties misinterprets prolonged amenorrhea as "menopause," assumes she is "sterile," and discontinues contraception. One could continue administering injectable progestins until the patient is age 50 if she experiences no problems.

NET produces substantially less amenorrhea than does DMPA (5), which may make NET more acceptable in some populations. Rates for other types of bleeding problems caused by NET appear comparable to those for DMPA.

Post-DMPA infertility for 6-12 months occurs in a fair number of women. However, fertility does return in over 80% of women within 1 year after DMPA is stopped. The mean interval for return of fertility is about 10

months. Extensive studies of DMPA throughout the world indicate that while fertility takes a number of months to return after the use of DMPA, infertility is *not* a serious complication (1,9,10).

Decreased libido, depression, headaches, dizziness, weight gain, and allergic reactions are complications of DMPA most commonly encountered. The effect of long-acting progestins on carbohydrate metabolism is still being investigated. Consider periodically evaluating carbohydrate metabolism in long-term DMPA users, especially when a marked weight gain occurs and when the clinician and patient wish to continue this form of contraception.

The effect of injectable progestin on blood pressure is minimal. In one large study, DMPA had no effect on blood pressure (12). While the number of DMPA Depo-Provera[™] users is still too small to be sure that all of its complications have been discovered, there is no evidence of thromboembolic phenomena or other circulatory diseases, as have been seen with estrogen-containing oral contraceptives (7,12).

Toxicologic studies of DMPA in beagle dogs showed that treated dogs manifested more mammary gland tumors; some of the tumors became malignant (13). Because of these studies, there has been concern over the possibility of breast cancer in women using DMPA. Investigators in the United States have conducted a case-control study of breast cancer among contraceptive users in a program that has provided over 7,000 women with DMPA from 1969-1978 (14); however, the study showed no increased risk of breast cancer in DMPA users compared with other contraceptive users.

Because of this concern over the possible development of breast cancer in DMPA users, you may wish to practice utmost caution by performing periodic breast examinations and by teaching patients to examine their own breasts.

NONCONTRACEPTIVE BENEFITS

There is some evidence that at least one of the injectable progestins (DMPA) does not suppress lactation and may even increase the duration of lactation (11,15). This would be a major advantage in many areas of Africa where successful and prolonged breast-feeding is of critical importance to the health of infants and young children. While it is known that DMPA does get into the breast milk in small quantities, no long-term effect on babies is known at this time (15).

DMPA has been used in the treatment of endometriosis and dysmenorrhea and may be a preferred contraceptive method in anemic women. It is curious that although DMPA has been implicated in the development of endo-

metrial and breast cancer in animals, it is used to treat these same conditions in humans. In Africa, where iron-deficiency anemia is very common, the decreased menstrual blood loss produced by DMPA is an important noncontraceptive benefit of this approach to contraception.

USER INSTRUCTIONS

1. Use an additional contraceptive method for the first 2 weeks after your first injection or whenever your clinician instructs you to.
2. Return to the clinic every 3 months for another injection.
3. Go back to the clinic if you have longer periods, spotting between periods, irregular periods, or no periods at all. (See Figure 12.1.) Most of the time, the change in your periods does not mean that there is a problem. But if the bleeding is bothering you, go back to the clinic to get a blood test for anemia or to change your method.
4. Remember that you may not be able to become pregnant immediately after you stop using the injection. Although it is usually possible to become pregnant after using the injection, it may take as long as 12-18 months before your periods are regular and you can become pregnant.
5. See your clinician if you develop these symptoms: decreased sex drive, weight gain, headaches, or dizziness. (See Figure 12.1.) The injection is a fairly new method, and it is not yet known whether it will cause an increased risk of blood clots. Watch out for severe headaches, blurred vision or partial blindness, severe leg pains, and chest pains. **CONTACT YOUR DOCTOR OR CLINIC IMMEDIATELY** if any of these symptoms develop.



DEPO-PROVERA®
(THE SHOT)

Danger Signals

- ☐ Weight gain
- ☐ Headaches
- ☐ Heavy bleeding
- ☐ Depression
- ☐ Frequent urination

Contact us if you develop any of the above problems.

FIGURE 12.1 Depo-Provera® danger signals.

THE MINI-PILL OR PROGESTIN-ONLY PILLS*

The Mini-Pill has been marketed since the early 1970's. These Pills contain small doses of the same progestins available in combined oral contraceptives. Ovrette[®] provides 0.075-mg norgestrel, which is 15% of the dose in Ovral[®], while Nor-Q.D.[®] and Micronor[®] provide 0.35-mg norethindrone, which is one-third of the dose in Norinyl 1 + 50[®] and Ortho Novum 1 + 50[®]. (See Table 12.1 for the names of other progestin-only Pills available in Africa.)

Just how much safer (or more dangerous) Mini-Pills are than combined Pills has not been demonstrated. Theoretically, the absence of an estrogen would make the Mini-Pill considerably safer. Thus, because of the theoretical relative safety of the Mini-Pill, family planning workers might feel comfortable prescribing a full year's supply at one visit.

EFFECTIVENESS

While taking Mini-Pills, approximately 40% of women consistently have ovulatory cycles, and 20% shift back and forth from ovulatory to anovulatory. The way in which progesterone in the Mini-Pill acts to prevent pregnancy is described in Chapter 11.

TABLE 12.1 Characteristics of progestin-only oral contraceptives available in Africa

Proprietary Name	Manufacturer	No. of Tablets	Progestogen	mg
<i>PROGESTIN-ONLY PREPARATIONS:</i>				
Exluton [®]	Organon	35	Lynestrenol	0.5
Femulen 0.5 [®]	Searle	28	Ethinodiol diacetate	0.5
Microlut [®]	Schering	35	Levonorgestrel	0.30
Micronor [®]	Ortho	35	Norethisterone	0.35
Micro-Novum [®]	Ethnor	35	Norethisterone	0.075
Noriday (Norod) [®]	Syntex	28	Norethisterone	0.35
Ovrette [®]	Wyeth	28	Norgestrel	0.075

The theoretical rate of effectiveness of the Mini-Pill is slightly less than that of combined oral contraceptives, falling more into the effectiveness range of the IUD. Theoretical failure rates for Nor-Q.D.[®] and Micronor[®] have been reported at about 1.25 pregnancies per 100 women using the method in 1 year.

*In this book, the term "Mini-Pill" refers only to progestin-only preparations and never applies to sub-50 mg-combination Pills.

Pregnancy rates are highest in the first 6 months of using the Mini-Pill. Ideally, a second method, such as a condom or spermicides, may be used as a backup during the first 1 or 2 months. However, this practice is not essential and should not be enforced if it would interfere with the user's continued use of the Mini-Pill.

CONTRAINDICATIONS

Since relatively few studies have been done on the use of the Mini-Pill, it is safest to assume that the absolute contraindications to the use of estrogen-containing Pills (see Chapter 11) also pertain to use of the Mini-Pill. However, it is not known at this time if there actually is an increased risk of thromboembolic disease associated with progestin-only contraceptives. As a result of the irregular bleeding produced by the Mini-Pill, undiagnosed abnormal genital bleeding is one of the more important contraindications to its use, especially in women over 35 years old. Progestin-only Pills should also be avoided in pre-diabetes (gestational diabetes), women with acute mononucleosis, women with irregular menses, and women with a history of an ectopic pregnancy.

PROFILE OF PATIENTS WHO MIGHT CHOOSE THE MINI-PILL

The Mini-Pill may be the initial oral contraceptive of choice for women who are over 35 or for women who have a history of headaches, hypertension, (see the section in this chapter on Pill dosage modification), or varicose veins.

If a hormonal method of contraception is to be used by a lactating woman once breast-feeding has been established, the Mini-Pill or a progestin birth control injection should be prescribed.

The Mini-Pill is most often provided after a patient has experienced one of the estrogen-excess side effects from the combined Pill. *The most common estrogen-related side effects dictating a change in method to the Mini-Pill are headaches, hypertension, leg pain, chloasma, weight gain, and nausea. Depression and weight gain may be either estrogen-excess or progestin-excess side effects. Monilia vaginitis, weight gain, and acne are progestin-excess side effects that may be improved by switching to the Mini-Pill.* It is important to remember that the Mini-Pill contains no estrogen and contains a smaller amount of the progestin than does the combined Pill (see pyramid of estrogen and progestin potency in Chapter 11). *Both long-acting progestins and the Mini-Pills seem to increase the length of time that a woman may successfully nurse, and both are preferable to combined Pills, which may decrease the flow of breast milk.*

**HEADACHES, HYPERTENSION, AND LEG PAIN—
THE MOST COMMON SIDE EFFECTS OF THE COMBINED
PILL—MIGHT DICTATE A SWITCH TO MINI-PILLS.**

COMPLICATIONS

Irregular menses, decreased duration and amount of menstrual flow, spotting, and amenorrhea are the major complications of the Mini-Pill. Headaches are less common than with the combined Pill. An increased risk of thrombophlebitis in users of the Mini-Pill has not been established. Drug circulars include side effects experienced in other body systems, such as edema, hirsutism, and alterations in hepatic function tests, metapyrone tests, and pregnanediol determination. Because the estrogen in combined Pills is thought to be associated with cardiovascular disease and the Mini-Pill only contains progestin, it is theoretically safer than combined Pills, but we do not have long-term scientific studies proving this.

NONCONTRACEPTIVE BENEFITS

Dysmenorrhea is diminished in some users of the Mini-Pill, although not so predictably as with combined oral contraceptives. The total blood loss in Mini-Pill users is also diminished.

USER INSTRUCTIONS

1. Take one Pill every day. As soon as you finish one packet of Mini-Pills, go right on to the next packet the very next day. *Never miss a day if you are taking Mini-Pills.*
2. If you miss one Pill, take it as soon as you remember, and take your next Pill at the regular time. Use a second method of birth control until your next period.
3. If you miss two Pills, take one of the missed Pills as soon as you remember, as well as your regular Pill for that day. Take the other forgotten Pill plus the regular one the next day. Use a second method of birth control until your next period.
4. If you do not have a period within 45 days of your last one, it needs to be determined immediately if you are pregnant. Expect changes in the time between periods and in the length of your periods.
5. You may have some spotting between periods. Some women have perfectly regular, normal cycles using the Mini-Pill. Many, however, experience irregular cycles. Some women have very infrequent periods (1 or 2 per year) while on the Mini-Pill.
6. Ideally, to improve the effectiveness of the Mini-Pill, you should use a second method for the first 2 months and for those women who are having regular periods during the midcycle days (days 12 through 18).

OTHER PROGESTIN-ONLY CONTRACEPTIVES CURRENTLY IN THE RESEARCH STAGE

SUBDERMAL SILASTIC CAPSULES CONTAINING PROGESTINS

These have been used experimentally as a means of providing reversible long-term contraception. It is hoped that single silastic capsules might provide effective contraception for 5 years or longer. A major problem is that the silastic capsules must be removed.

VAGINAL RINGS IMPREGNATED WITH PROGESTINS

Vaginal rings, worn by women for 21 days at a time during clinical trials, have provided effective (98%) contraception protection and have avoided the coitus-related inconveniences associated with diaphragms. They are not yet available commercially. A ring slightly smaller than a regular diaphragm (50-60 mm) is placed into the vaginal vault each month after menses like a diaphragm and left in place for 21 days. The ring releases progestins that are systemically absorbed and that may also have local effects. Rings that can be left in place for a full 3 months are being evaluated by the World Health Organization in several research centers throughout the world, including the center in Ibadan, Nigeria.

IUD'S THAT RELEASE A PROGESTIN

These IUD's have been used as a means of increasing IUD contraceptive effectiveness and of decreasing uterine cramping and total menstrual blood loss. Several progestins, including progesterone, have been used in these IUD's. A norgestrel-releasing IUD that may be used continuously for 6 years is now being evaluated by The Population Council, a private American organization.

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CHAPTER 13

INTRAUTERINE DEVICES

May I repeat, too, that this method is not suitable for every doctor, nor is it suitable for every woman. We must differentiate very carefully between individual cases.

*Dr. Ernst Graefenberg
Inventor of the Graefenberg ring — 1931*

Development of the modern IUD began in 1909 when Richter (R.) and Graefenberg devised intrauterine devices made of silkworm gut. Since then, IUD's have been made in various shapes including rings, spirals, T-shapes, 7-shapes, and others. The Lippes Loop[™] remains the most widely used IUD throughout Africa and, indeed, throughout most of the rest of the world. Today, IUD's are used by some 60 million women throughout the world.

The materials used to make the devices have also varied and have included silver, copper, and plastic. Some devices contain progesterone; the majority do not. (See Table 13.1.)

MECHANISM OF ACTION (1-5)

Several mechanisms of action have been suggested for IUD's:

1. Immobilization of sperm.
2. Increased motility of the ovum in the fallopian tube.
3. Local foreign-body inflammatory responses causing lysis of the blastocyst and/or prevention of implantation.
4. Mechanical dislodging of the implanted blastocyst from the endometrium.
5. Impairing implantation by disruption of the proliferative-secretory maturation process by progestin-elaborative IUD's.
6. Increased local production of prostaglandins, which inhibit implantation.
7. Competition of copper with zinc causing inhibition of carbonic anhydrase and possibly alkaline phosphatase activity. Copper may also interfere with estrogen uptake and its intracellular effects on the endometrium.

EFFECTIVENESS

The method effectiveness of IUD's is between 97% and 99% (1). The differences in effectiveness for different IUD's can be attributed to such IUD

TABLE 13.1 *Physical characteristics of IUD's, IUD strings, and IUD insertion mechanisms*

Type IUD	Length* (mm)	Width* (mm)	Insertor Barrel Widest Diameter (mm)	Color of Strings	Number of Strings	Other String Characteristics
Lippes Loop A ^c	33.0	22.5	5.26	Blue	1 or 2	1 thick; 2 thin
Lippes Loop B ^a	34.0	28.0	5.30	Black	1 or 2	1 thick; 2 thin
Lippes Loop C ^a	35.0	30.0	5.30	Yellow	1 or 2	1 thick; 2 thin
Lippes Loop D ^a	36.0	30.0	5.33	White	1 or 2	1 thick; 2 thin
Small Saf-T-Coil ^c	21.5	25.5	3.76	Green	2	Thin strings
Medium Saf-T-Coil ^a	32.0	30.0	4.50	Green	2	Thin strings
Large Saf-T-Coil ^a	33.0	38.0	4.50	Green	2	Thin strings
**Small Dalkon Shield ^c	20.5	22.0	18.50	Black	1	Knot on thick string
**Standard Shield ^a	21.5	24.9	19.48	Black	1	Knot on thick string
Copper-7 ^a	36.0	27.0	3.07	Black	1	Thin string
Copper-T ^a	36.0	31.5	5.96	Light Blue (variable)	2	Thin strings
Progestasert-T ^c	36.0	32.0	6.0	Translucent	2	Thin strings (one precut at 9 cm)

*Measured to nearest 0.5 mm. The length of the Loop series of IUD's increases after the IUD has been drawn into the inserter barrel and expelled. These are post-expulsion measurements.

**Dalkon Shields^a are no longer marketed. Because of risks of infection, spontaneous abortion, and maternal death occurring in users who become pregnant with the Shield in utero, it is recommended that all users have their Dalkon Shields^a removed.

characteristics as size, shape, presence of copper or progesterone (see Table 13.2), and to a number of other variables such as age and parity of the IUD user. One of the major advantages of the IUD is that its range of actual effectiveness for users (about 90%-96% effective) is quite comparable to its method effectiveness rates since patients can make relatively few errors (see Chapter 9). The user-effectiveness of IUD's depends on a number of administrative, patient, and medical variables, including ease of insertion, clinician experience, the possibility that the patient will not detect whether the IUD has been expelled, and the user's access to medical services.

CONTRAINDICATIONS TO IUD INSERTION (1,6,7)

Some women are restricted from using IUD's because of severe medical conditions. The contraindications listed below are meant as guidelines only; not all family planning clinicians are in agreement with them. Some clinicians believe that in the absence of strongly documented evidence for some of the contraindications, the contraceptive benefits warrant easing of the restrictions for IUD use. Others believe that because of the possibility that certain medical problems may arise from its use, it is better to restrict the IUD use to those women who have easy access to medical services. Still other authorities believe that limited access to medical services will probably not create a dilemma as long as women are initially screened to eliminate those who are predisposed to risks.

One of the main concerns about the use of the IUD is that women who use it are more likely to develop PID than women who do not use it (7). Because of the high rate of PID and sexually transmitted diseases in certain parts of Africa (see Chapters 5 and 6), this association may be of major concern and needs to be considered carefully.

ABSOLUTE CONTRAINDICATIONS

1. Active, recent, or recurrent pelvic infection (acute or subacute), including known or suspected gonorrhea.
2. Pregnancy (known or suspected).

STRONG RELATIVE CONTRAINDICATIONS

3. Cervical or uterine malignancy (known or suspected), including unresolved Pap smear.
4. Risk factors for PID:
 - post-partum endometritis,
 - infection following an abortion that occurred within the past 3 months,
 - purulent cervicitis, until controlled,
 - impaired response to infection (diabetes, steroid treatment, etc.),
 - recurrent history of gonorrhea.

TABLE 13.2 Overview of IUD effectiveness and complications*

Device	Size	Material	Year Introduced	Manufacturer or Distributor	Pregnancy Rate*	Expulsion Rate*	Removal Rate*	12-Month Continuation Rate
Lippes Loop [†]	A (small)	Polyethylene	1964	Ortho	8.0	6.9	11.7	63.6
	B	Barium Impreg.			5.8	6.5	21.1	59.2
	C	Nylon Tail			4.1	5.3	19.2	62.8
	D (large)				3.6	3.6	19.5	65.6
Saf-T-Coil [‡]	Nullip	Polyethylene Barium Impreg.	1967	Julius Schmid	0.1	10.0	15.4	78.3
	Multip	Nylon Tail			1.3	11.4	10.0	74.1
Copper-T 200 [§]	One Size	Polyethylene Fine Copper Nylon Tail	1978	Population Council	1.5	5.3	7.2	80.9
Copper-7 200 [§]	One Size	Polyethylene Fine Copper Nylon Tail	1973	G.D. Searle	1.5	3.3	4.2	87.6
Progestasert-T	One Size	Polyethylene T with polymeric membrane; Nylon tail	1976	Alza Corp.	2.5 (Nullip) 1.9 (Multip)	7.5 3.1	9.7	79.1

*Per 100 woman years.

5. Abnormal uterine bleeding.
6. History of ectopic pregnancy.
7. Impaired coagulation response (idiopathic thrombocytopenic purpura, anticoagulant therapy, etc.).

OTHER RELATIVE CONTRAINDICATIONS

8. Valvular heart disease (potentially makes patient susceptible to subacute bacterial endocarditis; some clinicians recommend prophylactic antibiotics in this situation).
9. Abnormal uterine shape (leiomyomata, endometrial polyps, bicornuate).
10. Cervical stenosis.
11. Small uterus.
12. Severe dysmenorrhea.*
13. Severe menorrhagia.*
14. Anemia.
15. Past history of severe vaso-vagal reactivity or fainting.
16. History of impaired fertility with desire for future pregnancy.
17. Endometriosis (possible).
18. Allergy to copper (known or suspected) or diagnosed Wilson's disease (copper IUD's only).

TYPES OF IUD's

There are two types of IUD's: those that are medicated and release hormones or copper and those that are not medicated. The IUD's currently available in Africa are shown in Figure 13.1; their physical characteristics are outlined in Table 13.1.

****Lippes Loops[®]** are the most commonly used IUD's throughout Africa. They come in either prepackaged sterile units or in less expensive packages containing 100 Loops that must be sterilized with an iodine (1:2,500 for Betadine[®]) or benzalkonium antiseptic solution for a period of 30 minutes before use.

****Saf-T-Coils[®]** come in separate, sterile packages that contain an IUD, an inserter, and, in some instances, a plastic sound. They are easy to insert and remove. Insertion may be done by either the plunging or the withdrawal technique since the outer plastic ring on the inserter barrel is adjustable. The inserter barrel is a bit narrower than the Lippes Loop[®] inserter.

****The Copper-T[®]** (or Tatum-T[®]) is more popular than the Copper-7[®] in most areas of Africa. This IUD comes in presterilized packages. Insertion is accomplished using the plunging technique in much the same manner as is used for the Lippes Loop[®]. At first, it is difficult to fold the upper limbs of the "T" down into the inserter barrel; but this becomes easier with practice.

****The Copper-7[®]** (or Gravigard[®]) comes in separate presterilized packages with an inserter. Insertion may be done by the push technique or by the

*Progestasert[®] IUD may be therapeutic.

**Known to be available in Africa.

withdrawal technique, as the cervical stop on the inserter is adjustable. The Copper-7[™] has the narrowest inserter barrel mechanism of all IUD's. Approximately halfway through the actual insertion by the withdrawal technique (or after a snap is felt when the upper limb of the Copper-7[™] pops out of the inserter tube), the insertion rod may be gently pushed up toward the top of the fundus to ensure high fundal placement. The withdrawal technique is then completed. This IUD appears to be used most in francophone Africa.

*The Progestasert-T[™] comes in separate presterilized packages and has a wide inserter barrel diameter at the end nearest the nonmovable plastic phalange. The inserter narrows down so that the end that must go through the internal cervical os is a good bit narrower. The Progestasert-T[™] must be inserted by the plunging technique.

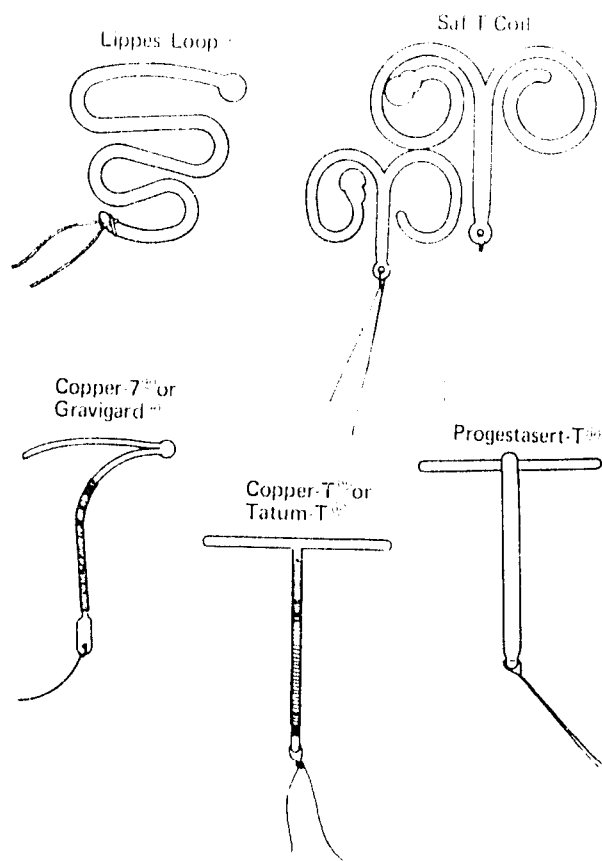


FIGURE 13.1 Five IUD's currently available in Africa.

FACTORS TO CONSIDER IN CHOOSING AN IUD

In selecting an IUD, it is important to remember the following: PROBABLY THE SINGLE MOST IMPORTANT FACTORS ARE THE COMPETENCE OF THE DOCTOR, NURSE, OR MIDWIFE AND HIS OR HER FAMILIARITY WITH

THE IUD SELECTED. It is better to master the use of one type of IUD than to use all of them with less competence. Table 13.3 is designed as a guide for clinicians in choosing an IUD. It is based on the assumption that all of the IUD's mentioned are available to the clinician and that the clinician is competent at inserting all IUD's.

IUD's can be inserted by a broad range of trained personnel. Studies from developed and developing countries show that nurses, nurse-midwives, physician assistants, paramedical personnel, and even rural village midwives can perform routine IUD insertion (8,9). Careful analyses have demonstrated that the apparent difference in performance between one IUD and another is often not as great as the differences between one clinical center and another. This means that the skill of the IUD inserter, the quality of counseling, selection, reassurance, and followup are probably more important than structural differences between IUD's. There is debate as to how many IUD's a nurse or midwife might insert before she is competent to insert IUD's in a rural health setting; however, it is probably wise to have performed 15-20 insertions before going out on one's own. A person who has inserted only four to six IUD's most likely will not have had sufficient experience with difficult insertions to start working unsupervised in a clinic.

INSERTION OF THE IUD

When during the menstrual cycle should the IUD be inserted? Just about any time during the cycle—unless pregnancy is possible. If pregnancy is a possibility, IUD insertion should be delayed until the next menstrual flow, which usually indicates that the woman is not pregnant (10).

MUST A WOMAN BE MENSTRUATING IN ORDER TO HAVE AN IUD INSERTED? ... NO! IUD's MAY BE INSERTED FOR WOMEN WHO ARE NOT MENSTRUATING (see Figure 13.2). A woman who is *NOT* menstruating may have an IUD inserted in the following situations:

- If she is post partum, has had no menses, and has not had sexual intercourse since delivery of her baby.
- If she is post partum and has had intercourse which was protected every time by condoms or vaginal spermicides. If the uterus is considered to be enlarged, one may want to perform a pregnancy test in this situation to determine if she is pregnant.
- If a menstruating woman has not had sexual intercourse since her last menses.
- If a woman has been using birth control Pills consistently or another method reliably, one may insert an IUD on any day of the cycle.
- Immediately after her menses.

TABLE 13.3 Choosing an IUD for an individual patient

Assumptions: (1) Cu-7[®], Cu-T[®], Progestasert-T[®], Lippes Loop[®], and Saf-T-Coil[®] are available. (2) Clinician is competent and familiar with insertion technique for each of these IUD's. (3) Patient and clinician have decided that an IUD is the method of choice. (4) No contraindications to IUD use exist. (5) The IUD is an option for some nulligravid women.		
Questions to help determine which IUD to use	Answer to question for the individual patient	IUD(s) which may be used or should not be used
Is the patient using the IUD for termination of childbearing or for spacing of children?	Termination (wants no more children).	Use an IUD that need not be removed and replaced at any set interval. Lippes Loops [®] or Saf-T-Coils [®] may be left in place indefinitely in the absence of complications. The 12-month limit on the Progestasert-T [®] is a strong deterrent to its use on a routine basis.
Has the patient ever been pregnant?	Spacing.	All IUD's acceptable.
	No, nulligravid patient.	Small IUD inserter barrel may facilitate IUD insertion. Cu-7 [®] diameter 3.07 mm Small Saf-T-Coil [®] 3.76 mm Consider using a paracervical block but carefully observe toxic limits of agents used.
	Yes: (1) post-therapeutic abortion	Use fairly small or medium-sized IUD: Cu-7 [®] , Cu-T [®] , small or medium-sized Saf-T-Coil [®] , Lippes Loop A [®] or B [®] or C [®] .
	(2) post full-term delivery, uncomplicated. (3) post full-term delivery, C-section.	Most IUD's acceptable. Consider using an IUD which may be inserted using withdrawal technique rather than expulsion technique: Saf-T-Coil [®] or Cu-7 [®] . Lippes Loop [®] is perfectly suitable after careful sounding of uterus.
Does patient have history of painful or heavy menses?	Yes, painful menses.	Consider using Progestasert-T [®] . Be sure not to insert too large an IUD.

Questions to help determine which IUD to use	Answer to question for the individual patient	IUD(s) which may be used or should not be used
How large is the uterus?	Yes, heavy menstrual bleeding.	Consider using Progestasert-T [®] . Of other IUD's, Cu-7 [®] and Cu-T [®] may produce less augmentation of menses than Lippes Loops or Saf-T-Coils [®] .
	Uterus sounds less than 4.5 cm.	No current IUD likely to be well tolerated.
	Uterus sounds 4.5-6.5 cm.	Use IUD with vertical length less than 3.0 cm; small Saf-T-Coil [®] is 2.2 cm long.
	Uterus sounds 6.5-9.9 cm.	Most IUD's acceptable.
Are there other social, medical, or personal factors which might indicate or contraindicate using a specific IUD?	Uterus sounds 10.0 cm or more.	The large Saf-T-Coil [®] , large Lippes Loop [®] , Cu-7 [®] , Cu-T [®] , Progestasert-T [®] . Strongly urge backup method of contraception.
	Allergy to copper or history of Wilson's disease.	Avoid use of Cu-7 [®] or Cu-T [®] .
	Patient using IUD after unprotected midcycle intercourse.	Use Cu-7 [®] or Cu-T [®] .
	History of expulsion(s) of previous IUD(s).	Use a more rigid IUD, such as a polypropylene Lippes Loop [®] . If too large an IUD has been used in small uterus, may need smaller IUD. If too small an IUD has been used in large uterus, may need larger IUD. The Progestasert-T [®] has been used with some success following multiple expulsions of other IUD's.
	Patient will have difficulty returning for annual exams.	Avoid IUD which must be replaced at certain intervals such as Cu-7 [®] , Cu-T [®] , or Progestasert-T [®] .
	Patient specifically requests a certain IUD.	Try to provide the IUD the patient requests. Never use an IUD the patient specifically does not want.

*Cu-7 = Copper 7[®]**Cu-T = Copper T[®]

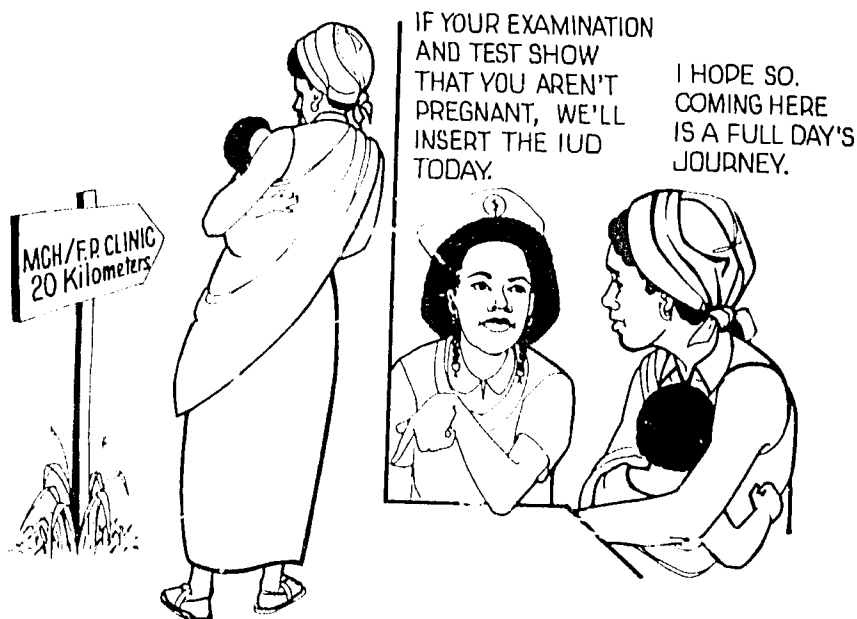


FIGURE 13.2 If you can determine that the woman is not pregnant, an IUD can be inserted even if she is not menstruating.

IN RURAL AREAS OF AFRICA AND IN SOME URBAN CLINICS, WOMEN MAY NEED TO TRAVEL A LONG TIME TO GET TO A FAMILY PLANNING CLINIC. THE INCONVENIENCE TO THE PATIENT CAUSED BY A POLICY THAT DICTATES WHEN IN THE MENSTRUAL CYCLE IUD'S ARE TO BE INSERTED CAN BE AN IMPORTANT OBSTACLE TO LAUNCHING AN EFFECTIVE IUD PROGRAM.

Case History: A patient who was 3 months post partum came to the family planning clinic wanting to use an IUD as her method of birth control. She had been nursing her baby, and she had not had sexual intercourse. Physical examination revealed that the uterus was firm and nontender and was involuting well. On the basis of the above history, the decision was made to insert an IUD. The insertion was easy as the post-partum period is a particularly easy time to insert an IUD. The patient was provided with an appointment for 6 weeks later at which time the strings to the IUD were seen at the cervical os. There was no uterine tenderness. The woman's menses returned at 11 months post partum.

ONE MUST TRUST THE HISTORY GIVEN BY WOMEN IN A FAMILY PLANNING CLINIC. THIS IS A BASIC PRINCIPLE IN PROVIDING THOUGHTFUL, DIGNIFIED FAMILY PLANNING SERVICES.

Move slowly and gently during all phases of IUD insertion. Refer to Figure 13.3 for the minimal equipment required for IUD insertion. Insertion differs slightly for the various IUD's, depending on the size and shape of the IUD and uterus (see Figure 13.4), the inserter barrel and plunger, packaging, and the strings. The following are instructions that would apply to inserting all IUD's.

FOR CURRENT INFORMATION, ALWAYS READ THE INSTRUCTIONS ON IUD INSERTION WRITTEN BY THE MANUFACTURER

1. **Explain** the procedure of IUD insertion to the patient to help her relax.
2. Perform a careful *bimanual exam* to rule out pregnancy and active pelvic infection and to diagnose the position of the uterus. When the tract of IUD perforations is located, it is almost always at 90° to the axis of the fundus. When the uterus is retroflexed—and this is not recognized—there is a greater possibility of uterine perforation at the time of IUD insertion.
3. After inserting a warm speculum (see Figures 13.5 and 13.6) and viewing the cervix, wash the cervix several times (three or more) with an antiseptic solution such as a 1:2,500 solution with iodine. If iodine is present in the antiseptic solution, ask the patient if she has a history of allergy to iodine. If she does, then use a benzalkonium chloride solution, hexachlorophene solution, or saline solution.
4. In some instances, intracervical local anesthesia may be injected at this point.
5. **Grasp** the anterior lip of the cervix with a tenaculum about 1.5-2.0 cm from the os. Close the *single-tooth tenaculum slowly, one notch at a time*. Use of a tenaculum is not always necessary, but it may be very helpful if there is stenotic internal cervical os *OR* if there is sharp flexion of the fundus anteriorly or posteriorly.
6. **Sound** the uterus slowly and gently. Place a cotton swab at the cervix when the sound is all the way in. Remove sound and swab at the same time. This permits measurement of the depth of the fundus to within 0.25 cm.
7. **Load** the IUD into the inserter barrel under sterile conditions.
8. Apply steady, gentle traction on the tenaculum, and introduce the inserter barrel through the cervical canal into the fundus.

THE TWO CARDINAL RULES FOR IUD INSERTION:

1. EVERYTHING DONE AT THE TIME OF IUD INSERTION *CAN* BE DONE SLOWLY AND GENTLY.
2. EVERYTHING DONE AT THE TIME OF IUD INSERTION *SHOULD* BE DONE SLOWLY AND GENTLY.

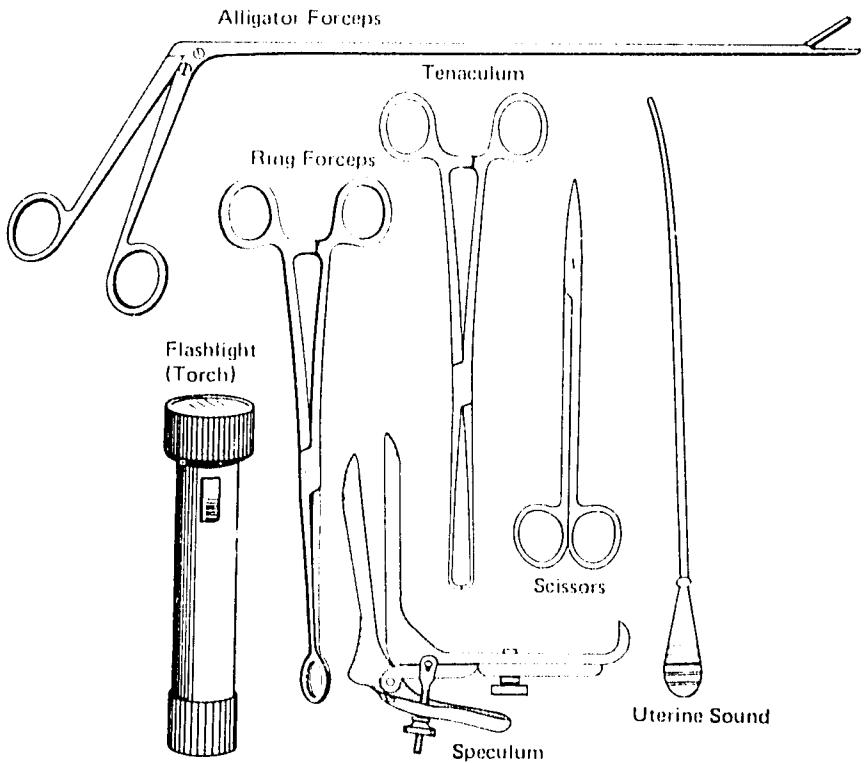


FIGURE 13.3 Minimal equipment for IUD insertion.

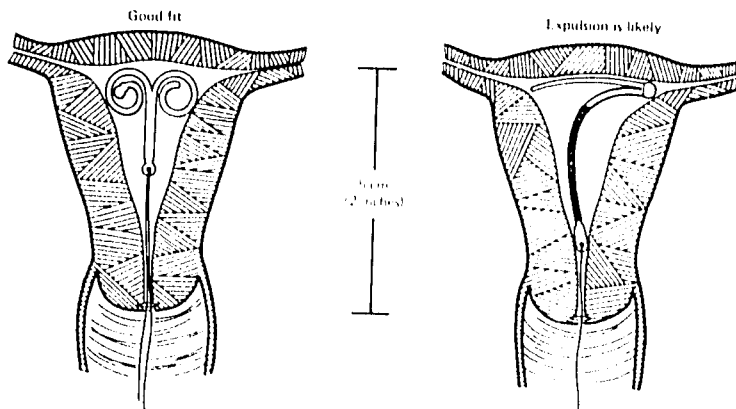


FIGURE 13.4 IUD fit for a small uterus, the Copper-7[®], and Saf-T-Coil[®].

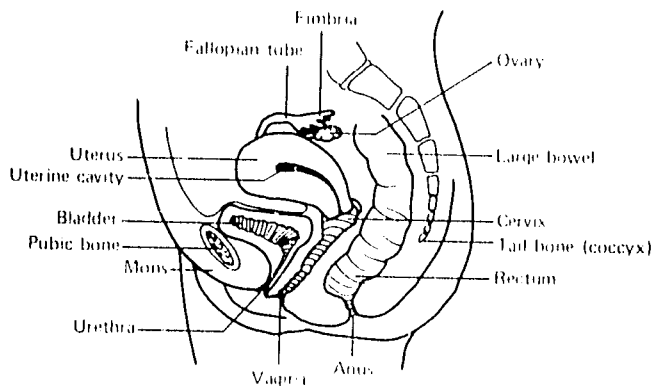


FIGURE 13.5 Side view of the pelvis.

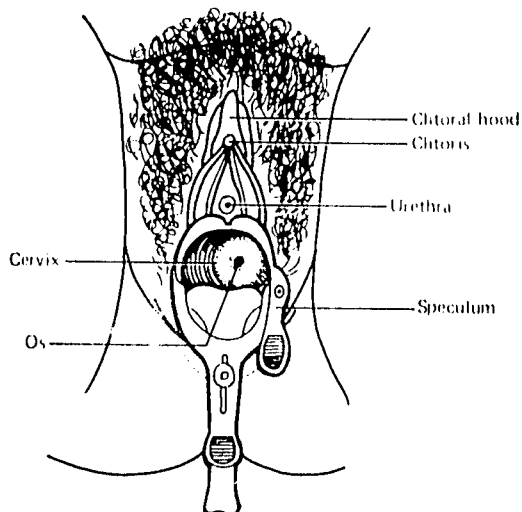


FIGURE 13.6 Cervix and os as seen through the speculum.

9. **Insert** the IUD into the cavity of the uterus by either plunging the inner plunger into the outer barrel (push technique) (see Figures 13.7 and 13.8) or by retracting the outer barrel over the plunger (withdrawal technique). The withdrawal technique is slightly preferred. Insertion should be done slowly and is usually possible without much force. (See box on post-partum insertion of IUD.)
10. Clip the strings. *Leave about 5 cm (or longer if being done immediately after an abortion). It is always possible to trim strings at a later date.*
11. Some clinicians have the patient feel for the strings of her IUD before she leaves the examining room. In any case, this procedure can be explained as part of the counseling process after the insertion.
12. Caution should be exercised when inserting IUD's for nulliparous women as they are more likely to experience vaso-vagal attacks and postinsertion pain necessitating immediate removal of the IUD. These problems are more common in nulliparous women who have anxiety, a narrow cervical canal, a small uterine cavity, an empty stomach, or a history of syncopal attacks. Gentleness, careful explanation, a warm and friendly environment, use of a small bivalve speculum, moving slowly, and judicious use of paracervical anesthesia may be of help in avoiding these two problems. Since the Lippes Loop[®] is the most widely used IUD in many African countries, we have included the following instructions for insertion. Its insertion is usually done by the plunging technique, as the plastic phalange on the inserter barrel is fixed. Insertion is usually fairly easy to teach. Removing the entire string from the inserter barrel is very important if a 4- to 5-cm tail is going to be left (4-5 cm out from cervical os). The string is cut by some clinicians at the time the Lippes Loop[®] is drawn into the inserter, and before insertion. This insures cutting the string at its maximal length. The insertion apparatus may be reused by washing the outer insertion barrel and the inner plunger and placing them into the same solution as used for sterilizing the Lippes Loop[®].

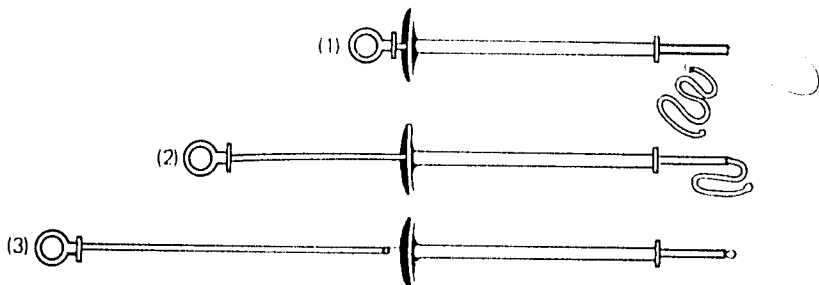


FIGURE 13.7 *Pulling Lippes Loop[®], through use of strings, into insertion mechanism.*

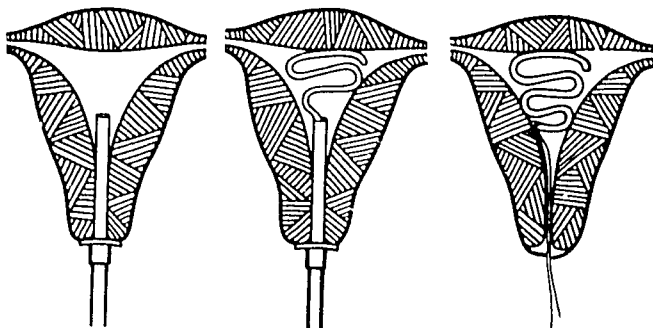


FIGURE 13.8 Lippes Loop™ being inserted into the uterus using the plunging technique.

PARACERVICAL ANESTHESIA OR PARACERVICAL BLOCK

Some procedures performed in a family planning clinic are painful, and local anesthesia may be used. A paracervical block using no more than 4 ml of 1% lidocaine without epinephrine is recommended to prevent pain from IUD insertion or difficult removal. PARACERVICAL ANESTHESIA IS PARTICULARLY BENEFICIAL AT THE TIME OF INSERTION IF THE WOMAN HAS NEVER BEEN PREGNANT OR IF A WOMAN HAS A HISTORY OF VASOVAGAL REACTIONS. Because of the possibility that the local anesthetic may be mistakenly injected into the vascular space, paracervical blocks should only be performed where facilities are available for resuscitation. Remember to ask the patient if she has any known allergies, especially to iodine or any local anesthetic.

A suggested procedure for performing a paracervical block follows:

1. Following bimanual pelvic examination, the clinician inserts a speculum into the vagina to obtain good visualization of the cervix.
2. Clean the cervix and vagina with antiseptic soaks.
3. Ask the patient to inform you if she experiences nausea, dizziness, ringing of the ears, or tingling of the lips from this procedure.
4. Apply the tenaculum to the upper lip of the cervix. Before doing this, some clinicians inject 1-cc of lidocaine at the tenaculum site.
5. Different clinicians use different placements of injections around the cervix. ONE TECHNIQUE IS TO INJECT 1-2 cc OF 1% LIDOCAINE AT 4 O'CLOCK AND ANOTHER 1-2 cc AT 8 O'CLOCK (A TOTAL OF 2-4 cc).
6. The needle is inserted just under the mucosa in the connective tissue. Since most of the smaller blood vessels and capillaries are in this region, this method assures rapid and adequate distribution of the anesthetic. Aspirate lightly with each injection to avoid direct intravenous injection.
7. Be aware of symptoms of toxic reactions as stated in instruction 3 above and treat accordingly.
8. Anesthesia occurs in 2-5 minutes.

IMMEDIATE POST-PARTUM IUD INSERTION

Uterine perforation and high rates of expulsion, the major problems associated with immediate post-partum IUD insertion, appear to have been overcome by hand insertion of a Lippes Loop[®] to which have been tied three biodegradable sutures (2). These three sutures project at a 45° angle from the upper limb of the Lippes Loop[®] and temporarily become embedded, preventing expulsion. While the patient is still in the delivery room, the sterile Lippes Loop[®] held between the index and middle fingers, is introduced into the vagina, past the dilated cervix and to the fundus of the uterus. Care must be taken not to displace the IUD while directing the 10-inch monofilament nylon tail toward the cervix. Kamal, et al., at the Cairo University in Egypt found a 1.2% expulsion rate at 3 months among 86 women provided with this IUD (2). Disappearance of the thread in 64% of cases is the remaining engineering problem with this approach to immediate post-partum contraception.

SIDE EFFECTS AND COMPLICATIONS

The rates of some of the complications from IUD use are listed in Table 13.2.

Eight potential complications from IUD's are listed in order of increasing severity.

SERIOUS COMPLICATIONS FROM IUD'S ARE PREVENTABLE.
WHEN IN DOUBT, TAKE AN IUD OUT.

1. Spotting, bleeding, hemorrhage, and anemia

Approximately 15% of women will have their IUD's removed because of bleeding or spotting. Bleeding is often heavier for women with IUD's. They may experience more days of bleeding, persistent bleeding, spotting between cycles, and even pallor or weakness. In addition to PID, the differential diagnosis must include a partial expulsion of the IUD, dysfunctional uterine bleeding due to an endocrine imbalance, cancer of the cervix or endometrium, cervical or uterine polyps, abnormal perimenopausal bleeding, leiomyomata, and postcoital spotting.

If bleeding is related to the IUD, here are several guidelines as to when to remove the IUD:

- If bleeding is associated with endometritis
- Whenever the patient wants it removed
- If there is an hematocrit fall of 5
- If the patient has a hematocrit level of 30-32
- If the IUD has been partially expelled

IRON SUPPLEMENTATION IS WISE FOR ALL IUD USERS WHO MAY BE AT RISK OF DEVELOPING AN IRON-DEFICIENCY ANEMIA.

2. Cramping and pain

MAY BE CAUSED BY OR BE ASSOCIATED WITH...

WHAT TO DO...

Sounding the uterus during the process of insertion

Sound slowly, gently; use smaller sound if meeting resistance.

Cramping immediately after insertion, for a day or so thereafter, or during first menses

If severe, may necessitate IUD removal; if mild, provide aspirin (2 or 3 tablets) or prostaglandin synthetase inhibitor.

Partial expulsion of an IUD

Remove IUD. If no infection, may reinsert another IUD.

Pelvic inflammatory disease

Remove IUD, treat infection and wait 3 months before considering reinsertion of another IUD. Provide alternative contraception.

Severe post-insertion pain, vaso-vagal reaction, syncope, seizures, and even cardiac arrest (very rare)

Atropine 0.4 or 0.5 mg intramuscular (or in paracervical block solution before insertion); pain medication; maintenance of cardiac output; remove IUD if necessary.

Too large IUD

May remove IUD and perhaps insert smaller one.

Spontaneous abortion

Diagnose pregnancy, remove IUD, evacuate uterus, rule out ectopic pregnancy.

Ectopic pregnancy

Refer for immediate surgery.

IUD that does not unfold correctly

Remove IUD and reinsert or insert a different IUD.

Whenever evaluating pelvic pain in a woman with an IUD in place, it is essential to rule out the possibility of an ectopic pregnancy. Vaginal discharge repeatedly surfaces as an early warning symptom that might have served as a clue to more serious complications

3. IUD expulsion: partial and complete

From 5%–20% of 100 users spontaneously expel an IUD within the first year (1). The symptoms of IUD expulsion may include unusual vaginal discharge, cramping or pain, intermenstrual spotting, postcoital spotting, dyspareunia (male or female), lengthening of the IUD string, ability to feel the hard IUD at the cervical os or in the vagina, or passage of the IUD itself from the vagina. IUD expulsion may cause penile pain or irritation.

IF EXPULSION IS NOT NOTICED, THE FIRST INDICATION THAT SOMETHING IS WRONG MAY BE A MISSED MENSTRUAL PERIOD, THE SYMPTOMS OF PREGNANCY, OR INABILITY TO FEEL THE STRINGS OF THE IUD.

The objective findings to look for include seeing the IUD at the cervical os or in the vagina, lengthening of the IUD string (partial expulsion), absence of the string (complete expulsion), inability to locate the IUD using various techniques of probing the uterine cavity, and absence of the IUD on ultrasound or on an X-ray film of the pelvis and abdomen. The differential diagnosis of the lost IUD is discussed in the next section. If partial expulsion occurs, the IUD should be removed. It may be reinserted right away (if there is no infection and no possibility of pregnancy) or after the next period. If the expulsion is complete, a new IUD may be inserted. Often, it is helpful to try a different size or shape IUD. The Progestasert-T[®] may not be expelled when other IUD's have been expelled repeatedly.

4. Lost IUD strings and other string problems

The patient may complain of an inability to feel her strings, gradual shortening of her strings, or irritation of her partner by IUD strings. However, the problem is more commonly detected during a followup visit to the clinic. There are two major reasons why clinicians become concerned if the IUD string is no longer detectable or is lost:

- The IUD may have been expelled; or
- The IUD may be in the abdominal cavity.

However, the IUD string may merely have been drawn up into the uterine cavity. The clinician should attempt to locate the IUD strings to rule out the above two complications. Use a sonogram first (to locate the IUD) if the method is available. A helix can be used to retrieve the strings in

some cases (see Figure 13.9). Examination often reveals that the strings are right where they should be, in which case the patient should be taught in the examination room to feel for the strings. Sometimes exploration of the cervical canal with a pair of narrow forceps, such as alligator forceps (see Figure 13.3), locates the strings immediately. Pregnancy must be excluded before further evaluation of lost IUD strings proceeds. The IUD may be felt with a uterine sound or removed with a variety of instruments, including alligator forceps, hooks, or forceps used at the time of hysteroscopy. X-ray techniques may also be employed, including the following approaches:

- Posterior to anterior and lateral of the pelvis following insertion of a marker IUD
- Posterior to anterior and lateral of the pelvis with a metallic sound introduced into the uterus
- hysterosalpingogram

If the strings are visible, the patient should be taught to feel them. If the strings are entirely within the endometrial cavity, it is usually desirable to remove the IUD and consider inserting another one, either the same or a different type. Because of its insertion mechanism, the Copper-7™ has

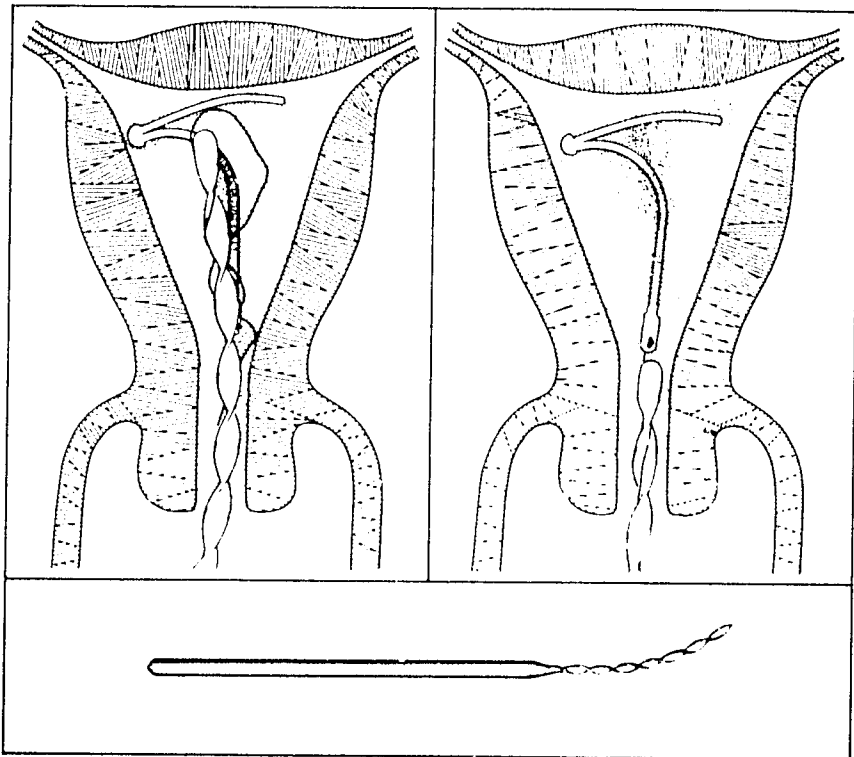


FIGURE 13.9 Helix used to retrieve lost IUD strings.

more string problems than other IUD's. A lost, shortened, or elongated string needs to be interpreted carefully.

Clinicians need to know how to interpret changes in string length:

- a. The "loop of string" may come out of the endometrial cavity, cause concern to the patient, *require a clinic visit* and a pelvic exam, and require the time of a physician or nurse practitioner to trim the string.
- b. If the "loop of string" comes out and is trimmed as per "a" above, it may slip back up into the uterus, leaving the patient and the clinician with the problem of "lost IUD strings."
- c. If the clinician cannot find the lost IUD strings, the patient may need to be hospitalized to locate or remove the IUD. This is of particular importance with copper-bearing IUD's.
- d. When the IUD string that comes out of the cervical os lengthens, usually "a" (above) has occurred, i.e., the intrauterine "loop of string," originally drawn up into the uterus, has come down from the uterine cavity. This has generally been found to be more common with the Copper-7™. **SOMETIMES, HOWEVER, THIS IS THE WRONG INTERPRETATION, and what has actually happened is that the IUD has been partially expelled into the cervical canal. If a misinterpretation occurs, the string may be trimmed and the patient sent out of the office with a PARTIALLY EXPELLED IUD. PREGNANCY MAY OCCUR AS A RESULT OF THIS MISINTERPRETATION.**

5. IUD removal

Removal of the Copper-7™ is occasionally difficult because it has a sharp angle that must be drawn through the internal cervical os. It may be complicated if the string loops over the top of the Copper-7™ IUD (see Figure 13.10). Removal may be painful. Unless embedded, Saf-T-Coils™ and Lippes Loops™ are associated with moderate to minimal pain or cramping upon removal. If a woman has had her IUD in place for 5 or more years, pain tends to be slightly worse because of embedding or narrowing down of the cervical canal. **THE FOLLOWING TECHNIQUES MAY HELP IN THE REMOVAL OF IUD'S:**

- a. Removal during menses is somewhat easier.
- b. **AVOID BREAKING THE STRINGS BY APPLYING GENTLE, STEADY TRACTION AND REMOVING THE IUD SLOWLY.** If the IUD does not come out easily, sound the uterus for 30 seconds and then rotate the sound 90° slowly.
- c. If gentle traction still does not lead to IUD removal, *dilate the cervix with dilators* (which should always be available in a clinic managing IUD complications). A paracervical block may be performed before cervical dilation to diminish pain. The cervix may also be dilated for difficult IUD removals through use of a laminaria tent. Use of a tenaculum to steady the cervix and straighten the anteversion or retroversion may assist removal.

- d. If the strings are not seen, probe for them in the cervical canal with narrow forceps.
- e. When the IUD (with or without its strings) is in the uterus, the endometrial cavity may be probed with alligator forceps (with which the strings or the IUD itself may be grasped), a hook, uterine packing forceps, or a Novak curette. Proficiency at removal of the IUD with one of these instruments when the strings are absent or entirely within the uterine cavity can prevent unnecessary hospitalizations.

If a woman has had intercourse at midcycle and the IUD was her only means of contraception, then removal of that IUD may result in implantation following a conception that has already occurred. Therefore, an IUD should usually not be removed in midcycle if the woman has had intercourse in the last 4-5 days, unless foam or condoms were used as a backup method. If the woman has serious pelvic inflammatory disease, it may be considered best to remove the IUD right away even if this increases her risk of pregnancy (see Figure 13.11).

6. Pregnancy with IUD still in place

Approximately one-third of IUD-related pregnancies are attributable to undetected partial or complete expulsions. But pregnancies may occur even if the IUD is in utero.

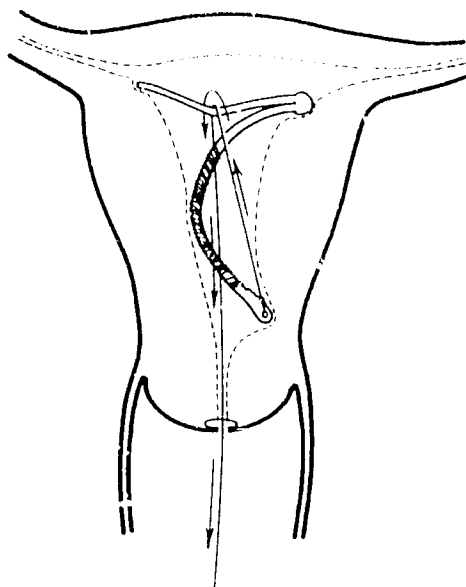


FIGURE 13.10 Potential problem in removing the Copper-7[®]. A kink in the upper limb of the Copper-7[®] is caused when the "loop of string" which comes out of the inserter barrel remains in place over the upper limb of the IUD. At the time of removal, pulling the string forcefully distorts the IUD in the manner shown above. When this occurs, the removal is very painful.



FIGURE 13.11 Remove the IUD with the first episode of pelvic inflammatory disease.

Pregnancy is one of the important complications that can occur with an IUD in place. There are two important reasons why the IUD should be removed if pregnancy is diagnosed. First, there is approximately a 50% chance that a spontaneous abortion will occur if the IUD is left in place. This compares with approximately a 25% chance if the IUD is removed (11). The second reason is the possibility of serious infection.

When pregnancy is diagnosed and the strings of the IUD can be located at the cervical os, the IUD should be removed immediately. If strings are seen, remove the IUD with gentle traction, telling her that there is about a 25% chance of a spontaneous abortion and informing her to return should bleeding, cramping, or signs of infection be noted (2).

If the patient wants to continue the pregnancy and does not want her IUD removed, she should be warned that (1) the risk of a spontaneous abortion is increased two- or threefold with the IUD in utero (to about 50%); (2) the likelihood of her pregnancy being ectopic is about 5%; and (3) the risk of a septic spontaneous abortion may be increased. The combination of infection and pregnancy, although very rare, is potentially fatal for an IUD user (1). In a pregnant woman with an IUD in place, some infections do not begin with the more typical symptoms (pain, discharge,

bleeding) but may present with nonspecific flu-like symptoms, such as fever, myalgias, headaches, nausea, or vomiting. The clinician must remember that a high percentage of these pregnancies with IUD's in place are ectopic (5%), and therefore the tissue should be carefully examined at termination.

FLU-LIKE SYMPTOMS PLUS PREGNANCY IN A WOMAN WITH AN IUD VERY LIKELY MEAN SEPSIS. THINK "SEPSIS" NOT "FLU" WHEN A PREGNANT WOMAN WITH AN IUD PRESENTS WITH FEVER, CHILLS, MYALGIA, AND HEADACHES.

7. Uterine perforation, embedding, and cervical perforation

The exact incidence of uterine perforations varies greatly from program to program and from clinician to clinician. It is further complicated by the fact that perforations are often "silent," occurring without bleeding or pain (other than the several hours immediately after insertion). Rates of perforation vary widely with the type of IUD and the expertise of the inserter. At the low end of the spectrum are the Copper-T[®] and the Lippes Loop[™]; the Dalkon Shield[™] is at the high end of the spectrum. Many providers of Lippes Loops[™] say the incidence of perforation is about 1 in 2,500 insertions (5). The symptoms of uterine perforation may include pain at the time of insertion, gradual disappearance of the IUD strings over several weeks to several months, bleeding after the insertion, and pregnancy. Objective findings include the absence of IUD strings, inability to withdraw the IUD if the strings are still present, and demonstration of the displaced IUD by radiology, hysteroscopy, or ultrasound. Cervical perforations may occur as an IUD is being expelled, and the IUD may be seen at the time of the speculum exam in one of the fornices. If the IUD is perforating the cervical canal, it may be grasped with alligator forceps, pushed back up into the endometrial cavity and then removed through the cervical canal. If the IUD is embedded in the uterine muscle (or is partially perforating the uterus), it may be possible to remove the device using the techniques described above. If the IUD is extrauterine and the patient is not pregnant, removal of the IUD with a laparoscope or following a laparotomy is usually feasible. If there is a pregnancy, it may go to term before the exact location of the IUD is known. *Uterine perforation with the Dalkon Shield[™] may be particularly treacherous, as this IUD may be missed completely on an X-ray examination of the pelvis, particularly in an obese patient.* While the Dalkon Shield[™] has been removed from the market, there are still some shields in place in women.

8. Pelvic inflammatory diseases

These are the most serious complications related to IUD use. The symptoms caused by pelvic inflammatory disease, objective findings, the differential diagnosis and its treatment are outlined in detail in Chapter 6.

PREVENT CHRONIC PELVIC INFLAMMATORY DISEASE:
REMOVE THE IUD WITH THE FIRST SIGNS OF PELVIC INFLAMMATORY DISEASE.

Generally it is best NOT to try to treat pelvic inflammatory disease with the IUD in place, in spite of the fact that this is possible in some instances. If the IUD is left in place, followup may be inadequate and a smoldering infection may persist that can progress from endometritis to a more generalized infection. In this way the more serious IUD-related problems, such as tubal occlusion, abscesses, peritonitis, and sepsis, may be more likely to occur. Once an infection has occurred, it is wise to wait 3 months before reinserting a second IUD. Some recommend waiting a full year following one episode of pelvic inflammatory disease before reinserting an IUD. Following an episode of pelvic inflammatory disease, women wanting subsequent children should be encouraged to use a method other than an IUD. Pelvic infection and pregnancy may be extremely dangerous as noted in Chapters 6 and 8.

Some physicians and nurse practitioners do try to treat pelvic inflammatory disease while leaving the IUD in place. If this is done, be sure to give a full 10-14 days of antibiotics and reexamine the patient at 10-14 days.

A CHRONIC FOUL VAGINAL DISCHARGE IN AN IUD USER IS PELVIC INFLAMMATORY DISEASE, UNTIL PROVEN OTHERWISE.

WHAT SHOULD A PROGRAM DO AT THE TIME OF AN IUD INSERTION IF 10% OR MORE OF WOMEN IN AN AREA HAVE A POSITIVE CERVICAL CULTURE FOR GONORRHEA?

There are areas of Africa where 10⁰/₀-15⁰/₀ of all asymptomatic women have a positive cervical culture for gonorrhea (12). This raises an important

question as to what practices should accompany the insertion of IUD's in this setting. Several approaches come to mind:

1. One approach would be to culture all women for gonorrhea, have the patient return at a subsequent date, and insert the IUD when it is determined that the culture is negative. If women travel from afar, however, this approach may not be practical.
2. The very minimum that should be done in a setting where gonorrhea is very common is to carefully evaluate the patient clinically for signs of gonorrhea. This would include questioning the patient about pain during intercourse, lower abdominal pain, and the presence of a vaginal discharge in recent days or weeks, and then looking carefully on physical examination for possible signs of infection such as lower abdominal pain, pain on cervical motion, and purulent discharge. An IUD should not be put in if there is presence of lower abdominal pain, of course, and, in general, should not be put in if the woman has a purulent discharge suggestive of gonorrhea.
3. A third approach would be to insert the IUD if there were not any apparent contraindications, take a culture at the time of insertion, and have the woman return for treatment and possible removal of the IUD if the culture is positive. This approach can be used where adequate facilities and supplies are available. In areas where pelvic inflammatory disease and sexually transmitted diseases are prevalent, clinicians should carefully screen potential IUD users. If screening is not practical, then the contraceptive benefits of the IUD should be carefully weighed against the reproductive health problems that may arise.
4. In the future, several technological advances might provide IUD's with advantages particularly important in an area with a high infection rate. An IUD that would elaborate a progestin for 6-10 years (this would decrease menstrual blood loss and produce a thick, difficult-to-penetrate cervical mucus) might diminish the risk of infection (although this possibility has not been confirmed). An IUD which would release an antibiotic capable of killing gonorrhea organisms might have certain benefits. A tailless IUD might deter ascent of gonorrhea organisms along the cervical string of the IUD. A tailless IUD may reduce the risk of pelvic inflammatory disease by eliminating the pathway for bacterial ascension into the uterus (see box).

THERE IS A CASE FOR TAILLESS IUD's (13-14)

Two recent reports from England indicate that the endometrial surfaces of IUD users may contain bacteria if the IUD has a thread attached which reaches down through the cervical canal into the vagina. This finding directly contradicts earlier findings of Mishell, et al., who found the endometrial cavity to be sterile if the device had been in place for more than 30 days. Sparks, et al., examined the uteri of 50 women not using IUD's following hysterectomies (15). All uterine cavities were sterile. However, bacteria were cultured from the endometrial surfaces of 14 out of 16 uteri removed from IUD users who had no clinical pelvic inflammatory disease. No bacteria were isolated from the endometrial surfaces of four women using IUD's that had no tails.

For an individual physician or a program to consider use of tailless IUD's, the clinicians following patients must have the necessary equipment and competence to remove IUD's that have no tail hanging down through the cervical os.

If an IUD is inserted in an area where rates of gonorrhea are high, it is particularly important that women be taught the IUD danger signals (most of which are early signs of pelvic infection) and told to return to the clinic immediately should these symptoms occur.

NONCONTRACEPTIVE BENEFITS

Profile of Patients Who Might Choose to Use an IUD

An IUD may be an excellent option for a woman who has had all the children she wants and who, for any reason, finds sterilization (male or female) an unattractive choice or difficult to obtain.

An IUD may be a good choice for the woman who has a fear of the Pill, cannot remember to take them, has difficulty in obtaining additional supplies, or has had a complication from Pills. Safe, effective, long-term use of an IUD can be recommended to a woman who has no history of pelvic inflammatory disease, has only one sexual partner, and, preferably, if she has access to medical care should she develop one of the IUD danger signals.

With the exception of progesterone-releasing IUD's which tend to decrease menstrual blood loss and dysmenorrhea, IUD's have relatively few noncontraceptive advantages. IUD's have been employed to prevent adhe-

ence of the two walls of the uterus by synechiae (Asherman's syndrome). Clinicians have also noted that women with post-Pill amenorrhea may begin to menstruate fairly regularly after IUD insertion.

INSTRUCTIONS FOR PATIENTS RECEIVING AN IUD

YOU ARE THE CAPTAIN OF YOUR OWN HEALTH TEAM; YOUR IUD IS *YOUR* IUD; LEARN THE IUD DANGER SIGNALS WELL
(See Figure 13.12)

Before you have your IUD inserted, here is a suggestion that may be of help to you:

Some women have a fair amount of pain or nausea immediately after their IUD is inserted; if you are going to have to walk a long distance after your IUD is inserted, you may want to come to the clinic with your husband, partner, or friend, in case you need someone to assist you. It is preferable to return home by vehicle when possible.

After your IUD has been inserted, here are six important instructions:

1. Before you leave the office or clinic, it is important to learn how to feel the strings that protrude 2 inches or so into the vagina. Your IUD may not be working if you cannot feel the strings or if you can feel the plastic part. If this happens, use another method until you can get to the clinic to have your IUD checked.
2. You *can* expel an IUD without knowing it. Check for the strings frequently during the first months you have the device, then after each period or any time you have abnormal cramping while menstruating.
3. Nuisance side effects of the IUD most commonly reported are increased menstrual flow, menstrual cramping and spotting, and increased mucous discharge. Remember that if you cannot tolerate the

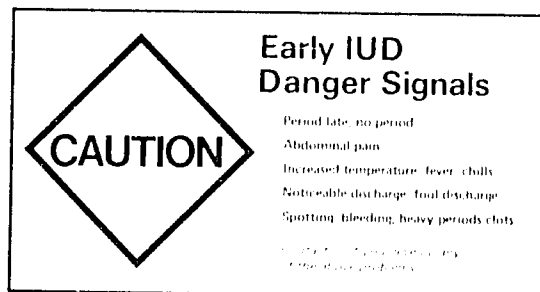


FIGURE 13.12 Early IUD danger signals.

IUD, you can always have it removed. Heavier menstrual bleeding may be serious if you are anemic. However, a small increase in the menstrual flow is normal with the use of an IUD, especially during the first two-three periods.

4. If at any time after getting an IUD you have fever, pelvic pain or tenderness, severe cramping, or unusual vaginal bleeding, contact your doctor immediately. These may be signs of infection. Infections from IUD's can be very serious and, if untreated, can lead to hysterectomy (removal of the uterus) or even death.
5. If you miss a menstrual period, contact your family planning worker immediately.
6. Do not remove an IUD yourself, and do not let your partner pull on the strings. The clinician will have a better idea of the angle at which it went in. It should come out the same way.

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CHAPTER 14

DIAPHRAGMS AND CERVICAL CAPS

The growing interest in vaginal contraceptives among women has not found its counterpart in the medical profession. Many physicians have little experience in the fitting of diaphragms and even if they have such experience, they may consider the time required for proper instruction of the patient excessive and nonremunerative.

Christopher Tietze, 1981

THE DIAPHRAGM

HISTORY, EFFECTIVENESS, AND MECHANISM OF ACTION OF THE DIAPHRAGM

HISTORY

Invented in 1838 by the German physician Dr. Frederick Wilde, diaphragms made of rubber were popularized in the early 1880's when they were dramatically described in Germany by C. Hasse, writing under the pseudonym of Wilhelm P.J. Mensigna. Because of its popularity in Holland, the diaphragm has also been called the "Dutch cap" or "Dutch pessary." A variety of chemicals have been used with diaphragms in addition to the modern spermicidal agents including cocoa butter, vaseline, salt, and vinegar. Some societies have even used a partially shelled-out half lemon. The effect of the lemon and its acidic juice may have offered couples a means of control quite comparable to a modern diaphragm filled with spermicide.

EFFECTIVENESS

The diaphragm becomes a much more effective method if its use is associated with an education program and with careful fitting and prescribing procedures (1-5). For maximum effectiveness, the use of a spermicidal agent inside the diaphragm is recommended.

Clinical researchers have reported a wide range of use effectiveness rates. Failure rates following diaphragm use have ranged from 2.0 pregnancies out of 100 diaphragm users per year (2) to 17 pregnancies out of 100 diaphragm users per year (5).

MECHANISM OF ACTION

The diaphragm is a dome-shaped rubber cup with a flexible rim. It is inserted into the vagina before intercourse so that the posterior rim rests in the

posterior fornix and the anterior rim fits snugly behind the pubic bone. The dome of the diaphragm covers the cervix, and spermicidal cream or jelly, placed in the dome before insertion, is held in contact with the surface of the cervix. The contraceptive effect of the diaphragm depends partly on its function as a barrier, decreasing the degree of contact between semen and the cervix, and partly on its function as a spermicide holder. The use of a spermicidal agent inside the diaphragm is essential for satisfactory effectiveness.

CONTRAINDICATIONS TO USE OF A DIAPHRAGM

The medical and social conditions that may make the diaphragm a poor contraceptive choice for a woman are as follows:

1. Allergy to rubber (latex) or spermicide.
2. Repeated urinary tract infections following its use. There is some evidence that diaphragm users develop cystitis and urethritis more frequently than women who use other contraceptives (6).
3. Abnormalities such as uterine prolapse, cystocele, rectocele, extreme and fixed uterine retroversion, vaginal fistulae, and vaginal septa may make diaphragm fitting difficult. It may be worthwhile to attempt a fitting with each of the rim types available, but in some cases, a satisfactory and stable diaphragm placement cannot be achieved.
4. Lack of trained personnel to fit the diaphragm and/or lack of time to adequately instruct the woman in its use.
5. Inability of user or partner to learn correct insertion technique.
6. Lack of privacy for insertion or lack of soap and water for washing the diaphragm.

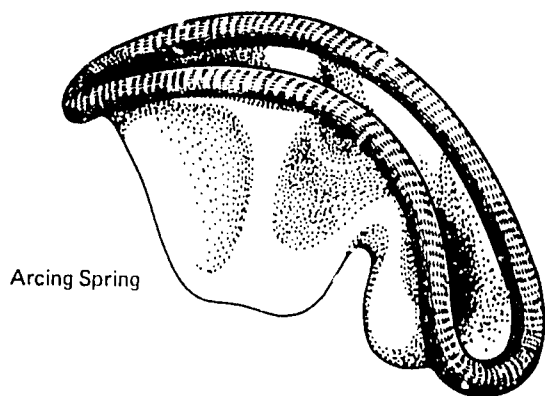
FITTING THE DIAPHRAGM

Diaphragms are available in a range of sizes (the size refers to the rim diameter, in millimeters). Diaphragms are available in three rim styles (Figure 14.1) which differ in the inner construction of the circular metal rim. Products currently available are listed below:

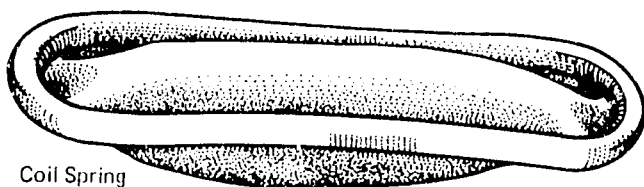
The **Flat Spring Rim** is a thin, delicate rim with gentle spring strength. A woman with a very firm vaginal muscle tone (generally a nulliparous woman) and/or a shallow notch behind the pubic bone arch may find the flat spring more comfortable than the coil or arcing rims. The flat spring folds flat for insertion. One example is the "Ortho-White Diaphragm", sizes 55-95, latex.

The **Coil Spring Rim** is a sturdy rim with a firm spring strength. Most women with average vaginal muscle tone and average pubic arch notch find the coil spring comfortable. It folds flat for insertion and can be used with a plastic introducer. Examples are the "Koromex Diaphragm", sizes 50-105, latex; the "Ortho Diaphragm" (coil spring), sizes 50-105, latex; and the "Ramses Flexible Cushioned Diaphragm" (coil spring), sizes 50-95, gum rubber.

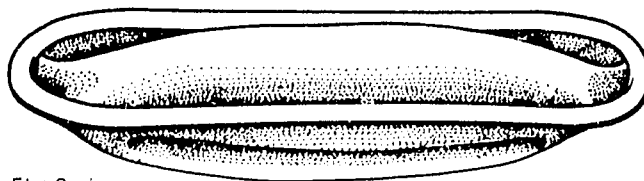
*Known to be available in Africa.



Arcing Spring



Coil Spring



Flat Spring

FIGURE 14.1 Three basic diaphragms currently available in Africa.

The **Arcing Spring Rim** is a very sturdy rim with firm spring strength. Most women are able to use the arcing rim comfortably and find that when folded, the diaphragm's arc shape makes correct insertion easier. The arcing rim can often be retained comfortably despite a rectocele, a cystocele, or lax vaginal

muscle tone. Examples include the Koroflex Diaphragm™, sizes 60-95, latex; Allflex Diaphragm™ (Ortho), sizes 55-95, latex; and the Ramses Bendex Diaphragm™, sizes 65-95, gum rubber.

Some arcing diaphragms (such as the Allflex™) fold at any point along the rim and are slightly less sturdy than the Koroflex™ (Holland Rantos) or the Ramses Bendex™ (Schmid) products. The Koroflex™ and Bendex™ fold at two points only (a hinge or bow-bend construction). Many women find that the bow-bend rim is easier to insert because the fold creates a narrow leading edge, and the two stiff halves of the “arc” can be held in the folded position close to either end of the arc, whereas the Allflex™ must be held in the middle.

A woman with a retroverted uterus or a very long, firm nulliparous cervix may find that correct insertion of an arcing spring diaphragm is much easier than is insertion of a coil or flat spring type. Many clinicians choose an arcing style for most patients and reserve the coil or flat spring types for women with very firm vaginal tone or those who do not find the arcing style comfortable.

A common error in diaphragm fitting is choosing a size that is too small. Vaginal depth increases during sexual arousal (3-5 cm in nulliparous women), and a too-small diaphragm may fail to maintain its position covering the cervix. A diaphragm that is too large, however, may also cause problems such as uncomfortable vaginal pressure, abdominal pain or cramping, vaginal ulceration, or recurrent urinary infection.

The goal in fitting the diaphragm is to select the largest rim size that is comfortable for the patient. (See Figure 14.2.) The choice of size and rim

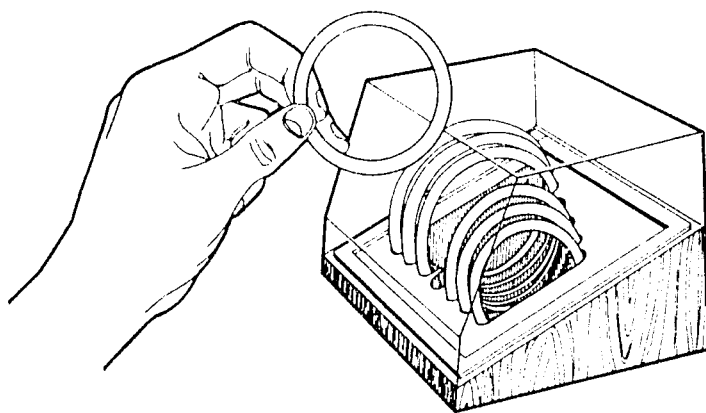


FIGURE 14.2 *Graduated fitting rings and their storage. Graduated fitting rings are used to determine the correct diaphragm diameter. Sample diaphragms may also be used for fitting. If clinics can provide women with the diaphragm they will be using during the clinic visit, they can practice inserting and removing their own diaphragm under the supervision of a family planning worker.*

type will depend both on the depth of the vagina and on the muscle tone of its walls. The importance of muscle tone explains why the diaphragm almost always seems to be a tighter fit when it is first inserted by the clinician and a looser fit several minutes later, after the patient has inserted it herself and is more relaxed. It is often necessary to choose a slightly larger size once the user's insertion technique has been checked.

Although diaphragm manufacturers produce sets of fitting rings (sample diaphragm rims with no dome), it is probably preferable to use whole sample diaphragms for fitting since the patient can then practice insertion and removal with an actual diaphragm. Fitting rings are not adequate for patients to practice with. Because different products differ somewhat in rim-spring strength, it is advisable to prescribe precisely the same brand and rim type as was used in fitting. Coil and arcing diaphragms are widely available; flat spring diaphragms may be harder to find commercially. Sample diaphragms used for fitting should be washed with soap and water and then immersed in a 70% alcohol solution for at least 20 minutes after each use.

SIDE EFFECTS AND COMPLICATIONS OF DIAPHRAGMS

The diaphragm is a very safe contraceptive (7). However, there are some problems that a woman may encounter while using the diaphragm. These include:

1. Allergic reactions to rubber (latex) or spermicidal agents.
2. Skin irritation in the woman or her partner caused by the spermicidal agent.
3. A foul-smelling, profuse vaginal discharge is produced when the diaphragm is left in place too long. This would occur with any foreign body left in the vagina.
4. Monilia vaginitis can recur if the diaphragm is not well cleaned and dried between uses. (Some women prefer to have two diaphragms available to permit time for each to dry after use.)
5. Recurrent cystitis can be caused by the upward pressure of the rim of the diaphragm against the urethra.

NONCONTRACEPTIVE BENEFITS OF THE DIAPHRAGM

The diaphragm and spermicide combination probably confers some protection against sexually transmissible infections. The diaphragm also may be used during menstrual flow to provide a barrier so that blood does not escape during intercourse. In addition, the diaphragm may have some protective effect against the development of cervical dysplasia.

PATIENT INSTRUCTIONS

You must *use* the diaphragm for it to be effective.

Use the diaphragm whenever you have intercourse, even during your period. Don't try to "guess" about your fertile times.

Plan to insert the diaphragm in plenty of time before intercourse. You can put it in just before intercourse or any time up to 6 hours beforehand.

If you find it difficult or impossible to follow the time rules established above, it is better to use the diaphragm anyway than to leave it in the drawer.

1. **To apply contraceptive jelly or contraceptive cream:** Hold the diaphragm with the dome down (like a cup). (See Figure 14.3.) Squeeze the jelly or cream from the tube into the dome (use about one tablespoon); spread a little bit around the rim of the diaphragm with your finger.

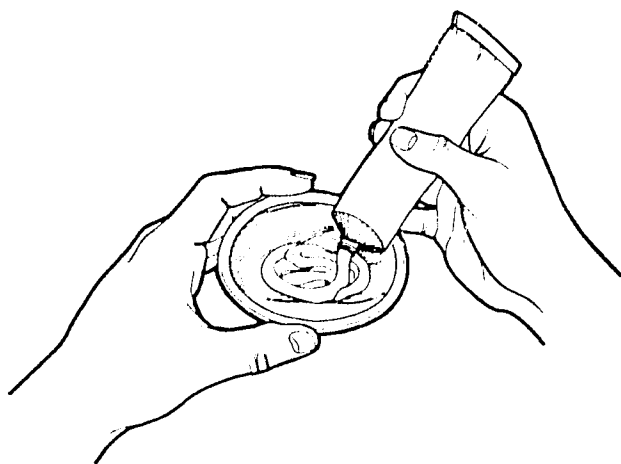


FIGURE 14.3 Placement of spermicides in the diaphragm. The sperm-killing cream or jelly goes inside the dome of the diaphragm. It should be spread in a smooth layer over the entire inner surface, including the rim.

2. **To insert your diaphragm:** With one hand hold the diaphragm dome down (spermicide in the dome) and press opposite sides of the rim together so that the diaphragm folds. Spread the opening of your vagina with your other hand, and insert the folded diaphragm into your vaginal canal. This can be done standing with one foot propped up (on

the edge of a chair, a bathtub, or a toilet), squatting, or lying on your back. Push the diaphragm downward and back along the back wall of your vagina as far as it will go. Then tuck the front rim up along the roof of your vagina behind your pubic bone. Once it is in place properly, you should not be able to feel the diaphragm except, of course, with your fingers. If it is uncomfortable, then most likely it is not in the correct position; take it out and reinsert it.

3. **To check the placement of your diaphragm:** When it is correctly placed, the back rim of the diaphragm is below and behind the cervix, and the front edge of the rim is tucked up behind the pubic bone. (See Figure 14.4.) Often it is not possible to feel the back rim. You should check to be sure that you can feel that your cervix is covered by the soft rubber dome of the diaphragm and that the front rim is snugly in place behind your pubic bone. The spermicidal cream (inside the dome of the diaphragm) should be next to your cervix.

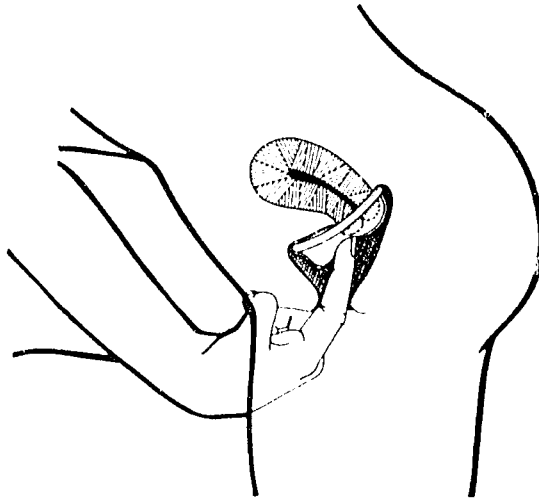


FIGURE 14.4 Checking for proper diaphragm placement. To check for proper diaphragm placement, women should be taught to feel for the firm cervix through the dome of the diaphragm.

4. **After intercourse,** leave the diaphragm in place at least 6 hours, then remove it whenever it is convenient for you. If you have intercourse more than once within the 6-hour period, you may want to use an additional application of contraceptive cream or jelly each time. Do not remove the diaphragm: use the plastic applicator to insert fresh jelly or cream in front of the diaphragm. If you wear the diaphragm continuously, remove and wash it at least once a day; but remember to allow the minimum of 6 hours after intercourse.

5. **To remove the diaphragm:** Place your index finger behind the front rim of the diaphragm and pull down and out. (See Figure 14.5.) Be careful not to puncture the diaphragm with a fingernail. If you find it hard to hook your finger behind the diaphragm, try a squatting position and push downward with your abdominal muscles. In other words, bear down as though you were having a bowel movement. Some women find it easier to remove the diaphragm by inserting a finger between the diaphragm and the pubic bone to break the suction created by the diaphragm in contact with the vaginal wall. Practice inserting and removing the diaphragm several times during the first week, until you can do so easily and are confident about checking its position.

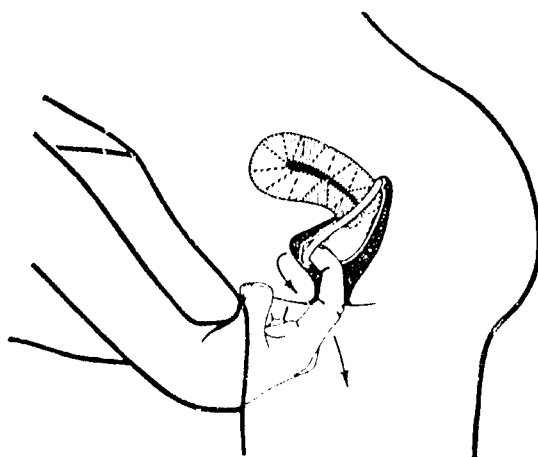


FIGURE 14.5 Removing the diaphragm. In teaching women to remove the diaphragm, they should learn to hook the rim with one finger and pull downward.

6. **After you remove the diaphragm,** wash it with mild soap and water, rinse it, and dry it with a towel. Store it in its plastic container. Do not use talcum powder or perfumed powder; it may damage the diaphragm or may be harmful to your vagina or cervix.
7. **Do not use vaseline or other petroleum products** when you are using your diaphragm; they can cause the rubber to deteriorate. If you need extra lubrication, you can use contraceptive jelly or saliva.

The above guidelines for using the diaphragm have been suggested by manufacturers on the basis of clinical judgment rather than studies. Keep in mind that the published effectiveness rates are based on studies using these guidelines. But above all, be flexible so that your patients do not abandon the use of the diaphragm when they cannot follow the guidelines exactly, as it is better to use it imperfectly than not at all.

THE CERVICAL CAP

Currently, there are very few cervical caps available for contraceptive use in Africa. For this reason, the cervical cap is described only briefly in this chapter.

The cervical cap is a thimble-shaped cup (a miniature diaphragm with a tall dome) that fits over the cervix and is held in place by suction between its firm, flexible rim and the surface of the cervix or cervical-vaginal junction. Cervical caps developed and popularized 20 to 40 years ago were constructed of silver or gold (more recently, impermeable plastic has been used), and were left in place for as long as 3 to 4 weeks.

In some sophisticated medical centers, an impermeable plastic cap intended for artificial insemination is available and has been used for contraception on a very limited basis by some clinicians. More commonly used are soft rubber caps, available in two styles manufactured in England for contraceptive use. Very limited accounts indicate that some women find the firm plastic cap to be uncomfortable. (See Figure 14.6 for the three styles.) Yet a soft rubber cap is not suitable for prolonged vaginal retention in most women because a strong odor develops after it has been in the vagina 24 to 36 hours.

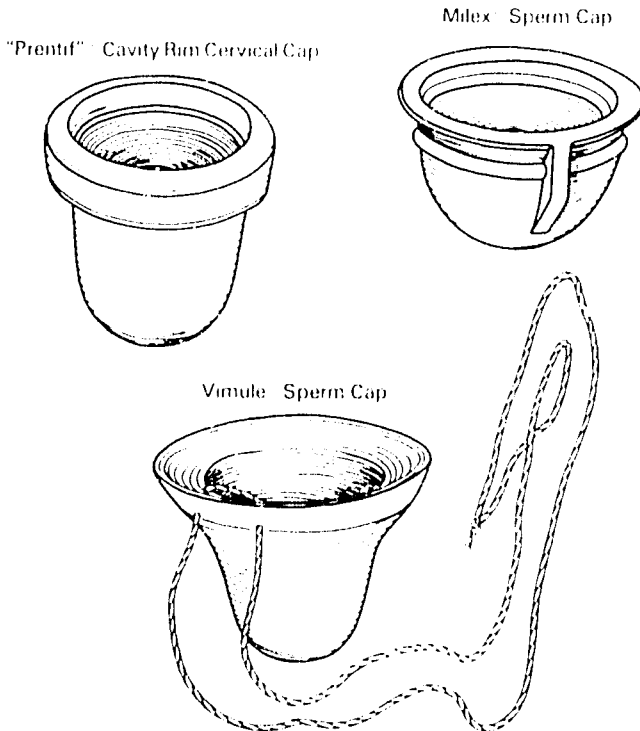


FIGURE 14.6 Three cervical caps.

Manufacturers' recommendations that accompany the rubber cervical caps suggest use of spermicide inside the cap (to fill one-third of the cup) and indicate time rules for insertion and removal that are almost identical to standard recommendations for use of the diaphragm with spermicide.

A cap that fits snugly enough to maintain suction between the cap rim and the cervix or vaginal vault is chosen by trying the various sizes available. (See Figure 14.7.) An opportunity for the patient to practice insertion and removal of her cap is essential. Most patients find that inserting a cap is somewhat more difficult than inserting a diaphragm.

Removal can also be difficult. One clinician asks each patient to try the cap first during a low-fertility time in her cycle to verify that it remains in position after intercourse (8).

The **"Prentif" Cavity-Rim Cervical Cap*** (internal diameter-22mm, 25mm, 28mm, 31mm) is a deep, soft rubber cap with a firm rim and a groove along the inner circumference of the rim to provide good suction. It can be fitted even when the cervix is quite long. (Manufactured by Lambert's, Ltd.)

The **Vimule Cap*** (outer diameter-42mm, 48mm, 54mm) is a shallower, soft rubber cup that clings to the vaginal vault rather than the cervix itself. It is useful for women with a very shallow cervix or cervical scarring. (Manufactured by Lambert's, Ltd.)

The **Milex Sperm Cap*** (internal diameters-28mm, 30mm, 32mm, 34mm, 36mm, 38mm) is a very firm, impermeable plastic cup. (Manufactured by Milex Products, Inc.)

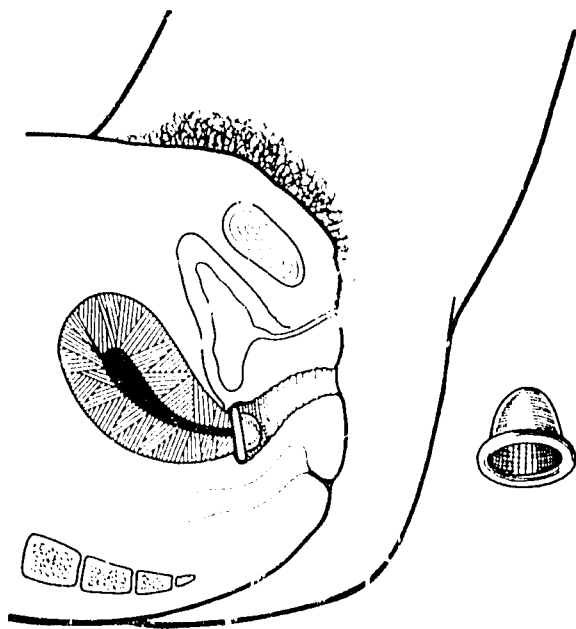


FIGURE 14.7 Cervical cap in position covering the cervix.

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CHAPTER 15

CONDOMS

With relatively high quality condoms now available, the major problem in effectiveness is clearly not the condom itself, but the user, who should be encouraged to be more consistent and careful in contraceptive practice if he wishes to prevent pregnancy.

*John J. Dunm, Phyllis T. Piotrow,
and Isabel A. Dalsimer, 1974*

HISTORY, MECHANISM OF ACTION, AND EFFECTIVENESS

HISTORY

Mechanical barriers covering the penis have been used for centuries for protection against pregnancy and infection, for decoration, and occasionally to produce penile or vaginal stimulation. A sheath worn over the penis can be traced back as far as 1350 B.C., when Egyptian men wore decorative covers for their penises. The great Italian anatomist Fallopius described the use of linen sheaths in 1564. Protective devices from animal intestines soon followed. It was not until the 18th century that penile sheaths were given the name "condom" and popularized by the libertines of the day as a means of "protection from venereal disease and numerous bastard offspring." Casanova (1725-1798) was among the first to popularize the condom as a contraceptive (1). With the advent of vulcanized rubber in the 1840's came mass production of condoms (or "rubbers") from synthetic materials (2,3).

MECHANISM OF ACTION

Condoms are rubber or processed collagenous tissue-sheaths that fit over the erect penis and act as a barrier to the transmission of semen into the vagina. Only about 1% of condoms are made from the caecum of young lamb intestines.

When the sizes of several different condoms were compared, each had approximately the same length (19.0 cm) and the same width (2.5 cm).

EFFECTIVENESS

For consistent users, or those who use the condom exactly as directed with each act of intercourse, the failure rate is 2 pregnancies per 100 woman years. This is the method failure rate. If 100 couples were to use the condom during a given year, 10 women are likely to become pregnant. (See Table 9.1

in Chapter 9.) The user effectiveness rate approaches that of the Pill when foam is used in conjunction with the condom. The high failure rate is often due to users' dissatisfaction because of decreased sensation and interrupted lovemaking. Very low failure rates with the condom have been reported from studies conducted in the United Kingdom (Table 15.1).

CONTRAINDICATIONS

Some men cannot retain an erection if a condom is used. Very rarely, men or women have been allergic to the rubber in condoms.

DISTRIBUTION OF CONDOMS

Because of several advantages of condoms, they are an important method of birth control for various populations. The condoms known to be available in Africa are listed in Table 15.2. Unfortunately, there are many rural areas in Africa where they are virtually unavailable at present. The following advantages of condoms should be kept in mind as countries consider if and how distribution of condoms could be increased.

1. The use of condoms allows participation of males in birth control responsibilities.
2. Condoms are a relatively inexpensive birth control method.
3. Condoms can be made readily available to most people. They can be purchased in the market, drugstores, and family planning clinics or from distributors.
4. Condoms are effective protection against the transmission of venereal disease; for this reason they should be encouraged among adolescents and among women who plan to delay childbearing for a number of years. This is especially true if these women will probably have several sexual partners before bearing a child. In areas of Africa where sexually transmitted infections are associated

TABLE 15.1 Condom failure rates per 100 couples using the method per year in five recent United Kingdom studies (4-8)

Name of Chief Investigator	Year	Method Failure Rate	User Failure Rate
Peel (4)	1969	0.8	3.10
Peel (5)	1972	1.6	3.90
John (6)	1973	0.4	4.80
Glass (7)	1974	—	4.00
Potts (8)	1975	—	0.83

with high rates of infertility and sterility, the routine use of condoms might assist greatly in decreasing infections of the uterus and the fallopian tubes.

5. Clinicians feel that use of the condom may prevent cancer of the cervix.

TABLE 15.2 Condoms known to be available in Africa

Atlas ^(a)	Hygex ^(a)
Con-form ^(a)	Lord Hygex ^(a)
Conture ^(a)	Prime ^(a)
Crepe de Chine ^(a)	R3 Aktiv-feucht ^(a)
Durapac ^(a)	R3 Excellent ^(a)
Durex ^(a)	R3 Med ^(a)
Durex Black Shadow ^(a)	R3 Naturcontact ^(a)
Durex Fetherlite ^(a)	R3 Plus ^(a)
Durex Fiesta ^(a)	R3 Superfeucht ^(a)
Durex Gossamer ^(a)	Sagami Wet ^(a)
Durex Nu-form ^(a)	Samoa ^(a)
Durex Supertrans ^(a)	Silkies ^(a)
Elarco Minors ^(a)	Sultan ^(a)
Gallant Special ^(a)	Tahiti ^(a)
Goldtex ^(a)	Trojan-enz ^(a)

SIDE EFFECTS AND COMPLICATIONS

The major complaint of condom users is that the condom reduces sensitivity. Some men are unable to enjoy intercourse or even to maintain an erection while wearing condoms. To increase sensitivity, natural-skin-textured or lubricated condoms may be used. Some people object to interrupting foreplay to put on the condom. In this instance, the female can be encouraged to put the condom on the male as part of foreplay. A very small number of people are allergic to rubber condoms; they should try using natural-skin condoms instead. The most common recurrent mistake that discourages couples from adopting the condom as their standard method is failure to use the condom consistently; this can lead to pregnancy.

NONCONTRACEPTIVE BENEFITS

In addition to providing protection against pregnancy, other benefits of the condom are:

1. Sex therapists occasionally recommend the use of condoms in the treatment of premature ejaculation, as they reduce sensitivity of the glans during intercourse (9).

2. Some women and men do not wish to have the penis in direct contact with the vagina. The condom is an effective barrier that may make intercourse more pleasurable if this concern exists.
3. Occasionally, men are unable to maintain an erection during intercourse. This often occurs in older men or in those who have had certain lower abdominal operations. The rim of the condom may have a slight tourniquet effect, helping to maintain an erection.
4. Lubricated condoms can reduce mechanical friction and irritation of the penis or vagina.
5. It has been found that, in some infertile couples desiring pregnancy, the woman's body makes antibodies to her partner's sperm. In such couples, the use of condoms for 3-6 months (the length of time depends on the level of the antibody titer and how long it remains elevated) can prevent the release of sperm antigens into the vagina.
6. Women have very occasionally been allergic to their partner's sperm and/or semen; urticarial and even anaphylactic reactions have occurred. Condoms would obviously prevent these allergies.
7. Condoms clearly can play a major role in the prevention of sexually transmitted diseases.
8. By diminishing sexually transmitted infections, condoms may diminish the likelihood of infertility or cervical cancer in some women.

Although condoms are currently used in most African countries only to a limited extent, interest is increasing in their use (10,11). Perhaps condoms would be a great deal more popular in Africa if some of the noncontraceptive benefits received greater emphasis, thereby offsetting the stigma often associated with condom use (e.g., promiscuity, prostitution).

USER INSTRUCTIONS

1. **USE CONDOMS EVERY TIME YOU HAVE INTERCOURSE.** When condom-using couples have an unplanned pregnancy, it is almost always because they did not use condoms correctly each time they had intercourse.
2. You or your partner should *put the condom on the penis before the penis is put in the vagina*. Roll the rim of the condom all the way to the bottom of the penis. Leave about one-half inch of empty space—not filled with air—at the tip, or buy condoms with nipple tips to hold the semen. (See Figure 15.1.)
3. After intercourse, hold onto the condom as you withdraw the penis, taking care not to spill semen anywhere near the opening to your partner's vagina. The penis should be withdrawn soon after ejaculation because if you lose your erection, the condom can slip off and pregnancy can result.

4. Try not to carry your condoms near to your body as body heat can deteriorate the rubber. You may want to lubricate the outside of your condom to help the penis enter the vagina. *DO NOT use petroleum jelly*, as it might cause the rubber to deteriorate. Contraceptive foam, saliva, or other lubricants should definitely be used if you have a tendency to tear your condom during intercourse. Condoms will stay good for about 2 years if stored away from heat. If condoms are kept in a relatively dry environment, they can last more than five years (12).
5. To increase the effectiveness of condoms, use contraceptive foam at the same time.

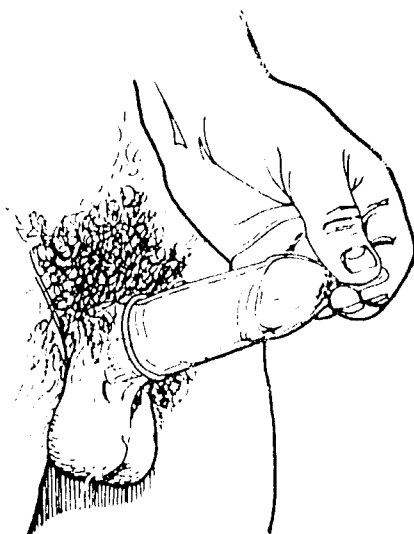


FIGURE 15.1 When putting on a condom without a reservoir end, pinch the tip to leave space for semen.

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CHAPTER 16

VAGINAL SPERMICIDES AND SPERMICIDAL FOAMS

HISTORY, MECHANISM OF ACTION, AND EFFECTIVENESS OF SPERMICIDAL AGENTS

For over 5,000 years, women have tried to use combinations of barrier methods and spermicidal agents to protect themselves against pregnancy. Their innovative attempts have been remarkable. The diaphragm-shaped lemon, with its own built-in spermicidal juices, is still used as a contraceptive; its modern replacement is the diaphragm filled with a spermicidal agent. Sponges with various spermicidal additives have been used for centuries. Colloid sponges containing spermicidal agents (like nonoxynol-9) are a new version of an old approach. Patentex[®] suppositories have been produced in Germany for 80 years and were distributed extensively by Margaret Sanger, a leader in the American birth control movement in the 1920's, only to resurface with use of a "new" spermicide (nonoxynol-9) in 1970.

Spermicides consist of two components—an inert base (usually foam, cream, or jelly), which carries the spermicidal agent in the vagina against the cervix, and a spermicidal chemical, which kills the sperm. Foam is placed deep in the vagina in the vicinity of the cervix. Coital movements spread the spermicide over the cervix, mechanically blocking the os and preventing entry of sperm into the cervix. The chemical effect of the spermicidal agent immobilizes and kills the sperm.

Since foam is the most widely used spermicide, it is discussed first and in most depth. (Aerosol foams known to be available in Africa are listed in Table 16.1.) With foam, there is a wide gap between the actual user effectiveness and theoretical effectiveness rates. Confusion over the actual effectiveness of contraceptive foam is widespread. During a 15-year period of study, failure rates of 1.55 to 29 pregnancies per 100 woman years of use have been reported (see Table 9.1 in Chapter 9 and Table 16.2 in Chapter 16).

TABLE 16.1 Aerosol foams known to be available in Africa

Delfen Foam [®]
Emko [®]
Dalkon Foam [®]
Patentex Schaum-Spray [®]

Foam users must be taught to use this method correctly and consistently to maximize its effectiveness. High failure rates are a reflection of both the inherent likelihood of method failure and careless use. The mistakes a foam user can make include:

- Using too little
- Failing to shake the foam container vigorously enough
- Failing to recognize that the foam bottle is empty
- Failing to have the bottle available
- Failing to interrupt intercourse to use foam
- Douching too soon after intercourse
- Forgetting to use the method altogether

TABLE 16.2 Reported failure rates for spermicidal foams

Investigator Reported	No. of Patients	Months of Use	Pregnancies (per 100 woman years)	Year Reported
Carpenter (1)	—	—	1.55	1970
Bushnell (2)	130	2,737	1.80	1965
Bernstein (3)	2,932	26,073	4.30	1974
Kleppinger (4)	138	1,116	7.60	1965
Mears (5)	—	722	16.60	1962
Tietze (6)	779	?	28.30	1967
Paniagua (7)	142	1,723	29.00	1961

Some of the most effective users of foam obtain it not from family planning clinics or private physicians but from drugstores. Foam can be used as the only method of birth control by some couples. Occasionally, a clinician will have a patient who has used foam as the only method of contraception without a failure for 5, 10, or even 15 years. Some couples will use foam in combination with condoms; if both methods are used correctly and consistently, the resulting effectiveness rate is extremely high. *Douching should not be considered a reliable contraceptive even if a spermicide is in the douching solution*, because sperm simply enter the cervical canal too quickly (as soon as 15 seconds after ejaculation). If a vaginal spermicide has been used as a method of contraception, douching after sexual intercourse should be delayed 6-8 hours.

CONTRAINDICATIONS

- Allergy to foam
- Unwillingness to use foam at the time of intercourse

IMPORTANT USES OF CONTRACEPTIVE FOAM

The advantages of foam are its safety, ready availability without a prescription, and effectiveness. The following are settings in which foam may be of help to your patients.

1. As a contraceptive alone or in combination with condoms.
2. As a contraceptive to use while waiting to begin the first pack of birth control Pills and during the first month of Pill use.
3. As a backup method in case a woman stops using Pills or runs out of Pills.
4. As the contraceptive to use for several months after a woman stops Pills and before she tries to become pregnant.
5. As a midcycle contraceptive to increase the effectiveness of an IUD, condoms, or natural family planning.
6. As the backup contraceptive method to have in case an IUD is expelled.
7. As a contraceptive method for the diaphragm user who has intercourse a second time before her diaphragm can be removed. (Foam should be added without removing or dislodging the diaphragm.)
8. As a backup method in case a condom breaks. An application of foam should be quickly inserted in this instance. This is the best you can do in a very discouraging situation. It may not help at all since sperm get up into the cervical canal very quickly.

SIDE EFFECTS AND COMPLICATIONS

1. Foams may produce rare allergic reactions.
2. Foams may produce vaginal irritation and a vaginal discharge.

NONCONTRACEPTIVE BENEFITS

1. Foam decreases the transmission of gonorrhea and trichomoniasis.
2. Foam provides vaginal lubrication.

USER INSTRUCTIONS

1. Shake the can vigorously before using so that there will be plenty of bubbles for the barrier and the spermicide will be mixed with the foam. (See Figure 16.1.)
2. See Figures 16.2 and 16.3 for the correct and incorrect placement of the applicator.
3. If you want to douche after intercourse, wait at least 6 hours.
4. Wash the applicator with soap and lukewarm water.

5. Keep a spare container of foam on hand. With most brands, there is no way to tell when you are about to run out.
6. The effectiveness of foam in preventing pregnancy can be increased if it is used with another method of birth control, such as condoms.

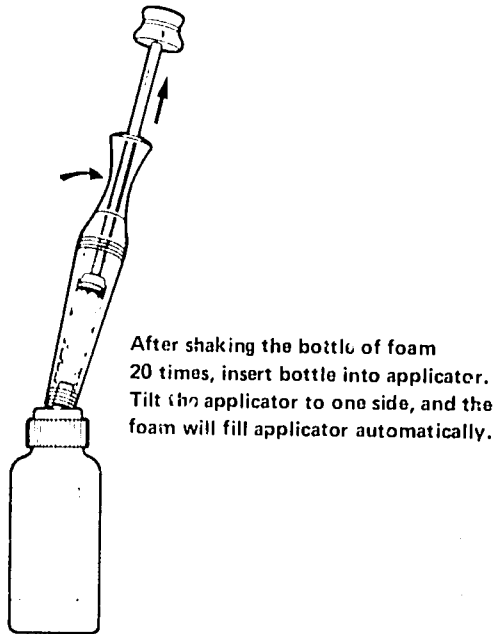


FIGURE 16.1 Using foam.

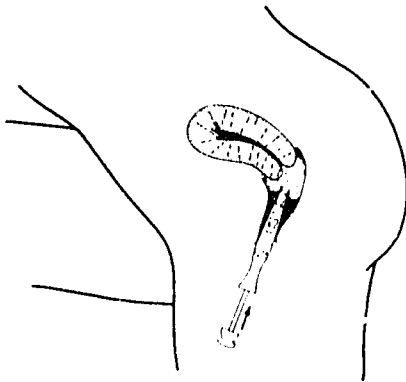


FIGURE 16.2 Correct placement of foam deep in the vagina.

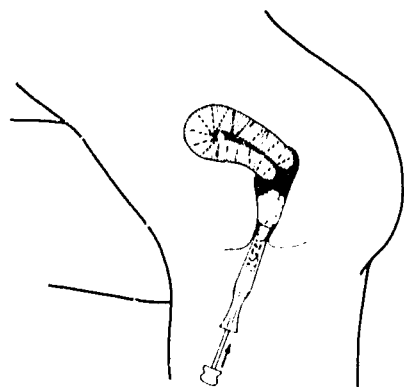


FIGURE 16.3 Incorrect placement of foam.

SPERMICIDAL SUPPOSITORIES, CREAMS, AND JELLIES

The following table is fairly representative of the spermicidal preparations that are currently available.

TABLE 16.3 Available spermicidal preparations

	Known to be available in Africa	Other
Foaming tablets and suppositories	Neo-Sampoon Tablets ^a Lorphylin Suppositories ^a Rendells ^a A-Gen ^a Orthofoams Syn-A-Gen ^a Gynomin ^a Antibion ^a Septon ^a Semeri ^a	Encare Suppositories ^a Semicid Suppositories ^a Intercept Suppositories ^a Patentex ^a
Creams, jellies, or gels	Delfen Cream ^a Ortho-Cream ^a Ortho-Gynol Creme ^a Koromex-A ^a Preceptin ^a Patentex ^a Ramses ^a	Lorphylin Jelly ^a Preception Gel ^a Certane Vaginal Jelly ^a Immolin Vaginal Cream-Gel ^a Emko Cream ^a Koromex Vaginal Jelly ^a Lanesta Gel ^a Milex Crescent ^a Ortho-Gynol Jelly ^a Copper Cream ^a

Tablets and suppositories must dissolve for a period of 10-30 minutes after being placed in the vagina before sexual intercourse occurs. In general, this is *not* the case with creams, jellies, or aerosol foaming agents. In some instances, a suppository or pellet will not dissolve completely and can cause increased friction, a penile or vaginal irritation, and/or decreased effectiveness. Some of the suppositories are difficult to remove from their foil packets. The suppositories or tablets may mistakenly be used rectally or orally. While this practice is completely ineffective in preventing pregnancy, it is not usually harmful.

Neo-Sampoon^a is a fairly new spermicidal foaming tablet that is available through a number of family planning programs in Africa. It contains the spermicide menfegol (p-methanylphenyl polyoxyethylene 8.8 ether). Clinical studies have reported that out of every 100 women who use Neo-Sampoon^a in a year, 5 can be expected to become pregnant (8). Small-scale multiclinic studies of Neo-Sampoon^a are also being conducted by the Family Health International. To date, 418 women have entered into these studies, and the 6-month cumulative pregnancy rate for Neo-sampoon^a users was 4.9 per 100 women or 7.6 pregnancies per 100 woman years (9).

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CHAPTER 17

NATURAL FAMILY PLANNING METHODS

INTRODUCTION

Periodic abstinence, rhythm, natural family planning (NFP), and fertility awareness methods are terms often used synonymously to describe birth control methods *based* on the cyclic pattern of fertile and infertile phases during the menstrual cycle. The “natural” in natural family planning does not refer to the naturalness of sexual abstinence nor is it intended to imply that taking one’s temperature is natural. It refers to the monitoring of *natural* physiological signs and symptoms to determine the fertile period.

The International Federation for Family Life Promotion states that “NFP methods are means by which the couple uses the daily observation of signs and symptoms of the fertile and infertile phases of the menstrual cycle to guide the timing of intercourse according to their desire to achieve or avoid a pregnancy” (1). (Implicit in this definition is the fact that couples will abstain from sexual intercourse if they wish to avoid pregnancy.)

NFP appeals to persons who wish to capitalize on knowledge of the fertile and infertile phases of the menstrual cycle for their approach to the timing of pregnancy, or to those who do not wish to use drugs or devices either because they are concerned about their side effects or for religious or other reasons. NFP can be used to help avoid or achieve pregnancy.

Recently there have been several reviews of methods based on periodic abstinence (1,2,3,4). Currently there are three main methods of NFP which are being promoted: the basal body temperature method (BBT); the cervical mucous method (CMM), or the Billings ovulation method; and the sympto-thermal method (S-TM). Their physiological bases have been studied by numerous investigators and are documented in several recent publications (1,3,4,5).

There has been a great deal of controversy over the use of NFP methods despite their advantages in terms of lack of side effects, nonphysician delivery, and educational value. The reluctance of many family planning administrators to include NFP methods in their programs usually stems from three concerns: (1) Although the method effectiveness is high, the use effectiveness is generally lower than desired; (2) Belief that these methods would be unacceptable and difficult to learn; and (3) Belief that the costs and utilization of service provider time would be higher than for many other methods if NFP was to be incorporated into existing services. Nevertheless, there does appear to be a renewed scientific and political interest in NFP.

CERVICAL MUCOUS (BILLINGS OVULATION) METHOD

Mechanism of Action

The cervical mucous method (CMM) is based on the woman’s observation of a sequence of changes in the quality of cervical mucus. Under the in-

fluence of estrogen, produced during the follicular phase of the menstrual cycle, the endocervical glands are stimulated to secrete mucus. (See Chapter 7.) Before follicular development, the woman experiences a sensation of dryness around the genital area. As the follicle(s) begins to develop and produce estrogen, the woman experiences a sticky sensation and cloudy or opaque, flaky or thick mucus may be observed on the underclothing or on tissue paper applied to the vulva.

As the time of ovulation approaches and the estrogen concentration increases to its highest level in the cycle, the mucus thins out and produces a wet, slippery, lubricative sensation and appears as a clear, egg-white-like substance which, when placed between the fingers, stretches so as to hang in strings (spinnbarkeit) without breaking. The last day of the wet, slippery sensation, which is identified retrospectively, is called the "peak" day (highest point of fertility). Following ovulation, the progesterone produced by the corpus luteum, even in the presence of estrogens, inhibits the production of the mucus, especially the type observed on the "peak" day. Thus, women can learn to predict and detect the time of ovulation and the fertile period through careful daily observation of the cervical mucus. A description of mucous changes is found in Table 17.1.

TABLE 17.1 Characteristics of cervical mucus in various phases of the normal menstrual cycle and the corresponding rules for intercourse*

	Phase of Menstrual Cycle	Approximate Number of Days in Idealized 28-Day Cycle	Characteristics of Mucus	Woman's Sensations	Rules for Intercourse
Phase 1	Menstruation	3-5	Mucus, indicating the onset of the fertile period, may or may not be present but is obscured by menstrual flow	Wet and lubricative	Abstain, since type of mucus, if any, cannot be ascertained
Phase 2	Postmenstrual	2-4	No mucus ("dry days")	Dry	Coitus is permitted but not on consecutive days since seminal fluid following intercourse may obscure the mucus.
			or	or	Abstain
Phase 3	Early pre-ovulatory days	2	Mucus present in small amounts Cloudy, yellow or white, and of sticky consistency	Sticky and or moist Sticky and or moist	Abstain
Phase 4	Immediately before, at, and after ovulation	3-5	Clear, slippery, wet, and stretchy, with the consistency of raw egg-white (Last day of this phase is known as the "peak symptom")	Lubricative and or wet	Abstain
Phase 5	Immediate postovulatory days	0-3	Small amounts of cloudy, sticky mucus or No mucus	Sticky and or moist or Dry	Coitus is permitted beginning on the fourth day after the last day of wet, stretchy mucus. Coitus permitted
Phase 6	Postovulatory infertile days	7-12	Usually no mucus, dry	Dry	
Phase 7	Late post-ovulatory days	0-3	Clear and watery	Sticky and or moist and or wet	Coitus permitted.

*Adapted from Figure 4, reference 1

User Instructions

One of the most striking findings of the World Health Organization's (WHO) prospective five-country study of the ovulation method (6) was that 93% of women, representing a wide range of cultural, educational, and socio-economic characteristics, were able to recognize and record the cervical mucous symptom during the first cycle following instruction in the method by an experienced teacher. What is particularly interesting was that 48% of the women in the El Salvador center were illiterate, yet they learned the method as quickly as the 11% and 8% of the women from the New Zealand and Ireland centers who had university degrees.

A simplification of the rules of the ovulation method states:

If you want to have a child:

1. Watch for the days of stretchy, wet, and slippery mucus. These may not occur in every cycle.
2. Have intercourse on the days when the woman is most aware of the feeling of mucous wetness.
3. Abstain for a day or two before each coitus to enhance husband's fertility.

If you do not wish to have a child:

1. Abstain during menstruation because bleeding might mask the mucous discharge, particularly in short cycles.
2. Abstain on days when mucus is present and for at least three days afterwards.
3. Abstain on days of intermenstrual bleeding and for at least three days afterwards.
4. While learning the method, abstain on alternate "dry" days prior to the onset of the feeling or observation of mucus (to minimize difficulty in recognizing the onset of mucous secretion because of the presence of seminal fluid).

Teachers of the Billings method stress that digital examination of the vagina and/or cervix is not necessary. They also state that the quantity of mucus produced is less important than the quality of the mucus (sticky, stretchy, thin, watery) and that the individual nature of the mucus should be described in the user's own terms whenever possible.

A special, simple stamp system was developed, particularly for illiterate women, for keeping a record of the menstrual cycle and cervical mucous discharge. Literate women can use the same system but are encouraged to write a couple of words describing the mucus each day. Alternatively, a plain lead or colored pencil can be used to indicate the daily observations with symbols devised by the woman herself or her instructor.

Effectiveness

The effectiveness of NFP depends greatly upon the woman's diligence in observing and recording the signs and symptoms of the fertile and infertile phases of the menstrual cycle, the motivation of the couple and their joint cooperation in abstaining from sexual intercourse, the couple's family planning intention, the quality of the instruction provided and, to a lesser extent, the regularity of the phenomena monitored to identify the fertile period. The effectiveness of the cervical mucous and sympto-thermal methods is not as affected by irregular cycles as is the calendar-rhythm method. User failures can occur because some couples may find the length of abstinence to be unacceptably long and may be tempted to take chances during the fertile phase, thereby reducing the effectiveness of all NFP methods.

In the WHO prospective multicenter trial of the cervical mucous-ovulation method (7), the unplanned pregnancies were classified as being related to

the method itself, inadequate teaching, inaccurate application of instructions, conscious departure from the rules, and uncertain. Using these categories, the pregnancy rates reported for the 725 subjects who learned the method and entered a 13-cycle effectiveness cycle study were 2.8, 0.4, 3.5, 15.4, and 0.5 pregnancies per 100 woman-years (modified Pearl index), respectively (7). The use-effectiveness of CMM, regardless of subclassifications, usually ranges from 5 to 40 pregnancies per 100 woman-years (1). (See Appendix A.)

BASAL BODY TEMPERATURE (BBT) METHOD

Mechanism of Action

BBT still remains the most quantitative of all available techniques which can be used in the home to *detect* ovulation. However, it has no value in *predicting* ovulation. Ovulation is detected by identifying a shift in temperature ($0.2\text{--}0.5^{\circ}\text{C}$ or $0.4\text{--}1.0^{\circ}\text{F}$) from a relatively lower level during the follicular phase of the menstrual cycle to a relatively higher level during the luteal phase. This temperature shift can be defined as one that occurs within 48 hours, and in which three consecutive daily temperatures are at least 0.2°C (0.36°F) higher than the last six daily temperatures before the start of the shift (9).

User Instructions

These four rules should be followed to assure accurate BBT readings:

1. Take the temperature in the morning, after a night's rest, immediately after awakening and before rising or drinking anything;
2. Use a certified clinical or expanded scale (fertility) thermometer; the temperature can be measured rectally or vaginally for 3 minutes or orally for 4-5 minutes;
3. Note any deviations from the normal routine (hours of sleep, fever, change of thermometer, etc.); and
4. If the mercury stops between two temperatures (graduations), record the lower temperature as the BBT reading.

There are several different ways of identifying a shift in temperature to define the beginning of the postovulatory infertile period, e.g., the use of a "coverline" drawn 0.05°C above the highest of the lower temperatures (excluding the first four days of the cycle and including at least six normal temperatures) and counting three consecutive temperatures above this coverline.

Producing and interpreting temperature charts requires considerable care. Body temperature can be altered by illness or emotional stress, and temperature levels may vary from cycle to cycle in the same woman. Furthermore, BBT may rise in different ways—abruptly, gradually, in a step-like pattern, the rise may be preceded by a sharp drop, and/or, less frequently, the rise may resemble a saw-tooth pattern (see Figure 17.1).

It is recommended that to produce an easily interpretable curve, the temperature should be charted on a scale where the distance covered by two days on the horizontal axis is equal to the distance covered by 0.1°C on the vertical axis. Figure 17.2 shows the same temperatures charted on three dif-

ferent scales. Although the expanded scale (2:1 ratio) graph (Panel C) is the easiest to interpret, the 1:1 scale (Panel B) is acceptable and is the one most frequently used by NFP programs.

Several studies have been undertaken on the occurrence of monophasic temperature curves in hormonally ovulatory menstrual cycles. These studies have postulated that in about 10-20% of ovulatory cycles, biphasic temperature patterns are not observed (5).

However, in a study conducted by Vollman (10), 7.2% of the 14,852 cycles observed (621 women) were monophasic. Vollman demonstrated associations between cycle length and age, and the incidence of monophasic patterns. In short menstrual cycles (7-17 days), 57.1% of cycles were monophasic. The rate decreased with the increase in length of the menstrual cycles and dropped to 5.8% at cycles of 24 days. In menstrual cycles of 25-32 days, the proportion of monophasic curves was lowest (1.8-4.8%). With menstrual cycles of 33 days and longer, the proportion of monophasic BBT curves steadily increased again and finally reached 41.3% in cycles of 60 days and longer. Since the length of menstrual cycles is known to vary with age, it is not surprising that Vollman found that monophasic cycles showed an age-dependent distribution. He concluded that, although monophasic BBT curves occurred at all ages, they characterize the adolescent and preclimacteric phases of a woman's reproductive life and are found at an average of 2% in mature, fertile women.

Effectiveness

For women who are willing to take and record their temperatures daily and to abstain regularly for more than half of the menstrual cycle, the tem-

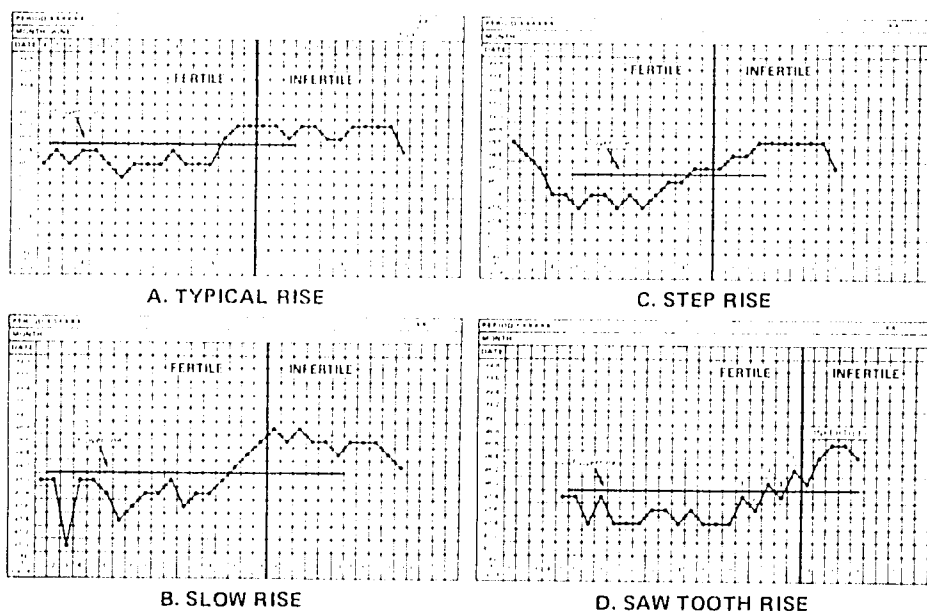


FIGURE 17.1 Common basal body temperature patterns. Adapted from Figure 3, reference 1.

perature method, when used alone, appears to be more effective than other periodic abstinence techniques. Pregnancy rates in early studies ranged from 0.3 to 6.6 per 100 woman-years of use when intercourse was restricted to the postovulatory phase of the cycle (10).

The major drawback of the temperature method alone is that abstinence is necessary for the entire preovulatory period. Furthermore, when ovulation does not occur, as is common around menarche, during lactation, and around menopause, BBT does not rise and abstinence throughout the cycle is required.

The results of selected studies are represented in Table 17.2.

CALENDAR (RHYTHM) METHOD

Mechanism of Action

The calendar method, commonly called the rhythm method, is the oldest NFP technique. It came into being in the 1930's after Drs. Ogino and Knaus independently published their findings that ovulation occurs about two weeks before menstruation (10). The calendar method is designed to predict the fertile period based on the duration of previous cycles. The method, as it was traditionally taught, requires knowledge of the lengths of the past 6 to 12 cycles.

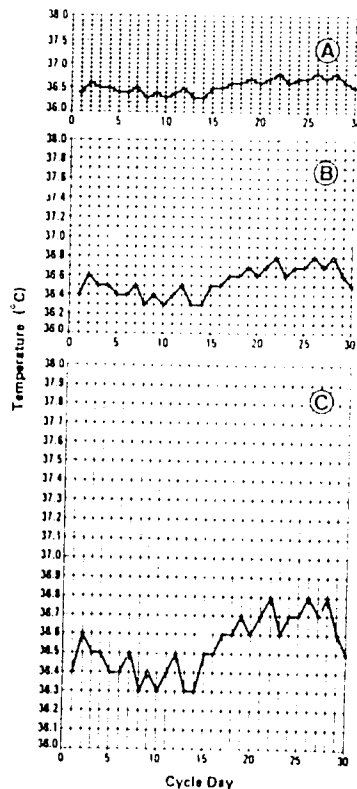


FIGURE 17.2 The same biphasic basal body temperature curve drawn on three different temperature scales.

Almost all NFP providers consider this method outdated. They believe that it should not be taught *alone* because, unlike the newer NFP methods, it does not reflect physiological changes associated with ovulation and fertility. Any unexpected wide variation in a woman's cycle length could result in a miscalculation of the safe period which would greatly increase the chance of an unplanned pregnancy. Furthermore, the method is useless in women with prolonged periods of anovulation such as occurs during the post-partum period especially with lactation.

Information is provided here on this method because it can be used in combination with other NFP methods.

Calculation of the fertile period is based on three assumptions: (1) on average, ovulation occurs 14 days (plus or minus 2 days) before the onset of the next menstruation; (2) sperm retain their fertilizing capacity for about 2-3 days (*but sometimes up to 7 or 8 days*); and (3) the ovum retains its ability to be fertilized for no more than 24 hours following ovulation.

User Instructions

Use a standard calendar or a menstrual diary. Record the length of each menstrual cycle over the most recent or next 6 to 12 cycles. The first day of bleeding is Day 1 in each cycle. The earliest day on which you are likely to be fertile is computed by subtracting 18 to 21 days from the length of your shortest cycle; "Minus-20" is most frequently used. Subtracting 8 to 11 days from the length of your longest cycle determines the first day on which you are no longer likely to be fertile; "Minus-10" is most frequently used. Therefore, the two numbers that result from these calculations represent the beginning of the fertile phase and the beginning of the postovulatory safe phase.

If, for example, you are practicing the rhythm method as it is most frequently used and your menstrual records show that your shortest cycle was 27 days and your longest cycle was 30 days, the first fertile day will be Day 7 of your cycle ($27-20=7$) and your first safe day will be Day 20 ($30-10=20$). See Appendix B for the calculation of the interval of fertility.

The decision on whether or not the woman is taught to subtract 18, 19, 20, or 21 from her shortest cycle length and 8, 9, 10, or 11 from her longest cycle length should be based on the couple's motivation to have more

TABLE 17.2 Selected studies of the effectiveness of the temperature (BBT) method*

Author	Country	Date	No. of Women	No. of Cycles	No. of Unplanned Pregnancies	Failure Rate
Guy and Guy	Mauritius	1965	1,491	16,735	112	8.03
Bartzen	U.S.A.	1967	296	4,824	79	19.5
Doring	W. Germany	1967	689 307 [†]	48,214 11,352	125 8	3.1 0.3
Marshall	U.K.	1968	255 321 [†]	3,545 4,749	57 26	19.3 6.6

*Modification of Table 1, reference 10. [†]Intercourse restricted to postovulatory phase only.

days available for intercourse and a little less method effectiveness or more effectiveness and less intercourse. Obviously, with a wider calculated fertile period, abstinence increases and the method will be more effective.

The wider the variation in cycle length, the longer the period of abstinence required. This method is somewhat inapplicable for women who have irregular cycles.

Effectiveness

Recently, little attention has been paid to teaching the calendar method alone. Therefore, no recent studies have been conducted on its effectiveness. The failure rate of the rhythm method is usually quoted as about 14-50 pregnancies per 100 woman-years based on studies conducted between 1937 and 1968 using retrospective analyses (10).

SYMPTO-THERMAL METHOD (S-TM)

Mechanism of Action

Approaches to identifying the fertile period which use BBT measurements to detect ovulation in combination with changes in cervical mucus, calendar calculations, and/or other parameters to predict ovulation are called the sympto-thermal method (S-TM). With this *multiple-indices approach*, if a woman cannot clearly interpret one sign, she can double check her interpretation with another. A thorough review of these methods was prepared by Parenteau-Carreau (11) and Population Reports (1).

Different NFP organizations have developed their own instructions and charts for the S-TM. The S-TM rules set forth in the World Health Organization NFP curriculum call for abstinence beginning either when calendar calculations so indicate (shortest cycle minus 20) or when the cervical mucous symptom is first observed, whichever comes earlier. The end of the fertile period begins either on the fourth day after the peak mucous symptom or on the evening of the third day of consecutive higher temperatures above a coverline—whichever comes later. Some S-TM organizations teach reliance only on calendar calculations or on mucous observations during the preovulatory period and on the temperature shift only to identify the postovulatory safe period. Such approaches are referred to as *calendar-thermal* or *muco-thermal methods*, respectively.

Other symptoms can be used to help identify the fertile period, but they are less common, less consistent, and less specific than cervical mucous changes and the BBT rise. They include intermenstrual pain (mittelschmerz, which can be interpreted as a pain in the lower back, abdomen, or side), intermenstrual bleeding, breast tenderness, and several other symptoms such as edema and mood changes.

Self-observed changes in the position, texture, moistness, and dilation of the cervix through digital examination appears to be a relatively accurate method of assessing the fertile phase of the menstrual cycle. The cyclic changes in the cervix appear to occur relatively consistently and they may be especially useful to detect the onset of fertility in the post-partum period.

However, some women may find this approach unacceptable. No information is available on the percentage of women who are able to discern cervical changes.

Among supporters of NFP, there is debate as to the advantages or disadvantages of single index (e.g., cervical mucus alone) or multiple-indices (e.g., S-TM) methods. Some NFP teachers insist that the use of cervical mucus alone is sufficient, stating that combining it with other indicators of ovulation may be less reliable than mucus only. Another argument put forward by those who advocate the cervical mucus method alone is that taking and interpreting daily temperature readings makes the combined method too complicated for many women in developing countries.

The promoters of the S-TM believe that the more indices monitored, the more effective the method. They also believe that the BBT shift is usually a more objective and reliable method for identifying the end of the fertile phase. In addition, when first learning NFP, it is claimed that the monitoring of several signs and symptoms will help the user to gain confidence in her ability to detect the fertile and infertile phase of the menstrual cycle. Results of effectiveness studies indicate that the multiple-indices methods may be somewhat more effective than single-index methods. Finally, while most providers of the cervical mucus method recommend total abstinence during the first cycle of learning, with the S-TM, intercourse can take place following the temperature shift in the first cycle.

Effectiveness

The effectiveness of S-TM was assessed in a number of clinical trials conducted since the mid-1970's and ranged from about 5 to 35 pregnancies per 100 woman-years (1).

The first international prospective study of S-TM was reported by Rice (12). The study was undertaken by NFP associations in five countries: Canada, Colombia, France, Mauritius, and the United States. Since the form of the S-TM practiced in each country varied, a standardized procedure was adopted. There were 723 volunteers who used the S-TM only; 299 other volunteers reported using another method of contraception during the fertile days in one or more cycles. The method failure rate was 0.75 pregnancies per 100 woman-years (range between centers: 0.45-2.58). However, the total mean use-effectiveness rate was 7.2 pregnancies per 100 woman-years (range between centers: 4.9-18.1). Life table pregnancy rates ranged from 3.3-15.6% (mean 8.2).

The results of selected other studies are presented in Table 17.3.

TABLE 17.3 Selected studies of the use-effectiveness of the sympto-thermal method*

Author	Country	Date	No. of Women	No. of Months	Unplanned Pregnancies	No. of Failure Rate
McCarthy	U.S.A.	1981	496	N/A	45	10.7 ^(a)
Medina	Colombia	1980	286	1882	54	19.1 ^(a)
						34.4 ^(b)
Wade	U.S.A.	1980	590	3399	47	11.2 ^(a)
						16.6 ^(b)

*Adapted from Table 2, reference 1. ^(a)Life Table Rate. ^(b)Pearl Index.

FERTILITY AWARENESS

A popular term receiving widespread use, especially in the United States, is fertility awareness methods. Activities such as learning about the reproductive processes and sexual function, observing basal body temperature, cervical mucus and other symptoms of ovulation, making graphs and keeping records, trying to determine if ovulation took place and even identifying the phases of maximum fertility and infertility are aspects of fertility awareness. Furthermore, the term is used in a neutral sense because the manner in which fertility awareness can be incorporated into a family planning regimen is left up to the woman/couple. That is, sexually active people can choose to abstain during the fertile period (natural family planning) or they can choose to use a barrier method (contraception).

It appears that there has never been a prospective, use-effectiveness, acceptability study conducted in couples who wish to combine fertility awareness with the use of barrier methods during the fertile phase. The only effectiveness data for such a regimen were obtained indirectly from couples enrolled in NFP studies who admitted to using barrier methods or coitus interruptus during periods of proscribed abstinence. Such studies, reviewed by Klaus (3), showed that CCM combined with barrier methods resulted in user and method failure rates of 6.8 and 0.2 pregnancies per 100 woman-years, respectively. The combination of the BBT method with barrier methods resulted in a user failure rate of 8.9 and a method failure rate of 1.4 pregnancies per 100 woman-years. It must be realized, however, that when using fertility awareness combined with barrier method it is almost impossible to determine if a resulting unplanned pregnancy was caused by the failure of the barrier method or the fact that an assumed infertile day was actually a fertile day. Carefully kept records of all acts of intercourse, unprotected and with barrier methods, would help to alleviate some of this problem.

Program administrators who wish to recommend to appropriate clients the possibility of combining fertility awareness with barrier methods during the fertile period should:

1. First ensure that the woman is able to identify the fertile period.
2. Suggest that only condoms be used if the woman is monitoring her fertility with the cervical mucous method only—the presence of spermicidal gel, cream or foam (with or without a diaphragm) could very well interfere with the woman's ability to identify the mucous characteristics.
3. Inform the couple that the method effectiveness of the combined approach is not as high as abstinence during the fertile period.

ADVANTAGES AND DISADVANTAGES

Since use of NFP does not employ drugs or devices, the only potential medical side effect is the risk of unplanned pregnancies with the attendant possibilities of maternal mortality. Although there has been some anxiety expressed about the possibility of an increased risk of spontaneous abortion and congenital defects among the offspring of NFP failures, IPPF reviewed the literature on this subject and concluded that "the present evidence does

not suggest that the risk, if any, is appreciable" and that there is "no need to warn prospective users of this hypothetical risk" (4).

When the rules of the newer NFP methods are followed, particularly those pertaining to sexual abstinence, the methods are highly effective in preventing unplanned pregnancy.

Advantages

No physical side effects.

Acceptors can be trained by paraprofessionals and lay volunteers.

After initial training and followup, many users are able to practice the method without additional assistance and at almost no expense.

Training increases awareness and knowledge of reproductive functions.

May help couples achieve pregnancy.

Responsibility for family planning is shared by both partners, which may lead to increased communication and cooperation. By requiring collaboration between partners, periodic abstinence can contribute to more equitable, cooperative marital relationships in areas wider than just family planning.

Acceptable to people who do not believe in "artificial" contraception.

Approved by the Catholic Church.

May be esthetically more acceptable than other coitus-related methods (condoms, spermicides, and withdrawal).

NFP availability may increase the number of initial family planning acceptors.

Disadvantages

In general, less effective than many other methods.

Relatively long initial instruction.

Requires daily monitoring and charting.

Requires strong commitment and cooperation from both partners to be effective.

Sexual abstinence may cause marital difficulties.

Some women experience fear of unplanned pregnancy.

Without use of volunteer teachers and instructors, the delivery of NFP could be expensive.

Using NFP to avoid pregnancy, intercourse must be confined to a limited number of days based on the method practiced:

Cervical mucus (alone):

—learners: 1/2 of the days of the cycle.

—experienced users: up to 2/3 of the days of the cycle.

BBT (alone): 7 to 13 days per cycle.

Calendar (alone): depending on cycle length and variability, may be as few as 1 to 3 days or as many as 10 to 20 days per cycle.

Sympto-Thermal: depending on the combination of techniques used, from 1/3 to 1/2 of the days of the cycle.

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CHAPTER 18

COITUS INTERRUPTUS OR WITHDRAWAL

Coitus interruptus, or the withdrawal method of birth control, has long been used as a contraceptive technique in Africa. It has been an important traditional method of fertility control in many communities throughout the continent. (See Chapter 2.) A couple using the withdrawal method may have intercourse in any way acceptable to them until ejaculation is about to occur, at which point the male withdraws his penis from the vagina. Ejaculation occurs completely away from the vagina and external genitalia of the female, thus preventing any possibility of conception.

As a method of birth control, withdrawal has distinct advantages over most other methods. It requires no devices, involves no chemicals, and is available at no cost. It does, however, have one strong disadvantage. The failure rate of withdrawal ranges from 10 pregnancies per 100 women per year (if withdrawal is used consistently) to 23 pregnancies per 100 women per year among actual users (1).

This failure rate is a result of several factors. Even when practiced faithfully, there is an inherent source of error in this method. There is a small possibility that preliminary ejaculatory fluid (often said to be semen stored in the prostate or penile urethra or in the Cowper's glands) can escape before the penis is withdrawn. The likelihood of failure caused by the release of preliminary ejaculatory fluid increases if multiple male orgasms occur within a short span of time since this fluid contains more sperm after a recent ejaculation. Another reason for contraceptive failure of coitus interruptus is the lack of self-control demanded by this method. The man may attempt to achieve deeper penetration at the time of impending orgasm and may not withdraw in time to prevent sperm from being deposited on his partner's external genitalia.

Lack of ejaculatory control (or premature ejaculation) is a contraindication to the use of the withdrawal method of birth control.

Among couples who use withdrawal, some use it consistently and prefer it to other methods, some use it sporadically, and some use it as an adjunct to other methods during midcycle when ovulation is most likely to occur.

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CHAPTER 19

PROMISING NEW METHODS

Four promising new methods of birth control include the *contraceptive sponge*, *long-term progestin-elaborating IUD's*, *tailless IUD's*, and *contraceptive vaccines*. A fifth, a male birth control pill called gossypol, has attracted a lot of attention.

CONTRACEPTIVE SPONGE

Vaginal contraceptive sponge

Natural sea sponges have been used since antiquity for contraception. In the 1970's, interest in the sponge concept led to the development of natural collagen and synthetic sponges and to the incorporation of spermicide in the sponge (1).

In 1983, the Food and Drug Administration (FDA) approved the first vaginal contraceptive sponge for marketing in the United States. This product is a small, pillow-shaped polyurethane sponge that contains 1 gram of nonoxynol-9 spermicide. The sponge has a concave dimple in one side which fits over the cervix and decreases the chance of dislodgement during intercourse. The other side of the sponge incorporates a woven polyester loop used to facilitate removal.

The sponge is available in one size without prescription. Prior to use, the sponge is moistened with tap water and inserted deep in the vagina. Once in place, the sponge provides *continuous protection for up to 24 hours* and

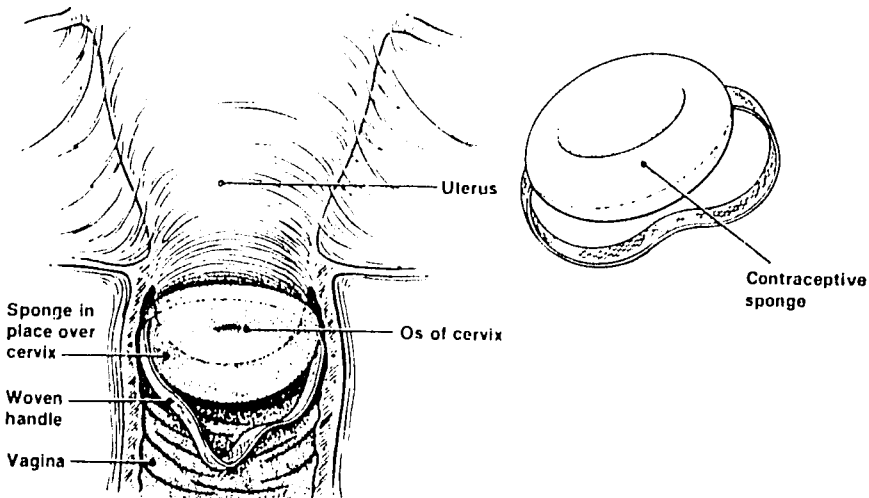


FIGURE 19.1 Contraceptive sponge.

does not require any additional measures for repeated intercourse during that time. After use, the sponge is discarded.

The sponge exerts its contraceptive effect by (1) providing a barrier between sperm and the cervix; (2) trapping sperm within the sponge; and (3) releasing spermicide contained within the sponge to destroy sperm.

Several studies of vaginal sponges have been reported. Small studies of collatex sponge users in other countries have found pregnancy rates from 1.1 to 3.6 for the first 6 months of sponge use (2). Data from a multicenter study in the United States comparing the sponge with the diaphragm found an overall 12-month pregnancy rate of 16.6 for sponge users and to 11.4 for diaphragm users (3). Although the difference between sponge and diaphragm effectiveness in this study was statistically significant, the rates indicate that the effectiveness of the sponge is clinically similar to that of the diaphragm.

Contraindications to using the sponge include (1) allergy to polyurethane or nonoxynol-9; (2) inability to learn correct insertion technique or to remember to use the method consistently; (3) anatomic abnormalities such as uterine prolapse, cystocele, rectocele, extreme uterine retroflexion or vaginal septum that interfere with proper placement or retention of the sponge; (4) history of toxic shock syndrome or vaginal colonization with *Staphylococcus aureus*.

There are relatively few side effects and complications associated with the use of the sponge: (1) irritation or allergic reactions; (2) difficulty in removing the sponge (6% of users in the United States); and (3) objections from partner (uncommon).

Although not yet documented, it is likely that benefits associated with spermicide use also accrue to users of the spermicide-containing sponge: (1) spermicides decrease the transmission of sexually transmitted infections including gonorrhea and trichomoniasis; and (2) spermicides may offer some protection against cervical neoplasia. (In addition, some sponge users find that absorption of vaginal secretions and ejaculate is a desirable side effect.)

IMPORTANT INSTRUCTIONS FOR SPONGE USERS

1. Use your sponge whenever you have intercourse.
2. Plan to insert your sponge in plenty of time before intercourse and when you have water available.
3. Do not use your sponge while you are having menstrual bleeding.
4. Toxic shock has not been a problem for sponge users so far, but watch for the early symptoms of toxic shock whenever you use your sponge.
5. If you find that the sponge is not in proper position after intercourse, then you may want to adopt another method of birth control.

PROGESTIN-ELABORATING IUD's

In the late 1970's, the Alza Corporation began to market the first progestin-elaborating IUD in the USA. The perceived advantage of this innovation was that it would enlist the aid of progesterone to prevent implantation without systemic effects (4). This IUD (called the "Progestasert System") has proven to have two additional remarkable advantages: It decreases the total amount of blood lost during the menstrual period, and it diminishes the amount of menstrual pain experienced by the user. The main drawback of the Progestasert System is that it must be removed and replaced in what many consider to be an unacceptably short period of time—one year.

Research is now underway to test IUD's which would release either progesterone or a more powerful progestin, norgestrel. It is entirely possible that one of these two IUD's will be available in the United States within the next ten years. Both norgestrel- and progestin-elaborating IUD's are being marketed in Europe today.

TAILLESS IUD'S

In our discussion of IUD's (Chapter 13), the case is made that much of the infection associated with IUD's may be attributable to the ascent of bacteria up the tail of the IUD (5,6,7). As infection is by far the most serious problem associated with IUD use, the elimination of the tail should minimize the risk of complications associated with infection, thereby constituting a major advance. Were we to move in this direction, we would be returning to an older approach but one which is widely and successfully used today in China (5,6,7).

The major disadvantage of a tailless IUD is that it leave us with the inability to readily identify the location of the inserted IUD. When available, simplified ultrasound techniques might easily overcome this difficulty.

Another problem with a tailless IUD is its removal. See the section in the IUD chapter relating to removal of an IUD when the tail is lost for suggestions as to how this second problem might be managed.

VACCINES

Throughout the world, mortality and morbidity rates have been profoundly reduced by vaccination. If the theory of vaccination also applies to the human reproductive system, it is possible that some day vaccination may be responsible for falling fertility rates as well (8).

For years, the possibility of a vaccine against pregnancy has been hypothesized. In time, some of the many naturally occurring ("self") antigens in the male or female reproductive systems might be induced through the process of vaccination to produce antibodies, thus preventing

pregnancy. We are, however, probably a number of years away from developing an effective, safe, inexpensive contraceptive vaccine.

GOSSYPOL (MALE PILL)

Gossypol (extracted from cotton plants) is a yellow phenolic compound which in tablet form has been clinically tested as a male antifertility agent (9). It has been noted in China during the 1950's that cooking with crushed cottonseed oil could lead to infertility and affected men more than women.

Since 1972, over 4,000 men have been treated with gossypol in China for periods of at least 6 months; more than half of these have been observed longer than 2 years. The initial dosage was 20 mg daily, and it usually took 2 months to produce infertility.

The drug has been found to have two effects. It suppresses sperm production. Also, it alters the structure and motility of sperm in the epididymis, including damage to the acrosomal cap and swelling of the mitochondrial sheath.

Potential side effects include weakness, lowered potassium levels in the blood, a decrease in libido, change in appetite, epigastric discomfort, nausea, and cardiac irregularities (with high doses).

Because only minimal research has been conducted, effectiveness rates have not yet been determined. It is known that normal sperm counts are restored for only 75% of men within months of gossypol's discontinuation (10).

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CHAPTER 20

PREVENTION AND MANAGEMENT OF COMPLICATIONS ASSOCIATED WITH MISCARRIAGE OR INDUCED ABORTION

Complications of illegal abortion account for 4 to 70 percent of maternal deaths in developing country hospitals and an unknown number of additional deaths outside of hospitals.

Laurie S. Liskin (1)

Clinicians who provide maternal health and family planning care will almost surely be called upon to evaluate or treat women who are having or have recently had an abortion, either spontaneous (miscarriage) or induced. (See Table 20.1.) This chapter has been included to meet the needs of clinicians who are called upon to manage complications from abortion.

PUBLIC HEALTH IMPACT OF PREGNANCY TERMINATION

MOST ABORTIONS CAN BE PREVENTED BY THE SAFE AND EFFECTIVE USE OF CONTRACEPTIVE METHODS.

Pregnancy and pregnancy termination are probably the most important health risks that women face during their reproductive years in traditional and developing societies. As the transition from a traditional to a developing society occurs, the risks of childbirth diminish dramatically, but more women face the risks associated with induced abortion and ectopic pregnancy. Experts reviewing these problems in Africa conclude that:

Although the real status of induced abortion is not known, it is generally accepted that as the underdeveloped communities become involved in the transitional process of development, an increasing incidence of induced abortion occurs.

Today, in the capitals of some African countries, societies are rapidly changing and entering the transitional process, so that induced abortion with all its associated risks, including complications and death, may be expected to increase in incidence (2).

TABLE 20.1 Number of admissions in African hospitals for abortion complications, selected studies, 1970-1979 (1)

Country	Hospital	Year	No. of Abortion-Related Admissions
Nigeria	Adeoyo Hospital, Ibadan	1965	453
		1966	615
		1967	754
Ghana	Korle Bu Hospital, Accra	1967	2,886
		1968	3,204
		1970	3,034
		1971	3,148
		1972	3,275
		1976	3,772
	Effia-Nkwanta Hospital	1970	835
		1971	885
		1972	824
	Koforidua Hospital	1970	345
		1971	408
		1972	255
Kenya	Kenyatta Maternity Hospital, Nairobi	1970	914
		1971	1,312
		1972	1,564
	Kenyatta National Hospital, Nairobi	1971	1,838
		1974	2,070
		1975	3,048
		1976	3,702
Mauritius	Civil Hospital	1970	1,028
		1971	593
		1972	751
	Victoria Hospital	1970	891
		1971	647
		1972	751
	7 rural hospitals	1970	350
		1971	498
		1972	668
	All hospitals	1973	2,013
		1974	2,285
		1975	2,479
		1976	2,515
Nigeria	Lagos Island Maternity Hospital	1962	1,700
		1963	1,800
		1964	1,600
		1965	2,100
		1966	2,200
		1967	1,900

TABLE 20.1 Number of admissions in African hospitals for abortion complications, selected studies, 1970-1979 (1) — Continued

Country	Hospital	Year	No. of Abortion-Related Admissions
	Lagos University Teaching Hospital	1964	171
		1965	194
		1966	122
		1967	157
		1970	177
		1971	196
		1972	229
Sierra Leone	Maternity and Connaught Hospitals, Freetown	1970	206
		1971	220
		1972	244
Uganda	Mulago Hospital, Kampala	1967	1,518
		1968	1,830
		1969	2,120
Zambia	University Teaching Hospital, Lusaka	1972	1,448
		1973	1,592
		1974	2,130
		1975	3,075
		1976	2,991

Clinicians concerned about health care for women in Africa must therefore expect to face increasing problems with the dilemma of abortion (3). Developing countries in other areas of the world have already experienced this serious problem. Studies in Latin America have demonstrated that complications of illegal abortion accounted for as much as 30% to 40% of maternal deaths (1). Similar rates have also been reported for some African urban hospitals. In the Lagos University Teaching Hospital, 51% of maternal deaths between 1966 and 1972 were attributed to abortion-related complications (4). In a 1980 study at Kenyatta National Hospital in Nairobi, the number of hospital admissions for septic abortion increased 100% between 1973 and 1978; septic abortion carried a high death rate (two deaths for every 1,000 septic abortion patients admitted) (5).

Because it is usually so difficult to gather accurate statistics on induced abortion, there are few comprehensive studies documenting complication rates. Worldwide experience does show, however, that abortion complications can be a substantial burden for limited health care facilities, blood bank supplies, and trained medical personnel (3,6).

Moreover, one recent survey of 60 developing nations throughout the world estimated that 13.7 million abortions were induced in 1976, yielding a ratio of 207 abortions per 1,000 live births. An estimated 70,000 to 140,000 women died in 1976 in these 60 developing countries from abortion complications, including between 600 and 6,000 women in Africa (7,8).

WHAT CAN YOU DO?

Clinicians will be called upon to provide the following important health services:

1. To recognize and manage the medical complications of abortion and teach patients the danger signs, so that problems can be identified and treated early.
2. To be prepared to provide treatment or referral for women who have complications. The extent of clinical services available for treating complications will depend, to some degree, on whether they are being delivered in a hospital or primary care center.
3. To provide contraceptive information and services. Women who have spontaneous abortions need time for full recovery before attempting another pregnancy. Women who have had induced abortions are likely to appreciate help and become effective contraceptive users. Acceptance rates as high as 90% have been reported by programs offering contraception to women after treatment for abortion (3). Effective contraception can prevent the occurrence of future abortions and their complications.
4. To keep careful statistical records so that the extent of abortion-related public health problems can be assessed and appropriate public health remedies can be considered.

COMPLICATIONS AFTER ABORTION

Complications can occur after any type of pregnancy termination. With spontaneous abortion (miscarriage), the most common problems are:

- infection;
- retained pregnancy tissue;
- bleeding.

These three problems are also common after induced abortion, particularly illegal induced abortion. With induced abortion, however, additional problems must also be considered, especially when illegal or nonphysician abortion is suspected:

- continuing pregnancy (despite the abortion procedure);
- damage (trauma) to the uterus and cervix;
- toxic reactions to chemicals or drugs used to induce abortion.

Whenever symptoms suggest miscarriage or induced abortion, it is important also to think of ectopic (usually tubal) pregnancy. *The early signs of ectopic pregnancy may be similar to the signs of abortion complications.* A woman with an ectopic pregnancy may have pain, irregular bleeding, breast tenderness, nausea, or a recently delayed or skipped menstrual period. (See Chapter 8 for more information on ectopic pregnancy.) The complications listed above are more thoroughly described in the following pages.

MANAGEMENT OF ABORTION COMPLICATIONS

INFECTION

Signs of infection are:

1. pain in the abdomen or pelvis
2. cramping or backache
3. fever and chills
4. foul-smelling vaginal discharge
5. prolonged bleeding or spotting
6. weakness, lethargy, or muscle aches
7. tenderness of the uterus and adnexae during pelvic exam or tenderness with cervical motion

Patients should be taught to watch for these signs and to seek help immediately if *any* of these occur, even in mild form after a spontaneous or induced abortion. Most often, signs of infection appear 2 or 3 days after abortion, but infection can begin earlier or as long as several weeks later.

Treatment depends on the severity and extent of the specific infection. *It is essential to be sure that no pregnancy tissue remains in the uterus.* If an incomplete spontaneous abortion (miscarriage) or an illegal induced abortion is suspected, then special care is needed to be sure that the uterus is empty. This should be done at the earliest opportunity.

If the patient is severely ill with weakness, low blood pressure (shock), or infection that extends beyond the uterus to involve the tubes (parametritis or salpingitis) or abdominal cavity (peritonitis), then urgent hospital care will be needed. Intravenous or intramuscular antibiotics and fluids should be started and immediate arrangements made to remove any remaining pregnancy tissue. Suction or sharp curettage of the uterus should be used and should not be delayed until hospitalization. Intravenous antibiotics are continued until the patient improves (remains afebrile for at least 24 hours, for example) and is able to change to oral treatment. If a hospital is far away, then antibiotics can be given intramuscularly or orally until the patient arrives at the hospital for intravenous administration. In other words, antibiotic therapy ought *not* be delayed.

If the infection is mild and involves only the uterus and no evidence of tissue remains in the uterus (continue to suspect it if, for example, the os is still widely dilated, the uterus is large, or cramping or bleeding persists), then

hospitalization may not be necessary. Antibiotics can be given by mouth, and the patient can be advised to rest at home. If there is satisfactory improvement when the patient is examined 2 or 3 days later (less pain, less uterine tenderness, no fever), then D&C or vacuum curettage of the uterus may not be necessary. If symptoms persist, worsen, or the uterus is tender or enlarged, then a D&C or vacuum curettage may be needed to be certain that no tissue remains in the uterus.

RETAINED PREGNANCY TISSUE

Signs of retained tissue after spontaneous or induced abortion are:

- abdominal or pelvic pain
- backache or cramps
- heavy or persistent bleeding, which may lead to shock (rapid pulse; sweaty, clammy skin; fainting or lightheadedness)
- an enlarged, soft, tender uterus noted at pelvic examination
- tissue visible at cervical os (opening)

Infection very often accompanies the problem of retained pregnancy tissue because the tissue is an ideal environment for bacterial growth.

Retained tissue is common after spontaneous abortion or after illegally induced abortion, when surgical techniques are not optimal. It is not as common when vacuum aspiration is used to induce abortion, occurring usually less than 1 in 25 times. Vacuum abortion is infrequently followed by a related problem, accumulation of blood clots in the uterus after surgery. This occurs once in 200 to 300 times. This can occur rapidly, causing very severe cramping pain that worsens within the first few hours after an initial vacuum aspiration. Examination shows a quite large, tense uterus that is very tender, with little or no bleeding at the cervix. In this situation, remove retained tissue or blood clots with vacuum aspiration or D&C and consider giving methylergonovine (Ergometrine[®]) or other oxytocics to help maintain firm uterine muscle tone and to expel any remaining tissue or clots.

BLEEDING

Some bleeding is to be expected after any termination of pregnancy. Often bleeding is scant (or absent) for the first 24 to 36 hours, and then increases somewhat as the uterine lining loses the hormone support that pregnancy provides. Moderate bleeding, similar to a menstrual period, then may occur and continue intermittently for as long as 6 weeks.

Bleeding heavier than that which occurs during a menstrual period, or that persists longer than 3 or 4 weeks needs to be evaluated. Initially, heavy bleeding may be caused by retained pregnancy tissue or by trauma to the cervix, vagina, or uterus from instruments or chemicals. Some anesthetics, such as halothane, may also cause immediate uterine hemorrhage as they interfere with normal uterine contraction. Prolonged bleeding may indicate retained pregnancy tissue.

Hemorrhage can also be caused by disruption in the normal blood-clotting sequence. This problem (disseminated intravascular coagulopathy - DIC) is rare but can be triggered by an instillation of hyperosmolar agents or a D&C for abortion in the second trimester, by a spontaneous abortion that is delayed (missed abortion), when a dead fetus remains in the uterus for days or weeks before spontaneous uterine contractions begin, or by severe infection.

Initial treatment for hemorrhage, such as repair of a cervical tear or removal of retained tissue, is often successful. If bleeding is very heavy or the patient shows signs of shock (rapid pulse, decreasing blood pressure, weakness, or faintness), then uterine massage to maintain firm muscle tone and oxytocics or ergometrine may be started while arrangements are made for further care, such as intravenous fluids, blood transfusion, and surgery.

DAMAGE TO THE CERVIX OR UTERUS

Damage to the vagina, cervix, and uterus is a very important problem, especially after illegal abortion or when abortion is self-induced. Uterine perforation and damage to intestines can result from an attempt to insert a foreign body (such as a stick) into the uterus. Vaginal injuries can also occur if the clinician fails to locate the cervix, or if caustic chemicals such as harsh soap or potassium permanganate are used. If induced abortion is suspected, it is important to watch for early symptoms of internal hemorrhage and intestinal injury. Rapid pulse, weakness, faintness, or decreasing blood pressure may be a warning that serious internal bleeding is occurring, possibly as a result of damage to the large uterine blood vessels in the broad ligaments adjacent to the uterus. Pain, vomiting, abdominal tenderness or rigidity, and decreased bowel sounds may be signs of intestinal injury.

Damage to the cervix or uterus is much less common during the course of vacuum aspiration abortion, but it can occur. More common are tears of the cervix from the clamp (tenaculum) used to stabilize it during surgery. Uterine puncture (perforation) is less frequent. If the perforation is caused by the uterine sound, then the uterine wound may close and heal without treatment. When such an injury is suspected, careful observation is required for the first 24 hours or so to watch for signs of intestinal injury and internal hemorrhage. If the uterus is perforated by a sharp instrument or by the vacuum curette, then surgery may be required to find and repair damage to the uterus, intestine, or bladder.

Cervical injury can occur as a result of forceful uterine contractions during late abortion induced with intra-amniotic prostaglandin, prostaglandin vaginal tablets, or intra-amniotic saline augmented with oxytocin. In a small fraction of patients cervical dilation fails to keep pace with the force of uterine contraction. The result is a spontaneous tear in the lower uterine segment (usually in the posterior fornix of the vagina, just below the cervix) through which the pregnancy is expelled. This problem can occur undetected with

surprisingly few symptoms, but examination with a speculum shows a "ragged" defect. The tear should be carefully sutured so as to avoid problems in future pregnancies.

TOXIC REACTIONS TO DRUGS OR CHEMICALS

Women who have attempted to induce abortion may also show toxic signs of poisoning with herbs, cathartics, or other drugs; symptoms depend on the specific agent used. Watch for kidney damage (anuria or oliguria) and for liver damage (upper abdominal pain, jaundice). Clinicians may also suspect attempted abortion if the vagina shows ulceration or bleeding from caustic chemicals, such as potassium permanganate or harsh soap.

Ergonovine poisoning can cause vomiting, diarrhea, thirst, itching, numbness, and tingling of the extremities, and can lead to confusion, cold skin, a rapid weak pulse, unconsciousness, and death (lethal dose, 26 mg by mouth) (9). Chloroquine poisoning causes headache, disturbances in vision, gastrointestinal upset, itching, and in some cases, rash. Toxic doses of quinine cause stomach pain, nausea, vomiting, and diarrhea, ringing in the ears, dizziness, and vision disturbances. Severe central nervous system effects of quinine poisoning include headache, fever, confusion, delirium, faintness, depressed respiration, coma, and death (lethal dose, 8 gm by mouth) (9).

These and many other drugs and herbal preparations are commonly viewed as abortion options. None, however, provides reliable termination of pregnancy, and serious toxic complications are frequent.

On occasion (1 to 3 in 1 000) (10,11), the attempt to induce abortion using vacuum aspiration is not successful. This problem is more common when an abortion procedure is performed before the seventh week of gestation (counting from last menstrual period) and may also be a problem when less than optimal abortion methods are used.

Signs of continuing pregnancy include persisting symptoms of pregnancy, such as nausea, breast tenderness, fatigue, and continuing or increasing uterine enlargement. In this situation it is important to think of tubal (ectopic) pregnancy, twin pregnancy, or pregnancy in a bicornuate uterus. In most cases, however, the intrauterine pregnancy was simply not evacuated during the initial abortion attempt.

LATE EFFECTS OF ABORTION

When complications occur following induced abortion, they can cause a range of long-term medical problems including chronic pelvic infection, which can lead to an increased risk of ectopic pregnancy and infertility. Due to the lack of studies that provide for long-term followup for uneventful abortions, the possible long-term medical risks are not yet known for cases when abortion is induced under satisfactory medical circumstances and no immediate complications occur.

The recent scientific literature from the United States is inconsistent about whether one abortion, or even multiple abortions, is associated with increased rates of adverse reproductive outcomes (miscarriage, prematurity, low birth weight) in subsequent desired pregnancies (12). Among current studies, two have demonstrated a significant association between a single induced abortion and problems of subsequent childbearing (13,14); the others have found either no association or such a small level of risk that chance could have accounted for the difference (14-21).

FACTORS THAT INFLUENCE (OR INCREASE) THE RISK OF ABORTION! COMPLICATIONS

Many factors influence the risk of abortion. The risk of complications is highest under the following circumstances:

1. The woman is in poor health.
2. The abortion occurs late in pregnancy.
3. The uterus is evacuated under unsterile conditions.
4. The clinician who performs the abortion is incompetent.
5. The woman is poorly educated to danger signs she should watch for after abortion.
6. Aftercare is poor if problems arise after abortion. No followup exam is performed after the abortion (2 weeks) to be sure that the uterus has returned to normal size and is not tender and that there are no other signs of continuing pregnancy, infection, or bleeding.
7. The tissue removed is not examined following the procedure so that the possibility of incomplete abortion, ectopic pregnancy, or molar pregnancy can be recognized at the time of surgery.
8. The woman has gonorrhea or other pelvic infection.

DANGER SIGNS AFTER ABORTION

- Fever
- Chills
- Muscle aches
- Tiredness
- Abdominal pain, cramping, or backache
- Tenderness (to pressure) in the abdomen
- Prolonged or heavy bleeding
- Foul vaginal discharge
- Delay (6 weeks or more) in resuming menstrual periods

Abortion is a traumatic event for everyone concerned: the woman, the family, and the clinician. Ideally, abortion can be prevented by the effective use of contraceptive methods.

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CHAPTER 21

STERILIZATION

"Do not have any more children," the supervising physician advised two women who, along with thirty other women, had come for family planning services. Sterilization facilities were not available. Since the nurse-midwife providing the contraceptives had a prejudice against the IUD, she gave the two women a supply of Pills. The women used the Pills until they could get no more because of a stock-out at the supply depot. They therefore stopped using the Pill and became pregnant. Both women died in childbirth.

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WHAT IS STERILIZATION ?

Voluntary sterilization is a surgical operation for permanent contraception. In women, the sterilization operation involves blocking or cutting both fallopian tubes to prevent the passage of ova and sperm. In this manner, fertilization is prevented. In men, the sterilization operation—called a vasectomy—blocks the vas deferens to prevent the passage of sperm. The effect of sterilization operations on the hormonal feedback between the pituitary and the gonads has been studied extensively (2-4). Levels of luteinizing hormone (LH), follicular stimulating hormone (FSH), testosterone and estrogen remain within the normal range after sterilization. Levels of serum progesterone are slightly reduced after tubal sterilization, according to recent reports (5,6). Even though the sterilization operation can be reversed in some cases, it should be considered permanent. Because of its permanence, the method is best for couples desiring no more children because their family is complete, or for couples who, for medical reasons, should not have any more children. It is important that couples choosing to be sterilized realize that the operation must be considered irreversible.

THE ADVANTAGE OF STERILIZATION

The operation has several advantages that add to its popularity:

- It is more effective than any other method of contraception. Studies from Singapore have shown cumulative failure rates of 0.47% at 12 months, 0.81% at 24 months, and 0.85% at 36 months following tubal sterilization (7).
- It can be easy to perform, depending upon the approach chosen.

- It carries only a one-time risk of complication, as opposed to the ongoing risks of other contraceptive methods.
- It can be performed not only at an elected point in time between pregnancies, but also post-partum and post-abortion.
- It is relatively safe with a very low mortality rate (8), in fact, much lower than that of pregnancy (See Table 21.1).

TABLE 21.1 Estimated mortality associated with pregnancy, childbirth, and sterilization by age, method, and developmental status of countries (8)

Developmental Status	Age Group	
	15-29	30-39
	(Rates per 100,000 pregnancies or procedures)	
Developed countries		
Pregnancy and childbirth	11-13	25-44
Female sterilization	10	10-15
Male sterilization	0	0
Developing countries (advanced)		
Pregnancy and childbirth	20-25	50-100
Female sterilization	20	20-30
Male sterilization	0	0
Developing countries (less advanced)		
Pregnancy and childhood	400-700	500
Female sterilization	50	50-75
Male sterilization	0.1	0.1

Note: As the results from studies of maternal mortality and sterilization safety become available, these estimates will need to be revised. The data from two recent studies suggest that female sterilization mortality in less advanced developing countries is even lower than estimated here, while male sterilization mortality is higher (9, 10).

THE DISADVANTAGES OF STERILIZATION

Disadvantages of sterilization are:

- **It must be considered irreversible.** Many disappointments may be prevented by carefully educating the patient about the permanence of the operation. The reversal operation requires a special skill and technologically advanced equipment, and it carries its own risk of complications. In many areas of Africa, the reversal operation is still far from practical.
- **It may not be accepted in all cultures.** Again, education is helpful in gaining understanding and support.
- **It carries a risk of complications,** although the complication rate is low and can be further reduced through careful medical screening. The complication rate depends significantly upon the skill of the surgeon. Complications of anesthesia are lower with the use of local, rather than general, anesthesia.

STERILIZATION IN THE MALE

VASECTOMY

Vasectomy is a simple procedure that can be performed safely even in remote areas, provided the procedure is done carefully. A good history and physical examination are important steps in making sure that the operation goes smoothly. Specifically, you should:

- Obtain a history of current medications and past illnesses and surgeries. Ask especially about any bleeding disorders or allergies to local anesthetics or pain medications. In a review of systems, ask about hypertension, heart disease, kidney or bladder infection, diabetes, phlebitis, anemia (including sickle cell), liver trouble, and venereal disease.
- Examine the patient for local infections (which should be treated before the operation is performed), inguinal hernia or previous surgery for a hernia, a fixed and undescended testicle, hydrocele or varicocele, and a thick, tough scrotum or scrotal lesions. These physical conditions can make vasectomy more difficult to perform.
- Some surgeons suggest preoperative tests for hemoglobin and possibly clotting times. But in most cases, a well-oriented history and physical examination can be enough.

Preoperative preparation

The patient's hair is cut from his scrotum and around his penis. The area is then bathed with soap and water, just before the surgery. The patient should prepare to rest for up to 2 days after the operation.

Procedure

Sterile technique is used to perform the procedure. The patient is placed in the supine position, the scrotum cleaned, and the area draped. The vasa (two

tubular structures, one on each side of the scrotum) are anchored with an atraumatic instrument or fingers. (See Appendix C for kit of vasectomy equipment.) One-percent lidocaine is infiltrated into the area to be incised. The skin and muscle overlying the vasa are incised. Through this small incision, the vasa are isolated and occluded and, in most cases, resected (see Figure 21.1). The same procedure is performed for the vas on the other side. The incisions are closed with absorbable suture. If possible, the patient should rest 15 minutes to half an hour, or longer if needed, before he leaves the examination room.

Complications

The complication rates for vasectomy are very low in comparison with the contraceptive methods used for women. Most of the complications are short term and minor, such as swelling, discoloration, and discomfort. These may be reduced by the use of ice packs, rest from strenuous exercise for a day or two, and scrotal support. Aspirin can usually relieve discomfort. With the exception of rare reports of serious infections, no major long-term clinical side effects have complicated vasectomy. (See Table 21.2.) Although millions of vasectomies have been performed throughout the world, deaths have been

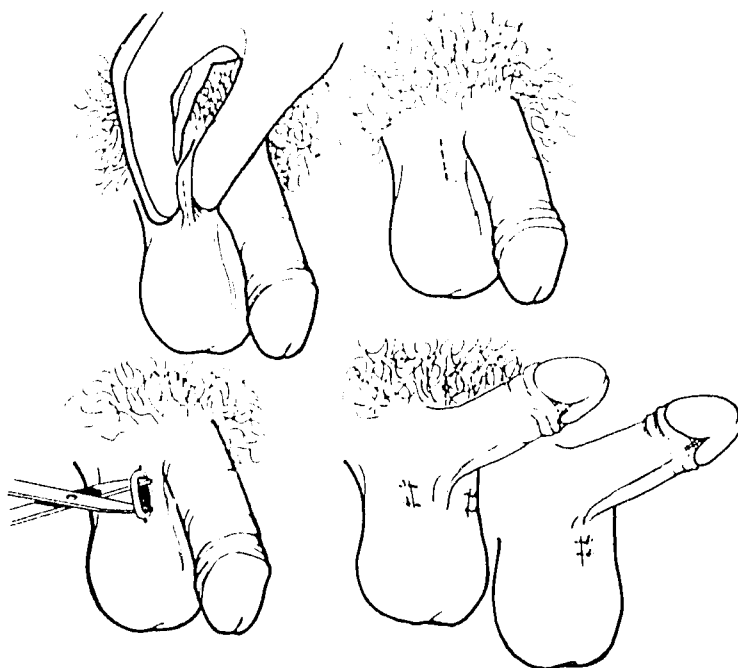


FIGURE 21.1 Sites of vasectomy incisions. A vasectomy is usually performed using local anesthesia. Once the vas is located (upper left), an incision is made in the anesthetized area (upper right), and a section of the vas is lifted out of the incision (lower left). Vasectomy may be performed using either one or two incisions, both of which are shown in the lower right-hand diagram.

rare. Most of the complications of vasectomy that do occur can be prevented by using aseptic technique and advising restraint from strenuous exercise for a day or two. Hematomas are also prevented by carefully stopping bleeding from blood vessels during the operation.

Infection is prevented by using sterile technique and sterilized equipment and by having the patient keep the incision clean. Should infection occur, it should be treated with antibiotics. Granulomas generally subside spontaneously. Those that persist can be treated with ice packs, bed rest, and, if needed, anti-inflammatory medication. Granulomas that increase in size and are painful may need to be removed surgically. Epididymitis usually subsides in a week. This condition can usually be treated with heat and scrotal support.

About one-half to two-thirds of men will develop sperm antibodies following vasectomy. Although there has been rather widespread publicity and worry about this finding, no physiologic evidence points to any pathologic complication arising from the condition (11,12). Two studies performed on vasectomized monkeys (13,14) indicated that the monkeys developed atherosclerotic plaques in the blood vessels at a greater rate than nonvasectomized monkeys. The development of the plaques was attributed to the circulating antibodies. These studies, however, have limitations: the number of animals studied was small, the groups of monkeys were not treated in the same way, and there is *no* evidence that monkeys and men respond in the same manner.

TABLE 21.2 Summary of medical complications of vasectomy (11)

Complications	Percentage of procedures (N = 24,961)
Hematoma	1.6%
Infection	1.5%
Epididymitis	1.4%
Granuloma	0.3%
Failures	0.4%

Reversibility

The operation for reversing vasectomy has mixed success and requires special training and sophisticated equipment. Success in rejoining the tubes and leaving an open pathway for the passage of sperm (reanastomosis) ranges from 40% to 90%. However, success in restoring the ability to conceive only ranges between 18% and 60% (15). Successful reanastomosis of the vas depends on the initial surgical procedure: the length of the piece of vas removed, where the incision was made, whether or not coagulation was used, the type of ligation material used, and the amount of time that passed between the vasectomy and the reversal procedure.

Postoperational instructions for the vasectomy patient

1. Following the surgery, you should return home and rest for about 2 days. If possible, you should keep an ice pack on the scrotum for at least 4 hours. This will reduce the chances of swelling, bleeding, and discomfort. You may be able to resume your normal activities after 2 or 3 days.
2. Avoid strenuous physical exercise for a week. Strenuous exercise means hard physical exertion to which you are normally unaccustomed or lifting or straining that could bring pressure to the groin or scrotum.
3. Do not shower or bathe for the first 2 days after the vasectomy.
4. The stitches will dissolve and do not have to be removed. (Note: this instruction must be modified if a permanent suture such as silk is used.)
5. You may resume sexual intercourse after 2 or 3 days if you feel that it would be comfortable; but remember, you are not sterile immediately. For most men, sperm has not been cleared from the tubes until after at least 10 ejaculations. Until then, use another method of birth control to prevent pregnancy. The best way of finding out if you are still sterile is to have the doctor look at your semen under a microscope. Take a specimen of your semen to the doctor for a sperm count after you have had 10 ejaculations.

QUESTIONS COMMONLY ASKED BY MEN

QUESTION	ANSWER
Is vasectomy the same as castration?	No. Vasectomy cuts only the passageway for your sperm. Your testicles will be unhurt.
How will vasectomy affect my manhood?	Vasectomy does not affect manhood. You will have the same ability for sex and other manly functions.
Will I still enjoy sex?	The operation should have no effect on your ability to enjoy sex. It merely prevents sperm from being released.
What happens to the sperm?	Your body absorbs the sperm
Are there any long-lasting effects from vasectomy?	There are no proven long-lasting effects that have been seen in vasectomized men. Some report that their wives enjoy sex more since they are no longer worried about getting pregnant.

FEMALE STERILIZATION

TUBAL STERILIZATION

Tubal sterilization operations may be performed just after delivery or abortion or at any point between pregnancies. Since we presume that the demand in Africa for post-partum and interval procedures is greater than the demand for post-abortion ones, we are restricting our discussion primarily to these two.

The effectiveness of tubal sterilization is similar whether performed post partum or in the interval period. Although postoperative morbidity following a post-partum procedure may be slightly higher, several advantages of performing the post-partum procedure during this time may offset the disadvantages:

1. The woman can make a decision in private; none of her neighbors need know she is having a sterilization;
2. Childbirth is one of the few times many women have access to or make use of medical services;
3. The procedure performed in the post-partum period is a simple and efficient operation and can be done with local anesthesia;
4. The post-partum procedure may be more convenient for the woman as she need not travel or make arrangements for a return visit to the hospital or clinic nor make additional child-care arrangements for her newborn;
5. The procedure performed post partum eliminates the additional expense of another hospitalization and travel.

Once the decision is made to perform the operation, other decisions must be made as well: which approach to use, what anesthesia to use, and what occlusive method to use. Basically, tubal sterilization requires the blocking of the fallopian tubes. Blocking of the tubes can be accomplished by several techniques:

- **Ligation and division** — the Pomeroy procedure is a commonly used technique in which the tubes are ligated with an absorbable suture and divided;
- **Ligation, division, and further separation** — the Irving procedure is a variation that involves ligating the tube, dividing it, then burying the medial stump;
- **Coagulation** — the tubes are coagulated with an electrocauterizing instrument. Bipolar coagulating instruments are safer than unipolar coagulating instruments;
- **Mechanical occlusion** — the tubes are blocked mechanically with clips, bands, or rings. The use of these occlusive techniques allows somewhat more hope for reversibility of the sterilization. Nonetheless, these techniques must still be considered permanent.

The fallopian tubes may be approached in two ways: through the abdomen or through the vagina. The abdominal approaches include laparotomy, mini-laparotomy, and laparoscopy. The vaginal approaches include colpotomy and culdoscopy. These approaches will be discussed in detail later in the chapter.

Either general or local anesthesia may be used for the sterilization procedure. In the majority of mini-laparotomy cases, local anesthesia is used. Local anesthesia may also be used successfully in both the post-partum incision procedure and the laparoscopic procedure. If local anesthesia is used, the patient should be adequately sedated so that she will be relatively pain free and calm enough to cooperate during the operation. Sedatives and analgesics may be used such as Demerol (meperidine) and Valium (diazepam). Given that much of the morbidity associated with the operation actually results from complications of the general anesthetic or excessive amounts of local anesthetic, we urge that anesthesia be used by persons with adequate training and with appropriate equipment and supplies for resuscitation in the event of a respiratory arrest.

ABDOMINAL APPROACHES

Most physicians are familiar with the female pelvic anatomy as seen from the abdomen (see Figure 21.2). The suspended nature of the oviducts makes them easy to manipulate, bring into view, and then ligate, occlude, or coagulate. Over 100 variations of abdominal tubal ligation have been developed (16,17). In this section, we describe three major methods: the post-partum incision, the mini-laparotomy, and the laparoscopy. The first two do not require highly specialized training or expensive and sophisticated equipment. Laparoscopy, however, requires both of these.

Preoperative preparations

- Obtain a history concerning pelvic disease or adhesions, last menstrual period, previous problems undergoing anesthesia, bleeding problems, allergies, current medications, activity limitations, and current contraceptive use. Some clinicians recommend that IUD's be removed at the time of surgery to reduce the risk of infection. Oral contraceptives should be discontinued for at least a month before any elective surgery to reduce the risk of thromboembolism. During this time the patient who discontinues oral contraceptives for this reason should use another form of contraception, such as a barrier method.
- Examine the patient to identify any medical conditions that may make the operation more difficult. Obesity increases morbidity and makes both mini-laparotomy and laparoscopy harder and lengthier to perform.
- Mini-laparotomy patients: Check for adhesions from endometriosis or pelvic infections; treat completely any local infections before performing the operation. Also, rule out the possibility of pregnancy. If, during the operation, you find any adnexal pathology or abnormality that requires corrective surgery, widen the incision to allow for adequate exposure.

- Laparoscopy patients: Check for severe cardiac or pulmonary disorders as the pneumoperitoneum may complicate these conditions. Since it may also exacerbate a hernia, it is important that you check for antecedents of hernia. Note any extensive scarring adhesions or leiomyomata that could make the operation more difficult.
- Given the frequent problems of long distances traveled by patients and the limited availability of transportation, we recommend the following procedures. It is desirable to take a Pap smear before surgical sterilization. If the results are available on the same day and are negative, you can perform the sterilization. If the results are unavailable that day and the cervix does not show any suspicious lesions, surgery can be performed. However, if suspicious lesions are observed, you should await the results from the Pap smear before going ahead with the sterilization.
- Take into consideration that women can become pregnant while waiting to return for another visit to obtain the test results and/or sterilization. In fact, they may be discouraged from returning at all. Therefore, it is preferable to perform the sterilization, and—if the test results later turn out positive—to perform a second surgical procedure, if necessary, thereby avoiding the possibility of the woman's becoming pregnant while she has cervical neoplasia.

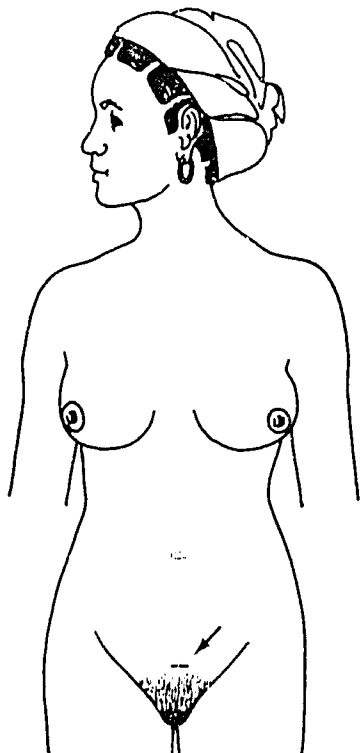


FIGURE 21.2 Incision site for a mini-laparotomy tubal ligation.

Post-partum incision and mini-laparotomy procedure

Sterile technique is used in performing both of these procedures. It is important that the bladder be empty prior to the abdominal incision. The site of the abdominal incision is cleaned and draped. The skin is infiltrated with a local anesthetic by the use of slow, careful, and deliberate movements through each layer. Gentleness to avoid causing the patient pain is the key to the success of this operation. No more than a total 300 mg of lidocaine without epinephrine is used. Alternatively, a spinal anesthetic or general anesthesia can be used, but a local anesthetic is usually preferred. A small, 2- to 3-cm transverse incision is made, about 3 centimeters above the pubis in nonpregnant patients (see Figure 21.2) or subumbilically in post-partum patients (see Figure 21.3). If the operation is performed within a day of delivery, a subumbilical incision should be adequate. If the operation is performed later, the fundus may have reduced in size, thereby requiring a small midline incision. Since thrombophlebitis is more common following a post-partum procedure, do not use estrogens to suppress lactation (18). In the interval procedure, the cornua is brought into view by manipulating the uterus with the uterine elevator. (See Figure 21.4.) In the post-partum procedure, the cornua should already be in view.

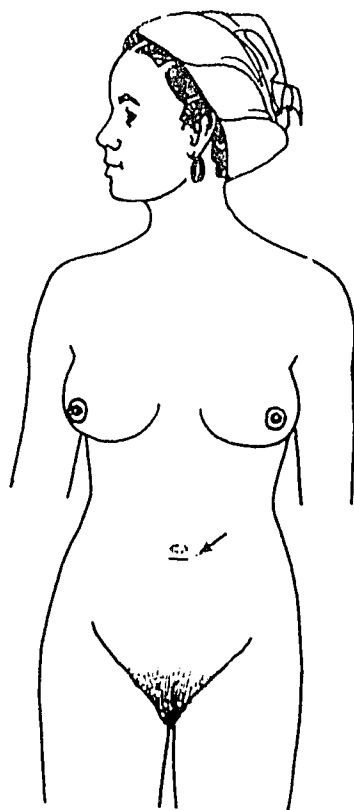


FIGURE 21.3 Incision site for post-partum tubal ligation.

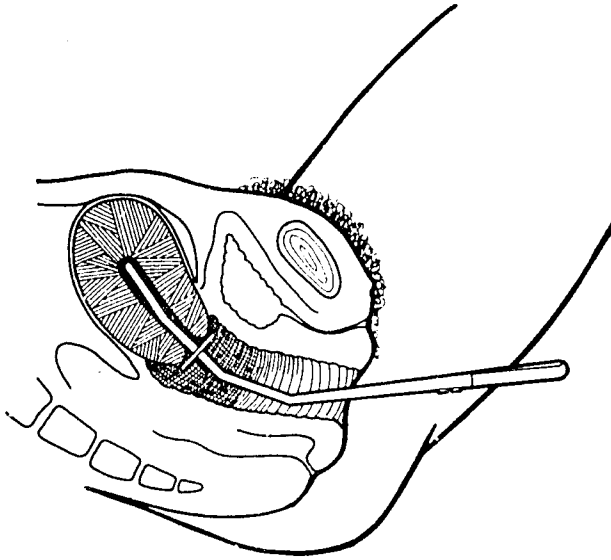


FIGURE 21.4 Uterine elevation. In performing a mini-laparotomy tubal ligation, a sound is used to elevate the uterus so that the uterus and the tubes will be closer to the abdominal wall.

The fallopian tube is grasped with an atraumatic instrument, then a ligature of plain catgut is placed around the tube. The tube is occluded with a clip, ring, or band, or by ligation, coagulation, or resection. Each layer is closed with an absorbable suture. For 2 days, the patient should rest at home or at the hospital. If she is post partum, she should avoid strenuous lifting for 1 week. (See Appendix D for kit of mini-laparotomy equipment.)

Complications

The low rate of complications makes this operation quite desirable. Complications, ranging between 0.4% to 1%, include wound infections, hematoma, uterine perforation with the elevating instrument, bladder injury, and sterilization failure (19). These complications can, for the most part, be prevented by careful attention to surgical techniques during the operation.

Reversibility

With ligation or mechanical occlusion of the tube, careful microsurgical techniques can have a 50% to 70% rate of reversal. This high success rate, however, reflects reports from experts operating on selected patients. Once again, the point needs to be emphasized that reversal procedures require specialized training and expensive equipment, and even sterilization performed by mini-laparotomy method should be considered permanent.

Laparoscopy procedure

Laparoscopic sterilizations can be performed using general anesthesia or local anesthesia. If local anesthesia is used, patients should be adequately sedated beforehand. The pelvic area is cleaned; then the abdominal site is cleaned and draped. Occasionally, it is necessary to catheterize the bladder. The cervix is stabilized with a cervical cannula, which will also permit manipulation of the uterus. A small, subumbilical incision is made. With careful outward traction on abdominal muscles, a Veress needle is inserted and directed toward the pelvis and away from the great blood vessels. After the needle has been placed in a safe position, roughly 3 liters of room air, carbon dioxide (CO_2), or nitrous oxide (N_2O) are infused into the peritoneal cavity. Currently, the low cost and convenience of using room air favor this substance. Insufflation should be sufficient to assure visualization, but not so excessive as to interfere with respiration. The needle is withdrawn and the trocar placed into the same incision. The incision is widened to 1 centimeter to accept the trocar. The trocar is directed toward the pelvis and away from the great vessels. The obturator is removed, and the laparoscope is placed so that a second incision can be made under direct vision. Either through the second incision or alongside the laparoscope (depending upon the laparoscope used), the forceps are inserted to grasp the oviduct. If no other structures are close to the oviduct, the tube is occluded. If coagulation is used, 2 centimeters of the oviduct are coagulated at midpoint and, if desired, transected. If clips are used, they are placed at the isthmic or proximal one-third of the tube (20). If bands are used, they are applied 3 centimeters from the cornual area (21). After both tubes are occluded, the pelvic organs are inspected for bleeding or injury, then the instruments removed, and the incision closed.

Complications

Complications are not necessarily more common following laparoscopy as compared with mini-laparotomy, but they can be more severe. For American complication rates, refer to Table 21.3. Anesthesia-related difficulties are, for the most part, caused by the use of general anesthesia. Complications such as mesosalpingeal tears, bowel burns, uterine perforations, or hemorrhage generally require laparotomy for repair. However, uterine perforation usually may be managed conservatively through observation if a patient's condition remains stable.

The rate of complications following laparoscopy is strongly influenced by the skill of the surgeon. Surgeons who have performed fewer than 100 cases a year may have a higher complication rate than surgeons who have had more experience (22). It is the use of coagulation that primarily results in bowel burns or perforations. Unipolar coagulation carries a greater risk for electrical accidents than other techniques; bipolar coagulation is a safer technique than unipolar coagulation (23). The risk of burns has influenced many laparoscopists to switch to rings, bands, or clips.

Over the past few years, studies have shown that the risk of dying from a laparoscopic procedure is low. Currently, the mortality rate is 6 to 15 deaths

per 100,000 procedures (22,24). The pregnancy rate following laparoscopic sterilization has been reported to be about 2.5 per 1,000 procedures over a 4-year period (25).

TABLE 21.3 *Major complications of laparoscopy for sterilization reported by members of the American Association of Gynecologic Laparoscopists, 1974-1975 (25)*

Complications	Number	Rate per 1,000 procedures
Total	76,842	
Failed attempts	513	6.7
Laparotomies:		
Bowel trauma	67	0.9
Hemorrhage	142	1.8
Other	115	1.4
Total	324	4.1

Reversibility

Again, tubal sterilization should be considered irreversible. However, reversal is more likely if only minimal tubal destruction occurs. Coagulation, especially when unipolar electrodes have been used, offers a poor chance for reversal because of the amount of tubal destruction it causes.

Patient Instructions

Preoperative

1. Depending on the exact procedure you are to have performed, you may need to bathe before the sterilization procedure.
2. Have someone come with you to the clinic or hospital where your surgery will be performed so that the individual may accompany you home after the procedure.
3. You will experience some pain after your procedure. Because it is desirable that you rest for several days and not be involved in any strenuous physical activity, make the appropriate arrangements in advance.

Postoperative

1. Following the operation, rest for about 2 days. You may then resume your normal activities when you are comfortable.
2. Avoid intercourse until it is comfortable to begin again.
3. Avoid strenuous lifting for about a week to allow the abdominal incisions time to heal.
4. Call upon your physician promptly if you develop
 - a) fever (greater than 100°F or 37.8°C),
 - b) fainting spells,
 - c) abdominal pain that is persistent or increasing, or
 - d) bleeding from incision sites.
5. You may take aspirin if you develop minor pains.

OTHER APPROACHES

Vaginal approaches

The absence of a visible scar, the ease of peritoneal entry, and the uncomplicated rapid recovery combine to make the vaginal approach to the ligation of the oviducts very attractive (26,27). However, certain complications make these approaches less attractive than the abdominal ones.

- **Colpotomy**

The classic "vaginal tubal ligation" has enjoyed much popularity in India and the United States, where surgeons have been trained and encouraged to perform vaginal surgery. In 1980, the International Planned Parenthood Federation Family Planning Handbook stated that colpotomy is "preferred in some cultures because it does not involve an abdominal incision." (28). However, the mini-laparotomy is now the favored method in the eyes of many international experts.

Procedure. With the patient in the lithotomy position after administering either general, spinal, or local anesthesia, the cul-de-sac is entered through a small incision. Each oviduct is brought into view, ligated, and cut. The incision is closed with absorbable suture. The patient can go home on the same day.

Complications. Several reports attest to the effectiveness (0.1%-2.9% failure rate) and relative safety (2.3%-13.3% minor complications) of the procedure (26). Nevertheless, a major disadvantage of the colpotomy is that complication rates are reported to be approximately twice as high as rates reported in various studies of mini-laparotomy procedures and laparoscopic tubal sterilizations. The higher rates are attributable to infection and hemorrhage. With proper patient selection (short vagina, pelvic relaxation, no previous PID), familiarity with pelvic surgery, adequate equipment, assistance, and appropriate anesthesia, these complications can be minimized.

- **Culdoscopy**

This procedure employs the endoscopic approach through the cul-de-sac and requires special skill and training. With the advent of the abdominal endoscopic approach, culdoscopy is seldom performed (27).

Hysterectomy

There is a significant debate as to the advisability of performing a hysterectomy for sterilization purposes. Some argue that the possibility of cervical and/or endometrial malignancy, abnormal uterine bleeding, myomata, pelvic relaxation, and other uterine problems that will eventually require a hysterectomy, make hysterectomy a more attractive contraceptive procedure for certain women than tubal ligation.

Many clinicians, however, do not feel that the hysterectomy can be justified when the primary goal of surgery is sterilization because:

1. The mortality for patients having a hysterectomy (62.5 per 100,000 procedures) is six times greater than the mortality for women having laparoscopic tubal ligations (29, 30).

2. The cost and time for recovery from a hysterectomy are much greater than for recovery from a tubal ligation (31).
3. The potential psychological impact of a hysterectomy is greater than that of a tubal ligation.

Refer to Table 21.4 for a review of the advantages, disadvantages, and the rates of failure, reversibility, complication, and mortality for the major methods of sterilization discussed above.

Other methods of tubal sterilization under research

A potentially promising alternative to the previously mentioned sterilization techniques is that of hysteroscopy. Silver nitrate, zinc chloride, phenol, cauterization with heat, cryosurgery, plastic occlusives, and tissue adhesives have all been used in attempts to produce tubal occlusion when placed transcervically into the uterine cavity (32). The efficacy of these methods has not yet been demonstrated.

TABLE 21.4 Sterilization methods and factors affecting their use (8)

	Male		Female		
	Vasectomy	Laparoscopy	Mini-laparotomy Laparotomy	Colpotomy	Culdoscopy
Advantages	Safe, slight morbidity, almost no mortality, simple, requires minimal extra training for physicians, inexpensive compared with female sterilization, brief: takes about 10-15 minutes	Low rate of complication, short recovery time, minimal morbidity, same equipment and skills can be used for endoscopic diagnosis procedures, leaves small scar	Can be done as outpatient procedure with local anesthesia, short recovery time, low equipment cost, relatively easy for physicians to learn, uses simple instruments	Leaves no abdominal scar, easily performed on women of high parity, brief: takes about 5-15 minutes, less postoperative pain, instruments are simple, cheap, and usually available	Leaves no abdominal scar, brief: takes about 10 minutes
Disadvantages	Not effective until sperm in reproductive system are ejaculated, occasional complications such as bleeding or infection	Difficult with obese patients, requires expensive equipment and intensive training	Difficult with obese patients, local anesthesia not suited to all patients	Higher complication rate	Requires greater surgical skill than laparotomy
Failure rate*	0.15%	0.2% to 2%	0.2% to 0.6%	0 to 0.055%	0 to 0.055%
Reversibility*	5%-70%	About 10%-50%	About 10%-50%	About 10%-50%	About 10%-50%
Complications	5%	0.1% to 7%	0 to 6.5%	1.6% to 13.3%	1.6% to 13.3%
Mortality	Almost 0	Low	Low	Low	Low
Skill required	General practitioner	Specialist	General practitioner or specialist	General practitioner or specialist	Specialist
Type of anesthesia	Local	General or Local	Local	General or Local	General or Local
Equipment maintenance	Easy	Difficult	Moderate	Moderate	Difficult
Recovery time	1-5 days	1-5 days	1-5 days	1-14 days	1-14 days
Facility	Outpatient	Outpatient or operating room	Outpatient	Operating room or outpatient	Operating room or outpatient

*Failure rates and the potential for successful reversal depends primarily on the type of tubal occlusion method. Reversibility also depends upon reversal techniques used

THE ROLE OF STERILIZATION WORLDWIDE AND IN AFRICA

Voluntary sterilization is one of the most popular methods of contraception in the world. (See Table 21.5.) About 100 million people have had a sterilization operation. In Africa, however, the rate of voluntary sterilization is one of the lowest in the world (33). (See Table 21.6.)

TABLE 21.5 Estimated number of couples using birth control, worldwide, by method, 1970 and 1977 (8)

	1970 millions	1977 millions
Voluntary sterilization	20	80
Oral contraceptives	30	55
Condom	25	35
IUD	12	15
Other Methods	60	65
Total	147	250
Abortion (annual incidence)	40	40

There is some evidence, however, that the demand for sterilization services may be great among African women. For example, physicians at Kenyatta National Hospital in Nairobi, Kenya, asked women who had five or more children and who had just delivered if they would like a sterilization operation performed. Fifty-nine percent said that they would (34).

In some cultures, laws or regulations may restrict sterilization. However, such statutes, laws, and regulations have undergone many changes over the past few years. Most countries now have no laws specifically covering voluntary sterilization as a contraceptive method. Thus, legal authorities generally believe that whatever is not expressly prohibited is permitted.

Each voluntary sterilization is estimated to avert 1.5 to 2.5 births. This is a higher number than provided by the continued use of any other contraceptive method (35,36). Sterilization is also easier for the patient, who does not need to obtain resupplies or visit the provider at regular intervals. In the long run, the individual may find that sterilization is less costly in terms of the amount of money and time that family planning generally requires.

TABLE 21.6 *Estimated number (in millions) of couples controlling fertility by voluntary sterilization, by country or continent (33)*

Country or Continent	Year				
	1970	1975	1977	1978	1980
China	4	30	35	36	40
India	7	17	22	22	24
Asia (excluding China, India)	1	2	3.5	4	5
United States	3	8	9.5	12	13
Europe	3	4.5	5.5	10	11
Latin America	1	2	3	4.5	4.5
Canada	0.5	0.5	1	1	1
Africa	0.5	0.5	0.5	1	1
Estimated World Total	20	65	80	90	100

COUNSELING OF PATIENT WHO REQUESTS STERILIZATION

In no other phase of family planning is it more important that decisions be based on clear, complete information. Individuals must be told repeatedly that, at present, sterilization procedures for both men and women are to be considered irreversible. Couples wishing to maintain the option of having children should be encouraged to use other approaches to birth control.

Information pertaining to permanent methods of contraception should be provided through discussions with individuals early in their reproductive years. The following guidelines for counseling are helpful in any discussion of sterilization. We have developed the BRAIDED mnemonic for remembering them.

Benefits: permanent; effective; repeated decisions or costs unnecessary.

Risks: surgery may lead to morbidity and mortality; expensive in short run; not 100% effective (slight chance of becoming pregnant in the future); operations to reverse procedure are expensive and may not be successful.

Alternatives: all reversible contraceptives and sterilization of the partner.

Inquiries: patient should be encouraged to ask questions; myths and misinformation should be cleared up.

Decision to change: patient should always feel she/he can freely decide not to undergo sterilization if he/she wishes, without experiencing clinician's hostility or punishment by society (e.g., withdrawal of social welfare benefits).

Explanation: the entire procedure and its possible side effects should be explained in detail. Clearly emphasize the permanence of the procedure along with accurate estimates of chances of reversal. Explain available data regarding potential psychologic and/or physiologic effects on hormones, weight, menses, and sexual response. It is also important that the patient be aware of the costs of the procedure and where it can be performed. It is important that the patient understand that operations attempting to reverse sterilization are major surgical procedures; the tubes cannot simply be untied.

Documentation: the patient's chart should note the method and timing of sterilization, any complications that occurred during or after the procedure, and the treatment and outcome of complications.

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SECTION IV

**PROVIDING FAMILY
PLANNING SERVICES**

CHAPTER 22

RELATIONSHIPS BETWEEN FAMILY PLANNING WORKERS AND USERS

Family planning is only as successful as the delivery of its services.

The key aims of service delivery are:

- gaining new acceptors of family planning,
- encouraging current users to continue planning their families through the effective use of safe methods,
- providing a reliable source of contraceptive supplies and information,
- identifying and dealing with complications effectively.

Your success in achieving each of these objectives will depend largely on the quality of the relationships established between your users and you and your colleagues. This chapter examines different aspects of the user-provider relationship, consolidating recommendations made throughout this book with others based on the authors' experiences. We hope that you find these suggestions to be constructive.

A good relationship between family planning workers and users is needed at all times: when educating the users (promotion and counseling), determining and providing the correct method, instructing the user in its use, and providing timely followup services. Developing and maintaining a good relationship takes time. But by investing it, you will help couples understand and feel comfortable with their method of choice, thereby increasing the likelihood that they will continue to plan their families. Poor care from an unmotivated family planning worker will not encourage a patient to return. The guidelines presented below are important to good working relationships in both the most and least sophisticated service delivery settings.

EDUCATION

Education, whether of family planning workers or users, has three purposes: 1) exposing people to alternative ways of identifying and solving problems, 2) exploring with them the relationship between these problems and family planning, and 3) instructing the individual woman about her own personal care. Community education is often achieved through women's and men's groups, schools, respected peers, the use of field educators, and media (music, drama, radio, newspapers). Teaching must be kept relevant to the individual; you must show how family planning affects the family on a daily basis, using words and ideas that mean something to the user.

CHOICE OF CONTRACEPTIVE METHOD

Decide what contraceptive method to recommend to a woman based on

her medical background, her plans for future pregnancies, her living conditions, pressures placed on her by her family or community, and her acceptance of the particular method.

To provide family planning services, you must have adequate supplies. Although another worker may be responsible for managing supplies, as a family planning worker, you must play a part in deciding what supplies are needed. (See Chapter 23.)

Determine if the woman has any contraindications to using the Pill (see Chapters 11 and 12), the IUD (see Chapter 13), the injectables (see Chapter 12), and the nonmedical methods (see Chapters 2, 3, 14-18). Help her explore her reproductive life plan as outlined in Chapter 9 and her feelings about the methods you may have helped her select.

Because pregnancy test reagents are costly and in short supply in Africa, many providers request that their users come during menstrual bleeding as a sign that they are not pregnant. (See Chapters 11-12.) *However, do not let this rule become a barrier to service delivery.* It is sometimes appropriate to give a woman Pills or an IUD when she is not bleeding since the distances between the woman's home and the service delivery point are often too great to force her to return another time. When appropriate, trust the woman's account of her history and, for example, instruct her to take the Pills on the fifth day of her next period. When appropriate, perform a pregnancy test to facilitate your decision to insert an IUD or to administer an injection at times other than during the menstrual flow. (See Chapter 20.)

In some systems of family planning delivery, physical examinations are not practical or possible — nor are they always necessary (1). Through the use of a checklist of contraindications for the Pill, IUD, and injectables (see Chapters 11, 12, and 13), it is possible to assess without a thorough physical examination whether or not a woman is healthy and can use family planning methods that have low morbidity rates.

Keep in mind that the use of contraceptives has a lower morbidity mortality rate than pregnancy (2). Since mortality related to pregnancy and childbirth is much higher in developing countries than in developed countries, the use of contraceptives is an even safer option by comparison. Further, these major side effects of the Pill reported from Western studies (cardiovascular ones) are believed to be far smaller problems in developing countries such as those in Africa (3). (See Chapters 11, 12.)

However, in clinics where other health needs are assessed and ministered to, physical examinations are frequently performed and are very beneficial. The physical examinations may include a breast examination for lumps, instruction about breast examination (see Figures 22.1-22.3), and a complete pelvic examination. When possible, the examination can include a blood pressure reading, a check for urine protein and glucose, a Pap smear, a VD check, and a hematocrit or hemoglobin test.

Give special emphasis to the methods that are—and will continue to be—available and that are best adapted to the needs, beliefs, and characteris-



FIGURE 22.1 Teach women to use the flat part of their fingertips to feel each area of the breast.

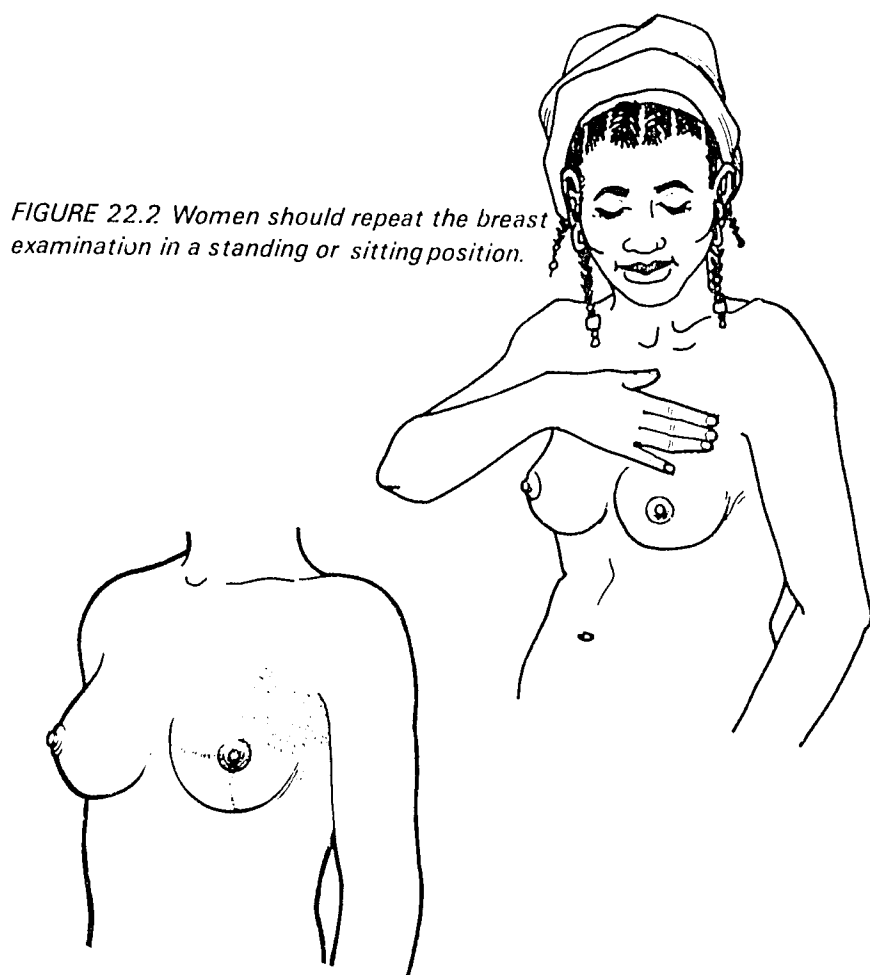


FIGURE 22.2 Women should repeat the breast examination in a standing or sitting position.

FIGURE 22.3 Most breast cancer occurs in the upper, outer quadrant of the breast.

tics of the user. (See Chapter 2.) After the choice has been made, clearly explain how to use the method.

PROVIDING GUIDANCE TO USERS

Instruction: Individual instruction is provided at the time the user seeks services. Explain each method—the Pill, injections, IUD, spermicides, natural methods, etc. Tell her how each works. *Take a positive tone* to explain the advantages of each but explain the side effects and disadvantages as well. Tell her what side effects she might have and what signs are indications that she needs to return. (Refer to Chapters 11-14, 16, and 19-21.) Explain that *some side effects cause changes but not problems*, such as a change in the menstrual flow or pattern. Ask what concerns and questions she has. Correct any misconceptions and fears she may have.

Followup: In a clinic setting, have the user return so you can check how well she is doing with the family planning method, but remember that too many visits will decrease her cooperation. In both the community-based program* and clinic settings, the user needs to be instructed to recognize the danger signs of her contraceptive method. (See Chapters 11-13.) Emphasize how important it is for her to return to the community distributor or the clinic if she has problems or questions or needs resupplies. Also emphasize the importance of resuming the use of family planning methods after childbirth.

Referral: What should you do if the woman has a problem caused by the use of her family planning method that you cannot handle by yourself and that requires equipment or supplies that are unavailable to you? For such purposes, organized and direct lines of referral *must* be established. Some examples of good referral practices include:

- Arranging for women who are experiencing side effects to be seen by your supervisor during the next scheduled visit.
- Communicating (by word of mouth, two-way radio, written message, telephone, or by other means) with a nearby clinic or hospital to receive guidance about users' problems.
- Sending women to a nearby clinic or hospital for diagnosis and treatment of problems that cannot be handled by the above approaches.

Note that each of these approaches involves recognizing the problem, communicating it, getting the advice of professionals with more knowledge or experience, and following up on the users' needs.

After a woman has been referred elsewhere, follow up to see how well her problem is being managed.

*Services provided by trained villagers selected from the community who are supervised by medical professionals

By referring problems, your skills, confidence, and effectiveness are enhanced. An added advantage is that nonfamily-planning problems experienced by women and their families are sometimes identified and resolved.

In summary, whether you are educating the user, helping her to choose a method, instructing her in the effective use of the method, or helping her deal with side effects or other problems as they arise, the quality of your relationship with each woman will depend on your ability to:

- demonstrate to her that you care about what she is experiencing,
- communicate relevant facts clearly,
- test whether the woman understands everything you feel she needs to understand,
- keep a record of the woman's family planning experiences and refer to it so that you can take into account the past in dealing with the present.

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CHAPTER 23

APPROACHES TO DELIVERY OF FAMILY PLANNING SERVICES

What are some of the key barriers to making the practice of family planning widespread? Most often they are misinformation, lack of motivation, and problems in distribution of supplies (1). This entire book addresses the barrier of misinformation. Chapter 22 deals specifically with motivating users and indirectly with motivating family planning workers. In this chapter, we will examine the advantages and disadvantages of alternative delivery strategies for distributing supplies and providing services under varying circumstances.

How do the family planning services offered in the health system you work in respond to your users' needs? Do you reach the right users with the right contraceptive methods and provide medical care in case there are complications? The range of health services offered within Africa differs tremendously from country to country. Some countries offer family planning services through well-developed clinic services with well-thought-out routes of referral. Some countries have established clinic-based systems but find that shortages in medical personnel and money prevent them from reaching remote populations. Therefore, these countries have begun to experiment with community-based approaches to providing health services, including family planning and/or commercial distribution of contraceptives (2). Some countries are in the process of developing basic health services and, hence, have not yet found an effective way to deliver family-planning services. The answer to providing family planning services lies not in just one approach to delivery, but more likely, in a combination of strategies, each of which provides for referral. Some basic strategies are examined below.

ALTERNATIVE DELIVERY STRATEGIES

The strategies used in Africa and other parts of the world for delivering family planning services are and must be varied (2). Several African nations have had some degree of success with family planning delivery strategies (2-10). See Appendix E for a description of some of these experiences.

Typically, delivery strategies need to be altered to meet the needs of different populations: couples living in urban areas, rural towns, villages, and remote and inaccessible areas. In urban areas and rural towns, family planning is most often made available in clinics (CLINIC-BASED SERVICES, CBS) that offer family planning services alone or in combination with other health services for women and children. (See Figure 23.1.) In villages and other remote and inaccessible areas and in urban sectors that do not have clinics, family planning may be made available through COMMUNITY-BASED DISTRIBUTION systems. Also, in these same areas or in areas where people are receptive to obtaining contraceptives from sources outside of the health care systems, commercial outlets may provide family planning (COMMERCIAL RETAIL SALES, CRS). A more detailed discussion of these three basic strategies is presented in Table 23.1.

MIX OF CONTRACEPTIVE METHODS USED IN A PROGRAM

Ideally, each family planning program should offer a balanced array of methods. However, the methods offered by a program are influenced a great



FIGURE 23.1 In many countries, family planning is primarily offered to mothers who make use of maternal-child health clinics.

TABLE 23.1 *Characteristics of principal approaches to providing family planning services*

DESCRIPTION	ADVANTAGES	DISADVANTAGES
I. COMMUNITY-BASED Local volunteers, usually village women, are recruited to educate their neighbors. The volunteers are also responsible for distributing the family planning methods to users. In their training, the volunteers learn the basic concepts of family planning, how each method must be used, what the contraindications and adverse effects are for each method, and how to maintain simple data collections systems. A physician, midwife, or family planning nurse supervises the volunteer's activities to manage any problems that may occur.	Users can obtain methods more cheaply. More convenient for patients, who need not travel long distances. Supplies are distributed by someone the patient knows and trusts. Post-partum mothers can be identified and visited. Followup is easier. User motivation is maintained at high level through continuous interaction with volunteer.	Initial program costs per user are high. Full maternal and child health family planning services are not offered. No immediate access to clinical staff for management of problems. Some health professionals resist volunteers offering services. User may lack confidentiality. User may lack confidence in nonmedical worker.
II. COMMERCIAL DISTRIBUTION Commercial distribution was begun with the knowledge that remote areas having no access to medical care somehow seem to have other types of consumer items available in retail outlets. If other supplies can reach these very remote areas, then so can family planning supplies. Most countries limit commercial distribution of oral contraceptives to pharmacies. Barrier methods, however, are sold in nearly every place: groceries, markets, and streets by hawkers.	Can reach very remote areas not reached by other programs. Users need not travel long distances. Distributors are motivated by profit from sales. Availability of methods is well publicized. User does not need to wait in lines to receive methods. User has privacy. Costs to the government can be low. Usually resupply to distribution points is reliable.	Patients must go to clinic for management of problems. It can be costly to start a program. Full services are not offered. Promotion and advertising of contraceptives may be subject to criticisms. Public health officials do not have control over resupply system
III. CLINIC-BASED SERVICES Clinic-based service is a reasonable approach in areas where health workers are available and users do not live far from the clinic. With some physician supervision, trained nurses and midwives examine women, prescribe the appropriate family planning methods, and manage problems.	Patients are seen at each visit by health care professionals. Problems can be spotted and treated at visit. A switch in contraceptive method can be quickly done at the clinic. Start-up costs low if Maternal Child Health services (MCH) already available. More complete services are offered.	Patients are primarily limited to those living close by. Followup depends upon user's returning to clinic. The nurse or midwife may not be familiar to the patient. Patients are expected to come on their own initiative. Patients may have to wait in long lines. The doctor or nurse may be a male, which would not be acceptable to women in some cultures.

TABLE 23.1 *Characteristics of principal approaches to providing family planning services—Continued*

DESCRIPTION	ADVANTAGES	DISADVANTAGES
a) MATERNAL CHILD HEALTH FAMILY PLANNING SERVICES As a starting point, the Maternal Child Health Family Planning program is preferred by many African governments because mothers can obtain several related services at one site, thus providing continuity of care, and because family planning can be provided for child spacing as part of maternal and child care, and not as a measure to "control fertility."	Can attract large numbers of mothers coming for other services. Users can receive pediatric, obstetric, and gynecologic care in one setting, along with family planning services. In theory, it offers an easier transition from post partum to family planning, and the reverse. Patients uncomfortable with the social stigma of birth control are not so easily identified as users of family planning. Family planning can be established as an important element in the health of women and children.	Family planning users are seen only after child and maternal health problems are attended to. Workers may be overworked and understaffed. Administrative functions are more complicated, especially if the resupply and reporting of service statistics for family planning services are not integrated with the support systems of the MCH program. Workers not always specifically trained in family planning may lack needed skills and motivation. The physical facility (clinic, health center) may not be able to accommodate the integration of family planning services.
b) FAMILY-PLANNING-ONLY Clinics offering only family planning services are often established in urban areas or large towns to meet an existing demand for contraceptives.	The family planning workers are more motivated to deliver family planning. More time can be spent counseling and educating each user. Generally, a better worker-to-user ratio exists for family planning. Workers who have received special training in family planning may be more effective. Unmarried women without children are more comfortable in this type of facility.	Users must be motivated to come on their own for family planning services. A smooth transition does not exist from the post-partum period to the time a woman needs family planning services or to the time when she needs antenatal care. Women must visit other facilities to receive other health services. Clinics lack the additional incentive of offering services that attract many mothers.

deal by the system in which they are distributed, as well as by the prevalence of different diseases in an area (see Chapters 5, 6, and 9), cultural or religious preferences, and the prospects for a reliable logistics system. We suggest the following in Table 23.2 as a guideline:

TABLE 23.2 Guidelines for Use of Contraceptive Methods with Alternative Delivery Strategies

	Clinic Based	Community Based	Commercially Distributed
Three types of oral contraceptives: 0.50 mg estrogen, sub-0.50 mg estrogen, and progestin only. The varying doses of estrogen can be tailored to overcome certain side effects such as spotting or bloating that occur in some women in response to a particular dose Pill. (See Chapters 11 and 12.)	X	X	X
Two types of IUD's: a copper, medicated IUD, and the full range of sizes of the Lippes Loop [®] or the Saf-T-Coil [®] . Some women respond better to one IUD than another. (See Chapter 13.) If the IUD is used in community-based programs, appropriately trained staff must insert the IUD and be available for followup.	X	X	
An injectable: Depo-Provera [®] or norethindrone enanthate. In countries where the injectables are approved for use, women who benefit from this method include: women who desire no more children but do not want to make the final decision to have a sterilization; women who live a distance from medical dispensaries; and women who find a visit every 3 months most convenient. (See Chapter 12.)	X	X	
A complete set of nonmedical methods: condoms, foaming tablets, foams, creams, jellies, diaphragms. Individuals who find these suitable are breast-feeding mothers; women who, for medical reasons, cannot use other methods; and women who are waiting to begin other methods of family planning. (See Chapters 2, 3, 14, 15, 16.)	X	X	X
Instruction in natural family planning methods: i.e., timing of ovulation, abstinence. These are good for women who find the other methods unsuitable. (See Chapters 2, 3, 17, 18.)	X	X	
Sterilization services: Where practical, these should be made available for women or men who desire to have no more children, especially those who have had frequent, short-interval births, or women whose lives may be endangered by pregnancy. (See Chapter 21.)	X		

ORDERING, MAINTAINING, AND STORING SUPPLIES

To provide family planning services, you must have adequate supplies. Although another worker may be responsible for managing supplies, you as a provider must play a part in deciding what is needed. Consider what supplies you want, how many users use the supplies, how frequently you receive shipments, and how much storage space you have.

1. Compute the supplies you will use for 1 year. Use the following guidelines:

Pills:

13 cycles per continuing user per year or 6.5 cycles per new user per year (assumes that not all new users will start on day 1 of the year)

Condoms:

144 (1 gross) per continuing user per year or 72 per new user per year

Foam:

2.5 bottles per continuing user per year (about 60 applications per bottle) or 2 bottles per new user per year

Jelly:

6 tubes per continuing user per year (about 25 applications per tube) or 3 tubes per new user per year

Diaphragms:

generally need only 1 per person, but quality of diaphragm should be checked about once every 2 years and replacement may be necessary

IUD's:

guideline is to stock 3 IUD's for every 2 acceptors—this allows for expulsion and periodic replacement

Sterilization kits:

a general rule-of-thumb is 2 per doctor

2. Calculate the size of reserve stocks. This is the amount of supplies you should have on hand to keep from running short if demand is higher than expected or if shipments are late. A handy formula is:

FREQUENCY OF SHIPMENT + TRANSPORT TIME

(Example: If shipments are delivered every 12 months, and time from order to delivery takes 6 months, then you will want an 18-month supply as safety stock.)

3. Store the supplies in a well-ventilated and dry area. (See Figure 23.2.) The temperature should not exceed 24° centigrade, and supplies should be protected from sunlight. Do not stack the boxes more than 8 feet (2.4 m) high. Keep supplies 1 foot (30 cm) away from the wall and 4 inches (10 cm) off the floor. The oldest supplies should be given out before newer supplies. Make certain the supplies are not outdated (11).

Pills: 5 years from date of manufacture; indicated on package
Foam: 5 years from date of manufacture; date not on package
Jelly: 5 years from date of manufacture; date not on package
Condoms: 3 years from date of manufacture; indicated on package
Diaphragms: indefinite, but probably about 5 years in hot, humid climate
IUD's: no time limitation

OBSTACLES AND POSSIBLE SOLUTIONS TO SERVICE DELIVERY

The discussions presented both in Chapter 22 and this one are simplifications of what actually happens when providing family planning services. Regardless of the delivery strategy used, all programs confront problems and constraints. A number of these, along with possible solutions, are included in Table 23.3.

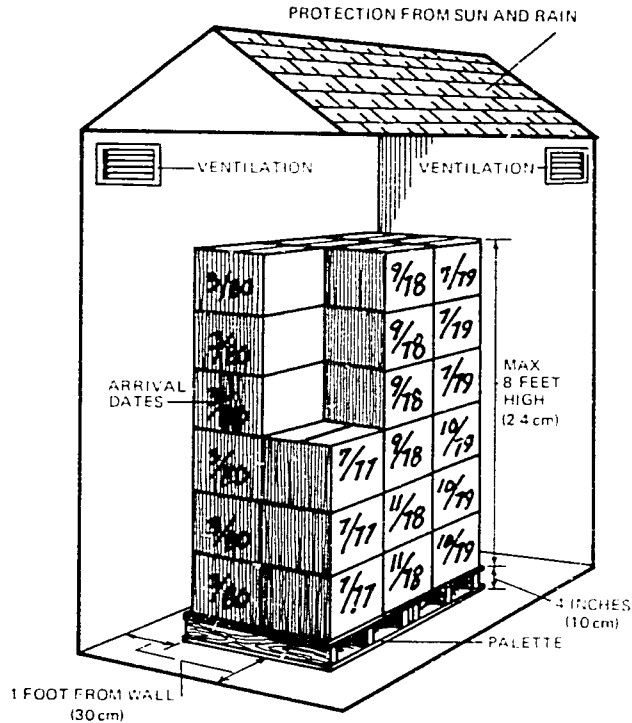


FIGURE 23.2 Guidelines for storing contraceptives.

GUIDELINES FOR PROPER STORAGE

1. CLEAN ROOM AND WHITEWASH WALLS.
2. CHECK ROOF FOR WATER LEAKAGES.
3. NO DIRECT SUNLIGHT ON THE SUPPLIES.
4. STOREROOM NOT SUBJECT TO WATER PENETRATION.
5. SUPPLIES TO BE STACKED AT LEAST 4 INCHES (10 cm) FROM FLOOR (Arrange dunnage of wood or steel).
6. SUPPLIES TO BE STACKED AT LEAST 1 FOOT (30 cm) FROM ANY WALL.
7. SEPARATE STACKS ACCESSIBLE FOR "FIRST IN FIRST OUT" (FIFO), COUNTING, AND GENERAL MANAGEMENT.
8. STACKS NOT MORE THAN 8 FEET HIGH (2.4 m).
9. IDENTIFICATION MARKS AND OTHER LABELS VISIBLE.
10. SUPPLIES TO BE ISSUED BY CARTON OR BOX LOT, IF POSSIBLE.
11. WELL VENTILATED.
12. WELL LIGHTED.
13. FIRE EXTINGUISHERS NOT BLOCKED.
14. VACCINES AND SERAS MUST BE STORED IN REFRIGERATOR.
15. OLD FILES, INFORMATION MATERIAL, OFFICE SUPPLIES, ETC., SHOULD BE STORED SEPARATELY.
16. INSECTICIDES AND OTHER CHEMICALS NOT TO BE STORED TOGETHER WITH CONTRACEPTIVES AND MEDICAL SUPPLIES.
17. STOREROOM TO BE DISINFECTED AND SPRAYED AGAINST INSECTS EVERY THIRD MONTH.
18. DAMAGED AND CONDEMNED SUPPLIES TO BE SEPARATED AND DISPOSED OF WITHOUT DELAY.
19. STORE KEYS MUST BE AVAILABLE AT ALL TIMES.
20. DAILY CLEANING OF STOREROOM.

TABLE 23.3 *Dealing with obstacles to the delivery of services*

Problems and Constraints	Solutions
1. Lack of services (particularly in rural areas but also in urban ones)	a) Increase policymakers' knowledge of the health and economic benefits of family planning. b) Increase the priority given to family planning in maternal child health units, particularly among nurses and nurse midwives. c) Place higher priority on family planning in training of physicians and nurses. d) Strengthen staffing and outreach services in clinics already offering family planning. e) Develop, improve, or expand community-based and/or commercial retail distribution systems.
2. Resistance of women to the concept of family planning	a) Compare contraceptive complications with risks of pregnancy; allay fears of contraception. b) Provide higher quality, more comprehensive family planning services. c) Use child health and well-baby clinics as sources of referrals for family planning services. d) Emphasize the health benefits of family planning and its voluntary nature.
3. Male opposition to birth control and to the concept of women playing an important role in decisions governing how many children a couple should have	a) Educate community leaders about benefits of family planning. (See Chapter 10.) b) Involve important men in the initial planning and promotion of contraceptive services. c) Provide methods women can use without knowledge of men if necessary. d) Educate schoolchildren about the family in today's society and the importance of planning it.

TABLE 23.3 *Dealing with obstacles to the delivery of services — Continued*

Problems and Constraints	Solutions
4. Destruction of traditional institutions that encouraged effective methods of birth control	a) Retain those traditional approaches that are safe and effective. b) Explain carefully the reasons why some traditional approaches may not be safe or effective. c) Encourage local involvement in establishing effective child-spacing services. d) Use neighbors in community-based distribution programs who can effectively communicate family planning concepts.
5. Lack of trained backup medical personnel in staff, hospital, and clinics and a lack of trained lower-level staff to act as village educators, recruiters, and distributors of contraceptives.	a) Retrain physicians, nurses, and midwives in family planning skills through intensive, short programs. b) Encourage and train nurses and midwives to then train community-based paramedical personnel (12). c) Emphasize family planning in training programs for midwives, nurses, and doctors. d) Thoroughly train supervisors of maternal-child health family planning workers to manage problems and reinforce training of lower-level family planning workers.
6. Privacy is unavailable in certain clinic settings	a) Provision of services in a private setting. b) Alter the flow of patients in maternal-child health family planning clinics in order to shorten waiting periods by changing staffing patterns, clinic hours, or the appointment system. c) Initiate commercial distribution (including the use of street vendors) of certain contraceptives.

TABLE 23.3 *Dealing with obstacles to the delivery of services — Continued*

Problems and Constraints	Solutions
7. Inaccessability and lack of acceptability in some quarters of <i>sterilization services</i>	a) Training of nurse midwives, physicians, and health assistants to perform mini-laparotomy procedures. b) Acquire necessary equipment. c) Set up a system to insure a constant supply of spare parts and other needed supplies for laparoscopic equipment. (See Chapter 22.)
8. Failure of influential leaders to recognize the importance of voluntary means of child spacing to the health of the individual and society as a whole	a) Explain to leaders the health benefits of family planning. (See Chapter 1.) b) Demonstrate that family planning leads to reduced health care costs. c) Increase the education of politicians on the implications of rapid population growth.
9. Laws prohibiting or customs discouraging the provision of voluntary contraceptive services for unmarried women	a) Initiate services that do not conflict directly with laws or customs of the land. b) Develop public information programs regarding health and social consequences of adolescent pregnancies. c) Ask national leaders to interpret laws according to present conditions and to communicate with leaders of other countries.

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CHAPTER 24

INTEGRATION WITH OTHER FAMILY HEALTH SERVICES

Programs that provide only family planning services and those that offer family planning together with other health services both have their place. (See Chapter 23.) The purpose of this chapter is not to advocate an integrated approach but to provide a working definition of integration. We hope that this definition will help those of you who are developing a program to determine which approach (or combination of approaches) will best serve your users' needs (1-3). For those of you who already have an integrated program, we hope that this working definition will help you to identify ways in which your program can be improved to meet the needs of your users more efficiently.

HIGHLIGHTS OF AN INTEGRATED APPROACH TO PROVIDING FAMILY PLANNING SERVICES

The perspective of an integrated program is to serve the family as a whole by providing all basic health services to all family members in one setting. In a clinic setting, this can be achieved by the following:

1. Training all staff members in family planning.
2. Training staff together so that they feel confident in each other's abilities, make more use of one another (by referring cases to colleagues with special skills), and are able to stand in for colleagues, etc.
3. Having one person supervise all staff members; specialists can assist, when necessary.
4. Providing a dependable supply of medicines, contraceptive supplies, and vaccines through one channel.
5. Referring all difficult cases to specialists and following through on the results of the referral.
6. Documenting family services so that a complete history of the family's health is maintained and available as a reference to all staff members.
7. Reporting all activities and outcomes in one document and reviewing the information as a team for the purpose of improving services.

SERVING THE HEALTH NEEDS OF THE FAMILY

All couples want to have a healthy family. An integrated family health program is one way of helping couples maintain the health of their families.

Listed below are several services that may be offered by such a family health program:

Objective	Services Needed to Meet Objective
1. Help the couple conceive when they are ready to have a child.	Reproductive education, use of contraceptives, treatment of infertility.
2. Help the mother have a healthy pregnancy.	Nutrition counseling, prenatal examinations, preparation for childbirth.
3. Help the child have a successful birth.	Assistance in childbirth.
4. Help the mother regain strength, offer good nurturing to the infant.	Nutrition counseling for mother and child, post-partum examinations.
5. Help family members prevent illness.	Well-baby examinations and immunizations, delaying next pregnancy (use of contraceptives).
6. Help family members regain health after illness.	Curative care.
7. Help the couple terminate childbearing when satisfied with family size.	Sterilization.

STAFF TRAINING AND RESPONSIBILITY

How might a successfully integrated family health program function? For this discussion, we will present an idealized setting. This hypothetical clinic is staffed by physicians, nurse-midwives, nursing sisters, a health educator/nutritionist, an environmental sanitation worker, a laboratory technician, a person responsible for dispensing medicines and managing supplies, and a registrar/secretary/recordkeeper.

All staff members are trained in family planning. All recognize how family size, birth interval, post-partum abstinence, and the use of contraceptives can affect the health and well-being of each family member. In addition, all staff members understand the menstrual cycle, the basics of reproductive physiology, and how the different contraceptive methods offered by the center work. They refer a user to someone more knowledgeable if they cannot fully answer a question.

All medical personnel (physicians, nurse-midwives, nursing sisters) receive specialized training in examining, educating, and advising users. They understand both the basis for each contraindication to use of the Pill, IUD, and injectable contraceptives and the predisposing factors that can be identified during a physical examination, from the woman's history, or from laboratory test results. Each medical staff member has been observed by a supervisor and colleague during counseling sessions with users and has worked at improving listening and explaining skills. Each medical staff member has also assisted in childbirths, inserted IUD's, and managed with a colleague and supervisor a variety of complications from the use of different methods. The individuals in this clinic know themselves and their colleagues to be skilled. They also know who does what best and are not ashamed to refer a user to a colleague or supervisor.

The staff works as a team. All of the team members have scheduled outreach activities. The staff members have divided the week into a schedule of clinics to organize their time and expertise: maternal care (prenatal, postnatal), well-baby, family planning, general morbidity, general community outreach, etc. Unlike some clinics, this hypothetical clinic is busy all week long. Most of the people who use the clinic are mothers and their small children. The majority live within a few kilometers of the clinic, yet a number of people who use the clinic come from 15 to 35 kilometers away, often by foot. The staff members know that if, during well-baby clinic, they are examining the children of a woman who has come from 18 kilometers away and she expresses interest in the Pill, they will be able to help her to determine if this is the right method for her, etc. As a result, the woman does *not* need to be told to come back on a day when family planning services are offered.

Conversely, while staff members satisfy a mother's need for family planning, they may also detect illnesses in her children and treat them on the spot. Often, the clinicians are able to identify signs of malnutrition. The clinicians can call upon the health educator/nutritionist to help the family establish a healthy diet.

The clinicians may call upon the environmental sanitation worker if they detect medical problems related to water supply or sanitation.

SUPPORT SERVICES

For the clinical aspects of the family health program to function successfully, administrative and technical support must be dependable.

In the idealized clinic we have just described, medicines, vaccines, and contraceptive supplies are periodically delivered. If supplies run short because of a crisis, the dispenser/supply officer can send in an emergency request and receive a special delivery. The staff members know that if women go away empty-handed or with a second-choice method, they may never come back.

Unless the staff members make a special request for assistance, their supervisor comes to the clinic once every 3 months. The supervisor is knowledgeable about and experienced in several aspects of family health, including family planning. When the team makes a special request, the supervisor brings along a colleague who is more skilled in a particular area (e.g., obstetrics, gynecology, nutrition, sanitary engineering, pediatrics). Staff members keep a record of difficult cases and other problems to discuss during their next visit with the supervisor. Occasionally, they schedule users' followup visits to coincide with their supervisor's visits. In this way, women can avoid making a journey to the hospital where the supervisor and other experts work.

All aspects of the family are documented in one file: family composition, reproductive health history, vaccination history, medical consultations, well-baby history, home environment, nutritional practices, deficiencies, interventions, etc. Since the same patient consultation form is used for family planning complications as for other forms of morbidity and the form is added to the family file, the amount of paperwork is kept to a minimum.

The clinic team benefits from the reporting system. On a monthly basis, the team members fill in one summary form that reports the number of persons served by type of service and the commodities consumed during the reporting period. This can provide the public health workers with a means of evaluating how effective the program has been.

The staff uses the reporting information at weekly meetings to 1) review difficult or special cases, 2) look at questions of clinical management and prevention, 3) examine the caseload, the number and types of referrals made, and the results of the referrals, 4) evaluate and plan outreach activities, and 5) assess requirements for changes in use of staff time or for commodities. Periodically, the staff members reevaluate the program by asking the questions listed below.

EVALUATING THE NEED FOR INTEGRATION

The idealized situation described above may not exist anywhere. However, you may already use some of the principles and practices presented above in your own program, whether it provides only family planning services or integrated family health services.

How well would integrated family planning services work within the context of your present program? The answer depends on the needs of your users, the availability of trained personnel and other resources, and the policies and ideologies of your government. Ask yourself the following questions to evaluate whether your present program needs some change:

1. How many people live in the area served by my program?
2. Where do they live?

3. Can I reach them with my system of services as it exists today?
4. What do people need most today?
5. What will people accept today, tomorrow, if more information is made available to them?
6. What resources, both from my program and from the community, are available to meet the needs of the people?
7. Are they willing to come to my clinic or outreach sessions?
8. Are there people who are reluctant to use services because of how they are offered? Examples: Married women who don't want to go to family-planning-only clinics. Single women who don't want to go to clinics for mothers and their children.
9. Am I making the best use of my own time, the time of my colleagues and staff?
10. Are there ways in which I could reorganize my staff and resources to provide better services to more people?

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CHAPTER 25

KEEPING FAMILY PLANNING VOLUNTARY

In much of the world, people feel that it is extremely important that family planning decisions be individual decisions, made without strong pressure from forces beyond the individual woman or couple. In other societies, particularly in countries that are already very crowded or are island nations, society as a whole has tended to determine the ideal family size for the average couple. When a society—through its political institutions, the media, the medical establishment, or the educational process—attempts to determine the number of children a couple should have, the individual man and woman lose a part of their freedom to make a voluntary decision as to their reproductive destiny.

Many of us would like to be able to determine what career we are to work in, whom we are to marry, where we are to live, what religion we are going to participate in, and how we are to spend our leisure time. Moreover, many couples throughout the world would like to be able to determine for themselves how many children they would like to have and when they would like to have them.

When a country adopts an alternative to the voluntary practice of family planning, authorities carefully examine the nation's natural resources, its population, the availability of productive land, migration patterns, the anticipated level of capital formation, educational opportunities, existing standards of living, medical resources, and the cultural heritage of a society. From these estimates, officials determine an acceptable population size and growth rate with respect to their development objectives and the resources available to the country. Based on desired population size and growth rate, officials then arrive at a desirable family size in order to maximize the quality of life for everyone in that society. It is likely that the individual preferences of some couples regarding ideal family size will come into conflict with the social norm.

Authorities can attempt to influence couples' decisionmaking about the desired size of a complete family in two ways. First, they can use positive incentives to encourage couples to have smaller families, such as giving an annual bonus or job promotion to each family that has only one or two children. The second major approach involves the use of disincentives. For example, couples may suffer a loss of medical care, loss of housing, or loss of educational opportunities for their offspring should they have more children than the number the authorities have established as appropriate.

While the population is growing rapidly in most areas of Africa, there are still broad expanses of unsettled land and many untapped resources. For these reasons, most African governments have not set policies directed at limiting population growth. On the other hand, many African nations—aware

of the potential effects on the quality of life of rapid population growth—are beginning to encourage voluntary family planning through maternal and child health programs.

Since voluntary family planning is new to most of Africa, it is too early to determine whether it will succeed in helping couples and countries to meet their respective objectives. For voluntary family planning to be given an opportunity to succeed, several conditions must be met:

- 1) Contraceptives must be made available on a voluntary basis at all post-partum clinics.
- 2) Voluntary contraceptive services must be made available to all who are sexually active and who do not wish to become pregnant. This includes adolescent as well as older women, and unmarried as well as married women.
- 3) Voluntary contraceptive and sterilization services must be made available to nulliparous couples as well as to high-parity women.
- 4) Voluntary sterilization services must be made available to all men as well as all women, and to rural as well as urban couples.

The authors of this book hope that *Contraceptive Technology: Africa* can play a small role in improving the level of understanding of modern contraceptives and that the availability of birth control methods will improve so that African couples will continue to be able to make decisions about childbearing on a completely voluntary basis.

APPENDIXES

APPENDIX A Selected studies of the effectiveness of the cervical mucous (Billings) method*

Author, Date & Reference Number	Place	Type of Study & Description of Participants	No. of Women	Length of Obser- vation	No. of Unplanned Preg- nancies	Pregnancy Rate			Discontinuation Rate Life Table % at 12 Months	
						Pearl Method Per 100 Woman-Years		Life Table % at 12 Months		
						Total	Failure(1)	User Failure(1)		
Ball 1976	Australia	Prospective study of experienced users recruited from NFP centers. Age: 20-39. Medical: ≥ 1 ovulatory cycle post partum.	122	1,626 Cycles	21	15.5(2)	2.9	6.6	NR	NR
Dolack 1978	USA	Retrospective study of experienced users with monthly follow-up by NFP center. Age: 19-48, mean 28 (3).	329	3,354 Cycles	27	9.7(4)	1.1	6.4	NR	NR
Klaus et al. 1979	USA	Prospective study of new (1/3) and experienced (2/3) users at NFP clinic. Age: < 18=8%, 18-39=80%, $\geq 40=11\%$. Education: ≥ 12 years 79%. Medical: post partum, postabortion, or lactating 11% (3).	1,090	12,283 Cycles	209	20.4	1.2	19.3	15.8	40.8
Mascarenhas et al. 1979	India (5 states)	Prospective study. Age: < 44. Medical: history of regular cycles, currently menstruating, not lactating.	3,530	39,967 Months	176	5.3	0.1	5.2	5.7	12.8
Medina et al. 1980	Colombia	Randomized, prospective study of new users. 3-5 months training, monthly follow-up. Age: 18-39, mean 27(3).	277(5)	1,967 Months	61	37.2	NR	NR	22.2	72.1
			130(6)	1,064 Months	30	33.8	NR	NR	24.2	60.1

APPENDIX A Selected studies of the effectiveness of the cervical mucous (Billings) method*

Author, Date & Reference Number	Place	Type of Study & Description of Participants	No. of Women	Length of Obser- vation	No. of Unplanned Preg- nancies	Pregnancy Rate Pearl Method Per 100 Woman-Years Method User			Life Table % at 12 Months Total	Discontinu- ation Rate Life Table % at 12 Months
						Total	Failure(1)	Failure(1)		
Wade et al. 1980	USA	Randomized, prospective study of new users. 3-5 months training, monthly follow-up. Age: 20-39, mean 27. Education: mean 14 years. Medical: regular cycles.	573(5)	3,232 Months	94	34.9	NR	NR	22.4	73.7
			191(6)	1,269 Months	42	39.7	5.7	34.0	26.7	73.7
Weissman et al. 1972	Tonga	Prospective study of new acceptors. Age: mean 33.	282	2,503 Months	53	25.4(7)	0.5(7)	24.9(7)	NR	NR
WHO 1981	El Salvador,	Prospective study of new users.	869(8)	2,701 Cycles	45	21.6	0.5	21.1	NR	NR
	India,	3 cycles training,	725(6)	7,514 Cycles	130	22.5	2.8	19.7	19.6	35.6
	Ireland, New Zealand, Philippines	monthly follow-up. Age: 20-38, mean 30. Medical: ovulating, history of regular cycles. Education: ≥6 years 70%, nonliterate 13%.	869(9)	10,215 Cycles	175	22.3	2.2	20.1	23.9 (at 16 Cycles)	45.9 (at 16 Cycles)

NR = not reported

NFP = Natural Family Planning

*Modification of Table 1 in Reference 1.

(1) Causes of failures generally as classified by authors. Method and user failure pregnancy rates may not equal total pregnancy rates because totals sometimes include other pregnancies classified in studies as neither method nor user failures. Except where other pregnancies are a small proportion listed as undetermined, such studies are noted.

(2) Sum of method and user failure pregnancy rates does not equal total because total includes 8 pregnancies following coitus on days of "sticky, cloudy mucus," taught as permissible by some study centers but not permitted under the protocol.

(3) Description covers a larger group than that reported; description of actual participants only is not reported.

(4) Sum of method and user failure pregnancy rates does not equal total because total includes 6 pregnancies classified as undetermined.

(5) Year beginning with start of training.

(6) Year beginning with end of training and start of followup.

(7) As recalculated by Marshall, Mosley, and Rochat.

(8) Training period.

(9) Total, including training and followup periods

APPENDIX B How to calculate the interval of fertility, using the "shortest minus 20, longest minus 10" calculation

Shortest Cycle (Minus 20)		Longest Cycle (Minus 10)	
If Your Shortest Cycle Has been	Your First Fertile (Unsafe) Day is	If Your Longest Cycle Has Been	Your First Postovula- tory (Safe) Day Is
21*	1	21	11
22	2	22	12
23	3	23	13
24	4	24	14
25	5	25	15
26	6	26	16
27	7	27	17
28	8	28	18
29	9	29	19
30	10	30	20
31	11	31	21
32	12	32	22
33	13	33	23
34	14	34	24
35	15	35	25

*Day 1 = First Day of Menstrual Bleeding

APPENDIX C

VASECTOMY KIT

Description	Quantity
Instrument pan and cover	1
Control syringes, 5cc Luer-Lok	2
Needles, hypodermic, 22g, 1/2" long	12
Needles, hypodermic, 25g, 1/4" long	12
Forceps, Halsted, mosquito, curved 5" stainless steel	2
Forceps, Allis intestinal, 5 x 6 teeth 6"	2
Needle holder, Collier, 5"	1
Blades, carbon steel, N/S Blades, sz 10	8 pkgs.
Handle, surgical knife, B-P No. 1030 No. 3	1
Forceps, hemostat, straight, 5-1/2", Kelly	4
Scissors, suture, standard 5-1/2" angled on flat stainless	1 pr.
Needles, taper point, mayo, 1/2" circle, sz. 6	2 pkgs.
Needle, skin suture, straight, triangular point, 2-1/2"	2 pkgs.
Clamps, towel, Backhaus 3"	4

APPENDIX D

MINI-LAPAROTOMY KIT

Description	Quantity
Surgical blades, size 10	8
Backhaus towel clamps, 14 cm	4
Allis clamp, 19 cm	1
10-ml control syringe	1
10-ml hypodermic syringes	4
20-gauge hypodermic needles, 4 cm	12
Dressing forceps, 14 cm	1
Tissue forceps, standard, 14 cm	1
Curved Halsted mosquito forceps, 13 cm	6
Straight Pean artery forceps, 15.5 cm	3
Dabcock tissue forceps, 19.5 cm	2
Curved artery forceps, 20 cm	1
Bozeman dressing forceps, 25 cm	1
Surgical knife handle	1
Mayo-Hegar needle holder, 17.5 cm	1
Straight triangular point suture needles 5.5 cm	2
Mayo taper point needles, size 6	12
Urethral catheter, size 14, French	1
Jacobs tenaculum	1
Hirschman proctoscope	1
Ramathibodi uterine elevator	1
Ramathibodi tubal hook	1
Stainless steel sponge bowl	1
Richardson-Eastman retractors	2
Abdominal retractor	1
Graves vaginal speculum (medium)	1
Suture scissors	1
Straight operating scissors, 15 cm	1
Curved Metzenbaum scissors, 17.5 cm	2
Instrument pan with lock lid	1

APPENDIX E

An Inventory of Village and Household Contraceptive Delivery Projects, 1962-1979

I. SOCIAL MARKETING

Country (Population in millions)	Dates	Sponsors	Potential Users	Products Sold	Retail Outlets	Wholesaler	Publicity, Advertising and Promotion	Total Sales
AFRICA								
*Ghana (11.3)	Start: 1970 Product launched 6/1971, program cur- tailed and modified 7/1971	Government Ghana National FP Program	Urban and semi-urban married couples	Conoom (Sultan) Pressurized foam (Emko)	Ghana National Trading Corporation stores (government owned) Licensed pharmacies	Ghana National Trading Corporation (government dis- tributor)	Consumer. POP—displays; Media-comprehensive cam- paign planned to include press, radio, cinema, TV, Billboards. All promotion stopped after 10 days of press ads. Retailer: none. RP: none.	7/1971-6/1972 condoms; 532,080 pieces foam; 121,288 cans
Ghana (11.3)	Start: 7/1976 Product launched 1/1979 Panther, SSS, 11/1979 Coral	Government and Westinghouse Health Systems	7.5% of nonpregnant women age 15-44 who are not using contracep- tion, not living in rural areas, and do not wish to become pregnant (N = 62,250)	Condom (Panther, SSS) Foaming tab- lets (Coral) OC (Floril)	Condoms, foaming tablets: retail shops, dance halls, bars, "mammy traders" (women street vendors) OC: pharmacies	Commercial distrib- utor	Condoms, foaming tablets; Consumer POP-countertop displays, posters, door- way banners; Media-press, radio; Other-billboards OC: Consumer; posters in clinics, pharmacies, hospitals. Retailer: printed training infor- mational materials. PR: none.	1/1979-10/1979 condoms; 1,265,020 pieces OC's; 68,124 cycles

APPENDIX E I. SOCIAL MARKETING (Continued)

Country (Population in millions)	Dates	Sponsors	Potential Users	Products Sold	Retail Outlets	Wholesaler	Publicity, Advertising and Promotion	Total Sales
AFRICA								
Kenya (15.4) Start: 3 1972; Product launch: 10 1972; end 7 1974		Government Population Services In- ternational (PSI)	One-half of "at risk" males age 18-30 with disposable cash in Meru test area (N = 50,000)	Condom (King)	All retail outlets, emphasis on larger shops	Commercial distrib- utor (Provided ex- clusive salesman, van, and sound equipment); mail- order	Consumer: POP-dispen- sers, metal shop signs, mobiles, shelf strips, booklets; Media—radio, cinema, press; Personal— samples, field educator; Other: leaflets, pamph- lets. Retailer: field educator salesman, printed training ma- terials. PR: day-long picnic seminar for 350 local leaders.	10 1972-9/1973: 137,827 (in- cludes 9,700 samples)
Kenya (15.4) Start: 8 1974; End: 3 1976		PSI	Urban males in cash economy	Condom (King) (Prime) (Featherlite) (Gossamer)	Urban and semi- urban shops	Commercial distrib- utor; mail-order	Consumer: newspapers, booklets	500,000 pieces per year average
MIDDLE EAST								
*Egypt (40.6) Start: 1978 Product launched 6 1979		IPPF (Egyp- tian Family Planning Association	Lower socioeconomic groups in greater Cairo area: 100,000 new users in 1979	Condom (Tops) Foaming tab- lets (Amman) IUD (Cop- per T)	Pharmacies, other retail outlets	Commercial distrib- utor; 4 field supervisors also promote and sell IUD's to physi- cians; free train- ing of physicians for IUD insertion	Consumer: POP—posters, stickers, displays, book- lets, list of partici- pating doctors for IUD insertion; Media—radio, press, TV; Other—book- lets, sampling. Re- tailer: samples, dis- counts, training. PR: radio, press, TV.	NA

APPENDIX E I. SOCIAL MARKETING (Continued)

Country (Population in millions)							
Dates	Sponsors	Potential Users	Products Sold	Retail Outlets	Wholesaler	Publicity, Advertising and Promotion	Total Sales
MIDDLE EAST							
Morocco (19.4) Start: 4 1969 End: 7 1970	Government	Undefined	Condom	633 tobacco shops in Basablanca	Government Tobacco Board	None	4/1969-7/1970 100,800 pieces
*Tunisia (6.4) Start: 7 1976	Government Syntex Corporation S Present: Government	Married couples who never used contracep- tives and OC discon- tinuers	Condom (Waha') OC (OP 50)	Pharmacies	Central Pharmacy of Tunisia; 4 commer- cial wholesalers	Consumer: POP—displays, brochures, posters. Re- tailer: promotion by firm representing pharma- ceutical companies, product brochures. Medi- cal community: detail- man and seminar for physicians and pharma- cists.	NA

*Ongoing program

FP = family planning

IPPF = International Planned Parenthood Federation

OC's = oral contraceptives

POP = point of purchase

PR = public relations

PSI = Population Services International

Source: Population Reports. Family planning programs. Social marketing: does it work? 1980 Jan; Series J, 21.

APPENDIX E

II. VILLAGE-BASED DISTRIBUTION

Country/ Implementing Organization ^a	Project Description, ^b	Evaluation Design ^c	Services Provided ^d	Results ^e
AFRICA				
Egypt American University in Cairo	(1974-1976); In Shanawan Area; household canvassing with village resupply employing local, salaried residents. All supplies provided free. Population: 14,000.	Baseline canvass provided estimates of use. Prevalence surveys and service statistics provided impact assessment.	orals condoms	One year after initial distribution, prevalence of contraceptive use increased from 18.4% to 31%, a 68% increase. Service statistics indicate that current prevalence of contraceptive use is 35%.
Egypt American University in Cairo; Ministries of Health and of Social Welfare	(1974-Pres.); In Menoufia Governorate; household canvassing with village-level resupply; employing local salaried residents; initial supplies free, resupply free of charge. Population: 200,000.	Four experimental treatment groups compare effects of resupply through clinic village depots and free supplies vs. paying for periodic contraceptive prevalence surveys and service statistics.	orals condoms -referrals for clinical methods -social welfare services	One year after distribution of contraceptives, prevalence of use increased from 19% to 27.6%, a 45% increase. Project expanded to population of 1.4 million.
Egypt American University in Cairo; Menoufia Governorate; Ministries of Health and of Social Affairs	(1978-Pres.); In Menoufia Governorate; integrating and upgrading existing delivery systems of family planning, health and social services, and training medical, paramedical, and social welfare personnel and local leaders to stimulate necessary community action for sustaining the level of contraceptive prevalence initiated to distribute contraceptives to households. Population: 1.4 million in 302 rural villages.	Before and after social, demographic, health, and contraceptive prevalence surveys; service statistics; input, output, and cost-effectiveness analysis; goal-achievement evaluation.	orals IUD's condoms foams -social welfare health and family planning services	Not yet available

APPENDIX E II. VILLAGE-BASED DISTRIBUTION (Continued)

Country/ Implementing Organization ^a	Project Description ^b	Evaluation Design ^c	Services Provided ^d	Results ^e
AFRICA				
Morocco Ministry of Public Health (MOPH);	(1977-Pres.); City of Marrakech; household canvassing; MOPH fieldworkers provide free OC's and condoms on two successive visits; resupply through MOPH dispensaries. Population: 1.2 million.	Pre- and post-delivery contraceptive prevalence surveys; comparison of rural and urban areas and male vs. female workers.	orals condoms -clinic referrals -malaria control -tuberculosis treatment -health census -immunizations	Limited distribution canvass of urban and semi-urban areas showed that 36.1% of eligible women were already using contraception. An additional 20% accepted pills or condoms as a result of canvass. Results are pending first evaluation analysis.
Tunisia National Office of Family Planning and Population (ONPFP); Sfax Governorate	(1976-Pres.); PFAD project: household distribution, using young local women, of free OC's (6 cycles) and resupply (9 cycles). Referrals and transpor- tation arranged for IUD's and fe- male sterilization. Ultimate re- supply through clinics and nurse- hygienists. Designed to test basic feasibility of household delivery and to estimate demand levels. Population: 40,000.	Service statistics client records, evaluation survey.	orals condoms -referrals for IUD's and ster- ilization	One year after initial distribution, contraceptive prevalence among married women of reproductive age (MWRA) increased from 5.9% to 15.3%. Introduction of IUD's and tubal ligations has further increased all method prevalence.

APPENDIX E II. VILLAGE-BASED DISTRIBUTION (Continued)

Country: Implementing Organization ^a	Project Description ^b	Evaluation Design ^c	Services Provided ^d	Results ^e
AFRICA				
Tunisia ONFPF: Jendouba Governorate	(1977-Present), PFPC project; household distribution by local women; free OC's (5 cycles); condoms, foams, jellies; limited resupply free with various permanent resupply systems to be tested. Referrals made for IUD's and sterilization. Study will also compare cost effectiveness of OC's only vs. family planning with basic maternal child health (MCH) services. Population: 140,000.	Service statistics client records, contraceptive prevalence surveys.	orais condoms foams referrals for IUD's and sterilization some MCH services	Initial household visits in first delegation (pop: 41,802) provided estimate of 15.5% MWRA as current users; and additional 33.3% of MWRA accepted free supplies and services.

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^aThis column shows the country and the organization responsible for implementing the projects, according to available documentation.

^bThis column provides brief information on the project's general characteristics. The dates in parentheses tell when the project began and ended. If no termination year appears, the project is assumed still active. Insufficient information for a number of projects accounts for some incomplete blocks.

^cThis column focuses upon the kinds of information that are or will be gathered, either as part of project activities or independent assessment efforts. Some projects include "treatment" and comparison groups in an experimental design. Since many community-based distribution (CBD) projects currently provide minimal entries in the "Results" column, this information can help anticipate the type of data and analysis that may eventually be reported.

^dThe first services listed pertain to those directly related to nonclinical fertility regulation. Next, the existence of a referral system is noted. A referral system indicates that distributors actively engage in promoting such service (e.g., transportation, scheduled appointments). Lastly, other services in which the agents are actively involved are indicated (e.g., maternal child care (MCH) improved nutrition, vaccinations, parasite treatment, etc.)

^eThe strongest results known are stressed. This means that actual measures of fertility reduction will appear, if available. Intermediate measures such as prevalence of contraceptive use will also appear if such information is available. Weaker measures like acceptor rates may be all that are available. When none of the above is available, the "Results" may show simple numerator data, or only administrative information such as number of retail outlets, agents trained, or commodity flow. Some projects have not reported results at this time.

Source: Population Reports. Family planning programs.
Community-based and commercial distribution: an inventory and appraisal.
1978 Mar; Series J, 19.

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