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Reproductive health research: the new directions

BIENNIAL REPORT 1996-1997

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Reproductive health research: the new directions

Biennial Report 1996–1997

Edited by

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Preface

The year 1997 marked the 25th anniversary of the Programme. It also marked a new turning point in the Programme's rich and distinguished history in several other ways.

First, with the convening of a WHO Scientific Group Meeting on Cardiovascular Disease and Steroid Hormone Contraception in November 1997 the Programme concluded a series of landmark studies on the safety and efficacy of fertility regulating methods. Initiated in 1985 with the establishment of a dedicated task force of experts from developing and developed countries, this initiative has produced a wealth of scientific information that has already had a significant impact on family planning policies and practices. A poll among a panel of 20 international experts, due to be published soon in the Lancet, illustrates the impact that the Programme has had in this field. Out of the ten most important advances in knowledge about safety or efficacy of fertility regulating methods listed by the panel, seven are subjects in which the Programme's task force played a major role. They include: the benefits and risks of oral contraceptives in relation to cancer; oral contraceptives and cardiovascular disease; the relation between oral contraceptives and breast cancer and between depot-medroxyprogesterone acetate and breast cancer; IUDs and pelvic inflammatory disease; suitability of copper-bearing IUDs for long-term use; and the issue of venous thromboembolism in users of third-generation oral contraceptives. An additional topic among the top ten identified by the panel was the safety and efficacy of the antiprogestogen mifepristone, an area in which the Programme has also been at the cutting edge through the work of one of its other task forces. A score of eight out of ten is an achievement to be proud of and a tribute to the hundreds of collaborators in some 50 countries around the world who have had the vision, skills and stamina to make it possible.

Second, the fertile initiative on safety and efficacy of fertility regulating methods has amply demonstrated the power of imaginatively conceived, carefully designed and meticulously executed mission-oriented research. It has also confirmed, once again, the Programme's adage that, where research is concerned, collaboration is key to success. Multicentre research studies in the biomedical and epidemiological spheres and calls for proposals for social science research on defined high-priority topics have traditionally constituted the backbone of the Programme's research

endeavours. This is likely to remain so for the years to come. But the traditional concept of interaction between the Programme and its worldwide network of collaborating institutions on a one-to-one basis, as between the hub and rim of a wheel, is changing in important ways. Many of the collaborating centres have reached the stage of maturity and sustainable independence and this, together with the revolutionary advances in electronic communication, is creating untold opportunities for people, institutions and countries to develop their own networks for collaborative research on common problems of regional or interregional scope. As you will discover in Part 1 of this Report several such networks addressing issues such as female genital mutilation, knowledge and attitudes with respect to emergency contraception and the (mis)use of caesarean section have started functioning in Africa and Latin America in the last year or two and more are expected to emerge shortly.

The third, and perhaps the most significant, reason why 1997 is likely to be recorded as a memorable year in the Programme's history relates to events that took place during 1994–1995. During that biennium, two major United Nations conferences—the International Conference on Population and Development (ICPD) and the Fourth World Conference on Women—were held in Cairo, Egypt, and Beijing, China, respectively. The nations of the world present at these meetings firmly endorsed the concepts of sexual and reproductive health and rights and their implications for the delivery of services and for research. Already prior to these conferences, the Programme and its highest governing body, the Policy and Coordination Committee (PCC), had been studying the implications of the reproductive health paradigm for the Programme's mandate and focus of its research. During the 1996–1997 biennium, this study was extended and led to the report *"Sexual and Reproductive Health Research Priorities for WHO for the Period 1998–2003"*.

The report proposes that, in line with the ICPD Programme of Action, the Programme address, in a focused manner, an expanded array of priorities in sexual and reproductive health, building on its work and achievements in fertility regulation. The research agenda would encompass, in addition to fertility regulation, high-priority research on unsafe abortion, maternal health, reproductive tract infections (including cervical cancer), and planning and programming in reproductive health. Aspects of research on adolescent reproductive health, harmful practices and violence against women, which are relevant to the Programme's mandate, would also be incorporated. This proposal for a focused expansion of the research agenda in the Programme will be submitted for consideration by PCC at its meeting in June 1998. Part 2 of this Biennial Report includes individual chapters on some of the topics that were highlighted at Cairo and Beijing as requiring intensified research efforts by governments, agencies and organizations active in the field. Written mainly by experts outside the Programme in their personal capacity,

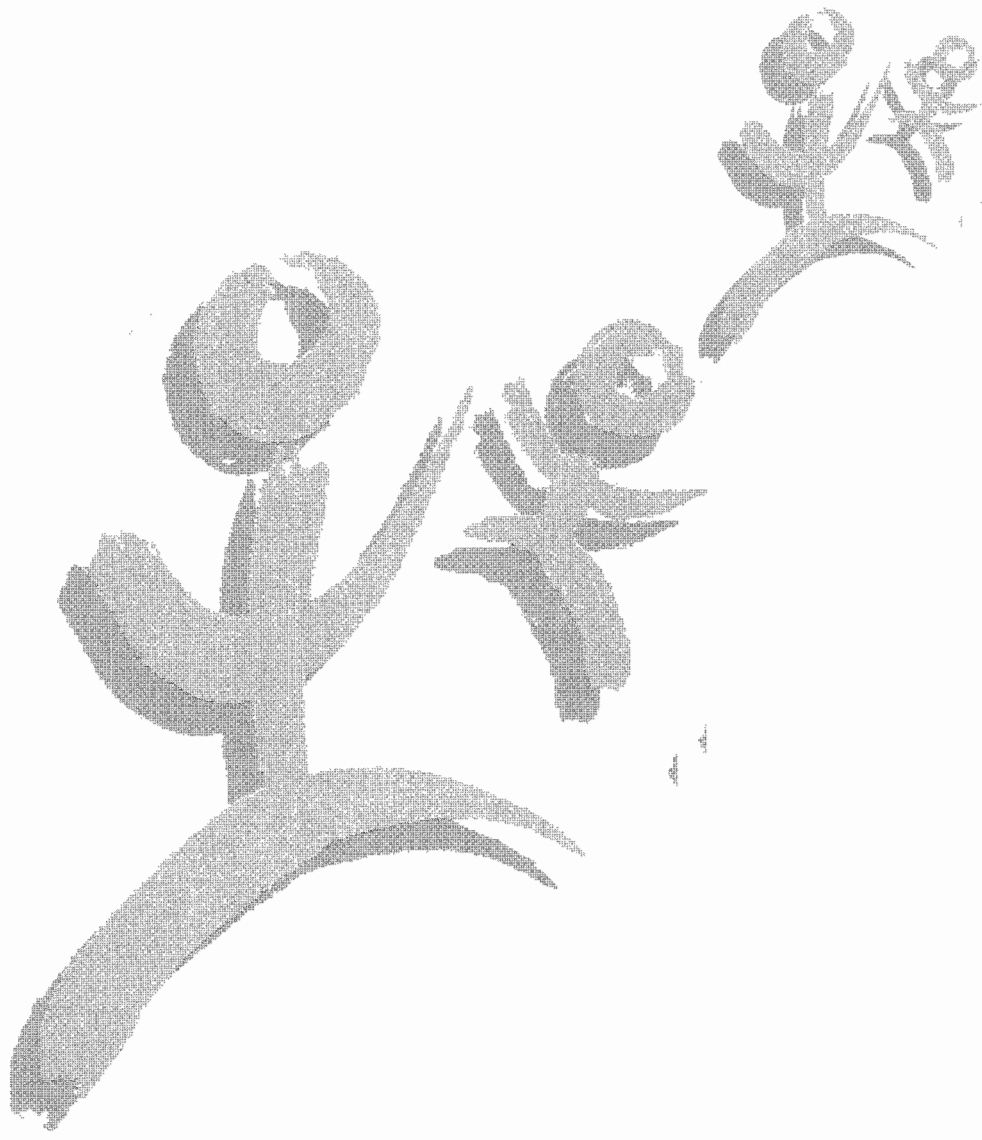
these essays provide a glimpse of the challenges in research that must be addressed if reproductive health for all is to become more than mere rhetoric.

In her acceptance speech on 13 May 1998, Dr Gro Harlem Brundtland, the first woman to become WHO's Director-General, observed *"The Cairo Summit put population and reproductive health on the agenda but there is still so much to do. We must help doing it".* The Programme and its worldwide web of collaborators and supporters stand ready to answer that call.

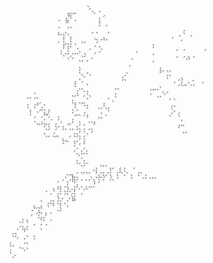
Paul F.A. Van Look, MD PhD
Director

Part 1

The work of the Programme in 1996–1997



Understanding people's reproductive health needs and perspectives



Highlights

- **Much unmet need for family planning persists, even in settings where knowledge of contraceptive methods is high. Studies suggest that many potential users choose not to use more reliable methods due to misperceptions and concerns about health-related risks. For example, a study in the Maldives found that knowledge of family planning was universal, but only 30% of couples were using a contraceptive method. Several studies, including one from Malaysia, found that non-use of contraceptives was linked to fears about side-effects.**

  This research highlights the continuing need for information, education and communication (IEC) campaigns to dispel misconceptions and allay fears about modern methods.

- **Research on vasectomy demonstrated that concerns and misperceptions about the procedure's impact on health and virility are important reasons why many men do not choose this method. Furthermore, research from Mexico among men who underwent vasectomy found that some believed vasectomy would protect them against HIV infection.**

  These studies stress the need to provide better information and counselling regarding vasectomy, especially to men. There may also be a need for prevention efforts with respect to sexually transmitted diseases (STDs) and HIV among men who undergo vasectomy.

- **Studies have found that despite health education campaigns and counselling, condom use among married couples remains stigmatized because of its association with infidelity. Research continues on: the acceptability of male and female condoms; the effectiveness of condom promotion; high-risk sexual behaviour in several countries; and men's views on sexuality and STD transmission. A new research initiative was launched on the dual risk of unplanned pregnancy and STDs, including HIV/AIDS.**

  Research already completed suggests that promoting condom use among couples for dual protection against both pregnancy and STDs may be more successful than for prevention of STDs alone. The newly launched initiative will try to identify ways to address the need for dual protection against unplanned pregnancy and STDs in different sociocultural contexts.

- **Unsafe abortion may persist even when family planning and legal abortion services are available. This was demonstrated by research in Turkey which found that many women tried to self-induce abortion before seeking legal abortion services. Despite the availability of family planning services, recourse to abortion remained high due to non-use of contraception and the failure of the widely practised traditional method of withdrawal.**

  Research on abortion has many implications for programmes and policies. For instance, it highlights the need to dispel fears regarding the negative health consequences of contraception and ensure an easy access to services. It also illustrates the key role of providing information and counselling regarding prevention of unplanned pregnancy and of the involvement of men in strategies to increase contraceptive use and reduce unwanted pregnancies.

- **Research on gender roles, sexuality and contraception has been carried out in several countries. In Thailand, a study found that, while there was little acceptance of wives' extramarital affairs, male visits to sex workers were considered the norm. In Mexico, research documented the belief that women should take primary responsibility for contraception, but men should be experts on sexuality and birth control. Research in Nigeria found that the decision to have a child was made by the husband alone in 17% of cases, and 30% of couples did not discuss whether to have another child.**

  Programme planners, policy-makers and researchers need to understand gender roles and socio-cultural norms in order to design appropriate IEC campaigns and plan more effective family planning programmes. This research also highlights the need to provide better family planning information to men.

• **Research from several countries, including China, Malaysia and Nigeria, documented the belief that wider access to contraceptive methods for young people would lead to promiscuity or "moral decay." Yet many studies have shown that despite lack of access to family planning services, many unmarried young people are already sexually experienced. In China, for example, a study found that many unmarried (but engaged) young women reported sexual activity, without access to formal family planning services. Few of these women used contraception during the first sexual encounter because they did not know where to obtain a method or because they were embarrassed to seek advice from family planning outlets for fear of disclosing their premarital sexual behaviour.**

These studies point to the need for information and services for young people and a need to overcome social disapproval of such services through culturally sensitive public education campaigns. Research on adolescent sexual behaviour provides information necessary for developing appropriate programmes and policies to promote safer sex and prevent unintended pregnancies and transmission of STDs, including HIV/AIDS, among young people.

• **Studies from several countries documented the serious consequences of unprotected sex among adolescents, especially for female adolescents. In the Republic of Korea, over 20% of male industrial workers and 10% of male students reported having made their partner pregnant. A study among male adolescents in Nigeria found that 13% had made their partner pregnant and that 67% of these pregnancies had been aborted. Among Nigerian female students, 10% reported abnormal vaginal discharge during the previous year and among male students, 8% reported a history of STDs, primarily gonorrhoea.**

Information about the extent of unwanted pregnancy and STDs among young people is critical for drawing policy-makers' attention to the problem.

• **Studies among adolescents show that knowledge about sexuality, reproduction, and contraception does not necessarily lead to the practice of safer sex. Nor does lack of knowledge result in young people abstaining from sexual intercourse.**

Programmes targeted at adolescents need to go beyond providing factual information to young people. Effective education programmes for adolescents should include negotiation techniques and life skills.

People's perspectives on fertility and contraceptive use

The Programme is involved in research to identify social, cultural, and behavioural factors, and problems in service delivery which limit access to, and impede the improvement of, reproductive health. This research focuses on the perceptions, fears, and concerns of potential users about the health-associated risks of contraceptive methods. It also examines the role of men in reproductive health and helps identify shortcomings in family planning services which may limit the choice of contraceptives available.

Malaysia

A study carried out among three ethnic groups in Malaysia found that poor uptake of some family planning methods was linked to fears and misconceptions about their possible side-effects.

The study was designed to identify differences in attitudes towards family planning among women from three ethnic groups: Chinese, Indian, and Malay. The research found that women from the Malay group favoured a larger family size than Chinese or Indian women and used contraception mainly for spacing births rather than for limiting family size. The Malay women reported generally low use of contraceptive methods—partly due to a lack of knowledge about modern contraceptive methods and partly due to a desire for larger families. They also disapproved of intrauterine devices (IUDs) because they require insertion by medical personnel, who are often men.

The Chinese women wanted to have fewer children than women from the other groups—mainly because they wanted to ensure that their children received a good education. Women from the Indian community reported using contraception both for birth spacing and for limiting family size.

The study also found some convergence in attitudes. All three groups reported a fear of side-effects as the most important reason for not using contraceptives and said there was little open discussion about contraception. All groups expressed concern that wider access to contraceptive methods would lead to "moral decay" among adolescents.

Maldives

A study carried out in the Maldives investigated whether attitudes to the sex composition of families (usually a preference for sons) had any affect on family size. Of the approximately 400 couples involved, 75% said they had no sex preference, and that the ideal family size was four children. Although knowledge of family planning was universal, only 30% of couples were using a method of contraception—signalling an unmet need for family planning services.

Nigeria

A study in Nigeria on beliefs and attitudes about sexual behaviour and contraceptive decision-making highlighted the need for information and education programmes on the use of contraceptive methods. The study, conducted in Oyo State, involved 4000

men and women aged 18–50 years. The decision about whether or when a woman should become pregnant was often a joint decision (47% of couples), but about 30% of couples never discussed it, and in 17% of cases the decision was taken by the male partner alone. The study also found that modern contraceptive methods were little used and that many respondents believed family size was determined by "God's will".

Providers' perspectives

Views of health care providers on different contraceptive methods and reproductive health technology can have key implications for service delivery and policy change. However, the role of providers in contraceptive acceptability and continuation of use has seldom been studied.

Thus, research was carried out in Nigeria on the attitudes of almost 300 traditional and religious healers (both Christian and Muslim) towards fertility and the family planning services they provide. While most of those interviewed maintained that traditional healers and western practitioners should work together in family planning, 26% of the traditional healers and 30% of religious healers opposed the use of modern contraceptive methods such as the pill. However, in advocating more "natural" forms of contraception, such as periodic abstinence, they demonstrated a poor understanding of the fertile period during the menstrual cycle. The findings underscored the importance of involving and training traditional and religious leaders who play an important role as service providers in areas where modern health services are less accessible.

People's perspectives on specific contraceptive methods

There are important lessons for programme planners and policy-makers in how people select, use, and discontinue a contraceptive method. Research is ongoing to determine some of the complex factors involved.

Vasectomy

A study in Mexico on the factors that influence men to undergo vasectomy documented the unexpected finding that some men believed the procedure would protect them against HIV/AIDS. This finding has led to detailed recommendations for an information campaign in Mexico about male sterilization and the need for HIV/AIDS prevention efforts among men who have undergone vasectomy.

The Mexico study involved 50 men planning to undergo a vasectomy, 100 men who had already undergone the procedure, and 50 men with no intention of having a vasectomy. The study found that men undergoing vasectomy reported they and their partners had more experience with "natural" and hormonal methods of contraception (including withdrawal, rhythm method, periodic abstinence, and the pill) and less experience with barrier methods than those who did not choose vasectomy. In addition, they reported a higher level of communication with their partners about sexuality and contraception. The most important factor in the choice of vasectomy was accessibility, including

the view that vasectomy is a simple procedure that does not involve "unpleasant feelings" after the operation.

Another study carried out among 1000 couples in China found that attitudes towards vasectomy were largely influenced by fears and misconceptions about the procedure. Respondents believed that vasectomy was not as simple or effective as female sterilization and that potential side-effects included negative effects on physical strength. While discussion between both partners was a key factor in the choice of contraceptive method, the couples did not have enough information about vasectomy to make an informed decision. One of the main conclusions of this study was that, since, in China, husbands generally have a higher level of education than their wives and are the main decision-makers, information about vasectomy should be targeted directly to men, rather than through their wives.

The diaphragm

A study in Turkey looked into the reasons why women choose to use the diaphragm as a method of birth control. Researchers are also investigating the use-effectiveness of this method and assessing the requirements for service delivery. The Turkish study is part of an interagency initiative involving comparative studies overseen by Family Health International (in the Philippines) and The Population Council (in Colombia).

Initial findings from the study in Turkey suggest that, in general, women who chose the diaphragm tend to be older and that both they and their husbands were better educated than women who choose other methods. The main reasons cited by diaphragm users for choosing the method were safety and the lack of side-effects. In addition, some women chose the diaphragm because they wanted to have control over contraception. The majority of other method users said they selected the method because of its effectiveness.

A higher percentage of diaphragm users reported having intercourse more than four times a week as compared to users of other methods. Patterns of urinary tract infections were similar for both diaphragm users and women using other methods. The final results from this study are due in early 1998.

Pregnancy prevention in the era of HIV/AIDS and STDs

In 1997, the Programme launched a new research initiative that will focus on the dual risk of unplanned pregnancy and STDs, including HIV/AIDS. The new initiative marks a shift away from the previous approach which focused exclusively on either prevention of STDs or pregnancy. The aim is to understand what sexually active individuals believe about the dual risk of HIV/AIDS and unwanted pregnancy, and what they consider as appropriate and effective protective measures against these risks.

Family planning and HIV/STD prevention

In Africa, a regional study will investigate the interface between

family planning and HIV/STD prevention. It will be carried out in Kenya, South Africa, Uganda, the United Republic of Tanzania, Zambia, and Zimbabwe, and possibly Botswana and Ethiopia.

A decline in fertility is reported in an increasing number of countries in this region—driven by a desire for smaller families and by an increase in the use of contraceptives. However, despite high levels of infection with HIV and other STDs in many countries, few people use condoms or other barrier methods, preferring to use mainly hormonal methods instead.

During the study, sexually active individuals will be asked how they evaluate the risks of unwanted pregnancy and STDs, including HIV/AIDS, and what strategies they use to avoid those risks. The project will examine possible ways of changing behaviour, with a particular focus on partner communication. The study is due to be completed by the end of 1999.

Prevention of STDs

The Programme is supporting a number of studies on the prevention of STDs. They include research on: the acceptability of male and female condoms (several countries); the effectiveness of condom promotion (China); high-risk sexual behaviour (Nigeria); male attitudes to transmission of STDs (Brazil); and the use of condoms among men (in five border towns in Nepal).

In Argentina, a Programme-supported study was carried out in a low-income district on beliefs and attitudes towards the prevention and treatment of STDs. The study explored the impact of cultural, psychological, and social factors, as well as the ability of women to negotiate with their sexual partner.

One of the key findings was that—despite health education campaigns and counselling—condom use among married couples remains stigmatized because it is associated with infidelity. This finding suggests that the promotion of condom use for dual protection against pregnancy and STDs may be more successful than for prevention of STDs alone.

The study also found that there was a need to ensure that people had access to accurate information on sexual and reproductive health. Those taking part in the study had little knowledge of STDs and of how they are transmitted, apart from HIV/AIDS. It was more common for men than women to discuss STDs and men were also more aware of STD symptoms. Some men believed that women are responsible for the spread of STDs because it is more difficult to know whether they are infected.

Determinants and consequences of induced abortion

About 20 million unsafe abortions are carried out every year. Performed by unskilled personnel or in unhygienic conditions, or both, these 20 million unsafe abortions are estimated to be responsible for the deaths of some 70 000 women, or about 13% of the nearly 600 000 maternal deaths that occur each year.

The Programme has funded a series of research projects aimed at determining the reasons and consequences of the widespread recourse to unsafe abortions. Most

of these studies have now been completed and a book describing the findings is in press. However, a series of new projects in Argentina, Bangladesh, China, and Sri Lanka has been initiated to explore remaining gaps in knowledge.

China

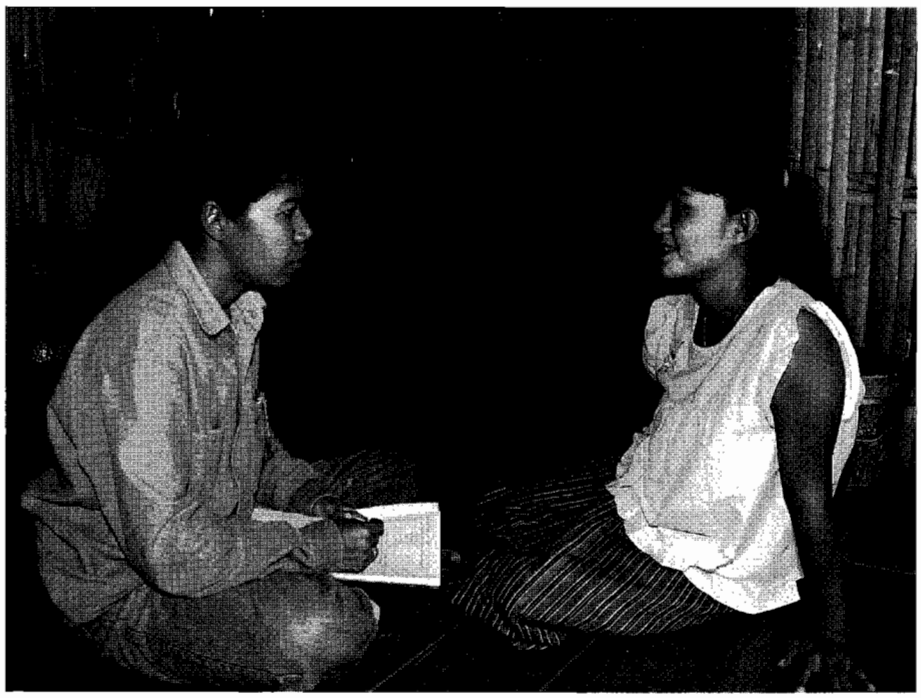
In China, a study on pregnancy before marriage compared the individual characteristics of young women who opted to have an abortion with those who went on to marry and give birth. The study found that almost two-thirds of the women—regardless of the outcome of the pregnancy—had never used contraception. The main reasons cited for this were lack of knowledge about methods, fear of side-effects, and not knowing where to obtain contraception.

Women with higher education and higher status occupations were more likely to choose abortion than marrying and having babies, as well as migrant women in uncommitted relationships, women with negative feelings about pregnancy, and women under 20—the minimum legal age of marriage in China.

These findings underscore the need for wider access to information and services related to family planning, regardless of age or marital status. The finding that many young people are sexually active before marriage, often in uncommitted relationships, has important implications for preventing pregnancy as well as the spread of STDs.

Turkey

A study carried out in Turkey, where abortion has been legal since 1983, showed that the legalization of abortion does not necessarily lead to the disappearance of unsafe abortion. The study found that before seeking medical help many women attempted



WHO PHOTO BY H. ANANDEN

a self-induced abortion using methods such as taking an overdose of medicine (aspirin or quinine) or intrauterine insertion of soap, marshmallows, chicken feathers, matches, or needles. Another common method was to ask a health care provider to insert an IUD.

The Turkish women involved in the survey wanted fewer children so they could be better cared for and educated. Although most women considered abortion to be a woman's right, it was nevertheless considered a "sin", and increasingly sinful the longer the pregnancy. All the women believed that abortion has an adverse effect on a woman's health.

Although women in the survey had access to family planning methods, very few were using modern contraceptive methods. Most either used traditional methods (mainly withdrawal), delivered unwanted children, or had repeat abortions. Despite major efforts by the Turkish family planning programme, recourse to abortion remains high—due to non-use of contraception or the failure of traditional methods.

The role of men in reproductive health

Many of the Programme's recent research projects have focused on the impact of gender roles and status, the empowerment of women, and interspousal communication on sexual and reproductive health issues. In 1995, the Programme launched a research initiative on the role of men in reproductive health. Many of these studies are still under way. Meanwhile five new projects were approved in 1997 in Brazil, China, Jamaica, Senegal, and Turkey.

A study involving over 400 married couples in Thailand focused on the impact of sex roles and partner communication on the risk of STDs. The study examined gender-based attitudes and behaviour in relation to extramarital sex, use of female sex workers, sex roles within marriage, and prevention of STDs. Although the study found there was little acceptance of wives' extramarital affairs, male visits to sex workers were considered the norm. Over 80% of husbands interviewed and almost 70% of wives did not consider it "strange" for husbands to visit sex workers. Almost 80% of husbands reported having had sex with a commercial sex worker at least once in their life, but only 5% had done so during the previous three months.

The researchers found significant differences between the views of husbands and wives on the sexual role of women. Over 90% of husbands did not consider it shameful for a wife to initiate sexual intercourse, while less than 70% of wives felt the same. In several instances there were wide variations in attitudes depending on the occupational status of the individual. For example, among blue-collar workers, 64% of wives and 40% of husbands maintained that men should get more pleasure from sexual intercourse than women, while only 28% and 14% of white-collar wives and husbands thought the same.

Asked whether they had changed their sexual behaviour after learning about HIV/AIDS, only about 20% of husbands and

17% of wives said they had. Of the husbands who reported a change in behaviour, about half said they had stopped visiting commercial sex workers. Meanwhile, about 20% of wives reported having tried to stop their husbands from visiting sex workers. Although most couples reported talking with their partner about sexual matters, the study found that discussion about extramarital sex, use of sex workers, and the use of condoms within marriage was difficult or impossible.

Birth spacing and maternal health

Over the past decade, there has been an increasing focus on maternal health issues, especially on maternal deaths. However, maternal ill-health and its psychological and social consequences have received little attention so far.

A study in Thailand assessed the influence of information and reproductive health education on mothers' beliefs about breast-feeding. The study involved women of childbearing age from both rural and urban areas, all with at least one child aged under two years. Researchers found that contraceptive uptake was high during the first two months after giving birth. Almost 60% of pill users and nearly70% of injectable users started using the method at that time. Although health workers in Thailand recommend that babies be exclusively breast-fed for the first three months, less than 50% were found to be exclusively breast-fed after one month, 34% after two months, and only 6% after three months. Knowledge of breast-feeding as a contraceptive method was found to increase with age.

The researchers concluded that there was a need to promote breast-feeding for the first three months both for the sake of the child's health and as a contraceptive method. This recommendation is important in view of concerns about the use of combined oral contraceptives while breast-feeding.

Elsewhere, a study carried out in Morocco investigated social and cultural factors that interfere with access to care and communication between women and health care providers. Researchers found that the women were ashamed and embarrassed about illnesses of the reproductive tract. Most women would not discuss the subject in public or even with their husbands. They had developed their own way of describing different forms of reproductive ill-health, although they used biomedical descriptions as well.

Access to medical care was limited by financial constraints and by women's acceptance of the decision-making authority of their husbands. While most of the women preferred private sector medical care, traditional medicine was used more often.

Reproductive health of adolescents

Adolescents are at high risk of unintended pregnancy and STDs, including HIV/AIDS, because of their sexual behaviour, their lack of information, and limited access to sexual and reproductive health services. About 12 million babies are born to adoles-

cent mothers every year—endangering the health of both mother and infant.

Most sexual and reproductive health services fail to make provision for the special needs of adolescents. In response, the Programme has conducted research on the extent of unmet need for sexual and reproductive health information and services among adolescents. This research is critical for developing appropriate programmes and policies to promote safer sex and prevent unintended pregnancies and transmission of STDs including HIV/AIDS.

Adolescent sexuality

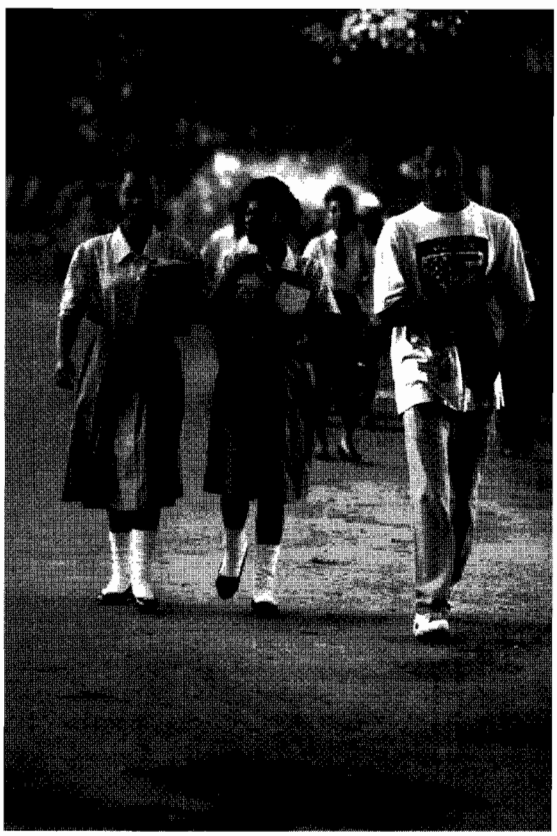
Studies completed in Nigeria, the Philippines, the Republic of Korea,Thailand, and Viet Nam indicate that a high proportion of male adolescents are sexually experienced. They include over 70% of male adolescents in the Nigeria study and over 75% of factory workers in the Republic of Korea and Thailand.

A study in the Republic of Korea, involving over 800 school and university students aged 15–23, found that two-thirds of sexually experienced males and one-third of sexually experienced females reported more than one lifetime sexual partner. Meanwhile, another study involving male students and male industrial workers found that over 75% of the industrial workers were sexually active, compared to fewer than 40% of the students.

Elsewhere, a study on the reproductive behaviour of university students in Viet Nam, found that 98% of women and over 75% of men believed that sexual intercourse should only take place within marriage. The study also found gender differences in the longevity of partnerships, with 90% of sexually experienced females staying with their first partner compared to only 55% of males. A similar study involving over 1000 students in the Philippines found that 18% were sexually active, of whom the majority were monogamous and with their original sexual partner.

A study in Nigeria involving 4000 men and women aged 18–50 found that over a third of respondents became sexually active during adolescence (11–18 years). Experience of rape during adolescence was reported by 4% of males and 7% of females. Some respondents (5%) also reported having sexual intercourse between the ages of six and 10, while 2% reported having been sexually

WHO PHOTO BY A. WAAK



abused (forced intercourse) at that age.

The Nigerian study also found that adolescent sexuality was a controversial issue. Some participants opposed the provision of sex education and contraception for adolescents on the grounds that it would lead to promiscuity. This suggests there is a need for community education about the benefits of reproductive health services for adolescents and that such education should also be targeted to community leaders and opinion leaders.

Gender roles among adolescents

Perceptions of gender roles are a key determinant of expectations of male and female sexuality. A study in rural areas of Thailand, involving 1200 men and women aged 15–24, found that premarital sex was more acceptable for men than for women. While 25% of men and 60% of women believed that men should not have sex before marriage, as many as 95% of women and 60% of men said it was unacceptable for women to do so. Also, of those who had ever been married, almost 90% of the men but less than 30% of the women reported having premarital sexual intercourse. Almost half of the men who had never been married and about a third of the married men reported having their first sexual encounter with a sex worker.

Meanwhile, another study in Thailand, involving male and female adolescent factory workers, found that, while for 85% of women their husband was their first sexual partner, only 6% of males reported marrying their first sexual partner.

Contraceptive use

A study on sexual behaviour and contraceptive use among over 2500 unmarried but engaged couples in Shanghai, China, found that premarital sexual intercourse was higher in rural counties (86%) than in urban Shanghai (60%). This finding contradicts the assumption that greater exposure to the media and rapid modernization in urban areas compared to rural areas invariably leads to higher levels of premarital sex. The researchers suggest that the difference may be a reflection of better living conditions in rural areas and the ability of unmarried rural men and women to live together once engaged.

Although sexual activity is high among this population, only one in five sexually experienced women reported using a contraceptive method during the first sexual encounter. Furthermore, about 40% of those who reported using a contraceptive method used less reliable methods such as the rhythm method and withdrawal. Contraceptive use was higher among sexually experienced women in urban areas (24%) than in rural areas (17%).

As a result of strict limitations on family size in China, and the social stigma attached to a child born out of wedlock, most premarital pregnancies (90%) were reported to have ended in abortion, and only few women opted to marry early.

Some women said they did not use contraception during the first sexual encounter because they did not know where to obtain a contraceptive method. Others were embarrassed to seek advice

from family planning outlets for fear of disclosure of their premarital sexual behaviour. These findings point to a need for information and services to be provided for unmarried men and women in China, especially couples who have recently become engaged.

Elsewhere, in the Philippines, over 50% of sexually experienced students interviewed reported using contraception during their first sexual encounter, mainly (75%) the rhythm method or withdrawal. However, 50% of sexually experienced students said they were now using effective contraceptive methods compared to 5% at their first sexual encounter.

The consequences of adolescent sexuality

Unsafe sex among adolescents and young adults can have serious consequences, especially for young women. In a study involving sexually experienced male industrial workers in the Republic of Korea, over 20% reported having made their partner pregnant; the corresponding figure for students was 10%. Although most of these pregnancies were aborted, 13% of the industrial workers and 11% of the students had fathered a child.

A similar study among male adolescents in Nigeria found that 13% had made their partner pregnant and that 67% of these pregnancies had been aborted. Among female adolescents, almost 10% reported having had at least one pregnancy. Most (77%) ended in abortions, 7% miscarried, and 16% resulted in the birth of unintended babies. In southwest Nigeria, over 40% of sexually active female adolescents reported having had at least one abortion.

Unsafe sex among adolescents can also lead to the transmission of STDs, including HIV/AIDS. A study in Nigeria among students aged 15–24 found that 10% of young women reported abnormal vaginal discharge during the previous year and 25% said they were unsure if their partner might have a STD during the previous year. Among the male students, 8% reported a history of STDs, primarily gonorrhoea (93%).

Relationship between knowledge and behaviour

Studies among adolescents have shown that knowledge about sexuality, reproduction, and contraception does not necessarily lead to the practice of safer sex. Nor does a lack of knowledge result in young people abstaining from sexual intercourse.

In a study in rural Thailand, where 80% of adolescents knew about HIV/AIDS, condoms were seen as a means of preventing transmission of STDs and not for use within marriage. Of the sexually experienced males, 76% reported using a condom during their first encounter with a commercial sex worker, although only 23% of those who had sex with commercial sex workers used a condom every time. Nearly half of those who visited sex workers maintained the sex workers were free of STDs because they underwent regular medical checks.

Among male factory workers in Thailand, 20% reported using a condom during their first sexual encounter with women who were

not commercial sex workers, while 54% used one during the initial encounter with a sex worker. Meanwhile, 24% of young married men who reported extramarital sex during the last 12 months said they did not consistently use condoms. Among the young women involved in the study, 88% maintained that men should use condoms with casual partners, while only 46% believed they should use them with wives or regular partners.

In the Republic of Korea, a study among male students and industrial workers found almost universal knowledge that HIV can be transmitted by having sex with an infected person, and many of the young men knew that STDs could be prevented by using condoms. However, the study also found misconceptions about the transmission of STDs including HIV/AIDS. Over half of the industrial workers and over 60% of the students believed that STDs could be transmitted by kissing. Among those who were sexually experienced, 80% of industrial workers and 73% of college students reported having had sex with a commercial sex worker. However, condom use was low: 23% of industrial workers and 40% of students reported using a condom during their first visit to a sex worker and 39% and 48%, respectively, at their most recent visit.

A similar study among adolescents in Nigeria found that, although all those involved had heard of HIV/AIDS, 44% of the men and 17% of the women reported having sex with a casual partner or sex worker without consistently using a condom.

Developing new methods of fertility regulation

Highlights

• **In November 1997, the Scientific Review Committee for Technology Development and Assessment reviewed the Programme's existing research portfolio and reprioritized the product leads. Since the previous review in 1995, work had been either completed or terminated on several potential products. The new list contains seven high-priority leads—five for methods for women and two for male methods.**

The research portfolio of the Programme in the area of development of new methods is reviewed every two years to ensure that research efforts are sharply focused on leads that are most promising for product development.

• **Research was undertaken on the antiprogestogen mifepristone to see if it could be developed as an oral contraceptive that could be taken either daily or weekly. Daily doses of 0.5–1 mg and a weekly dose of 5 mg mifepristone produced changes in the lining of the womb that could potentially prevent implantation of a fertilized egg. Encouraged by these findings the Programme conducted studies in small numbers of women to test whether these doses would be effective in preventing pregnancy.**

The final results from these studies will not be available until later in 1998. Interim results indicate that dosage levels that do not disrupt the menstrual cycle apparently do not produce a reliable contraceptive effect. Since the aim of these studies was to find out if mifepristone could be used for contraception without disturbance of the menstrual cycle, these results are considered disappointing and hence research in this area will not be continued.

• **Progress continues to be made in the work to develop levonorgestrel butanoate as a new injectable hormonal contraceptive. Since 1996, research has focused on reformulating the product to prevent clumping of the suspension during prolonged storage and on optimizing the sterilization method. Initial results suggest that particle aggregation and adhesion can be solved by modifying the formula and by switching from a glass ampoule to a prefilled single-use syringe.**

Levonorgestrel butanoate would provide contraceptive protection for up to three months with a single 10 mg dose. Such a low-dose preparation would expose a woman to a lesser amount of synthetic hormone than does depot-medroxyprogesterone acetate (DMPA)—the currently available three-monthly injectable. The lower dose would also result in less suppression of the ovaries, which in turn would result in fewer women experiencing amenorrhoea. In addition, fertility would be restored more rapidly after stopping the injections than is the case with DMPA.

• **In ongoing research to develop two new methods of emergency contraception using the antiprogestogen mifepristone and the progestogen levonorgestrel, the Programme has established that, when administered within 120 hours of unprotected intercourse, mifepristone dosages of 10 mg and 50 mg appear to be as effective as the 600 mg dose in preventing pregnancy. Programme studies have also shown that levonorgestrel is more effective than the Yuzpe method for emergency contraception and has considerably fewer side-effects.**

The most commonly used method of emergency contraception today is the Yuzpe method. It involves the use of four high-dose oral contraceptive pills administered with an interval of 12 hours. Apart from the inconvenience of the 12-hour regimen, this method fails to prevent pregnancy in about 25% of cases. In addition, it often involves unpleasant side-effects ranging from nausea and dizziness to headaches and vomiting. The new methods being developed by the Programme are intended to be more effective than the Yuzpe method, with fewer side-effects.

• **The Programme was the first to show that the use of a prostaglandin 36–48 hours after the administration of mifepristone was more effective in terminating an early pregnancy than the use of mifepristone alone. The Programme is now conducting studies to find out if misoprostol—a commonly available and inexpensive prostaglandin that can be administered orally—can be used in combination with mifepristone for early termination of pregnancy. A one-year study,**

involving over 2000 women in 14 centres, will determine the optimum dose of misoprostol needed to ensure a complete abortion up to 63 days after the last menstrual period.

Studies suggest that many women undergoing an induced abortion would prefer a safe and effective non-surgical method. Developing a method that is based on a drug that can be taken orally is expected to have special advantages. Misoprostol is currently marketed in over 60 countries for the prevention and treatment of gastric ulcers. It has a good safety record, is inexpensive, can be stored at room temperature, and has the advantage of being orally active. The study will compare the effectiveness of different regimes of oral and vaginal administration of misoprostol after pretreatment with mifepristone.

• **The Programme is supporting research on the development of prototype hormonal contraceptives for men. The new products are either a combination of two synthetically produced hormones—a progestogen (levonorgestrel butanoate) and an androgen (testosterone buciclate)—or the androgen alone. They will act by stopping the production of sperm in the testes. The aim is to reduce the amount of sperm in semen to undetectable or very low levels incompatible with fertility. The method would involve three-monthly injections and would be reversible.**

At present, men have access to only three forms of contraception—the condom, withdrawal, and vasectomy. Calls have been made at various international fora to increase contraceptive choices for men in order to enable them to take greater responsibility for fertility regulation.

• **Encouraging results have been achieved in research conducted over the past 6–7 years on a new non-surgical method of vasectomy. This method involves the percutaneous injection of liquid silicone to block the two ducts (vasa deferentia) that carry sperm from the testes. The plugs can be removed easily suggesting that this approach may be readily reversible. The liquid silicone contains a hardener which enables it to set quickly and form a tight seal or plug within the vas deferens thereby blocking the passage of sperm from the testes.**

There is a need for a non-surgical and reversible alternative to vasectomy for men who want a non-hormonal, long-lasting but non-permanent method of contraception. Results of a study carried out some years ago in Indonesia indicated greater than 90% efficacy of this approach. A similar study conducted recently in Europe yielded a disappointingly low level of efficacy, about 5%–10%. Further animal studies are proposed to see if the method can be improved.

• **In 1990 the Programme had concluded a licensing agreement with a pharmaceutical company for the manufacture and distribution of a levonorgestrel-releasing vaginal ring. But following reports of vaginal lesions among women involved in Phase III clinical trials, it was decided to redesign the ring. A trial of a redesigned placebo ring suggests that it does not produce lesions and that it would be suitable for further development. In 1997, the Programme's pharmaceutical partner decided to withdraw from the project and return the licence to the Programme. The Programme is now considering the possible development of a new higher-dose version of the redesigned vaginal ring in collaboration with the Contraceptive Research and Development Program (CONRAD).**

The Programme is pursuing this lead in response to women's expressed need for long-acting, effective methods of contraception which are under their own control. Acceptability studies done by the Programme suggest that many women will find this method suitable for their contraceptive needs.

In response to the need for new methods of fertility regulation to meet varied and changing individual reproductive needs, the Programme is continuing to support research on the development of a range of new or improved technologies. In December 1995, the Programme convened a meeting of biomedical and social scientists, drug development experts, health care planners and women's health advocates to review its technology development activities. The Scientific Review Committee ranked the activities as high, medium or low priority (see Table 1) according to four criteria: user needs and preferences; feasibility of development into a product; feasibility of service delivery; and commercial interest and potential.

In November 1997, the Scientific Review Committee reconsidered the existing research portfolio and reprioritized the product leads (see Table 2). During the intervening two years, work was either completed or terminated (owing to unfavourable results) on several potential products. For example, research on the development of an antiprogestogen-only daily oral contraceptive is no longer being pursued by the Programme following unpromising results from initial trials.

During 1996, work was also discontinued on a progesterone-releasing vaginal ring, and on two oral contraceptive products which failed to produce promising results: a once-weekly and a once-monthly pill, both using the antiprogestogen mifepristone. Meanwhile, a comparative study of the copper intrauterine device (IUD) (TCu380A) and a prototype frameless IUD (FlexiGard) was closed down in 1997 after the Flexigard failed to fulfil expectations of lower expulsion and removal rates.

Highest priority is now being given to continued research on the development of seven new products. They include several forms of long-acting hormonal contraception for both men and women, emergency contraception, non-surgical abortion, and non-surgical reversible vasectomy. Other product leads have been accorded medium or low priority. This chapter documents the work undertaken by the Programme prior to the November 1997 review of priorities.

High-priority leads

An antiprogestogen-only daily pill (mifepristone)

Current hormonal contraceptives sometimes have side-effects which women find unacceptable. Data suggest that up to 20% of women who start using oral contraceptive pills or injectable contraceptives discontinue their use within the first year because of unacceptable side-effects or health concerns. Scientists have therefore been on the lookout for compounds that can produce the same antifertility effect as the current hormonal methods but without the associated side-effects. Antiprogestogens—compounds that block the activity of the hormone progesterone—hold that promise. It has been shown in studies, for example, that in humans, depending on the dose given, daily administration of the antiprogestogen

Table 1. Priorities accorded to the Programme's product leads by the Scientific Review Committee in December 1995

High-priority leads
For women
An antiprogestogen-only daily pill (mifepristone)
An antiprogestogen-only weekly pill (mifepristone)
A three-monthly injectable (levonorgestrel butanoate)
A six/twelve-monthly injectable (advanced prototype hCG immunocontraceptive)
Antiprogestogen-only emergency contraception (mifepristone)
Progestogen-only emergency contraception (levonorgestrel)
Non-surgical abortion regimen (mifepristone plus misoprostol)
For men
A three-monthly injectable (levonorgestrel butanoate plus testosterone buciclate)
Non-surgical vas occlusion (silicone plugs)

Medium-priority leads
For women
An antiprogestogen-only monthly pill (mifepristone)
Contraceptive vaginal ring (levonorgestrel-releasing)
Contraceptive vaginal ring (progesterone-releasing)
Natural family planning (calendar method) and postpartum contraception (improved lactational amenorrhoea method)

Low-priority leads
For women
An estrogen-free daily pill (sequential mifepristone and progestogen)
Frameless IUD (interval insertion)
Frameless IUD (postplacental insertion)
A six- or twelve-monthly injectable (prototype hCG immunocontraceptive)
For men
A three-monthly injectable (testosterone buciclate alone)

Table 2. Priorities accorded to the Programme's product leads by the Scientific Review Committee in November 1997

High-priority leads
For women
A three-monthly injectable (levonorgestrel butanoate)
A six/twelve-monthly injectable (hCG immunocontraceptive)
Antiprogestogen-only emergency contraception (mifepristone)
Progestogen-only emergency contraception (levonorgestrel)
Non-surgical abortion regimen (mifepristone plus misoprostol)
For men
A three-monthly injectable (levonorgestrel butanoate plus testosterone buciclate, or testosterone buciclate alone)
Non-surgical vas occlusion (silicone plugs)

Medium-priority leads
For women
Contraceptive vaginal ring (levonorgestrel-releasing)
Natural family planning (calendar method)
Postpartum contraception (improved lactational amenorrhoea method)

Low-priority leads
For women
An estrogen-free daily pill (sequential mifepristone and progestogen)

mifepristone results either in inhibition of ovulation or in changes in the lining of the womb (endometrium) such that implantation of a fertilized egg cannot take place.

In 1995, studies were initiated by the Programme to determine the feasibility of using mifepristone as a minipill. Two approaches were adopted: (*a*) to identify the dose of mifepristone which disturbs the development of the endometrium but does not inhibit ovulation and hence does not cause disturbance of the menstrual cycle; and (*b*) to evaluate the biological effects of those doses of antiprogestogens which block ovulation.

A two-centre study was carried out in Santiago (Chile) and Szeged (Hungary) to assess the effects on the menstrual cycle of continuous daily administration of 1 mg of mifepristone for 150 consecutive days (five months). Overall, the results indicated that continuous treatment with 1 mg of mifepristone interferes with endometrial development. However, in the treated women up to half of the menstrual cycles were disrupted, with suppression of ovulation. This suggested that the daily dose would need to be lower than 1 mg if disruption of the menstrual cycle is to be avoided.

The Programme's Collaborating Centre in Stockholm (Sweden) looked at the effects on ovarian and endometrial functions of three months' treatment with daily doses of 0.1 mg and 0.5 mg of mifepristone. The results indicated that both these doses would not cause any disturbances in the menstrual cycles. However, the 0.1 mg dose was too low even to cause any changes in the endometrium. The 0.5 mg dose appeared to interfere with the development of the endometrium.

A study was then conducted in 1997 in Stockholm and Szeged to see if the 0.5 mg dose was sufficient to prevent pregnancy. Both centres were planning to recruit 20 women who would use the daily mifepristone pill as their only method of contraception for a period of six months. The women would record bleeding patterns, the timing of menstrual periods and side-effects during the treatment period.

Although the final results of the above study will only be available in 1998, interim findings are disappointing. Thus, until other leads emerge in this area—e.g. experience with other antiprogestogens or new information about other routes of administration—the Programme has decided not to pursue this lead further.

An antiprogestogen-only weekly pill (mifepristone)

Studies carried out in monkeys suggest that a twice weekly dose of mifepristone could be identified that had no effect on the sex hormones or ovulation or the length of the menstrual cycle but that impaired endometrial development and prevented pregnancy. Encouraged by this, the Programme initiated studies in 1995 to determine if in women infrequent (weekly) administration of a relatively low dose of an antiprogestogen could suppress endometrial development without suppressing ovarian function.

The first study was carried out by the Programme's Collaborating Centre in Stockholm (Sweden) to evaluate the feasibility of weekly administration of mifepristone in women with normal cycles. Fourteen women were recruited in this trial and two treatment cycles were followed. During the treatment cycles the women received either 2.5 mg (nine women) or 5 mg (five women) of mifepristone at weekly intervals for eight weeks. Results showed that both doses did not affect the length of the cycle and there was no spotting or other side-effects. Changes in the development of the endometrium were observed with both doses, although they were less pronounced with the lower dose.

In 1996, to evaluate whether the changes seen with the 5 mg dose were sufficient to prevent pregnancy, a study was planned in which 20 women would use the weekly dose of 5 mg as their only method of contraception for up to six months. By the end of September 1996 all 15 women had been recruited for the study, and 13 had completed at least one month of treatment. A total of 39 months of exposure was obtained. One woman became pregnant in the second month of treatment, but several women successfully used the method for 4–6 months. However, by the end of October 1996, another woman had become pregnant and, as required by the protocol, the study had to be discontinued.

The data obtained in this study are currently being analysed. However, it seems that the weekly interval is too long to achieve a reliable contraceptive effect with a 5 mg dose of mifepristone. As more frequent administration, for example every three days, is not practical, there are no plans to carry out any further studies of the intermittent administration of mifepristone in women.

Three-monthly injectable (levonorgestrel butanoate)

As many as 15 million women worldwide now use injectable contraceptives—one injection providing protection from 1–3 months depending on the product used. Of these, about 12 million women use depot-medroxyprogesterone acetate (DMPA), a three-monthly injectable based on a progestogen. Although highly effective, this product can cause irregular bleeding and amenorrhoea. It is estimated that 50%–80% of women who give up using DMPA do so because of menstrual problems. Another disadvantage is that the return to fertility is often delayed once injections are stopped.

The Programme is supporting research on the development of a new kind of injectable contraceptive (levonorgestrel butanoate) designed to protect women for three months with fewer side-effects than DMPA. Because the new contraceptive contains a lower dosage of synthetic steroid hormone than other injectable contraceptives, it is expected to cause less suppression of the ovaries, less amenorrhoea, and a quicker return to fertility once the injections are stopped.

Levonorgestrel butanoate was initially tested to determine its effectiveness in blocking ovulation and the duration of protection at

various doses. Next, the product was tested in a multicentre comparative study involving another injectable contraceptive already on the market, norethisterone enantate (NET-EN), both given in the form of an injection lasting two months. Both products had the same high contraceptive efficacy and both caused some steroid-related side-effects. However, after a year, NET-EN caused greater weight gain and more erratic bleeding patterns than levonorgestrel butanoate.

Animal studies have also been carried out, involving monkeys, to determine the optimum particle size for the compound, which is formulated as a crystalline suspension. The studies showed that by increasing the size of the particles, the release of the product could be slowed down, the duration of protection extended, and the amount of steroid needed reduced. An optimal particle size was then determined and a manufacturing process established. Meanwhile, a one-year toxicology study in animals did not reveal any unexpected side-effects.

Since 1996, research has focused on reformulating the product to prevent clumping of the suspension during prolonged storage. Although the product has been shown to have good chemical stability after several years' storage at different temperatures,

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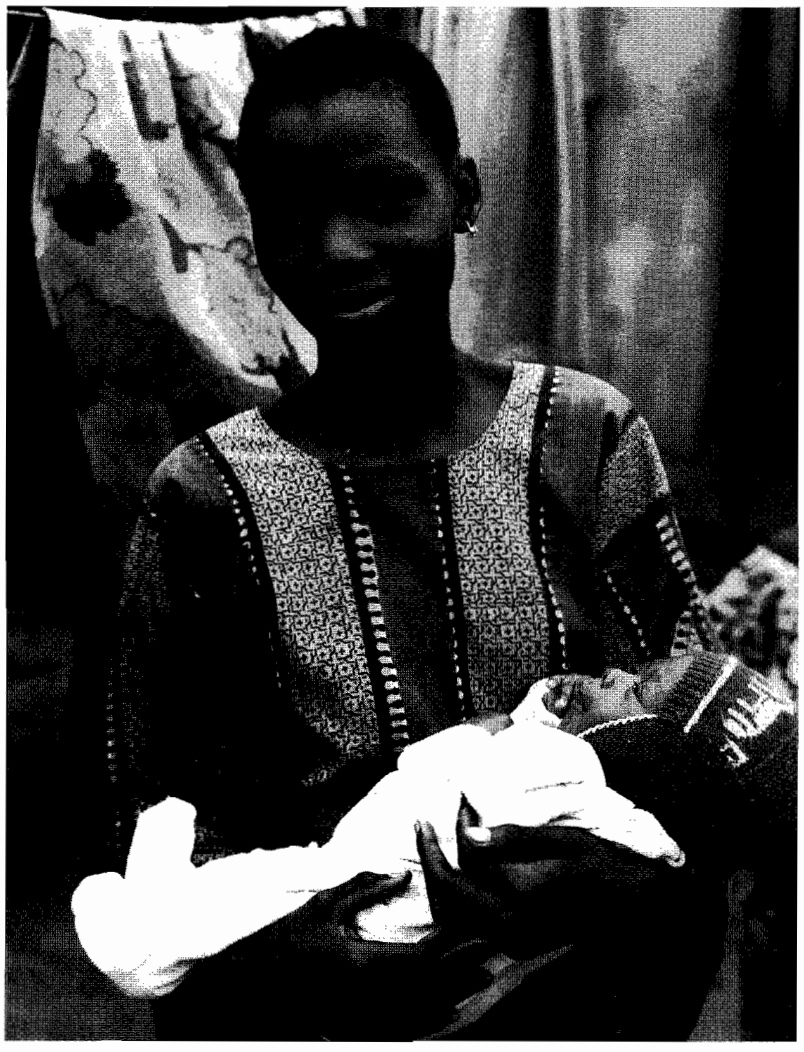


over time, the crystal particles tend to aggregate and stick to the sides of the glass ampoule—making it difficult to resuspend. Initial results suggest that this problem can be solved by modifying the formula and the manufacturing process, and by switching from a glass ampoule to a prefilled single-use syringe. It was also found that sterilization by gamma-irradiation induced up to 4% impurities. Thus, work is ongoing to optimize the sterilization procedure for this preparation. This investigative work is being carried out with technical input from the Contraceptive Research and Development Program (CONRAD) in the USA. Once these studies have been completed, clinical trials will resume—probably in 1999. When the optimum dosage has been determined, a multicentre study will be carried out to compare the new injectable with DMPA.

In the meantime, the Programme is negotiating with pharmaceutical companies to ensure the continued development and eventual manufacture of the product—together with guarantees that it will be made available at a low price for use in the public sector in developing countries. Because the product is easy to synthesize, it is expected that production costs will be low.

Immunocontraceptives

The Programme has been supporting the development of an immunocontraceptive since 1973. This new form of contraception protects against pregnancy by stimulating the body's immune system to produce antibodies in the blood that block a crucial stage in the reproductive process.

The method is likely to be of interest to women who want a contraceptive that is free of the side-effects associated with existing hormonal methods (including contraceptive pills, injectables, and implants), does not require insertion of a device (such as an IUD), and is relatively long-lasting but not permanent.

The immunocontraceptive being developed by the Programme works by preventing the implantation of a fertilized egg in the womb. It produces antibodies that bind to and neutralize the action of a hormone, human chorionic gonadotrophin (hCG), which is produced by a fertilized egg. This prevents pregnancy and menstruation occurs at or around the expected time, and the fertilized egg is expelled. The antifertility effect ceases when the level of hCG antibodies in the blood drops at the end of the period of protection.

The first clinical trial with the Programme's prototype hCG immunocontraceptive (Phase I safety trials) was carried out in Australia during 1986–1988, and involved 43 volunteers who had previously chosen to be sterilized and were therefore not at risk of pregnancy. No serious adverse effects were reported. However, a subsequent clinical trial (Phase II efficacy trial) launched in Sweden in 1993 and involving fertile women was halted when the injection was found to cause an unacceptable reaction at the injection site, which had not occurred during the Phase I trial.

The prototype product is now being reformulated to avoid these

side-effects and preclinical safety studies and Phase I and Phase II clinical trials are due to resume in 1998. If the planned clinical trials are successful, the way would be open for the development of an initial product which may require a series of two or three injections in order to provide protective cover for six months. However, researchers are also working on the development of an improved version which will provide the same duration of protection with a single injection, and on a version which will provide a longer duration of protection (12 months). Studies are also being carried out on the possibility of producing the immunocontraceptive in a form that can be taken orally.

Although the antifertility effect of the immunocontraceptive will end after the six- or 12-month period, research is under way to determine ways of safely interrupting and reversing its effect for women who may change their mind and wish to become pregnant prior to this. In the meantime, women who opt for this kind of contraception will be counselled to ensure that they understand the long-acting nature of the product, and that its action cannot be reversed before the end of the specified duration of effect.

It is estimated that a further 5–7 years of clinical testing and product improvement will be needed before a first-generation product will be available. Meanwhile, a second-generation synthetic, bioengineered product is also under development, in collaboration with industry, and could be available within the same or a slightly extended time-frame.

A licensing agreement for eventual manufacture of the product has been concluded between Ohio State University and an industrial partner. This agreement, together with a collaborative research and product supply agreement between the company and WHO, will ensure that the immunocontraceptive is made available to the public sector in developing countries at the lowest possible price.

Emergency contraception

Until recently, the Programme was the only international body involved in the research and development of emergency contraception. For almost a decade, the Programme has supported efforts to develop two alternative methods of emergency contraception—one using the antiprogestogen mifepristone, and the other using the progestogen levonorgestrel. Both mifepristone and levonorgestrel have been on the market for some time: what is new is their proposed use as emergency contraceptives.

Emergency contraception was first used in the 1960s to prevent pregnancy in rape victims. Since then it has been used by women in the event of unprotected intercourse or recognized contraceptive failure. However, emergency contraception is not yet widely available. In many countries, family planning service providers have not been trained in this method of contraception and many women do not even know it exists.

The most commonly used method of emergency contraception today, the Yuzpe method, involves the use of an elevated

dose of an oral contraceptive. An initial dose of two pills (comprising estrogen and progestogen) is followed by two more to be taken 12 hours later. Apart from the inconvenience of the 12-hour regimen, which may entail taking pills in the middle of the night, this method fails to prevent about 25% of pregnancies. In addition, it often involves unpleasant side-effects ranging from nausea and vomiting to headaches and dizziness. The new products being developed by the Programme are intended to be more effective than the Yuzpe method, with fewer side-effects.

Efforts to ensure that emergency contraception is available at the lowest possible price to women in developing countries are being spearheaded by the Interagency Consortium on Emergency Contraception (see page 42), of which the Programme is a member.

1. Mifepristone

Research on the use of mifepristone as an emergency contraceptive began in 1989 following the discovery that the compound can be used to block ovulation or to prevent the implantation of a fertilized egg in the lining of the uterus—depending on the stage of the menstrual cycle at the time of administration. The earliest trials involved almost 1200 women who had sought emergency contraception following unprotected intercourse or contraceptive failure. A single dose of mifepristone was given within 72 hours after intercourse and found to be more effective than the Yuzpe method, with fewer side-effects. However, women using mifepristone were more likely to have delayed menstruation than those using the Yuzpe method.

A follow-up study—involving over 1700 women in Australia, China, Finland, Georgia, the United Kingdom, and the USA—compared the effectiveness of the original dose (600 mg) with two lower doses (50 mg and 10 mg) to determine the lowest effective dose required. All three were found to be equally effective. In this study, mife-pristone was given up to five days after intercourse but it appeared to be less effective once 72 hours had passed. Overall, the drug prevented 85%–90% of pregnancies that would have occurred without emergency contraception.

2. Levonorgestrel

Since 1990, the Programme has been investigating the possibility of using levonorgestrel for emergency contraception. Levonorgestrel has a long-established safety record as a component of oral contraceptive pills and as the active ingredient in Norplant, the contraceptive implant.

An early comparative study in Hong Kong , Special Administrative Region of China, involving over 800 women, found that levonorgestrel was as effective as the Yuzpe method, with fewer side-effects. In each case, treatment was initiated within 48 hours of intercourse and a second dose given 12 hours later. A follow-up study involving about 2000 women in 14 countries was launched in 1995. The aim was to confirm the findings of the earlier study and determine whether it was possible

to delay the start of emergency contraception up to 72 hours after intercourse. Initial results from this study suggest that levonorgestrel is more effective than the Yuzpe method with considerably fewer side-effects. The study was completed in 1997 and the results are due to be published in the second half of 1998. This trial has already had a major impact in the field. On the basis of the interim results, the Interagency Consortium for Emergency Contraception selected levonorgestrel as the method to be introduced in family planning services through model introduction programmes in Indonesia, Kenya, Mexico, and Sri Lanka.

During 1998–1999, a multicentre study involving almost 4200 women will compare the effectiveness and side-effects of a single 10 mg dose of mifepristone with levonorgestrel given both as a single dose and in two doses. Meanwhile, a parallel study in Hong Kong, involving about 2000 women, will look at the effectiveness of giving levonorgestrel in two doses each 24 hours apart—a more convenient time interval than the 12-hour regimen used in earlier trials.

3. Emergency insertion of an IUD

In some cases, insertion of a copper IUD can be used as an alternative form of emergency contraception. One advantage is that an IUD can be inserted up to 5 days after ovulation, i.e. up to the estimated time of the start of implantation—which is 48 hours later than hormonal methods. Once in place, the IUD provides immediate contraception and can be used for up to 10 years. However, this method is not recommended for women who have never given birth or those who are at risk of STDs.

An analysis of 19 studies of postcoital insertion of IUDs revealed a failure rate of only 0.1%—suggesting that this method is 15 times more effective than the Yuzpe method. However, only one of these studies compared the actual and expected numbers of pregnancies. And while no studies reported side-effects or illness after IUD insertion for emergency contraception, emergency insertion is carried out at a later stage in the menstrual cycle than routine insertion and therefore may be more difficult.

The Programme has launched a new study in China involving 2000 women which will investigate the efficacy, acceptability, side-effects, and possible complications of emergency insertion of an IUD.

Non-surgical abortion

Globally, an estimated 150 000 unwanted pregnancies end in abortion every day. Of these, as many as 55 000 are carried out in unsafe conditions—involving 200 deaths a day. In countries where abortion is legal but not widely available due to a shortage of medical facilities and trained manpower, the availability of non-surgical abortion could help reduce the number of unsafe abortions and maternal deaths. For many women, non-surgical abortion appears to be more acceptable than surgical methods. However, non-surgical abortion can only be safely carried out in those areas where surgical back-up facilities are avail-

able in the event of occasional failure.

The Programme has been involved in the development of non-surgical methods of abortion using antiprogestogens since 1983. It was the first to demonstrate that an antiprogestogen pill (mifepristone) followed 36–48 hours later by administration of a prostaglandin could terminate an early pregnancy. This method is now registered for use in China, France, Sweden, and in the United Kingdom. However, gemeprost, the prostaglandin initially employed most commonly, is expensive and is not stable at room temperature. The Programme is therefore now studying the use of another prostaglandin, misoprostol, as a replacement for gemeprost.

Misoprostol—currently marketed as Cytotec in over 60 countries for the prevention and treatment of gastric ulcers—has a good safety record, is less expensive, can be stored at room temperature, and has the advantage of being active when given orally.

Initial studies involving the use of mifepristone and misoprostol indicated that this combination was effective in terminating pregnancies of up to 49 days. However, a 1993 study carried out at the WHO Collaborating Centre in Edinburgh, United Kingdom, indicated that the use of oral misoprostol was less effective than vaginal administration of gemeprost in pregnancies of longer than seven weeks. These findings were confirmed by follow-up studies which showed that increasing the initial dose of mifepristone (from 200mg to 600 mg) did not improve the efficacy of this method beyond 49 days of pregnancy—indicating that the dosage and method of administration of misoprostol are critical in ensuring the termination of pregnancy up to 63 days. If the method were highly effective only within the first seven weeks of pregnancy, it would not be a useful choice for women in developing countries, as many fail to contact health services early enough.

The Programme is now supporting a further one-year study, involving over 2000 women in 14 centres. The aim is to determine the optimum dose of misoprostol needed to ensure an effective abortion up to 63 days after the last menstrual period. The study will also compare the effectiveness of different regimes of oral and vaginal administration of misoprostol. Initially, all the women volunteers will be given the same dose (200mg) of oral mifepristone. Two days later—the time required for mifepristone to take full effect—different regimens of misoprostol will be started.

A disadvantage of non-surgical abortion is the amount and duration of bleeding that occurs afterwards, which lasts twice as long as bleeding after surgical abortion involving vacuum aspiration. This could have an adverse effect on women's health—especially in countries where anaemia is prevalent. The Programme is therefore seeking to find ways of reducing blood loss and thereby further improve the acceptability of non-sugical abortion.

Although the Programme has not provided support for research on the termination of second trimester pregnancies, it provides

technical advice as well as mifepristone and placebo tablets for some of the studies. One completed study involved the use of mifepristone to prime the cervix prior to induction of abortion with different prostaglandin regimens. The aim was to find a way of reducing the long and painful process of abortion at this stage of pregnancy. The study involved 98 women who were given a 200mg dose of mifepristone followed by oral or vaginal administration of misoprostol every three hours up to a maximum of five doses. Among those given misoprostol vaginally, the average time involved in achieving abortion was nine hours and 90% of the women aborted within 24 hours. The corresponding figures for those given oral misoprostol were 13 hours and 69%. Although the vaginal route was more effective, most women preferred the oral route. A follow-up study will examine whether effectiveness of administration could be improved by increasing the dose of misoprostol.

Meanwhile, the Programme is also supporting a study investigating the use of misoprostol as a preoperative treatment for softening and dilating the cervix before a surgical abortion is carried out by vacuum aspiration. In order to determine the lowest effective dose of misoprostol and the shortest time interval needed before surgery, different doses of misoprostol, administered orally or vaginally, are being assessed. The study, involving 225 women with pregnancies of 8–12 weeks' duration, is due to be completed by mid-1998.

Three-monthly injectable for men

At present, men have access to only three forms of contraception—the condom, withdrawal, and vasectomy. To increase the choice available, the Programme is supporting research on the development of a prototype hormonal contraceptive for men. The new product is a combination of two synthetically produced hormones—a progestogen (levonorgestrel butanoate) and an androgen (testosterone buciclate). The new contraceptive, which is being developed in collaboration with the US National Institutes of Health (NIH) and the Contraceptive Research and Development Program (CONRAD), acts by stopping the production of sperm in the testes. The aim is to reduce the amount of sperm in semen to very low or undetectable levels. The method would involve three-monthly injections and the contraceptive effect would end within a few months after the injections were discontinued.

In recent multicentre trials, a similar product that involved weekly injections was rated as highly acceptable by the men involved—although many expressed interest in a longer-lasting contraceptive that would require fewer injections. In the two-year study using weekly injections of testosterone enantate (a synthetic derivative of the male hormone testosterone), the method was found to be 98.6% effective—at par with the effectiveness of hormonal methods for women, including oral contraceptives. When the injections were stopped, the average times taken for men to return to normal fertile

levels of sperm production, or to reach pre-treatment levels, were 112 and 201 days, respectively. And all of the 33 babies so far born to couples who had taken part in the study, were healthy and of normal weight. The four-continent trials involved over 399 couples aged 21–45 from 9 countries. Most had volunteered because of dissatisfaction with existing forms of male and female contraception.

However, the use of testosterone alone has two major drawbacks: the frequency of injections needed to maintain suppression of sperm production and the unpredictable effect of raised levels of testosterone on behaviour and prostate changes over time. Because of this, the Programme is supporting the use of a combination comprising a progestogen (levonorgestrel butanoate) to suppress sperm production, together with a smaller dosage of testosterone (testosterone buciclate) to ensure maintenance of normal levels of testosterone.

Although preliminary small-scale trials with testosterone buciclate were promising, the start of clinical trials of the combined product has been delayed because of production problems. It was discovered that, in its current microcrystalline form, the testosterone buciclate clumps together and adheres to the side of the glass vial. The solution is difficult to resuspend and there is a 10% reduction in the concentration. An additional concern is that the formation of small particles could clog up syringes and alter the intended duration of effect. Similar problems have also been encountered in the formulation of levonorgestrel butanoate.

During the past year, 24 preparations—involving different concentrations of testosterone buciclate and types and levels of flocculating agents—have been developed and stored at different temperatures in Hypack syringes. The main modification has been the addition of a flocculating agent to maintain the dispersal of the steroid microcrystals and avoid clumping. Preliminary results indicate that all the test preparations can be readily suspended and easily expelled from the syringe. Although the least concentrated suspension had the best flow characteristics, a concentration higher than previously thought possible appears to be stable and can be readily expelled from the syringe.

Once the reformulated product is ready, preclinical studies and clinical trials will be resumed. While the clinical trials are under way, studies involving both male volunteers and their partners will be carried out to assess the acceptability of this new form of contraception.

In the meantime, discussions are under way with industry to ensure the continued development and eventual manufacture of the three-monthly injectable for men, and guarantee its availability at low cost to the public sector in developing countries.

Non-surgical reversible vasectomy

Although about 40–50 million couples today have opted to use vasectomy as their preferred method of contraception, changing family circumstances prompt

many to seek a reversal of the procedure. But reversal involves skilled microsurgery and fertility is successfully restored in only about 30%–40% of cases.

An added deterrent for many men is the surgical intervention and perceived discomfort involved in undergoing a vasectomy. Although the availability today of less-invasive "no-scalpel" vasectomy is encouraging an increasing number of men to opt for this form of permanent contraception, there is a need for a non-surgical and a more easily reversible method of sterilization for men who want a long-lasting method of contraception.

The new sterilization technique—developed in the Netherlands—involves the injection of liquid silicone to block the two ducts (vasa deferentia) that carry sperm from the testes. The liquid silicone contains a hardener which enables it to set quickly and form a tight seal or plug within the vas deferens—thereby blocking the passage of sperm from the testes. The plug can stay in place indefinitely or be removed by a minor incision.

Programme-supported Phase I trials carried out in China and Indonesia over the past 6–7 years provided encouraging preliminary data on the effectiveness of the silicone plug method. However, they also highlighted the need to determine the exact volume of liquid silicone needed and the correct injection pressure required to ensure that the sperm ducts were securely sealed off. If the injection pressure is too low, the liquid may not be in contact with the interior wall of the duct before the plug forms—leaving gaps through which sperm can pass. But if the injection pressure is too great, this can cause a small tear in the side of the duct, some leakage of sperm, and the formation of scar tissue.

During 1995 and 1996, the New York-based AVSC International and the manufacturer carried out Phase I trials in the Netherlands to assess the effectiveness and any complications associated with the silicone plug method. The study

WHO PHOTO BY H. ANANDEN

involved 74 men who had requested vasectomy—49 using the silicone plug method and a control group of 25 who underwent routine vasectomies. This study was halted after follow-up sperm-counts revealed that, although all the men with silicone plugs had reduced sperm counts, only 5%-10% had undetectable levels of sperm in their semen (i.e. were azoospermic). However, there was less incidence of leakage of sperm through the outer wall of the duct than in the earlier trials carried out in Indonesia.

These findings suggest that a slightly larger volume of silicone may be needed and possibly a greater injection pressure. Other possible adaptations could include reducing the viscosity of the silicone to make it more fluid and quicker to disperse before setting.

During 1997 the Programme did not support any research on the silicone plug method. However, if an improved injection procedure is developed and future company-funded studies produce promising results, the Programme may consider supporting further trials in developing countries. A consultation meeting will be held during the first half of 1998 to review the available data. In the meantime, a Memorandum of Understanding has been agreed with the manufacturer to ensure that, if it proves successful, the eventual product will be made available at the lowest possible price to the public sector in developing countries.

The Programme has also continued to fund two long-term follow-up studies in China on the efficacy and reversibility of two other methods of vas occlusion. One study involved an assessment of return to fertility among 56 men who had undergone microsurgery to reverse a vasectomy, and a further 75 men who had undergone removal of vas occluding medical-grade polyurethane (MPU) plugs. During the three-year follow-up after the reversals, all the men in both groups had sperm in their semen and there was no significant difference between the concentration of sperm after one month. However, from three months onward, the sperm concentration was significantly higher in the plug-removal group. The pregnancy rate was almost 99% in the plug-removal group, compared with 66% in the microsurgery group.

Also in China, the Programme continued to support a prospective 10-centre study to compare the effectiveness of reversal of three methods of vasectomy, using microsurgery: no-scalpel vasectomy; vas occlusion with methylcyanoacrylate (MCA); and vas occlusion with medical-grade polyurethane (MPU) plugs. The reversal was found to be easiest in the no-scalpel group and most difficult in the MCA group, as a result of morphological changes induced in the vas. The highest concentration of sperm and the largest number of pregnancies occurred among the no-scalpel group, followed by the MCA plug-removal group, and the MPU plug-removal group.

Medium-priority leads

Hormone-releasing vaginal ring

In response to women's expressed need for long-acting,

effective methods of contraception which are under their own control, the Programme is continuing to support the development of a hormone-releasing vaginal ring.

Following collaboration with industry in testing a series of different progestogens released from vaginal rings, a prototype ring releasing a small daily dosage of levonorgestrel was selected for development. In 1990, after the completion of tests for safety, efficacy, and acceptability, the Programme concluded a licensing agreement with a company based in the United Kingdom for the manufacture and distribution of the product. However, following reports of vaginal lesions among women involved in Phase III clinical trials, it was decided to redesign the ring into a thinner, more flexible device that would exert less pressure on the vaginal wall. Results from a subsequent multicentre trial of a redesigned placebo ring suggest that the ring does not produce lesions and that it would be suitable for future development.

In 1997, the company to which the ring was licensed decided to withdraw from the project and focus instead on the development of a combined contraceptive ring releasing a progestogen and an estrogen. As a result, negotiations have been initiated for the return of the licence to the Programme.

Because of concern at the limited efficacy of the current dosage of levonorgestrel—especially for heavier women—the Programme is now considering to develop a new, higher-dose version of the redesigned vaginal ring in collaboration with CONRAD.

Natural family planning

Although surveys indicate that the rhythm or calendar method is the most extensively used method of natural family planning worldwide, there has been little or no scientific evaluation of any of the suggested calendar-based rules for determining the period of abstinence.

The Programme is collaborating with the Institute for Reproductive Health (IRH) at Georgetown University in the USA in studies to determine how couples identify the fertile period. The studies reveal key differences in knowledge of how to use the method between people in developing countries and elsewhere.

In Peru, the Philippines, and Sri Lanka the women interviewed had generally been taught about the method by a relative or friend and had only a limited understanding of how it worked. Some tried to increase the reliability of the method by extending the period of abstinence—sometimes inappropriately. There was a strong demand among these users for information and counselling on the calendar-based rules. Their reasons for choosing this method of contraception included its low cost, availability, and freedom from side-effects. On the other hand, in Hungary, all those interviewed reported the appropriate use of a combination of cervical mucus observations, body temperature monitoring, and/or use of the calendar method. Couples reported having chosen the method after experiencing side-effects from

other contraceptive methods and said they considered it a healthier and more natural method. They appreciated the closeness that the method encouraged between sexual partners as well as the freedom of sexual expression during the non-fertile period.

During 1998–1999, the Programme intends to collaborate with IRH in supporting a multicentre trial to assess the efficacy and acceptability of a simplified calendar method.

Lactational amenorrhoea method

Since 1984 the Programme has supported research on the contraceptive effect of breast-feeding. The aim is to determine the duration of infertility, the indicators for the end of infertility, and the mechanism involved in suppression of the ovaries during the breast-feeding period. The information will especially benefit women who have no other means of contraception as well as countries with limited resources for family planning.

In 1988, a group of international scientists meeting in Bellagio, Italy, issued a consensus statement on the effect of breast-feeding on fertility. In what became known as the Bellagio Consensus, they concluded that women who are fully or almost fully breast-feeding and amenorrhoeic have a less than two per cent risk of becoming pregnant during the first six months after delivery. Guidelines issued in 1989 point out that, once women no longer meet all three criteria, they should adopt another family planning method if they wish to avoid pregnancy.

In December 1995, a second Bellagio conference confirmed the earlier findings and concluded that it may be possible to reduce the criteria without comprising the effectiveness of the method. While amenorrhoea remains a key requirement for ensuring low risk of pregnancy, it may be possible to relax the requirement of full or almost full breast-feeding and to extend the duration of use beyond six months.

Additional research is now needed to establish the conditions under which the modified requirements can be adopted. However, funds for this area of research have declined—despite the revived interest in breast-feeding in many countries as a result of the UNICEF/WHO baby-friendly hospital initiative. No new research was initiated by the Programme during the 1996–1997 biennium and no further studies are planned during the 1998–1999 biennium.

Low-priority leads

Estrogen-free oral contraceptives

The most common reasons for discontinuation of combined oral contraceptives are hormonal side-effects—mainly due to the estrogen component in the pills—and the fear of long-term adverse effects such as the risk of cardiovascular complications or breast cancer. The emergence of antiprogestogens, which interfere with the normal development of maturing follicles in the ovaries, has opened the way for development of a new type of estrogen-free sequential pill. The replacement of estrogen by an antiprogestogen would avoid the estrogen-induced side-effects and

possibly lower the risk of certain types of cancer.

To investigate the feasibility of this approach, the Programme has carried out a study involving the use of 5 mg of mifepristone during the first 15 days of the menstrual cycle, followed by 10 mg of medroxyprogesterone acetate (MPA) up to the 28th day of the cycle. The study, involving 10 sterilized women volunteers over three menstrual cycles, found that menstruation was fairly regular and that 50% of the women did not ovulate during the three cycles. Endometrial biopsies taken during the third menstrual cycle showed either delayed or irregular development.

Levonorgestrel-releasing IUD

Previous studies have demonstrated that IUDs that release a regular dosage of a progestogen are effective in preventing pregnancy and in reducing menstrual blood loss. However, a major drawback of these IUDs was their short life span (12–18 months) which is too short for most family planning programmes.

A higher-dose levonorgestrel-releasing IUD, developed with support from The Population Council, was found to have a pregnancy rate of 1.1 per 100 woman–years after five years. However, by then, one in five users had discontinued the method because of persistent amenorrhoea.

Between 1993 and 1997, the Programme launched a series of studies, involving over 3000 women in 20 centres, to compare the use of a copper IUD (TCu380A) and the higher-dose levonorgestrel-releasing IUD. Initial findings show that, while failure rates were almost identical after three years, use of the levonorgestrel-releasing IUD resulted in significantly higher rates of removal for medical reasons, bleeding (with or without pain), amenorrhoea, and hormone-related reasons. By the third year, there were only two removals for amenorrhoea for the TCu380A device compared to 146 for the levonorgestrel-releasing IUD. These comparative studies will continue throughout the 1998–1999 biennium.

Expanding family planning options

Highlights

• **The Programme continues to play a major role within the interagency Consortium on Emergency Contraception, providing technical input to ensure the availability of emergency contraception in developing countries. In its efforts to introduce emergency contraception, the Consortium has adopted the strategic approach developed by the Programme. The aim is to ensure that the new method is introduced within a broad range of contraceptive methods and not promoted as a primary method of contraception.**

Emergency contraception was first used in the 1960s, but it is not yet widely known or available. Wider use of this method could prevent millions of unwanted pregnancies and abortions.

• **In support of efforts to introduce the female condom in developing countries, the Programme is coordinating a female condom working group, in collaboration with WHO's Division of Reproductive Health (Technical Support) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The working group has produced information materials, initiated research, and provided assistance in making the product available. An information pack has been produced for policy-makers, programme managers, and others involved in reproductive health care.**

The female condom is a woman-controlled method and the only contraceptive for women that can protect against both pregnancy and sexually transmitted diseases (STDs). However, the method—like emergency contraception—is virtually unknown to both providers and potential users. Its use in developing countries should help to prevent the transmission of STDs (including HIV) and pregnancy.

• **Work has continued on making Cyclofem and Mesigyna—the once-a-month injectables developed by the Programme—available to developing countries. The Concept Foundation—a Bangkok-based non-governmental organization committed to making reproductive health technology available to developing countries—has closely monitored the quality of Cyclofem produced in Indonesia and Mexico, and obtained registration of the product in 15 countries. An application has been made in the USA for registration of Cyclofem and registration in the European Union is also being sought.**

Registration of Cyclofem in the USA would allow it to be distributed in developing countries by the US Agency for International Development (USAID).

The strategic approach used to increase contraceptive choice by ensuring a mix of existing methods (see Chapter on *Assessing an improving reproductive health services*) is also being applied for methods which are new or unknown to potential users and providers. The aim is to establish awareness of the availability of new methods within the existing mix of methods. Initial trials are focusing on two methods: emergency contraception and the female condom.

Emergency contraception

Emergency contraception—involving the use of a high dose of estrogen—was first used in the 1960s to prevent pregnancy in rape victims. In the early 1980s the high-dose estrogen treatment was replaced by a modified regimen of combined oral contraceptive pills known as the Yuzpe regimen after its inventors. Since then emergency contraception has been used by women in the event of unprotected intercourse or recognized contraceptive failure. However, emergency contraception is not yet widely known or available. Wider use of this method could prevent millions of unwanted pregnancies and abortions.

The Programme continues to play a major role within the interagency Consortium on Emergency Contraception[1], providing technical input to ensure the availability of emergency contraception in developing countries. In its efforts to introduce emergency contraception, the Consortium has adopted the strategic approach developed by the Programme. The aim is to ensure that the new method is introduced within a broad range of contraceptive methods and not promoted as a primary method of contraception. Careful planning is essential to ensure that the public, including religious and political leaders, are aware that this method is not a form of abortion. Emergency contraception should be available in the event of contraceptive failure and promoted as a bridge to other contraceptive services, especially for young people. In addition, it should be readily available on demand for those who need it.

Preliminary studies are focusing on user perspectives on contraceptive methods and service delivery, and determine what changes are needed in both service delivery and management to provide quality emergency contraception services. The Consortium is currently focusing on the introduction and availability of the emergency contraceptive Postinor-2, comprising two 750 mcg tablets of levonorgestrel, available in a blister pack.

The Programme and The Population Council are the lead agencies for the research and evaluation involved in the studies

[1]The member organizations of the Consortium are: The Concept Foundation (Bangkok), the International Planned Parenthood Federation (London), the Pacific Institute for Women's Health (Los Angeles), Pathfinder International (Boston), The Population Council (New York), the Program for Appropriate Technology in Health (Seattle), and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (Geneva).

on the introduction of emergency contraception in Indonesia and Sri Lanka (the Programme) and in Kenya and Mexico (The Population Council). Initial assessments carried out in Indonesia and Sri Lanka in early 1997 revealed little or no awareness of emergency contraception as well as many misconceptions about the method. These findings were used in the design of introductory studies, information materials, and training for providers. Limited service provision of Postinor-2 began in both countries in 1997. In Sri Lanka, where an emergency contraception hotline was set up, demand has been significant, while in Indonesia there has been only a small uptake so far. An evaluation of the provision and uptake of Postinor-2 in both countries will be carried out in late 1998.

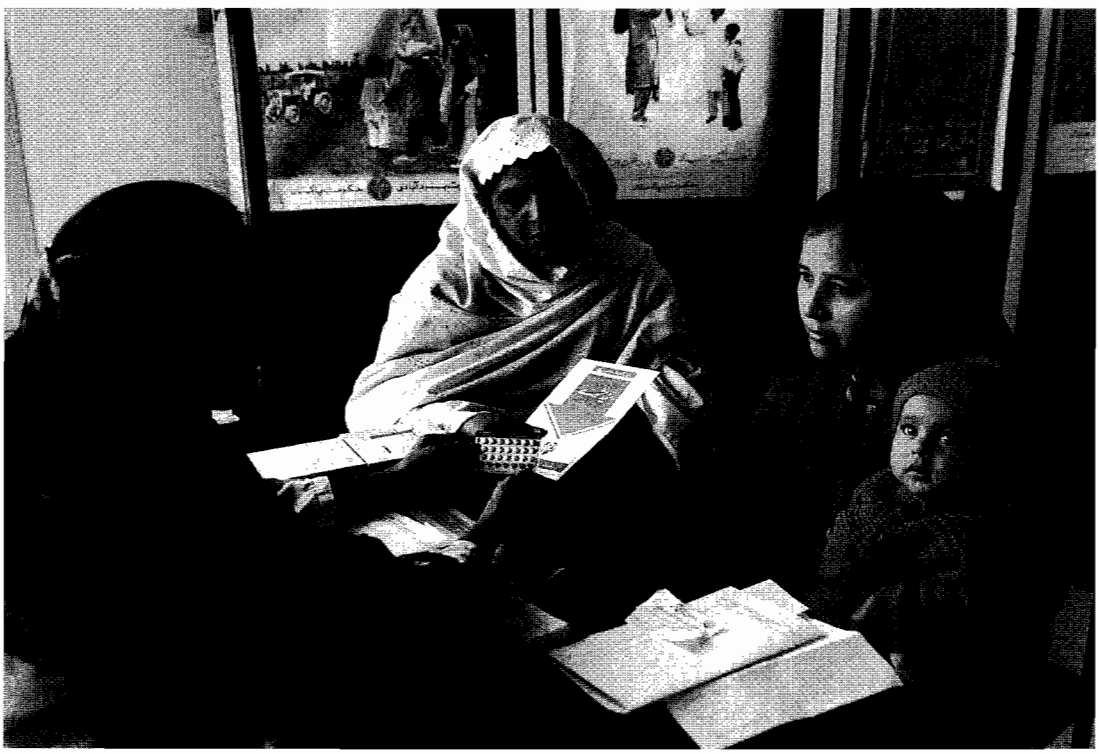
Introductory studies are also due to begin in Pakistan and Tanzania in 1998. Elsewhere, the Yuzpe method of emergency contraception is being introduced in South Africa and Zambia.

The Consortium, which was established in late 1995, has produced a package of information and advocacy materials, including service delivery guidelines, a framework for introduction, as well as information material for clients, providers, and decision-makers. A model training curriculum is also available.

The female condom

The female condom is a woman-controlled method and the only contraceptive for women that can protect against both pregnancy and sexually transmitted diseases (STDs). However, the method—like emergency contraception—is virtually unknown to both providers and potential users.

Acceptability studies carried out in several countries have



UNICEF PHOTO BY JOHN ISAAC

shown that the method is acceptable to some women and men, including first-time family planning users. The method would also be suitable for women at high risk of contracting or transmitting HIV and other STDs and for those seeking alternative contraceptive methods.

In support of efforts to introduce the female condom, the Programme is coordinating a female condom working group, in collaboration with WHO's Division of Reproductive Health (Technical Support) (RHT) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The working group has produced information materials, initiated research, and provided assistance in making the product available. An information pack has been produced for policy-makers, programme managers, and others involved in reproductive health care. Meanwhile, the working group is continuing to review information on the use of the female condom as well as the outcome of research studies. Guidelines for programme managers on the introduction of this method are now being developed.

The Programme is also supporting research on the contraceptive efficacy and acceptability of the female condom. Programme-supported studies are also under way in South Africa to determine whether the female condom can be safely re-used. It is anticipated that, because of its relatively high price, the product will be used more than once. If the studies show this to be safe and viable, guidelines will be developed for the safe re-use of the product. Meanwhile, in an effort to make the female condom more widely available, UNAIDS and WHO have negotiated a public sector price of about US$ 0.60 and are continuing to monitor cost-related issues.

Monthly injectable contraceptives

Injectable contraceptives have been in use for over 20 years and are now used by about 15 million women worldwide. The most widely used products are DMPA (depot-medroxyprogesterone acetate) which provides contraceptive protection for three months after a single injection, and NET-EN (norethisterone enantate) which protects for two months. Although these methods are highly effective, the progestogen content causes irregular menstrual bleeding—a factor that has limited their more widespread use.

In efforts to provide a suitable alternative, the Programme has developed two injectable products for use on a monthly basis: Cyclofem and Mesigyna. Both products contain an estrogen as well as a progestogen, thus ensuring a regular monthly bleeding pattern for most women who use them.

Over the past two years, work has continued on making once-a-month injectables available to developing countries. The Concept Foundation—a Bangkok-based non-governmental organization committed to making reproductive health technology available to developing countries—has closely monitored the quality of Cyclofem produced in Indonesia and Mexico, and obtained registration of the

product in 15 countries. In Mexico, production of Cyclofem in a non-reusable syringe (Uniject) has been delayed and is now due to begin in the second half of 1998. In the USA, an application has been made for registration of the product with the US Food and Drug Administration (FDA), which would allow distribution by the US Agency for International Development (USAID). Registration in the European Union is also being sought.

Mesigyna is available in the private sector in Latin America and the manufacturer is now planning to make it available in Pakistan.

Evaluating reproductive health care

Highlights

- **A WHO Scientific Group reviewed the results of the Programme's study as well as other studies on the effect of the use of hormonal contraceptives and other risk factors on the risk of cardiovascular disease and whether the risk of cardiovascular disease varies between different compositions of combined oral contraceptives. The Group concluded that for women of reproductive age the overall incidence and death rate from cardiovascular disease is very low, and that any heightened risk for women who use oral contraceptives is very small if they do not smoke or have other cardiovascular risk factors. However, the risk of heart attack and stroke among women who smoke or have high blood pressure is further increased by the use of combined oral contraceptives.**

  This expert opinion has important implications for the use and prescription of hormonal contraceptives.

- **A study has found that the use of depot-medroxyprogesterone acetate (DMPA) has a strong protective effect against uterine myoma. The protective effect appears to last for more than 10 years after the last DMPA injection.**

  The over 12 million users of DMPA and past users will find these results reassuring.

- **A study is under way to determine the effect of oral contraceptives on women with a history of gestational diabetes (diabetes during pregnancy). Another study is examining the relationship between the use of hormonal contraceptives and bone mass.**

  The use of oral contraceptives can lead to changes in blood sugar levels as well as in the level of insulin and glucose in the body. The study will provide new knowledge on the safety of oral contraceptives for women who had impaired glucose tolerance during a previous pregnancy. Osteoporosis affects an estimated 75 million people in Europe, Japan, and the USA, including one in three postmenopausal women and most elderly people. The study on bone mass in users of oral contraceptives will contribute new knowledge about the safety of hormonal contraceptives.

- **Data collection for a major five-year collaborative study involving post-marketing surveillance of women using the contraceptive implant Norplant was completed in 1997. The aim was to discover any major short- or medium-term side-effcts that may not have been identified in clinical trials.**

  This study will provide information on the safety of Norplant under normal conditions of use.

- **To assess the feasibility of carrying out a study of the possible effects of non-surgical abortion on future births, surveys were carried out in Beijing, Chengdu, and Shanghai on the prevalence of previous non-surgical abortions among pregnant women attending antenatal clinics. The prevalence was found to be almost 10% in Beijing, over 17% in Chengdu, and 3% in Shanghai. The main study will begin in these cities during 1998.**

  This study will provide information on the effect of non-surgical abortion on the outcome of subsequent pregnancies.

- **Analysis of data from the WHO Collaborative Study on Neoplasia and Steroid Contraception has provided reassuring evidence that the risk of endometrial cancer is not increased by use of the intrauterine device (IUD). These findings were not affected by the duration of use or by the age of the user when the device was inserted or removed.**

  Over 110 million women use the IUD for contraception. This finding further strengthens the knowledge on the safety of copper-bearing modern IUDs.

- **A study—the first of its kind—is being conducted to determine the effect of steroid hormone contraceptives on the progression of HIV infection. The study will include two groups of women who are HIV-positive but have not yet developed AIDS: women using steroid hormone contraceptives, and those using non-hormonal methods of contraception.**

  The findings from this study are expected to have major implications for the care and family planning practice of HIV-positive women.

- **A study was launched to determine whether the use of hormonal contraceptives by HIV-positive women increases the amount of HIV shed in the lower genital tract. Another study is examining whether the use of hormonal contraceptives leads to thinning of the lining of the vagina and whether this affects local immunity and modifies susceptibility to HIV and other sexually transmitted infections.**

  The findings of the first study will have important implications for prescription of hormonal contraceptives to HIV-positive women. The second study will provide the basic physiological information needed to understand the relationship between the use of hormonal contraceptives and transmission of STDs (including HIV).

- **Recruitment is nearing completion for the first multicentre trial to evaluate the impact of a new antenatal care programme on the health of mothers and newborns. The new programme consists of four antenatal visits, and it limits antenatal tests, clinical procedures, and follow-up actions to those scientifically proved to be effective in improving the health of mothers and newborns.**

  This study is expected to have major implications for optimizing the use of resources in reproductive health care services.

- **A multicentre trial of misoprostol was launched to evaluate the drug's effectiveness when used to reduce blood loss during the third stage of labour. The study, involving 20 000 women in nine countries, will compare rates of severe postpartum haemorrhage among women given oral misoprostol and those given injected oxytocics.**

  If misoprostol is found to be effective, this is expected to lead to large-scale trials of the prostaglandin in rural areas where medically trained staff are not available.

- **The Programme is planning to conduct a series of studies on the prevalence of genital tract infections in selected populations and epidemiological studies on lower genital tract infection and the effect of male chlamydial infection on sperm function.**

  These studies are important because there is little information available on the prevalence of STDs in developing countries. Moreover, most available information is based on limited data from selected samples involving high-risk groups in geographically disparate regions.

Steroid hormone contraceptives and the risk of cardiovascular disease

The main work has now been completed on a WHO collaborative study to determine whether the use of steroid hormone contraceptives increases the risk of cardiovascular disease (heart attack, strokes, and venous thromboembolism).

Currently used, low-dose combined oral contraceptives (containing an estrogen and a progestogen) were developed after the earlier generation of higher dose combined pills used in the 1960s and 1970s was found to increase the risk of cardiovascular diseases. By 1985, combined pills contained a third less estrogen and a tenth of the progestogen dose of the pills in use in the 1960s. In addition, some of the current brands contain newer progestogens.

The introduction of low-dose pills led to an apparent reduction in the risks associated with the earlier combined pills. But the information was based almost exclusively on data from developed countries and it was unclear to what extent other factors may have contributed to this.

The aim of the WHO study was to examine the risk from currently available oral contraceptives and to assess to what extent the apparently lower risk was associated with:

- more careful screening by doctors to avoid use of the pills by women at risk of cardiovascular disease
- improved diagnosis for these diseases
- the new pill formulations.

An additional objective was to assess the risk of cardiovascular disease associated with progestogen-only contraceptives.

The study, involving almost 3800 women under the age of 45 years with cardiovascular disease and a control group of 11 200 women, was carried out in 17 countries in Africa, Asia, Europe, and Latin America. The study, which was coordinated by the Department of Epidemiology and Public Health, University College Medical School, London, was the first of its kind to focus mainly on women in developing countries.

The findings relating to venous thromboembolism were published in 1995, those on stroke in 1996, and the findings on heart attacks in 1997. The results relating to cardiovascular risk and the use of other hormonal methods, including progestogen-only pills and injectables, and combined injectables, are due to be published in the journal *Contraception*.

In November 1997, WHO convened a Scientific Group Meeting on Cardiovascular Disease and Steroid Hormone Contraception to review the results of the WHO study and other available scientific data on:

- the overall incidence of cardiovascular disease among women of reproductive age
- the impact of the use of hormonal contraceptives and other risk factors (including high blood pressure, diabetes, and smoking) on the risk of cardiovascular disease
- whether the risk of cardiovascular disease varies between different compositions of combined oral contraceptives.

The Scientific Group concluded that for women of reproductive age the overall incidence and death rate from cardiovascular disease are very low, and that any heightened risk for women who use oral contraceptives is very small if they do not smoke or have other cardiovascular risk factors. However, the risk of heart attack and stroke among women who smoke or have high blood pressure is further increased by the use of combined oral contraceptives.

The Scientific Group also assessed the possible links between the use of oral contraceptives and specific forms of cardiovascular disease:

Heart attack

For women with no risk factors for cardiovascular disease, there is no increase in the relative risk of heart attack, regardless of age. Nor is there any increased risk for former users of combined oral contraceptives.

Ischaemic stroke (involving a blood clot or restricted blood flow)

For women with no risk factors for cardiovascular disease, the risk of ischaemic stroke is increased by about 1.5-fold. The level of risk does not increase with prolonged use of oral contraceptives, and there is no increased risk for women who had used oral contraceptives in the past.

Haemorrhagic stroke (involving a burst blood vessel)

For women under 35 who are non-smokers and do not suffer from hypertension, the use of oral contraceptives does not increase the risk of haemorrhagic stroke, regardless of the duration of use. And there is no increased risk for past users. However, there is a 2-fold increase in risk among users of oral contraceptives who are over age 35.

Venous thromboembolism

While current users of combined oral contraceptives have a low absolute risk of venous thromboembolism, it is 3–6 times higher than that of non-users. The risk is probably greatest in the first year of use. Although the risk declines with continued use, it persists until discontinuation. Formulations containing desogestrel and gestodene probably carry a small increased risk of venous thromboembolism beyond that attributable to formulations containing levonorgestrel.

The IUD and endometrial cancer

Analysis of the large amount of data from the WHO Collaborative Study on Neoplasia and Steroid Contraception has provided reassuring evidence that the risk of endometrial cancer is not increased by use of an intrauterine device (IUD). These findings were not affected by the duration of use or by the age of the user when the device was inserted or removed.

DMPA and uterine myoma

A hospital-based study involving over 3500 women in Thailand has been assessing the relationship between the use of the 3-monthly injectable contraceptive depot-medroxyprogesterone acetate (DMPA)—used by

about 12 million women worldwide—and the development of uterine myoma. The study found that the use of DMPA had a strong protective effect against uterine myoma (fibroids) and that it was even greater for women who had used DMPA for longer than five years. The study also found that the protective effect lasts for more than 10 years after the last DMPA injection. The authors of the study estimated that the number of surgical interventions for uterine myoma would have been 7% higher without the current level of DMPA use in Thailand.

An unexpected finding of this study was that the risk of uterine myoma was higher among women who had been sterilized using the tubal ligation method.

Oral contraceptives and diabetes

The Programme is supporting a study in Venezuela to determine the effect of oral contraceptives on women with a history of diabetes during pregnancy. The use of oral contraceptives can lead to changes in the blood sugar level as well as in the levels of insulin and glucagon in the body. The study compares carbohydrate metabolism in women using a standard oral contraceptive containing ethinylestradiol and levonorgestrel and in those using non-hormonal contraceptive methods. Data collection is expected to be completed by the end of 1998.

Hormonal contraceptives and bone density

A study on the relationship between the use of hormonal contraceptives and bone density is now nearing completion. Loss of bone mass leads to development of osteoporosis, commonly known as "brittle bone disease". Osteoporosis affects an estimated 75 million people in Europe, Japan, and the USA, including one in three postmenopausal women and most elderly people. The disease is rare in Africa, common in India, and occurs most frequently in Europe and North America. Osteoporosis and associated fractures are a major cause of sickness, death, and medical expense worldwide.

The study was carried out in seven centres in Bangladesh, Brazil, China, Egypt, Mexico, Thailand, and Zimbabwe and involved over 2500 women aged 30–34. Bone mass was compared between women who had used hormonal contraceptive methods for at least 24 months and a control group of women with no or less than six months' experience of using hormonal methods. The data are now being analysed.

Post-marketing surveillance of Norplant

Data collection for a major collaborative study involving post-marketing surveillance of women using the contraceptive implant Norplant was completed in 1997. The study, which was carried out by Family Health International. The Population Council, and the Programme, involved over 16 000 women in 32 family planning clinics in eight developing countries.

The aim was to discover any major, short- or medium-term side-effcts that may not have been

identified in clinical trials. The study compared rates of complications and disease among Norplant users with those for women who chose an IUD or sterilization. The women were followed up for five years, even if they switched to another contraceptive method. The overall follow-up rate was over 96%—far higher than expected.

The study was coordinated by the Programme, which supported the studies in Egypt, Indonesia, Sri Lanka, and Thailand. Participating centres in Bangladesh were supported by Family Health International, while The Population Council supported those in China and Colombia. The findings of the study were reported at a meeting at the Washington DC-based Institute of Medicine and at the XV FIGO World Congress of Gynecology and Obstetrics in Denmark. Further analysis of the results is now under way.

Safety and efficacy of intrauterine devices (IUDs)

A series of major studies on the safety and efficacy of IUDs has produced a mass of data of key importance for family planning services and women. The IUD is currently used by about 110 million women—mainly in developing countries. It is the second most widely used form of contraception after sterilization.

The multicentre studies, launched by the Programme between 1978 and 1982, focused on three copper IUDs—TCu220C, TCu380A, and the Multiload—which were at that time being introduced into family planning programmes in developing countries.

The results of the studies on the use of TCu220C and TCu380A by women at 9,11, and 13 years were published in 1997. The pregnancy rate for women using the TCu380A was significantly lower at every stage than for those using the TCu220C. However, after 11 and 13 years of use, the TCu220C had a significantly lower rate of removal due to pain, bleeding, or both. For both devices, most removals after 11 years

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were for non-medical reasons. After 13 years, 51% of women using the TCu220C and 57% of those using the TCu380A had stopped using it for non-medical reasons. The most frequently cited reasons were the intention to become pregnant and "no further need". Pregnancy rates for both devices were consistently higher, for unknown reasons, in the Chinese participating centres than in non-Chinese centres.

Meanwhile, another ongoing multicentre study, involving over 3500 women in eight countries, is comparing the safety and efficacy of the Multiload 375 and TCu380A devices. Results after seven years show that women using the Multiload 375 had higher rates of pregnancy and expulsion than those using the TCu380A. The difference in the rate of pregnancy is seen after two years but only becomes significant after four years. In this study, the data from the Chinese centres involved does not vary from the findings elsewhere.

Condoms

Contraceptive efficacy of condoms

Although studies have confirmed that the use of condoms is effective in preventing transmission of sexually transmitted diseases (STDs), including HIV/AIDS, findings on their contraceptive efficacy have shown wide variations. It is believed that most failures are the result of incorrect use rather than method failure.

The Programme is supporting a study in two centres in China to determine the comparative effectiveness (of both the method and its use) between using the condom alone and using the condom together with hormonal emergency contraception. The study is due to be completed by late 1998.

Non-latex and standard latex male condoms

New non-latex male condoms have now been developed which have a longer shelf-life than standard latex condoms and may be more acceptable to users. However, acceptability has only been evaluated so far among couples using other forms of contraception, and there is little information on the relative effectiveness of the two kinds of condoms in preventing pregnancy.

A new comparative research study will examine pregnancy rates among 3000 volunteers from several countries using two types of non-latex condoms and standard latex condoms. Volunteers will be asked to keep a diary, recording acts of sexual intercourse and details of condom usage over a six-month period—enabling researchers to distinguish between user and method effective-ness. In addition, continuation rates for all three types of condom will be examined.

The study will also determine breakage and slippage rates for the three types of condom and assess whether this can be used to simplify premarketing testing of new condoms for approval by regulatory authorities.

Vasectomy and prostate cancer

Although most studies have shown that vasectomy is a safe contraceptive method with

no adverse consequences for health, two studies from the USA in 1993 suggested that 20 years after vasectomy there was an increased risk of developing prostate cancer. While other studies from the USA and the United Kingdom did not support these findings, recently published work from China and India also indicates an elevated risk of prostate cancer in men who have undergone vasectomy.

In view of these conflicting findings, the Programme launched a hospital-based study in China, Nepal, and the Republic of Korea—countries where vasectomy is widely used. The study included over 400 men with prostate cancer, and a control group of over 1200 men without the disease. Data collection has now been completed in all three countries and analysis is due to start in early 1998. The Programme has also provided technical assistance to the Indian Council of Medical Research, New Delhi, India, to facilitate a similar multi-centre study in India, and is also supporting a multicentre study in New Zealand.

Abortion

Unsafe abortions

WHO estimates that 20 million unsafe abortions are carried out every year—95% of them in developing countries. In an effort to determine the extent of complications and deaths arising from unsafe abortions, and the health care costs involved, the Programme launched a series of hospital-based studies in nine countries where access to safe abortion is limited. The studies, carried out in Bangladesh, Benin, Brazil, Chile, Ethiopia, Guatemala, Senegal, Thailand, and Uganda, have highlighted the severe consequences (including death) of unsafe abortions for women's health (see also page 14).

Impact of induced abortion on future pregnancies

Since many women who terminate an unwanted pregnancy intend to have a child at a later date, it is important to establish whether induced abortion will have any adverse effects on a future pregnancy.

An abortion performed by skilled personnel and carried out by vacuum aspiration during the first three months of pregnancy has been amply demonstrated to be a safe procedure, with few, if any, long-term adverse effects. However, there is a need to determine the possible consequences of multiple abortions and abortion in young women who have never given birth.

Since 1994, the Programme has been supporting a hospital-based study in China, where about 10 million legally induced abortions are carried out every year. The study involves following a group of women from the eighth week of pregnancy through to the birth to determine any differences in the outcome of pregnancy between those who previously had an abortion and those who had not. The study focuses on events such as illnesses during pregnancy, spontaneous abortion, premature births, low birth weight, and infant deaths and illnesses at or near the time of the birth. The

findings are due to be published in late 1998 or early 1999.

Non-surgical abortion

In China, the use of non-surgical abortion to terminate early pregnancies (up to 63 days) is increasing rapidly. This abortion method involves taking an antiprogestogen pill (mifepristone) followed 36–48 hours later by oral vaginal administration of a prostaglandin analogue. There is, at the present time, no scientific information on the effect of non-surgical abortion on the outcome of subsequent pregnancies.

To assess the feasibility of carrying out a study of the possible effects of non-surgical abortion on future births, surveys were carried out in Beijing, Chengdu, and Shanghai on the prevalence of non-surgical abortions among pregnant women attending antenatal clinics. The prevalence was found to be almost 10% in Beijing, over 17% in Chengdu, and 3% in Shanghai.

The main study will begin in these cities during 1998, involving 4500 women with a history of non-surgical abortion, 4500 women with a history of surgically-induced abortion during the first three months of pregnancy, and 4500 women with no history of induced abortion. The women will be enrolled at their first antenatal care visit and followed up until one month after giving birth.

Contraception and HIV

Use of contraceptive steroids by women infected with HIV

Most women infected with HIV are of reproductive age. Since HIV infection does not appear to affect fertility, women who are HIV-positive continue to need a reliable method of contraception. However, some of the most effective methods of contraception involve the use of steroid hormones and it is not known whether these will have an effect on the progression of HIV/AIDS—either by interacting with the virus itself or indirectly through their effect on the immune system.

The Programme is now carrying out a study—the first of its kind—to determine the effect of steroid hormone contraceptives (including oral contraceptives, the injectable contraceptive DMPA, and the contraceptive implant Norplant) on the progression of HIV/AIDS. The comparative study will include two groups of women who are HIV-positive but have not yet developed AIDS: women using steroid hormone contraceptives, and those using non-hormonal methods of contraception (sterilization, barrier methods), or no contraception. Women will be recruited from four centres in Brazil, Thailand, and Zambia, including 660 using hormonal methods and 340 using non-hormonal or no methods. They will be followed up every six months over four years to assess the progression of HIV/AIDS. The findings are expected to have major implications for the care and family planning practice of HIV-positive women.

Steroid hormone contraception and shedding of HIV

The Programme has launched a study to determine whether the use of hormonal contraceptives by HIV-positive women increases

the amount of HIV shed in the lower genital tract. The findings of this study will have important implications for prescription of hormonal contraceptives to HIV-positive women.

Four groups of HIV-positive women will be enrolled in the study: current users of the contraceptive implant Norplant, the contraceptive injectable DMPA, oral contraceptives, and non-hormonal methods. The tests will include specimens taken from the lower genital tract as well as regular blood tests to determine the level of HIV infection and measure hormone levels.

Effect of steroid hormones on vaginal lining

The Programme is supporting a study to determine whether the use of hormonal contraceptives leads to thinning of the lining of the vagina and changes in local immunity, and whether these in turn modify susceptibility to HIV infection, as well as other sexually transmitted agents including human papillomavirus (HPV). The study is being done in response to recent data from animal studies showing that the monkey equivalent of HIV, simian immunodeficiency virus (SIV), can be transmitted through the vaginal lining (epithelium). Research has also shown that administering progesterone to monkeys leads to thinning of the vaginal lining and increased susceptibility to SIV infection.

The study is being carried out in Sweden and includes women using combined oral contraceptives, the contraceptive injectable DMPA, and the contraceptive implant Norplant, as well as a group of women using non-hormonal methods. Vaginal biopsy specimens will be used to measure the effect of hormonal contraceptives on the thickness of the vaginal epithelium in comparison with that of women using non-hormonal methods.

New antenatal care programme

Recruitment is nearing completion for the first multicentre trial to evaluate the impact of a new antenatal care programme on the health of mothers and their newborns. The new programme consists of four antenatal visits, and limits antenatal tests, clinical procedures, and follow-up actions to those scientifically proved to be effective in improving the health of mothers and newborns.

The study is being carried out in collaboration with WHO's Division of Reproductive Health (Technical Support) at four centres in Argentina, Cuba, Saudi Arabia, and Thailand. It will involve about 25 000 women recruited at antenatal clinics over an 18 month period. Since recruitment began in May 1996, almost 22 000 women have been enrolled in the study. Recruitment in Cuba, Saudi Arabia, and Thailand was completed by the end of 1997 and will end in Argentina in April 1998.

The study will focus on key indicators for maternal and newborn health including: preeclampsia (high blood pressure accompanied by protein in the urine, and fluid retention) and life-threatening eclampsia, anaemia following childbirth, severe urinary tract infection, and low birth weight babies.

Use of misoprostol in third stage of labour

Postpartum haemorrhage is a leading cause of maternal death in both developing and developed countries. Although the use of oxytocics in the management of the third stage of labour reduces the amount of bleeding and the need for blood transfusions, these agents can produce side-effects, are administered by injection, and have to be kept under refrigeration.

Some prostaglandin preparations have proved to be potentially effective in preventing postpartum haemorrhage but these are expensive and have to be administered by injection. There is a need for a cheap, effective, oral preparation which could be routinely used during the third stage of labour in places where refrigeration is not available and there is a shortage of medically trained staff.

Misoprostol—a prostaglandin currently marketed as Cytotec in over 60 countries for use in the prevention and treatment of gastric ulcers—has attracted widespread attention because of its ability to trigger strong uterine contractions. Misoprostol remains effective after storage for long periods at room temperature and is rapidly absorbed after oral administration.

In 1997, the Programme launched a multicentre trial of misoprostol to evaluate its effectiveness when used to reduce blood loss during the third stage of labour. The study, involving 20 000 women in nine countries (Argentina, China, Egypt, Ireland, Nigeria, South Africa, Thailand, and Viet Nam), will compare rates of severe postpartum haemorrhage among women given misoprostol and those given oxytocics. If misoprostol is found to be effective, this is expected to lead to large-scale trials of the drug in rural areas where medically trained staff are not available.

Prevalence of sexually transmitted diseases

The Programme is planning to conduct a series of studies on the prevalence of genital tract infections in selected populations, epidemiological studies on lower genital tract infection, and the effect of male chlamydial infection on sperm function.

Chlamydial lower genital tract infection

There is little information available on the prevalence of STDs in developing countries. Most available information is based on limited data from selected samples involving high-risk groups in geographically disparate regions. However, studies on the prevalence of active chlamydial and gonococcal lower genital tract infections among both low- and high-risk populations can give some indication of epidemiological patterns. A series of Programme-supported studies on the prevalence of lower genital tract infections has been launched and others are planned in several countries.

In China, although STDs are not as common as in other Asian countries, surveys carried out in STD clinics suggest that the prevalence of STDs is increasing. Studies are being carried out in three

provinces involving women undergoing an induced abortion and others attending family planning clinics. Both groups are being tested for chlamydial infection and other STDs. Meanwhile, a multicentre study in China, which has now been completed, indicated that STD prevalence among the groups studied was related to the non-use of condoms, the number of induced abortions, multiple sexual partners, and low socioeconomic status.

In Malaysia, a study has been completed in a STD clinic in Kuala Lumpur on the detection of chlamydia infection in men, using urine samples. The main finding of this study is that, in a population with a high incidence of chlamydial infection, urine analysis is a suitable alternative to analysis of male urethral swabs. There is also evidence that, for women, a urine test could replace a cervical swab. A similar study is now under way in Zimbabwe.

Elsewhere, the Programme has launched a study in Indonesia to determine the prevalence of gonorrhoea and chlamydial infection in both partners of infertile couples, patients with ectopic pregnancy, antenatal women, men and women attending a STD clinic, and a group of 300 commercial sex workers. The study, which is being funded by AusAID, is due to be completed by late 1998.

Prevalence of chlamydial infection in male adolescents

A consequence of the lowering of the age of first sexual intercourse, especially among male adolescents in many societies, has been an increase in the number of young men contracting chlamydial urethritis. Because this infection may produce no symptoms in up to 80% of cases, this group is probably a major source of chlamydial genital tract infection in adolescent or young women.

In Chiang Mai, Thailand, a study on the prevalence of chlamydial urethritis in adolescent males was completed in 1996. The study involved interviews with over 800 male vocational school students, of whom over 60% completed a questionnaire and provided a urine sample. The overall prevalence of chlamydia was 11%. The students who provided urine samples tended to have less sexual experience but a higher rate of previous STDs or urethritis than those who did not give a urine sample. The findings suggest that, while the prevalence of chlamydial urethritis may be high compared to studies in developed countries, it may be overestimated due to overrepresentation of students with a history of STDs or urethritis.

Assessing and improving reproductive health services

Highlights

• Stage I activities involve an assessment of family planning and other reproductive health services. Assessments were conducted in Burkina Faso, Chile, Ethiopia, and Myanmar.

In **Burkina Faso** strengthening the management and quality of reproductive health services, including information, education and communication activities, logistics, human resources, issues related to HIV/AIDS and services for adolescents, was recommended.

The **Chilean** assessment identified the need to broaden contraceptive options by improving the quality of care for existing methods as well as introducing injectable contraceptives. It also highlighted the need for involving men and meeting the reproductive health needs of youth.

In **Ethiopia** a broad range of reproductive health issues was addressed with emphasis given to operationalizing reproductive health, improving quality of care and broadening contraceptive choice.

The **Myanmar** assessment identified the need to expand access to and availability of public sector reproductive health services, to strengthen the capacity of the community and the private sector to provide services, and to improve the quality of care for a range of reproductive health issues, including contraception, management of reproductive tract infections, prevention of unsafe abortion and management of its complications.

• Stage II activities develop appropriate strategies to introduce or reintroduce new and/or existing but underutilized methods while improving the overall quality of care for all methods and reproductive health services more generally. Stage II activities were conducted in Bolivia, Brazil, Myanmar, South Africa, Viet Nam and Zambia.

In **Bolivia** the research focused on improving quality of care and developing a strategy to introduce injectable contraceptives.

In **Brazil** the project developed a municipality-level model for operational and management changes to improve quality of reproductive health services and to broaden contraceptive choice.

In **Myanmar** the Stage II project will develop a district-level model for strengthening family planning and other reproductive health services provided by the public and private sectors, and the community.

The **South African** study aims to expand contraceptive choice by developing a strategy for introducing male and female condoms, emergency contraception and referral systems for sterilizations.

In **Viet Nam** the Stage II study is assisting the Government in developing a strategy for depot-medroxy progesterone acetate (DMPA) introduction within the context of improved quality of care in the provision of all family planning methods.

The **Zambia** project aims at broadening contraceptive options by introducing emergency contraception and DMPA, while strengthening the provision of other methods.

• Stage III activities apply Stage II research findings to policy development and wider programme development and implementation. Stage III activities are under way in Brazil and will soon commence in Viet Nam.

The lessons learned in the Stage II project in one municipality in **Brazil** have been applied to restructure reproductive health services in other municipalities in the country.

Stage I Assessments

Bhutan

A preliminary review was carried out in Bhutan to assess the current availability of contraceptive methods and the need to introduce new methods, in particular the feasibility of introducing the contraceptive implant Norplant.

A wide range of contraceptive methods is already available in Bhutan, including combined contraceptive pills, the contraceptive injectable depot-medroxyprogesterone acetate (DMPA), IUDs, condoms, no-scalpel vasectomy, and tubal ligation. However, access and availability remain constrained and improved quality of IEC materials and strengthened technical and managerial support for family planning services are required.

Although Norplant would provide an additional option as a long-term reversible method, major programmatic challenges would be faced in its introduction.

It was recommended therefore that a full assessment of contraceptive availability and the need for introduction of new methods should be carried out before a decision was made on the possible introduction of Norplant or other new methods. Support for this assessment will be requested as part of the 1998 United Nations Population Fund (UNFPA) country programme.

Bolivia

In Bolivia, a workshop was held in mid-1996 to review the findings of the assessment carried out in 1995 and to develop a plan of action. The report presented at the workshop concluded that, while there has been some improvement in women's health care in Bolivia over recent years, most managers and health workers as well as the public have little understanding of the concept of reproductive health.

Obstetrical services, including antenatal care and delivery, are underused because they are too

The goal of the Programme's work on the Introduction and Transfer of Technologies for Fertility Regulation is to undertake research to help governments in broadening options for fertility regulation, taking into account the needs of individuals and couples and the capabilities of health care services. Three stages are involved in the approach.

Stage I comprises an assessment of the existing status of family planning in a country, the mix of contraceptive methods being provided, the extent of coverage and service infrastructure, as well as obtaining information on users' needs.

Stage II research activities involve the development of the most appropriate means by which new and/or underutilized methods may be best introduced or reintroduced in the context of improved quality of care. This stage involves an examination of the delivery system's ability to provide services, and users' perspectives on the service system and on the specific contraceptive technology. It addresses policy, organizational and management capabilities, as well as quality of care, suggesting changes necessary to introduce a chosen method.

Stage III applies research findings from Stage II to policy development and planning. Decisions are made as to whether or not it is appropriate to expand use of particular methods on a larger scale. If expansion is recommended, a strategic plan for providing the method throughout the family planning programme is developed. This includes preparing training plans, establishing the necessary infrastructure, providing information, education and communication (IEC) materials, upgrading logistics systems, and organizing supply sources and possible local production.

expensive, difficult to access, culturally inappropriate, and the public has little confidence in them.

Despite improvements in family planning services, access remains restricted in many areas due to a shortage of adequately trained personnel, lack of supplies, high cost, and poor location of services. The range of contraceptive options available in the public health sector is largely restricted to condoms, pills, and the intrauterine device (IUD). Access to sterilization (tubal ligation) is difficult and injectables are only available in the private sector. Lack of access to reproductive health services in the public sector leads many women to use private practitioners, traditional medicine, and other health care institutions.

The quality of care in contraceptive services is poor, especially in counselling and free choice of methods. On the other hand, there is a need to take some contraceptive products off the market, including those with an unproven safety record and those for which safer, lower-dose substitutes are available.

Political developments in Bolivia, especially implementation of the Law of Popular Participation, have opened the way for improvements in the quality of health care. However, local government leaders lack the skills needed to identify the most urgent needs or to plan and execute programmes which benefit the population. Meanwhile, at the central level, initiatives are delayed by the slow machinery of government, and quality of care is compromised by a high turnover of personnel, especially physicians.

Other problems highlighted by the Stage I assessment include shortages of drugs, equipment, and other supplies due to an inadequate distribution system; poor monitoring and evaluation of both obstetrical and family planning services; and a failure to involve women in decision-making on the design and implementation of reproductive health services.

In response to these findings, the Ministry of Health has developed a Stage II proposal described later.

Burkina Faso

An assessment was carried out in Burkina Faso in late 1996 by the Cellule de la Recherche en Santé de la Reproduction (CRESAR) with support from UNFPA and technical assistance from The Population Council's regional office for Africa.

The conclusions and recommendations of the assessment report focus on: management and quality of services; IEC and other strategies for the development of reproductive health; gender and sociocultural factors in reproductive health; young people and reproductive health; logistics and human resources; reproductive rights; and issues relating to HIV/AIDS. The findings are now being studied with a view to making plans for Stage II research activities.

Chile

A limited assessment was carried out in Santiago, Chile following a proposal by the Ministry of Health to introduce injectable contraceptives into family planning services.

The assessment team reported that, while some aspects of reproductive health care were good, largely due to the availability of trained midwives, the concept of reproductive health is not widely understood and therefore not implemented at the primary health care level. Care is largely restricted to antenatal care, fertility control, and breast-feeding.

Among the unmet needs identified were: reproductive health of adolescents; better advice on family planning; wider contraceptive choice; greater focus on the diagnosis, treatment, and prevention of sexually transmitted diseases (STDs) including HIV/AIDS; and care of women beyond their reproductive years. The assessment also found that health education and health promotion were not considered a high priority and that many health care providers failed to take account of clients' perspectives of service delivery.

The range of contraceptive methods available was limited to one brand of combined oral contraceptives and the IUD. Moreover, some midwives were not well informed about other methods. Condoms are provided as a temporary method, without any information for the men who use them. Tubal ligation is considered not as a voluntary form of contraception but as a preventive measure in cases where pregnancy would involve a high medical risk. Vasectomy is almost non-existent. Although the staff in family planning clinics have the expertise to provide injectable contraceptives, the availability of disposable syringes and needles is limited and they have to be purchased by the clients themselves.

None of the clinics visited by the assessment team had gynaecologists but all had an adequate number of highly professional midwives. However, many of the midwives had not received post-curricular training to update their technical skills, and they spent too much time on administrative issues or doing work that could be carried out by less specialized staff.

The assessment team found evidence of a continuing reduction in the number of births, an increase in the number of reproductive tract infections (RTIs), a rise in mortality rates from gynaecological cancers, and an increase in the percentage of women over 50 years of age requesting health care.

These findings were discussed at a workshop in Santiago in August 1996, and it was recommended that research should be carried out to determine ways of improving reproductive health services including: shifting the emphasis from maternal care to the broader concept of reproductive health; ensuring a free and informed choice of a broader range of contraceptive methods including injectables; improving the relationship between users and providers; giving greater priority to health education activities; encouraging the participation of men in reproductive health care; and addressing the reproductive needs of young people.

Ethiopia

A Stage I assessment was carried out in Ethiopia to identify the need for new contraceptive

nancy, appropriate pain control, inspection of placental tissue, post-abortion monitoring and counselling, management of abortion complications, and treatment of RTIs.

The team recommended that new technical guidelines on abortion should be widely disseminated and backed up by refresher training courses for providers on all aspects of abortion service delivery and by regular supervision to reinforce technical skills and practices in the field.

The Ministry of Health is considering the introduction of non-surgical abortion, using mifepristone and misoprostol. However, the assessment team recommended that priority should be given to improving the quality of surgical abortion services instead. They pointed out that under current service delivery capabilities non-surgical abortions could only be provided saefly in national and provincial hospitals—thereby limiting availability to a relatively small number of women. Further research concerning appropriate approaches to service delivery of non-surgical abortion is required.

The findings and recommendations of the assessment were discussed at a national workshop in September 1997 and a national technical working group on abortion was established to oversee implementation of the recommendations.

Zambia

The Stage I assessment in Zambia has had a major impact on reproductive health services. Information from the assessment, together with WHO's *Medical Eligibility Criteria for Contraceptive Use* formed the basis for a new policy document, entitled *Family Planning in Reproductive Health: Policy Framework and Guidelines*, which is the first component of a new national reproductive health policy and action plan. The national plan will also draw on the findings of a safe motherhood needs assessment carried out in 1996.

Review of Stage I assessments

A review of all Stage I assessments carried out to date found that, despite significant differences in the range and availability of contraceptive methods, as well as in geographical, social and political systems, many of the conclusions are common to all the countries involved. They include the need to:

- broaden contraceptive choice
- improve quality of care in family planning and reproductive health services
- give higher priority to helping increase the take-up of existing methods than to introducing new ones.

The review also notes that management capacity is generally not strong enough to successfully introduce new methods on a wide scale and with an adequate level of care.

In addition, the assessments:

- identified issues in the provision of family planning and other reproductive health services which require policy or programme action;
- identified other research, especially health systems research, required in reproductive health; and
- acted as a catalyst for improved

coordination with donors.

Also highlighted was the need to take some contraceptives off the market. These include formulations comprising unacceptably high dosages of hormones and products inadequately tested for safety. These problems underline the fact that many developing countries have inadequate drug regulatory mechanisms and limited control over methods available through the private sector.

Also, the assessments pointed to the need to link the introduction of new contraceptive methods to improvements in overall quality of care in reproductive health services. The aim is to use the introduction of new methods as a catalyst for upgrading the quality of care with which all methods are delivered.

In some countries, social attitudes to contraception were found to be heavily influenced by race, ethnicity, class, religion, and gender. In Bolivia, for example, the low uptake in public sector family planning services was partly attributed to ethnic and class differences between clients and providers, while in South Africa, during the apartheid era, a racially motivated family planning programme focused on the use of injectables for African women, while denying them the right of informed choice. Elsewhere, religious and traditional cultural beliefs have impeded the use of both modern services and specific methods. Meanwhile, all assessments found evidence of the effect of gender imbalances on contraceptive choice as well as the influence of family, peers, and even neighbours on decisions about contraceptive use.

The three underlying principles of country-ownership, participation of all stakeholders, and an open, transparent process have proved critical to both conduct of the assessment and acceptance of the findings. The difficult challenge of bringing together policy-makers, programme managers, and researchers with community and district-level providers, women's health groups, and young people has proved successful in countries as different as Brazil and Viet Nam. The involvement of WHO as a technical partner has helped validate the conclusions of the country-based and country-owned report.

Stage II research

Bolivia

A study was launched in Bolivia in early 1997 to steer the introduction of injectable contraceptives and improve the overall quality of care in family planning services. A situational analysis has been completed in two districts, La Paz and Santa Cruz, and the data are now being analysed. Initial results indicate that overall health care is weak and they point to major problems in the provision of services such as difficulty in access; extremely long waiting times; lack of clinic records; physicians arriving late; and poor interpersonal relations between clients and providers. There is very little training for providers in family planning and choice is largely restricted to IUDs.

Research began by determining users' and providers' perspectives on contraceptive methods and available services and on the

to determine why women choose to use DMPA, their continuation rates, and the reasons for continuing or discontinuing this method. The service delivery system is also being investigated to determine what technical and managerial adaptations are needed to ensure an improved quality of care in the delivery of DMPA and other methods.

A workshop was held in early 1997 to assess progress prior to expansion of DMPA delivery to the level of communes. One outcome of the workshop was a decision to introduce DMPA in selected districts in eight additional provinces — a faster pace than originally envisaged.

The Stage II study is due to be completed in mid-1998 and will be followed by a workshop. Stage III activities are expected to begin soon afterwards.

Zambia

The Stage II research study began with a review of the experience of CARE International in the provision of DMPA and other contraceptive methods in 26 government clinics in Livingstone and Lusaka. The findings were used to finalize a training curriculum for providers.

A situation analysis was then carried out at 11 health centres and hospitals at the three study sites, i.e. rural districts in the Copperbelt area. During 1997, staff at the study sites were trained in the use of all available contraceptive methods: combined oral contraceptives, male and female condoms, DMPA, and emergency contraception, as well as referral for IUD insertion and sterilization using tubal ligation.

The availability of a broader choice of methods has led to a significant increase in the uptake of contraceptive methods, with 50% of clients choosing DMPA. In addition, several women used emergency contraceptive pills in the month after providers had been trained in their use.

In early 1998, the research project will be broadened to include other aspects of reproductive health such as obstetric care and safe motherhood activities as well as the training of staff in STD diagnosis and management.

Stage III expansion

Brazil

In Brazil, a Stage III project is continuing to apply the lessons from the Stage II project in Santa Barbara to help improve contraceptive choice and other reproductive health services in two groups of municipalities. The two have both been motivated by the success of the Santa Barbara project and are pursuing a similar participatory approach, but are receiving different levels of technical support.

Viet Nam

Planning is under way for a Stage III project designed to provide strategic support to making DMPA more widely available in Viet Nam. The study is expected to be implemented in the second half of 1998.

Evaluation of the strategic approach

An independent evaluation of the strategic approach for introduction of contraceptive meth-

ods will be carried out during the first half of 1998. The aims are to:

- assess the impact of the strategy, its ability to improve quality of care in the delivery of all methods being provided, and its feasibility in relation to time, costs, and human resources;
- refine the design and implementation of the strategy to enhance feasibility and impact as well as its application to other reproductive health issues; and
- guide future Programme activities in the area of technology introduction and transfer.

Case studies of activities in Bolivia, Brazil, Myanmar, South Africa, Viet Nam, and Zambia will be used to: illustrate how the strategic approach and its core principles were applied in different regions and programme settings; highlight the key lessons learned; provide a basis for Stage III implementation; and make recommendations on the future application of the strategy by the Programme and others.

The evaluation team, comprising two independent external consultants, will review the case studies and visit Brazil, Viet Nam, and Zambia. The report on the evaluation will be considered at a meeting of the Scientific Review Committee in June 1998.

Assuring quality of contraceptive methods

Since the quality of contraceptive products is fundamental to user satisfaction and confidence in family planning services, the Programme is making efforts to determine how widespread is the problem of poor-quality contraceptive products and to identify the cause.

In Bangladesh, for example, quality-related problems have been identified involving a range of contraceptive products available in the public sector. They include: sticky and crumbling oral contraceptive pills; non-suspendability of injectable contraceptives, including vials that had been opened and tampered with; IUDs that were tarnished and/or missing strings; and condoms that did not meet procurement specifications.

The Programme is continuing

WHO PHOTO H. ANENDEN

(LDCs), the emphasis will be on reproductive health needs assessments and on definition of research priorities, together with efforts to strengthen research capabilities through training, core support, and intraregional partnerships.

• **Between 1990 and 1997, the Programme provided technical support and financial assistance to 22 institutions in 11 countries in the Asia and Pacific regions, including five least developed countries.**

In the coming years efforts to strengthen research capacity will build on the existing momentum of intraregional cooperation through regional research initiatives, regional networking mechanisms and appropriate designation of WHO Collaborating Centres. The Programme will also develop appropriate strategies and support programmes—ensuring the right mix between research training, core support, research project funding, and intraregional support for research and technical support.

• **In August 1997, a special session at the XV World Congress of the International Federation of Gynaecology and Obstetrics (FIGO) in Copenhagen, Denmark, focused on reproductive health in Eastern Europe. The papers presented at this session will be published during 1998.**

Eastern Europe urgently needs to strengthen its capacity to conduct reproductive health research. The special session at the FIGO World Congress was designed to highlight reproductive health problems in that region and to generate increased interest in research to solve those problems.

• **A survey involving 1200 readers of the Programme's newsletter *Progress in human reproduction research* has found that most readers find it interesting and useful—both for themselves and for the organizations for which they work. Most respondents (over 90%) indicated that the level of technical language and amount of detail included is "about right" and that the readability is "good" or "very good."**

Progress remains the flagship of the Programme's communication materials aimed at policy-makers, scientists and the general public. The impact of this publication extends beyond its readers, with nearly 20% of respondents saying that they disseminate to others the information they get through *Progress*, 19% saying that they use it for teaching, and 10% saying that they use it for initiating new research projects.

The Programme continues to support research capability strengthening in developing countries in an effort to enable these countries to:

- carry out research aimed at promoting the reproductive health of their populations; and
- participate in global research on reproductive health problems.

Since 1994, there has been a convergence in the interests of global and national research on reproductive health. The common research agenda has grown out of a recognition of the need to address research issues in the broader context of reproductive health, thus narrowing the gap between the focus of global and national research agendas. An added factor is the increasing capacity of the Programme's network of over 100 research centres to initiate research of national and global relevance which is complementary to Programme-initiated research activities.

During 1996–1997, research training grants were awarded to 48 scientists, of whom 10 were women. Table 1 shows the breakdown of the grants by discipline.

Table 1. Research training grants awared during the biennium 1996–1997, by discipline

Andrology	3
Clinical management	2
Clinical trials	2
Epidemiology	11
Laboratory techniques	2
Medical demography	1
Medical records	2
Microbiology	1
Molecular biology	1
Operations research	1
Public health	5
Reproductive endocrinology	2
Reproductive medicine	1
Research management	2
Sexually transmitted diseases	4
Social sciences	4
Statistics	3
Toxicology	1
Total	**48**

During 1997, Long-term Institutional Development (LID) grants were awarded to a total of 22 institutions: five in the Africa/Eastern Mediterranean regions; six in the Americas; and 11 in the Asia/Pacific regions. Emphasis was placed on the conduct of research, and infrastructure support was designated for the identified research programmes. In addition, resource maintenance grants were given to 17 institutions: three in the Africa/Eastern Mediterranean regions; eight in Latin America; and six in the Asia/Pacific regions.

Small grants were awarded to 27 institutions, including 17 in the Africa/Eastern Mediterranean regions, seven in the Americas, and three in the Asia/Pacific regions. In many cases, these are used for the purchase of scientific journals in countries where foreign exchange is difficult to secure. The grants are also used to purchase laboratory supplies.

During 1997, two of the newly established Regional Advisory Panels met for the first time in Cuba (for the Americas) and Thailand (for the Asia/Pacific regions). The Panels bring to the Programme's work a thorough understanding of reproductive health issues, problems, and priorities in the relevant region and thus provide a basis for planning, research, research capability strengthening, and the dissemination of research results. The new Panels have been established to replace the former Committee on Resources for Re-

grammes in their areas. One outcome was a recommendation to include family life education in the school curriculum.

Cameroon

The Centre for Human Reproduction Research at the University of Yaoundé, Cameroon, received LID grant support from 1987–1996, followed by a resource maintenance grant in 1997.

During 1997, the Centre had 23 ongoing research projects: eight in the field of reproductive biology, eight on maternal and infant health, one on abortion, four on contraception, one on infertility, and one on STDs. Five of these were funded by the Programme, 12 from national sources, and the rest from other international groups. The research included studies on a rationalized approach to anaesthetic care in reproductive health, the cost of premature baby care, effects of steroid contraception on liver function tests for hepatitis B carriers, and a comparative study of the use of misoprostol and oxytocin to induce labour.

Côte d'Ivoire

Since 1995, the National Institute of Health in Abidjan has hosted the 48-member National Research Cellule on Reproductive Health, which was established in 1989 as part of the African Network on Research on Reproductive Health. An application by the Cellule for a LID grant has been put on hold until the Programme's financial situation improves. In the meantime, a pre-LID grant in 1996 enabled the Cellule to carry out a review of reproductive health care in Côte d'Ivoire.

During 1997, four research projects were under way: two on maternal and infant health, one on abortion, and a fourth on reproductive health services. In addition, the Cellule continued its collaboration with the Programme by initiating a process to determine reproductive health research priorities.

Democratic Republic of Congo

In 1995, a research Cellule was established in the former Zaire to compile a data bank on reproductive health and plan activities outside the capital, Kinshasa. In 1996, small grants were awarded to the Cellules in Kinshasa and Lumumbashi to start these activities, and three members of the Cellules attended workshops and courses organized by the Programme.

Ethiopia

The Department of Obstetrics and Gynaecology at the University of Addis Ababa was awarded a LID grant from 1990–1994, a resource maintenance grant in 1995, and annual small grants since 1996 for library support.

During 1996, the results of a five-year UNFPA-supported study on the return of fertility after removal of an IUD were published. Ongoing research studies—none of them Programme-funded—included: the management and outcome of multiple pregnancies, gestational trophoblastic disease, the use of the contraceptive implant Norplant, and the use of contraception following an abortion or birth.

In 1997, a Reproductive Health Research Unit was established

and a number of clinical research studies initiated, mainly on maternal and infant health.

Kenya

In Kenya, the Programme is collaborating with four institutions which together comprise the National Centre for Research in Reproduction (NCRR). NCRR has proved successful in providing opportunities for a comprehensive human reproduction training and research programme that has benefited not only Kenyans but also scientists from other parts of Africa. In addition to a steady flow of research results from its four constituent institutions, the establishment of a Programme-supported Master's Degree programme at Nairobi University in 1993, under the auspices of NCRR, has helped broaden its role as a regional training centre.

During 1997, 20 research projects were ongoing at the Institute of Primate Research at the National Museums of Kenya. They included 11 studies on reproductive biology, including five on contraception, one on maternal and infant health, one on infertility, and two on STDs. Elsewhere, the University of Nairobi's Reproductive Biology Unit was carrying out eight basic science research projects involving animal models. And the University Department of Obstetrics and Gynaecology was conducting six research projects—six of them with support from the Programme. Meanwhile, the Kenya Medical Research Institute, which received a small grant from the Programme, was involved in four research studies on: the early diagnosis and treatment of cervical cancer, mother-to-child transmission of HIV, semen quality, and the prevention and management of STDs, including HIV/AIDS, among street children.

Mozambique

The Department of Obstetrics and Gynaecology at the National University of Maputo has received a LID grant since 1989. During 1996, ongoing research included studies on: eclampsia during pregnancy; use of the prostaglandin misoprostol in induced abortion; the impact of genital infection on the outcome of pregnancy; and premature detachment of the placenta.

Meanwhile, the results were published of a comparative study of over 2000 caesarean deliveries undertaken by assistant medical officers trained for surgery (46.3% of deliveries) and by specialist gynaecologists and obstetricians (53.7% of deliveries). The study found no significant differences—regardless of who performed the caesarian operation—in the number of maternal deaths or duration of postoperative hospital stay. And the total number of wound ruptures was similar in both groups. However, there was a slightly increased incidence of superficial infection of the wound in the group operated on by medical assistants.

During 1997, the Department was conducting research projects on neonatal deaths, intrauterine adhesions, the psychological aspects of teenage pregnancies, and the role of men in contraceptive decision-making.

Nigeria

The Programme is collaborating with a number of institutions in Nigeria. The Department of Obstetrics and Gynaecology at the University of Ibadan, which receives small grants for library facilities and laboratory support, is carrying out mainly clinical and epidemiological research, with increasing input from social scientists. Projects under way in 1997 included a study on the introduction of the emergency contraceptive pill, efficacy studies on different dosage oral contraceptives, contraceptive method switching, and abortion in rural areas.

The Department of Obstetrics and Gynaecology at the University of Benin, Benin City, a former recipient of a LID grant, currently receives a small grant for laboratory supplies and journal subscriptions. During 1997, the main research was a community-based study on determinants of infertility in both rural and urban areas.

Elsewhere, researchers at Ogun State University are involved in four Programme-supported studies: a comparative study of the effectiveness of the Yuzpe and levonorgestrel methods of emergency contraception; a comparative study of the contraceptive effectiveness of latex and non-latex condoms; determination of normal ranges of reproductive hormones; and trials of misoprostol and oxytocics in the management of the third stage of labour.

Senegal

The Department of Obstetrics and Gynaecology at Le Dantec Hospital, University of Dakar, has collaborated with the Programme in a range of projects since 1981. In November 1996, the International Centre for Training and Research in Reproductive Health (CEFOREP), which is attached to the Department, started to function as a national NGO. Due to its financial difficulties, the Programme was unable to approve a LID grant for the Centre for the period 1996–2000. However, a small grant was awarded to support the Department's documentation centre and journal subscriptions during 1996 and 1997.

During 1996, the Department hosted an international workshop on the role of men in fertility, family planning, and reproductive health, and collaborated with the Programme in organizing a national-level course on epidemiological methods for reproductive health research. And in 1997, the Department hosted the regional workshops on protocol development for the studies on reproductive health services for adolescents and on improving antenatal care.

South Africa

Following the readmission of South Africa to WHO in May 1994, the Programme has expanded its links with researchers and institutions in the country. In 1997, the Programme organized a research training workshop in Durban to finalize the protocol for a multicountry study on family planning and sexual behaviour in the era of HIV/STDs.

Collaboration with the Reproductive Health Research Unit at the Soweto-based Baragwanath Hospital has steadily increased since 1993. In 1997, the Unit was

involved in nine ongoing research projects, including three supported by the Programme. They included studies on: the acceptability of non-latex condoms; reasons for discontinuation of contraceptive methods; re-use of the female condom; and the involvement of men in reproductive health. In addition, the Unit continued to provide support to the National Department of Health, the Directorate of Maternal, Child and Women's Health, and the AIDS Directorate, as well as provincial health departments.

Uganda

The Department of Obstetrics and Gynaecology at Makerere University in Kampala has had a LID grant since 1989. The main lines of research include epidemiological studies of fertility, contraception, and maternal and perinatal health, as well as clinical research on the role of hormones in infertility and contraception. Projects under way during 1997 included studies on infertility, testicular function in HIV-positive men, and trials of the efficacy of several drugs in preventing mother-to-child transmission of HIV.

A wide range of research projects have been supported under the current LID grant. They include studies on: the use of different contraceptive methods, male infertility, and teenage pregnancy, as well as a rural community-based study on reproductive health needs.

Zambia

The Department of Obstetrics and Gynaecology at the University of Zambia was designated a WHO Collaborating Centre for Research in Human Reproduction in 1973. Support for institution strengthening included a LID grant from 1987-1991. Since then, the Centre has received small grants for library facilities and laboratory supplies.

Research has included a comparative study of the effectiveness of copper IUDs, mother-to-child transmission of HIV, and studies on infertility, maternal health, and adolescent reproductive health.

The Stage I assessment for contraceptive introduction carried out in 1995 has had a major impact and resulted in the development of the first phase of a national reproductive health policy and plan of action in 1996.

Zimbabwe

The University of Zimbabwe Department of Obstetrics and Gynaecology has had a LID grant since 1988. The Department has carried out a wide range of research including studies on: male sexuality and HIV/STD risk awareness; unplanned pregnancy; epidemiology of HIV; mother-to-child transmission of HIV; diabetes during pregnancy; pelvic inflammatory disease; cervical cancer; and post-abortion counselling on family planning.

Other countries in Africa

Elsewhere in Africa, the Programme is continuing to support: a study in Botswana on sexual behaviour and the risk of HIV among adolescent girls; a study in Ghana on the sexual behaviour of commercial sex workers and "free women"; and a study in Togo on fertility transition in rural Africa.

Eastern Mediterranean Region

Egypt

The University of Alexandria Department of Obstetrics and Gynaecology, one of the Programme's long-term partners, was designated a WHO Collaborating Centre for Research in Human Reproduction in 1972. The Programme's institutional support for the Centre ended in 1980 but it continues to receive grants for the maintenance of library and laboratory facilities. During 1997, a total of 77 research projects were under way: 24 on infertility, 42 on maternal and infant health, and 11 on contraception. The Centre also organized 24 training courses, workshops, and seminars.

The Egyptian Fertility Care Society (EFCS), established in 1972, has a research network including all university and Ministry of Health teaching hospitals involved in research on issues related to family planning. EFCS has been receiving a LID grant since 1992. During 1997, the Centre completed several large-scale research projects on unmet needs in contraception and reproductive health care in Egypt and on female genital mutilation. EFCS has also been awarded grants to analyse the data from studies on fertility patterns among migrant populations in Egypt and on the use of maternal health services by pregnant women.

Islamic Republic of Iran

The National Research Centre for Reproductive Health is receiving a small grant from the Programme for library support. During 1996, the Centre established reproductive health research networks in six provinces, with a separate reproductive health research committee located in each of the country's 30 universities.

During 1997, eight research projects were under way, none of them supported by the Programme. They include three on contraception, two on maternal and infant health, and one each on unwanted pregnancy, postmenopausal problems, and infertility.

Pakistan

The National Research Institute of Fertility Control has been a WHO Collaborating Centre for Research in Human Reproduction since 1976. During 1997, it received a small grant for library resources and laboratory supplies. The Centre has been involved in research studies on contraception (including the introduction of Norplant in Pakistan) and maternal and infant health.

Sudan

The University of Khartoum Department of Obstetrics and Gynaecology has received a LID grant since 1989. The Department has carried out research on maternal and infant health, abortion, contraception, and adolescent health. During 1997, research studies were under way on screening for rubella antibodies among pregnant women, contraceptive awareness and usage among educated women, the relation between physical growth during puberty and the start of menstruation, and the effect of a desogestrel oral containing low-dose contraceptive pill

on lipid metabolism in Sudanese women.

Tunisia

The Tunis-based Centre for Research in Human Reproduction is a large government clinic providing services for family planning and the management of infertility. It also acts as a reference centre for the scientific evaluation of existing and new methods of contraception. The Centre has been supported by the Programme for over 20 years and currently receives a small grant for library and laboratory support. In 1997, a resource maintenance grant was also awarded.

During 1997, the Centre was involved in four research projects—two of them funded from national sources. They included studies in the areas of reproductive biology, abortion, STDs, and contraception. One of the major interests of the Centre is to continue the ongoing study on cervical cancer screening on a nationwide scale. The Centre also held a workshop during 1997 to lay the groundwork for the establishment of a Maghrebian research network. The workshop was attended by 19 researchers from Algeria, Morocco, and Tunisia.

Meanwhile, the Tunisian Endocrine Society is continuing to publish a journal on endocrinology and reproductive health research—launched in 1995 with financial support from the Programme. The aim of the journal is to disseminate in French important research findings of particular relevance to Africa. The journal has also included French translations of articles from the Programme's newsletter *Progress in human reproduction research.*

Other countries in the Eastern Mediterranean region

The Programme is seeking ways of extending its collaboration to other countries in the Eastern Mediterranean region. Two collaborative research projects have been launched in Saudi Arabia: one on evaluation of a new model of antenatal care and the other on diabetes during pregnancy. Elsewhere, in Morocco, the Programme is supporting a research project on women's attitudes towards, and perceptions of, reproductive health.

Eastern Europe

In January 1994, a Scientific Working Group on Reproductive Health Research in Eastern Europe was established to promote and coordinate research and training throughout the region. The first six research proposals were developed that year, but some research has been delayed due to the lack of donor support. The research is designed to address three major problems in reproductive health in eastern and central Europe: family planning and contraceptive choice; the health consequences of abortion; and perinatal care.

The use of modern contraceptive methods remains low in most countries in the region and abortion is a major method of fertility regulation. Three of the research proposals are designed to investigate the reasons for this and suggest possible solutions. The first of these, which is under way, is investigating why few people use

modern contraceptive methods despite the existence of family planning services. The second study is a comparative clinical trial on the safety, efficacy, and acceptability of once-a-month and three-monthly injectable contraceptives—methods not widely available in the region. The third study, planned to start in 1998, investigates the acceptance and continuation rates of different contraceptive methods by women who have already given birth.

Elsewhere, a perinatal audit project is under way in Latvia, Lithuania and Russia to determine why the countries of Eastern Europe have perinatal mortality rates two to four times higher than in western Europe.

Two additional research proposals on the use of medical abortion in early pregnancy and on abortion-related morbidity and mortality are still under review. While financial difficulties have prevented the initiation of further studies, the Programme's protocol on standardized management of infertility was adapted in Yerevan, Armenia, in a study to investigate the causes of infertility.

In August 1997, a special session at the XV World Congress of the International Federation of Gynaecology and Obstetrics in Copenhagen, Denmark, focused on reproductive health in Eastern Europe. The papers presented at this session will be published during 1998.

During 1996–1997, the Programme continued to provide technical and financial support for the annual postgraduate course for training in reproductive medicine and reproductive biology at the University of Geneva, Switzerland, which included several participants from Eastern Europe. Meanwhile, a Scientific and Technical Advisory Group on Training in Reproductive Health has been established by the WHO Regional Office for Europe to coordinate training in Eastern Europe. In addition to the need for additional funding, there is a need to build up capacity for social science research and to increase the involvement of scientists from the Central Asian Republics.

The Americas Region

In the Americas region, collaborating institutions supported by the Programme are involved in a large number of research projects on topics relating to national and regional reproductive health problems. They include studies carried out by the three regional research networks—clinical/epidemiological, social sciences, and basic sciences—as well as by institutions at the national level.

During 1996, five regional research initiatives were under way. Three centres in Brazil, Chile, and Mexico are investigating the acceptability of emergency contraception in Latin America. In another research study—still at the review stage—institutions from Argentina, Bolivia, Cuba, and Peru are planning to investigate men's perceptions and behaviour in the sexual and reproductive decision-making process. Another recently approved regional study, involving institutions from Argentina, Brazil, Cuba, Guatemala, and Mexico with funding from the European Union, will investigate the

problem of the increasing number of caesarian deliveries in Latin America. Elsewhere, women's views on the quality of antenatal care will be evaluated in a multicentre study involving centres in Argentina and Cuba as well as Saudi Arabia and Thailand. In addition, four centres in Argentina, Chile and Mexico have identified the need for a new regional research initiative on the biological processes involved in emergency contraception using hormonal methods. Preliminary work was undertaken in 1997 to draw up a detailed plan of activities to be initiated in 1998.

At the same time, the centres are involved in research projects that address national priorities. Of the 216 studies under way in 1996, 33 projects (15%) were supported by the Programme through capacity-building grants and 82 projects (38%) were funded from national sources.

The involvement of regional centres in the global research effort is underscored by the 25 projects (12%) supported by other Programme components and the 76 studies (35%) funded by other international agencies.

In an effort to improve the links between capacity-building grants and research implementation, it was required that grant applications reviewed during the 1996–1997 biennium should be linked to specific research proposals. The proposals were subjected to the full scientific and ethical review process which was carried out, for the first time, by external reviewers. During 1997, 94 external reviewers were asked to review 18 grant-funded projects. Of these, four were rejected and two withdrawn by the principal investigators. Of the remaining 12 projects, four were approved and one rejected by the Programme's Scientific and Ethical Review Group, and eight are still under review.

During 1996–1997, the Programme collaborated with 25 institutions in 12 countries in Latin America. Of these, 13 received major support for institutional strengthening or research grants, 11 received small grants, and one a Technical Cooperation between Developing Countries grant.

Argentina

The Programme continues to support the Rosario-based Centre for Perinatal Studies (CREP) and the Department of Obstetrics and Gynaecology at the Centre for Medical Education and Clinical Investigation (CEMIC) in Buenos Aires. CREP carries out research in the areas of maternal and infant health, adolescent health, and reproductive health epidemiology, and also serves as a training and research methodology referral centre both at the national and regional levels. It is one of the four centres involved in the antenatal care research project and is due to take part in the misoprostol trial and in the regional study on caesarian deliveries. CEMIC is involved in a regional Reagent Production Programme for the development of reproductive hormone assay kits.

Elsewhere, the Buenos Aires-based Centre for Population Studies is the coordinator as well as one of the study sites for the regional study on men's perceptions and behaviour in the sexual

and reproductive decision-making process. In addition, the Institute for Experimental Biology and Medicine was awarded a LID grant in 1997 for research on basic science aspects of male fertility and infertility.

Research in reproductive epidemiology and endocrinology was supported through small grants to the Centre for Endocrinology at the Children's Hospital and the Laboratory of Growth and Development Research at the National Pediatric Hospital, both in Buenos Aires, as well as the Centre for Applied and Experimental Endocrinology in La Plata.

Bolivia

Researchers from Bolivia helped plan, and will implement, the regional social sciences research initiative on men's perceptions and behaviour in sexual and reproductive decision-making. This study is due to start in 1998.

Brazil

The Campinas Centre for Research and Control of Maternal and Infant Disease (CEMICAMP) at the University of Campinas is the main recipient of Programme support in the country. The grants are being used for training in research methodology as well as for research on contraceptive introduction and other aspects of women's reproductive health. CEMICAMP is one of three study sites implementing the regional study on acceptability of emergency contraception. In addition, it is conducting one of the three regional projects on informed consent. CEMICAMP also acts as the regional coordinating centre for introductory trials of the Programme's once-a-month injectable contraceptive, Cyclofem, in Latin America—helping countries develop national capacity for research and data management.

In addition, the Programme provides a small grant to the Centre of Reproductive Biology in Juiz de Fora. This centre is mainly involved in reproductive biology studies involving monkeys.

Chile

In Chile, the Programme is continuing to support three institutions in Santiago: the Chilean Institute of Reproductive Medicine, the Unit of Reproductive Biology and Development at the Catholic University of Chile, and the Institute for Maternal and Child Health Research. All three centres participate in Programme-supported institutional development activities and act as regional training centres. The University of Chile also continued to receive a small grant for support of research on basic reproductive biology.

In addition to its research on reproduction in monkeys, the Unit of Reproductive Biology and Development has taken the leadership to establish and coordinate the regional basic sciences network that will study the mode of action of emergency contraception using oral contraceptives. Meanwhile, the Institute of Reproductive Medicine is coordinating and participating in the regional study on acceptability of emergency contraception, which got under way in early 1997.

Colombia

Since 1980, the University of Valle, in Cali, has collaborated with the Programme in implementing the national programme in human reproduction. The Centre, which is currently receiving a small grant from the Programme, is involved in plans to reduce maternal mortality in Colombia. The aims are to: develop operational research to improve delivery of maternal health services; support epidemiological studies on the development of risk models for the primary causes of maternal morbidity and mortality in Colombia; and improve the network conducting research on maternal care.

Cuba

In Cuba, research in reproductive health is conducted by the National Coordinating Network for Research in Human Reproduction, in coordination with other public health programmes. The Network also collaborates extensively in various multicentre trials of the Programme.

The Institute of Endocrinology continues to conduct basic sciences research on reproductive immunology and is involved in the Regional Reagent Production Programme conducted in coordination with the Institute of Nutrition in Mexico City and CEMIC in Buenos Aires. Meanwhile, the Institute will implement the regional research initiative on men's perceptions and behaviour in sexual and reproductive decision-making.

Elsewhere, the America Arias Hospital is taking part in the ongoing multicentre antenatal care project and in the regional study on caesarian deliveries, due to begin in 1998.

Guatemala

The Guatemalan Research Group in Reproductive Health receives support to develop a reproductive health research unit for epidemiological and health service studies. Research projects include a large follow-up study of mothers and their children which began 10 years ago when the women were still pregnant. The aim is to evaluate the reproductive health experience of women from urban areas with different sociocultural backgrounds. Other key projects include the development of Spanish language software for perinatal and maternal mortality surveillance programmes, and the implementation of new technology to evaluate quality of care within mother and infant health care systems in urban areas.

Mexico

The Department of Reproductive Biology at the Mexico City-based National Institute of Nutrition is the main recipient of Programme support in the country. The Institute maintains a very high standard of research and plays a key role in collaborating with the Programme and other research centres in the region, as well as participating in the regional programme for the production of reagents for reproductive hormones. The Department is also one of four centres which comprise the regional basic sciences network. In 1997, the Department continued to receive grants for resource maintenance and training.

The Programme also supports the Reproductive Biology Department at the University of Coahuila in Torreon, which is involved in research on contraception and the impact of environmental pollution on reproductive health. A grant is also provided for the M.Sc.course in reproductive biology run by the National Institute of Health in Cuernavaca. Over the past six years, graduate students have included 12 young scientists from Programme-supported centres in Argentina, Chile, Cuba, Guatemala, Mexico, Panama, Peru, and Venezuela. Also, the Programme is supporting activities at the Institute for Scientific Research at the University of Durango. The Institute is collaborating with centres in Brazil and Chile in implementing the regional study on the acceptability of emergency contraception.

Panama

The Centre for Research in Human Reproduction has carried out research in areas such as sickle cell anaemia and the use of contraceptives, reproductive health of adolescents, and infertility. Since 1997, the Centre has received small grant support and is implementing a project on the use of emergency contraception as part of its continued collaboration with the Programme's research group on post-ovulatory methods of fertility regulation.

Paraguay

The Centre for Rural Interdisciplinary Studies (CERI) continued to receive support under the Technical Cooperation among Developing Countries initiative. CERI is involved in a twinning venture with the Centre for Population Studies (CENEP), Buenos Aires, Argentina. The twinning arrangement aims to enhance CERI's research capability in social science research.

Peru

The University Peru Cayetano Heredia received a LID grant from 1986–1996 and is currently receiving a resource maintenance grant. The University has carried out research in areas such as the reproductive health of adolescents, reproduction at high altitude, reproductive immunology, and population and demography. The University also serves as a resource and training centre in reproductive health. The University's Institute for Population Studies will be one of the sites in the four-country social science research initiative on men's perceptions and behaviour in decision-making on sexual and reproductive health.

Venezuela

In 1997, the Programme awarded a resource maintenance grant to the Mother and Child Foundation (FUNDAMATIN), a private non-profit organization. FUNDAMATIN is involved in research on infertility, family planning, endocrinology, and reproductive biology. A research grant was also awarded to the Venezuelan Institute for Scientific Research (IVIC) to investigate pathophysiological mechanisms linked to eclampsia. In addition, the Department of Biology at the Simon Bolivar University in Caracas, which conducts research in

reproductive biology, continues to receive small grant support.

Asian and Pacific Regions

The establishment in 1997 of a Regional Advisory Panel for Asia and the Pacific (replacing the former Regional Subcommittee) led to a strategic review of activities in the Asian and Pacific regions. The review was prompted by several factors: the magnitude and diversity of reproductive health issues in this populous region, which far exceed the financial and human resources available to the Programme; the adoption of a holistic approach to reproductive health in response to the 1994 International Conference on Population and Development and the 1995 Fourth World Conference on Women; and the establishment of Family and Reproductive Health as a programme area by WHO, incorporating the Programme with its updated research priorities.

Among the new strategic approaches recommended by the Regional Advisory Panel is an increase in cost-effectiveness by focusing collaboration on a few selected institutes and countries and by addressing key issues with the greatest potential impact. In addition, strategies will be tailored to the development status of individual countries. In the more advanced countries, the emphasis will be on drawing up a national research agenda and national coordinating mechanisms and on encouraging regional and global cooperation and partnerships, with less emphasis on core support and external training. Elsewhere, in the least developed countries (LDCs), the emphasis will be on reproductive health needs assessments and on definition of research priorities, together with efforts to strengthen research capabilities through training, core support, and intraregional partnerships.

Efforts to strengthen research capacity will build on the existing momentum of intraregional cooperation through regional research initiatives, regional networking mechanisms and appropriate designation of WHO Collaborating Centres. There is also a need to develop appropriate strategies and support programmes—ensuring the right mix between research training, core support, research project funding, and intraregional support for research and technical support.

In addition, plans will be developed for the Programme to: work in partnership with the selected countries and institutes to mobilize additional resources through approaches to aid agencies in the region and elsewhere; develop twinning arrangements between institutes in developed and developing countries; and assist institutes in the development of fund-raising strategies.

Between 1990 and 1997, the Programme provided technical support and financial assistance to 22 institutions in 11 countries in the Asian and Pacific regions, including five of the least developed countries.

China

Since 1979, the Programme has provided about U$ 15 million for collaborative activities in China, in one of its most successful research capacity-building efforts.

In addition, UNFPA has provided US$ 13 million for projects executed by the Programme on behalf of WHO. Meanwhile, the Chinese Government has invested twice the US$ 28 million combined input from WHO and UNFPA in the form of capital construction costs, staff salaries, and additional running expenses.

With the expansion of China's institutional research capacity, the Programme announced its intention to modify the strategy for collaboration. Following a review in 1996, a new strategic framework for collaboration on reproductive health and family planning between China and WHO was agreed in 1997, together with a workplan for 1998–1999.

During the 1996–1997 biennium, the Programme supported 32 research projects. They included 24 carried out by WHO Collaborating Centres (six in the Beijing-based National Research Institute for Family Planning; seven at the Shanghai Institute of Planned Parenthood Research; eight at the Sichuan Family Planning Research Institute; two at the Tianjin Municipal Research Institute for Family Planning; and one at the Peking Union Medical College Hospital in Beijing).

In addition, the Programme has also provided support to other research institutions including: the Family Planning Research Institute of Zjejiang, the Division of Reproductive Endocrinology and Infertility at the Peking Union Medical College Hospital, the Peking University Institute of Population Research, and the National Evaluation Centre for the Toxicology of Fertility Regulating Drugs.

Research projects have included studies on contraception, infertility, HIV/STDs, abortion, and reproductive tract infections.

Democratic People's Republic of Korea

The Programme implemented a UNFPA-supported project at Pyongyang Maternity Hospital aimed at strengthening capacity for research in family planning. Research carried out at the Hospital has included studies on IUDs

WHO PHOTO BY H. ANENDEN

and the use of combined oral contraceptives.

India

Indian scientists and research institutions were among the first to collaborate with the Programme. Since then, the Programme has helped strengthen research capability in India through a range of grants to institutions and research training awards for the development of human resources. By the end of 1996, the Programme had provided a total of US$ 11 million in support to India.

Four Indian institutes have been designated WHO Collaborating Centres for Research in Human Reproduction: the All India Institute of Medical Sciences in New Delhi, the Institute for Research in Reproduction in Mumbai, the Centre for Reproductive Biology and Molecular Endocrinology in Bangalore, and the Department of Obstetrics and Gynaecology at the Postgraduate Institute of Medical Education and Research in Chandigarh.

In 1997, the Indian Government launched a Reproductive and Child Health Initiative designed to ensure integrated delivery of services for fertility regulation, maternal and child health, safe abortion, reproductive tract infections, and STDs. The new initiative is intended to shift the focus to quality instead of quantity and will involve decentralized participatory planning.

The Programme is currently supporting two research projects at the All India Institute of Medical Sciences: one on emergency contraception and the other on an injectable contraceptive for men. Meanwhile, a re-entry grant is being used to support research at the Institute for Research in Reproduction. The Institute has been involved in research on a range of topics including immunocontraception, development of diagnostic tests for infertility, reproductive tract infections, breast-feeding and lactational amenorrhoea, and studies on the acceptability of contraceptives.

Indonesia

The National Family Planning Coordinating Board is responsible for organizing and implementing the national family planning programme in Indonesia. Since late 1994, following the Board's restructuring of its research network, research programmes are now concentrated in three centres: the Faculty of Medicine at the University of Indonesia in Jakarta, the West Indonesian Reproductive Health Development Centre at the University of Sumatra, and the Medical Faculty at Airlangga University in Surabaya.

The Human Reproduction Study Group at the University of Indonesia Faculty of Medicine has been receiving a LID grant since 1992. The Group is collaborating with the Programme on studies of long-acting hormonal methods of fertility regulation. The Human Reproduction Study Group at Airlangga University received a LID grant from 1992–1996 and is now receiving a small grant for journal subscriptions.

Meanwhile, the West Indonesian Reproductive Health Development Centre was awarded a LID grant in 1996 after submitting a strategy for research. The grant

will initially be used for institutional strengthening including staff training. Research will focus on improving the family planning programme in Sumatra, the adoption of safe motherhood practices, and the investigation and management of infertility and genital tract infections.

Lao People's Democratic Republic

The Institute of Maternal and Child Health, a Ministry of Health institution in Vientiane, was established in 1989 to carry out research to improve maternal and child health. During 1995 and 1996, the Institute was supported by the Technical Cooperation between Developing Countries Initiative to work with the Institute for Health Research at Chulalongkorn University in Thailand.

Since 1997, the Institute has been receiving a LID grant, which is being used to support training and for research in areas including: reproductive tract infections, maternal and neonatal morbidity and mortality, contraceptive preferences and continuation rates, and cervical cancer.

Mongolia

The State Research Centre on Mother and Child Health and Human Reproduction in Ulaanbaator was established by the Ministry of Health in 1988. In addition to its status as the most advanced mother and child care hospital in the country, it is a research centre for family planning and maternal and child health.

In 1992, the Centre received a LID grant to carry out research on contraception, infertility, maternal and child health, and the quality of care provided by family planning services. During 1997, the Centre was involved in several research projects including: trials of an IUD and of the injectable contraceptive DMPA, two infertility studies, and research on menstruation, contraceptive use, and STD prevalence. In addition, the Centre took part in a multicentre study on emergency contraception, which was coordinated by the Programme.

Myanmar

In Myanmar, five institutes collaborate with the Programme: the Department of Medical Research of the Ministry of Health (the focal point for collaboration with the Programme); the Institute of Medicine 1 and Institute of Medicine 2, both in Yangon; the Central Women's Hospital, Yangon; and the Institute of Medicine in Mandalay.

In addition to a LID grant since 1993, funding has been provided for training and journal subscriptions. During 1997, the Department of Medical Research completed research projects on contraceptive practice following abortion; infertility; and a UNFPA-funded study on contraceptive acceptability and effectiveness. Two new studies were launched on the quality of antenatal care in outpatient clinics and on the socioeconomic characteristics and behaviour of adolescent mothers.

Nepal

The Institute of Medicine at Tribhuvan University in Kathmandu has been receiving a LID grant since 1995. The Institute is conducting a Programme-

supported, hospital-based study on prostate cancer and vasectomy. During 1996–1997, several new research proposals were submitted to the Programme and are currently under review.

Sri Lanka

Research in reproductive health in Sri Lanka is carried out by four multidisciplinary Task Forces—based in Colombo, Galle, Jaffna, and Peradeniya—and coordinated by a Colombo-based National Coordinating Committee. During 1996–1997, 42 research projects were under way, including three funded by a LID grant.

Thailand

In Thailand, reproductive health research is carried out by nine public health institutions and activities are coordinated by the Department of Obstetrics and Gynaecology at Khon Kaen University. Since 1987, the Programme provided a grant to help strengthen the research capabilities of the institutions to enable them to carry out research on contraception. The institutes also receive additional funding from UNAIDS, the Faculty of Medicine at Khon Kaen University, and the Thai Research Council. During 1997, the institutes were involved in research on osteoporosis, mother-to-child transmission of HIV, thalassaemia, antenatal care, and psychosocial aspects of HIV transmission.

Viet Nam

The Programme is providing LID grant support to the Institute for the Protection of the Mother and Newborn (IPMN), a Hanoi-based tertiary-level hospital for women. The long-term aim of this grant is to establish IPMN as a south-east Asian regional centre for research and information on maternal and child health care and reproductive health. In the short-term, the funding is being used for research training and to equip research facilities. UNFPA has also provided support through the Programme to extend research capacity building to up to nine institutions in Viet Nam. During 1997, research studies were initiated on lower genital tract infections and a long-term follow-up to an IUD trial that began in 1991.

Elsewhere in the country, the Programme is supporting the development of research capacity at Hung Vuong Hospital in Ho Chi Minh City. During 1997, the LID grant supported research on female sterilization and on the use of ultrasound scanning to investigate female infertility. The Centre is also planning to carry out research on male and female contraceptive methods and on STDs.

Capacity building for communication and dissemination of research information

In parallel with efforts to strengthen the research capacity of its collaborating institutions worldwide, the Programme is also encouraging the development of effective communication skills. The aim is to help individual researchers develop the skills needed to publish their research findings in international journals and enable institutions to communicate effectively with policy-makers, the public, and the mass media.

Scientific writing workshops

Since 1991, workshops have been organized, in collaboration with the WHO Office of Publications, to help scientists in institutions collaborating with the Programme improve their skills in writing scientific papers for publication in international journals. During the past biennium, workshops in English were held in China, Egypt, and India. More than 70 researchers were trained in these workshops.

Meanwhile, in French-speaking Africa—which has few national or regional reproductive health journals—the Programme is supporting the publication of a French language journal in Tunisia (*Revue maghrébine d'endocrinologie-diabète et de reproduction)*, as well as conducting scientific writing workshops in French. In 1996, a regional workshop in Cameroon was attended by 14 researchers from Benin, Cameroon, Côte d'Ivoire, Niger, Senegal, and Zaire.

Communication workshops for scientists and policy-makers

The Programme is committed to improving scientists' ability to use the mass media to communicate with the general public, who both invest in and benefit from reproductive health research.

During the 1996–1997 biennium, workshops on communication skills have been held in India and Zimbabwe—with an enthusiastic response from both scientists and the media. At both workshops, journalists highlighted a large unmet public demand for reproductive health information and urged scientists to issue more information on their research findings.

Technical assistance to communication units

During 1996, the Faculty of Medicine at Khon Kaen University in Thailand received technical assistance from the Programme to help expand the activities of its communications unit. The Faculty has since recruited new communications personnel and is planning to use the university radio and TV stations to communicate information on reproductive health research. A request from the Faculty in 1997 for designation as a WHO Collaborating Centre for Communication and Dissemination of Reproductive Health Information is under review pending more long-term experience in the field of public relations.

Elsewhere, during 1997, the Programme provided technical assistance to the public relations office at the All India Institute of Medical Sciences in New Delhi.

Survey of readers of the Programme's newsletter

A questionnaire survey involving 1200 readers of the Programme's newsletter has found that most readers find it interesting and useful—both for themselves and for the organizations for which they work.

The survey, carried out in early 1997, revealed that 94% of respondents find it "very interesting" or "quite interesting", 86% find it "very useful" or "quite useful" for themselves, and 76% find it "very useful" or "quite useful" to the organization for which they work.

The questionnaire—included in 10 000 copies of *Progress in human reproduction research*—also found that most readers (86%) shared their copy with 4–20 other people. Meanwhile, of the several hundred copies sent to libraries, it was estimated that each copy is read by almost 20 people on average.

Most of the respondents were scientists, researchers, and physicians in either government service or private practice. Health (and family planning) workers, midwives, and nurses account for 14% of readers, while the others include journalists, librarians, educators, and women's health advocates. The amount of time spent reading the newsletter varied, but the average time spent was 25 minutes.

Many of the readers also read other newsletters on fertility regulation. Over half read the IPPF medical bulletin and over a quarter read *Outlook*, while a smaller number read the *Network* newsletter and the *Population bulletin* of the United Nations.

Most respondents (over 90%) indicated that the level of technical language and amount of detail included is "about right" and that the readability is "good" or "very good."

Table 1. Distribution of professions of respondents

Profession	*Percentage*
Scientist/researcher	26
Physician (government health/family planning service)	24
Physician (private practice)	11
Health/FP worker (including nurse, midwife, etc.)	14
National/international civil servant	12
Other (editor, journalist, librarian, teacher, etc.)	13

Table 2. How readers of the newsletter use the information.

How information is used	*Percentage*
To keep "up-to-date" with the field	29
To disseminate information to others	20
For teaching/training	19
For reference purposes	14
To initiate new research	10
For patient management	7
For discussion with others	2

Rethinking sexual and reproductive health research: new priorities and approaches in the post-ICPD era

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Twenty-five years ago the Special Programme of Research, Development and Research Training in Human Reproduction had its origin in a worldwide call for the improvement of existing family planning methods and the development of new methods that would be effective, safe, acceptable and inexpensive. The research programme that was established and subsequently developed responded to this call, while helping developing countries to strengthen their capacity to participate in the global research effort organized by the Programme.

In 1984, a review of the structure and functions of the Programme resulted in, among others, a new policy of strengthening research capacity. Increasingly, the Programme was being asked to support developing countries' own initiatives in research, often in areas of reproductive health beyond fertility regulation. While retaining a focus on fertility regulating technologies in its global research agenda, the Programme shifted its support in institutional development towards helping developing countries identify their own reproductive health needs, establish their own priorities and address them through research. The research extended to maternal health, infant survival and sexually transmitted diseases (STDs).

In the next ten years, widespread discussion of fertility regulation and related reproductive health issues, especially in the contexts of sexuality and of human rights, led to fundamental changes in understanding and international consensus on the need to pay attention to health problems relating to sexuality and reproduction. In this chapter we provide a brief review of these discussions, highlighting the changes in thinking that are affecting the way sexual and reproductive health research is planned and carried out.

The concept of sexual and reproductive health

Although the term "reproductive health" has been used by scientists, practitioners, and consumer groups for some years, its widespread acceptance came in 1994 with the adoption by 178 countries of the Programme of Action of the International Conference on Population and Development (ICPD), held in Cairo, Egypt.

Reproductive health is not just the absence of disease or infirmity of the reproductive system or of its processes. It refers to a spectrum of conditions, events and processes throughout life, ranging from healthy sexual development,

comfort and closeness and the joys of childbearing, to abuse, disease and death. Profoundly life-affirming and life-threatening conditions make up reproductive health. Perhaps more than with any other health condition, the social, psychological and physiological factors are interrelated in reproductive health.

The Fourth World Conference on Women, held in Beijing in 1995, reaffirmed this concept while advancing the idea of women's fundamental human right to reproductive and sexual self-determination and the notion of sexuality and sexual health as being of central importance to people's well-being. It is for this reason that we now talk in terms of sexual and reproductive health.

Why sexual and reproductive health is important

Sexual and reproductive health is at the centre of human dignity, relationships and well-being. The private nature of sexual and reproductive health does not diminish its significance in the lives of men and women in every culture. Everywhere sexuality and sexual behaviour have profound consequences on individuals, families, and societies.

The magnitude of reproductive ill-health

Our knowledge of the negative consequences of sexual relationships on health is incomplete, but estimates of reproductive ill-health worldwide indicate an unacceptably high prevalence of preventable conditions, unnecessary suffering, and often devastating consequences for individuals and families.

Many men and women are not able to have the number of children they desire. Demographic surveys indicate, for example, that at least 120 million couples would like to limit their family size but are not currently using any form of contraception. One consequence of unwanted pregnancy is the resort to abortion. Each year an estimated 40–50 million pregnancies are terminated by abortion. Some 20 million of these are carried out under unsafe conditions resulting in hundreds of thousands of deaths and disabilities. On the other hand, about 8% of couples, or 60–80 million people worldwide, experience infertility.

Nearly 600 000 women die each year from pregnancy-related complications. The vast majority of these deaths occurs among women in developing countries because they do not get life-saving care in time. Many who experience complications survive but suffer permanent disability.

Recent community-based epidemiological studies suggest that women bear a heavy burden of reproductive tract infections (RTIs), a problem that has not received due attention until recently. The incidence of RTIs, especially STDs, including infection with the human immunodeficiency virus (HIV) which causes the acquired immunodeficiency syndrome (AIDS), is increasing dramatically in much of the developing world, affecting men

and women alike. Each year there are more than 300 million new cases of curable STDs, many among young people.

An additional 500 000 women develop cervical cancer every year, most of them in developing countries. More than 200 000 women die each year from this disease which is a sequela of human papillomavirus (HPV) infection, one of the most common STDs.

Another poorly documented problem is that of violence and its connection to reproductive ill-health. Evidence accumulating from small studies, however, suggests a link between battery during pregnancy and miscarriage, premature labour and low birth weight. Sexual coercion, the act of forcing other individuals through violence, threats, or deception to engage in sexual behaviour against their will, can result in psychological trauma, unwanted pregnancy, and STDs. Recent conflicts have exposed the use of rape as a strategy of war; many hundreds of thousands of women have been raped in wars in this century alone. Increasing attention is also being given to the problem of female genital mutilation, documenting its magnitude, explaining the underlying motives, examining its consequences and analysing the lessons learned from local efforts to eradicate it. An estimated 135 million women and girls worldwide have been subjected to this practice.

The sexual and reproductive health of young people remains a neglected area of public health in many countries. Today's young people mature physically earlier than did their parents, they marry on average later, and they are exposed to different social influences than were their parents. Yet young people are often denied access to the information and services that could help them make wise decisions around sexuality and reproduction. Given the age structure of many populations in developing countries, vast numbers of young people are entering their reproductive years ill-prepared to protect themselves and their sexual and reproductive health.

Women bear most of the responsibility in sexuality and reproduction through contraceptive use, pregnancy, childbirth and lactation. They also bear most reproductive ill-health, in part because many do not have control over their sexual lives or have access to the services and information they need. But successful strategies to improve sexual and reproductive health must involve men, taking into account their roles and responsibilities, and their needs and concerns, in sexuality and reproduction.

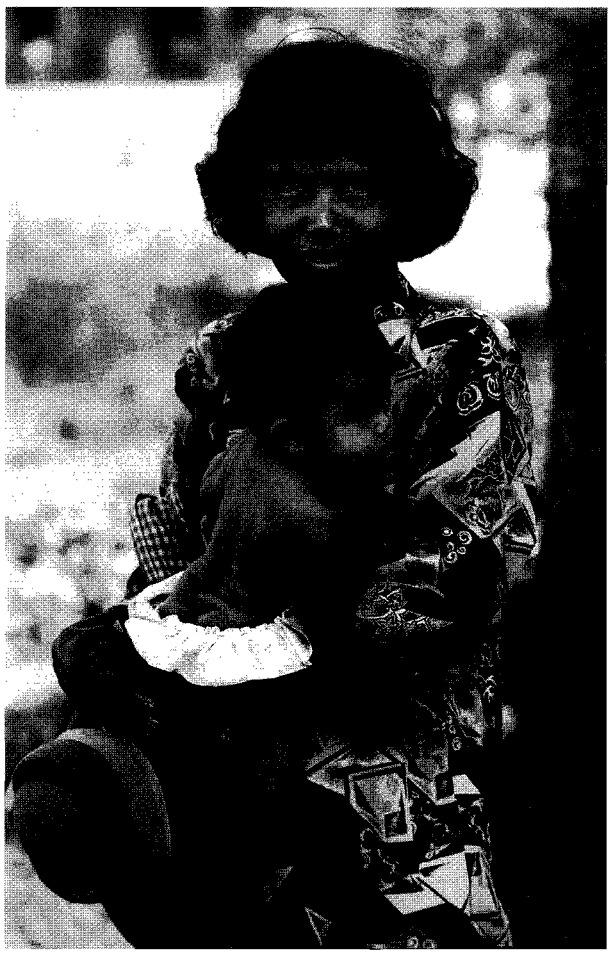
Moving the agenda forward: recognizing the distinctiveness of sexual and reproductive health

To many, reproductive health is simply "family planning plus" or family planning services plus basic maternity care and the treatment of RTIs. This idea, however, is not correct. The intellectual foundations of reproductive health, as debated and

defined in Cairo and Beijing, are different than those that guided family planning and maternal and child health programmes for several decades. To the well-established scientific paradigms of biomedicine, epidemiology and demography are now added sexuality, ethical and human rights perspectives and, from the social sciences, gender analysis.

• *Sexual and reproductive health is rooted in a human rights discourse.* The Cairo and Beijing conferences drew upon the Universal Declaration of Human Rights and other international covenants and conventions to expand the notion of rights in sexual and reproductive health. Previously, respect for rights in reproduction was interpreted narrowly to mean that women and men should not be subjected to extreme forms of coercion, such as being sterilized against their will. Now, referring to well-established concepts such as liberty, security and consent, reproductive rights implies autonomy and dignity in sexual relations and freedom from coercion and abuse. The Beijing conference was most specific in stipulating that for women this means having the right to refuse unwanted sex, and to be protected from abuses such as rape, battery and genital mutilation.

UNICEF PHOTO BY JOHN ISAAC



• *Sexual and reproductive health has strong ethical foundations.* This emphasis emerged, in part, as a reaction to decades of family planning programmes designed to meet demographic rather than health objectives. The ethical principle of "respect for persons", for instance, stipulates that programmes must address the needs of women and men in reproduction, and not treat them simply as the means of controlling population growth. When applied to reproduction, the ethical principle of "justice" requires an equitable allocation of benefits and responsibilities between women and men.

• *Sexual and reproductive health encompasses both positive and negative dimensions of well-being.* This is quite different from the biomedical conceptualization of disease as either "absent" or "present". Sexual and reproductive health

includes a spectrum of states and incorporates both pleasure and danger: on the one hand comfort, physical closeness, the life-affirming value of sexual intimacy, and mutually respectful relationships; on the other, fear, distress, sickness, disability and even death.

- *Sexual and reproductive health is both threatened and enhanced within human relationships.* The health of the individual is directly related to the quality of his or her intimate relationships. Biomedical reasoning focuses on the history of an illness within a single individual or, for communicable diseases, on the mechanisms by which the individual is infected. To understand and to improve sexual and reproductive health a broader frame of analysis is required: the individual in his or her social network and relationships, over time.
- *In sexual and reproductive health universally applied definitions do not tell the whole story.* A pregnancy evaluated as "normal" by health providers may, at the same time, cause considerable distress to a woman who does not wish to be pregnant, and lead her in many settings to risk her life to terminate it. Obstetric fistula, for example, may lead to more than debilitating incontinence; a woman suffering this stigmatizing condition may be abandoned by a family unable to cope.
- *Sexual and reproductive health requires bold new thinking about interventions and what can be done best by whom.* A number of problems in sexual and reproductive health cannot be addressed by health services alone or possibly at all. For example, medical personnel are usually poorly educated, motivated and equipped to confront the sequelae of sexual coercion, much less to prevent it in women's lives. Similarly, most health services are ill-prepared to offer appropriate sexuality education to young people. Other sectors must be brought in, ranging from education to legal aid organizations and criminal justice systems.

But even within the realm of health care, services must be rethought. The status quo of vertical programmes and family planning standing alone is insufficient to respond to the needs of women and men around sexuality and reproduction. It is not enough, for example, to add the treatment of STDs onto family planning services. Providers will need distinctly new skills and attitudes to listen to clients, to understand the context in which infections have been transmitted, and to respond with appropriate advice and care. Sexual and reproductive health care is more than the sum of its component parts, indeed, more than "family planning, plus".

The distinctiveness of sexual and reproductive health has implications for research. New perspectives, such as those of law, bioethics, and sexuality are necessary and interdisciplinary explorations are essential. New research topics, questions and approaches are also required.

Moving the agenda forward: making explicit basic principles for research

As part of the new agenda in sexual and reproductive health, research will be based on four basic principles:

- *Research will address the broad context of sexual and reproductive health, not just fertility regulation.* There is a current imbalance in our knowledge and understanding of sexual and reproductive health, and this must be addressed. The urgent need to respond to the threat posed by the AIDS pandemic, for instance, has led to the recognition of sexuality and sexual health as important.
- *Research will take as its starting point the needs of women and men at different stages in their lives.* Young people, whether they are married or not, deserve special attention, not least because this is a time when basic behavioural patterns are formed that can have important influences on sexual and reproductive health later in life.
- *Research will incorporate a gender perspective.* Gender analysis, an important theoretical perspective from the social sciences, puts both men and women in the frame of investigation. It questions how the social roles and identities they have been given—as boys and girls, men and women, fathers and mothers—influence their sexual behaviour and their sexual and reproductive health. More specifically, gender analysis examines how the imbalance in power between men and women affects sexual relationships, fertility regulation and reproductive outcomes.
- *Research will contribute to greater equity.* The commitment to equity derives from the ethical principle of justice; it challenges the scientific community to direct research toward reducing unfair burdens and addressing the needs of disadvantaged groups. This means, for instance, reducing the burden of contraception on women, attending to the high cost of sexuality and reproduction to women, and, in addition, responding to the special needs of marginalized, vulnerable, and under served people.

Moving the agenda forward: posing new questions

An agenda for research that uses as its starting point the spirit and content of agreements made at the Cairo and Beijing conferences will raise new questions and use new approaches. Sexuality and violence, for example, have not typically fallen within the purview of public health research programmes. In fact, many research, service and advocacy organizations now find themselves without the necessary knowledge and tools required to address these new issues. If the imperatives of Cairo and Beijing on gender relations and reproductive rights are taken seriously, even the more straightforward goals in fertility regulation and reproductive morbidity and mortality must be examined in new ways.

Given this situation, it is possible that some of the most productive questions and

promising avenues for research have not yet been defined, or may not be defined given the way research is currently organized. Important issues may be dismissed as "not researchable". As a result, critical new areas for action to improve sexual and reproductive health may go undiscovered.

Moving forward in the field of sexual and reproductive health requires modification of the process of scientific enquiry to create space for an explicitly exploratory phase, one that does not normally fit into carefully designed and controlled research. The resulting fresh insights and creative new hypotheses would then be explored, as always, through rigorously defined studies addressing well-formulated questions leading to new knowledge on which to act to improve sexual and reproductive health.

To this end WHO is considering creating forums where practitioners, health advocates and scientists from different disciplines reflect together on some of the new and challenging areas of sexual and reproductive health. Take, for example, one of WHO's stated programme goals and turn it into a question for discussion: What do women and men of different ages, and in different societies, consider as equitable and responsible relationships, and sexual fulfilment? If they believe that these words cannot describe their sexual relationships, what do they believe are the factors contributing to this? The answers obvious from one discipline or perspective may not be so obvious from others.

The dialogue between people with different perspectives would help refine our understanding of terms that have entered our vocabulary since the ICPD, clarify goals, reframe old questions, and generate new hypotheses about the relationship between social and biological factors in sexual and reproductive health. It would be the foundation for truly multidisciplinary work. This is critical for the development of the field of sexual and reproductive health and essential for a productive new research agenda.

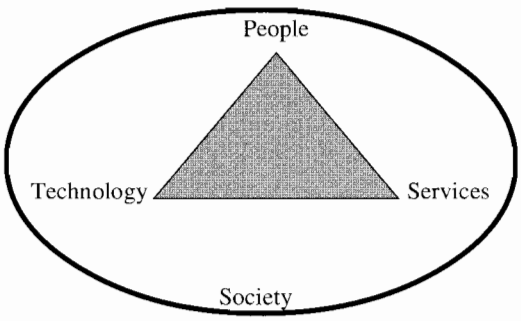
Implications for WHO's research programme in sexual and reproductive health

The complexity of sexual and reproductive health, the recognition of its distinctiveness, and the questioning of how problems are conceptualized and how interventions are defined, provides the backdrop against which WHO now identifies research priorities and plans pragmatic actions to improve sexual and reproductive health worldwide.

Through the work of WHO and others, research in sexual and reproductive health has made its greatest advances and impact in the area of technology development. Further significant improvements in sexual and reproductive health will not be achieved solely through technological solutions, however. At least as important will be a better understanding of the complex

interrelationship between society, people, services and technology (see Fig. 1). While important progress has been made in understanding how services should be structured to apply the technologies most effectively, less has been achieved in understanding the beliefs, the knowledge and desires of the people who are meant to benefit. Even less have been the gains in understanding how social factors like poverty, gender differences and cultural or religious influences affect reproductive health.

Fig. 1. Relationships between society, people, services and technology



There is a need for greater attention to these other elements in order to assess what further understanding of them is required to accelerate improvements in sexual and reproductive health in different settings. The challenge is to use the needs of people as the starting point. Those needs should guide the development of technology and the definition of interventions, including services.

The Programme's governing body, the Policy and Coordination Committee (PCC), has followed the discussions of sexual and reproductive health and noted the international consensus on the need for concerted action across a wide range of challenges. In 1995, PCC agreed a broad mandate for the Programme's work and, in 1996, commissioned a report on global needs and priorities in sexual and reproductive health research with recommendations on a research agenda for WHO. A thorough and widespread process of consultation and peer review resulted in a report on "*Sexual and Reproductive Health Research Priorities for WHO for the Period 1998-2003*" (unpublished WHO document HRP/STAG(15)/1998/8.1a).

The report, which will be submitted for consideration by PCC in June 1998, proposes that in line with the ICPD Programme of Action the Programme address, in a focused manner, an expanded array of priorities in reproductive health, building on its work and achievements in fertility regulation and closely related reproductive health areas. The research agenda would encompass, in addition to fertility regulation, high priority research on unsafe abortion, maternal health, reproductive tract infections (including cervical cancer) and planning and programming in reproductive health. The anticipated research programme would be developed in collaboration with related WHO Divisions and Units and would also incorporate aspects of research on adolescent health, harmful practices and violence against women which are relevant to the Programme's mandate. The Programme's commitment to the basic principles described above and to a more truly multidisciplinary way of working, will mean that these familiar topics will be researched in novel and ultimately more illuminating ways.

Fertility regulation: still a core research issue

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The Programme of Action of the landmark 1994 International Conference on Population and Development (ICPD), held in Cairo, Egypt, devotes an entire chapter to "Technology, Research and Development". In this chapter, the international community recognized that, "research, in particular biomedical research, has been instrumental in giving more and more people access to a greater range of safe and effective modern methods for regulation of fertility" (*1, paragraph 12.10*). The chapter goes on to say that, notwithstanding this progress, many people still cannot find a family planning method that suits their needs. This is true not only for women but especially for men, for whom no new methods have been developed in decades. The chapter also notes that the growing incidence of sexually transmitted diseases (STDs), including HIV/AIDS, demands substantially higher investments in new methods of prevention, diagnosis and treatment. It concludes, "improved collaboration and coordination of activities internationally will increase cost-effectiveness, but a significant increase in support from governments and industry is needed to bring a number of potential new, safe and affordable methods to fruition, especially barrier methods" (*1, paragraph 12.10*). The Programme of Action calls for research on gender perspectives, particularly women's, as well as on the needs of users, emphasizing that the research should be conducted in strict conformity with internationally accepted legal, ethical, medical and scientific standards.

At ICPD the nations of the world agreed by consensus that improved methods of birth control and improved technologies to protect sexual and reproductive health remain high priorities within the overall global agenda for population and reproductive health. The UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) lies at the very heart of international cooperation in this field.

Unmet need for contraception and the demand for improved technologies

If there were no unwanted fertility in the world or if couples were able to achieve their reproductive goals in a completely safe and effective manner, there would be little justification for according continued priority to research in fertility regulation technologies. However, it is now well established and exquisitely documented that there is still considerable un-

"To ensure that all people have the opportunity to achieve and maintain sound reproductive and sexual health, the international community should mobilize the full spectrum of basic biomedical, social and behavioral and programme-related research on reproductive health and sexuality."

Programme of Action, International Conference on Population and Development (*1, paragraph 12.11 (c)*).

wanted childbearing throughout the world and great continuing dissatisfaction with the family planning options available (*2, 3, 4*). The data make it clear that many millions of men and women wish to terminate or limit childbearing but lack the information and means to do so in a manner which they regard as satisfactory to their needs. The statistical definition of unmet need—number of people who wish to limit or space future births but are not using contraception—must be substantially enlarged to include people who are dissatisfied with their present methods of birth control, people who lack access to what they regard as appropriate methods, and so on. Ruth Dixon-Mueller and Adrienne Germain have described this expanded definition of unmet need (*5*). There is, thus, both a quantitative and a qualitative dimension to unmet need that together argue powerfully for continued and intensified research in this area.

Women's advocacy organizations throughout the world have in recent years articulated the priorities for research as they see them. These priorities include research on methods that protect not only against unwanted pregnancy but also against increasingly prevalent reproductive tract infections (RTIs) including STDs, and, most importantly among these, HIV/AIDS. The increased prevalence of RTIs and STDs, along with the increasingly well-recognized association between STDs and HIV/AIDS, makes research that protects against these reproductive health problems of higher priority than ever before. The women's advocacy agenda, which has been widely adopted by the major research centres and research support agencies, includes three central priorities:

- male methods;
- microbicides and other barrier approaches that protect against STDs/RTIs and may also protect against pregnancy; and
- postcoital methods of birth control.

Increasingly, the major research support organizations, including HRP, have directed their efforts toward these key areas. This represents a true international response to the articulated interests of user groups, particularly those representing women, as called for at ICPD. Not only HRP, but also The Population Council, the Contraceptive Research and Development (CONRAD) Program supported mainly by the United States Agency for International Development, and the Consortium for Industrial Collaboration for Contraceptive Research and Development, supported by the Rockefeller, Mellon, Hewlett and Buffett Foundations, have all largely embraced this core set of contraceptive research and development priorities.

Programme priorities and realities

The movement away from demographic goals to reproductive health goals in service delivery programmes around the world implies a significant shift in

these programmes from a supply-based to a demand-based orientation. This means that programmes need to provide quality services, responding carefully to users' needs and demands. These aspects were not accorded high priority when family planning services were seen in the context of achievement of demographic targets.

Quality of care means many things, including a range of contraceptive choices, effective information and counselling on the pros and cons of the different choices, responding effectively to concerns about (and actual experience with) side-effects, as well as the ethical imperative of treating patients with dignity and respect. The truth is, however, that even in places where programmes have made considerable progress in improving the human interaction between clients and providers, the deficiencies of existing technologies often still leave clients dissatisfied or frustrated with them. No matter how well counselled an oral contraceptive user is about the side-effects she might expect, when the side-effects do occur they are frequently unacceptably unpleasant. No amount of sympathetic counselling and provision of information can counteract unwanted bleeding, cramping, and nausea. Research programmes have to do more to find options for women that enable them to avoid the side-effects that so frequently deter them from long-term effective use of the contraception they need and want.

But what about men? Women quite legitimately question why they should bear nearly all of the responsibility for regulation of fertility. The lack of effective technological options for men gives great legitimacy to the allegation that science has discriminated against women in this field. There have been increasingly urgent calls for men to assume greater responsibility for reproductive health (e.g. the ICPD Programme of Action (*1*), Chapter IV), but with nothing available other than the condom and vasectomy, the ability of men to respond to this demand is difficult. Science must work to provide reproductive health programmes with new options for men that can fill the wide gap between a barrier method and a permanent method of fertility control.

Promising directions for technology development

Male methods

Research on male methods is still at a relatively early stage and there is an enormous gap between the need and demand for novel male contraceptives, on the one hand, and the state of development or even the state of basic knowledge about the functioning of the male reproductive system, on the other. This is not to say, however, that impressive advances in knowledge have not been made in recent decades on the reproductive system of the male, but research is still at a relatively early stage in terms of finding effective interventions that can be converted into products. The recent discus-

sions initiated by HRP, the Rockefeller Foundation and other interested parties have identified the epididymis as an attractive target for new research. Development of an epididymal agent, that would disrupt neither the production of sperm in the testes nor the secretion of the male hormone testosterone, could produce a male contraceptive that does not interfere with potency, and yet prevents sperm motility, and/or egg recognition and binding.

The need to develop novel methods for men cannot be overemphasized. But equally important from the perspective of increasing male involvement is behavioural research. Until recently, survey research and other forms of social science inquiry have largely neglected the male. In the last few years, however, the Demographic and Health Surveys have increasingly included questionnaires for men in order to better understand the importance of male attitudes and practices, as well as communication between partners, in determining male involvement in reproductive behaviour and decision-making. Far more work is needed to understand what might prove to be effective communications and programmatic responses to the particularities of male reproductive attitudes, practices and behaviour.

Vaginal microbicides and barrier methods

With respect to vaginal microbicides and improvement of barrier methods, the state of science is considerably more advanced. Here, it appears that applied research on various existing compounds and devices could yield important products in the relative near term. Collaborations between scientific institutions and private industry would appear to be particularly promising here because of the high articulated demand from women for products that will protect against both unwanted pregnancy and RTIs and STDs. Again, behavioural research would be particularly helpful in identifying potential constraints to the use of products that may become available in the near term. Of course, protection against unwanted pregnancy and protection against STDs and RTIs do not need to coexist in a single product. The search for an effective combined formulation should in no way hinder the development of products that act on these needs separately: all women want protection against infections and disease throughout the period of their lives when they are sexually active, but not all women at all times throughout their reproductive lives need protection against pregnancy. Both types of product, i.e. those that combine and separate these functions, are therefore desirable.

Postcoital methods

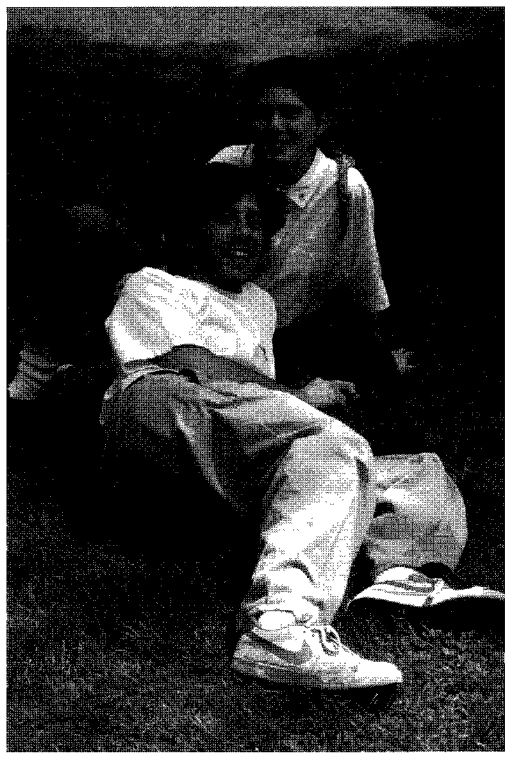
It is hard to overstate the political constraints in the way of development of postcoital methods for regulation of fertility. The fact is that practically no established pharmaceutical firm is willing to risk secondary

boycotts or other political attacks on established product lines for the sake of bringing to market methods which some may construe as abortifacients. This means that, notwithstanding the extremely advanced state of science with respect to leads in this area, the potential for commercial availability of such products through conventional pharmaceutical manufacturing and marketing is quite limited. For this reason, donors have increasingly turned to research institutions in developing countries where the political climate is less overtly hostile to commercialization of leads in the postcoital area. Apart from the importance of vigorously pursuing the development of a new generation of postcoital approaches that would represent a significant advance from the present leads based on the antiprogestogen mifepristone and emergency contraception products, major attention needs to be given to public education and communication efforts that clearly distinguish between products that are unambiguously abortifacients and those which are not—based on accepted definitions of when pregnancy begins.

Concluding comments

Three points need to be made by way of conclusion. First, recent social and behavioural research suggests that deficiencies in the properties of existing methods of contraception and in the systems through which they are delivered play a very important role in whether or not modern contraception is practised. Recent studies of the underlying structure of unmet need in developing countries reveal that concerns about the effectiveness and side-effects of present methods of contraception represent a significant impediment to their wider use (*5*). Thus, the demand for improved methods clearly remains a high priority as far as individuals and couples throughout the world are concerned.

Second, it is absolutely critical to bring the pharmaceutical industry back to the field of contraceptive and reproductive health technology development. Thirty years of declining interest by industry simply must be reversed if significant progress is to be made in this field. Recent intensified efforts to improve collaboration between the public sector research institutions, including HRP, and industry have shown some promising areas for



WHO/PAHO PHOTO

properly conducted clinical trials. Moreover, most prevention and curative interventions are based on clinical experience rather than field studies. It is therefore necessary to find out through research which treatment regimens and preventive strategies are most effective as well as most feasible in resource-poor settings.

Programmes for delivering services to mothers

Pilot safe motherhood programmes have been conducted in developing countries under the auspices of multilateral, bilateral and national agencies, incorporating elements that contributed to the decline of maternal mortality in industrialized countries during the 19th and 20th centuries. Such practices include, among others: clean delivery; community-based midwifery; use of antibiotics, blood transfusion and oxytocic drugs; and provision of essential antenatal care. Evidence from observational studies has, in general, supported the value of such programmes.

The book entitled *Mother-baby package: implementing safe motherhood in countries* (*1*) produced by WHO in 1994 summarizes the approach to the implementation of safe motherhood programmes, from needs assessment, through action plan to monitoring and evaluation. *The design and evaluation of maternal mortality programs* (*2*) published by the School of Public Health, Columbia University, offers an alternative approach centred on life-saving services. The relative effectiveness of the different strategies and tools for maternal health care needs to be assessed through health service research. Such research will help developing countries to use their limited resources more efficiently.

The key to success in maternal care

Experience from family planning and child health programmes has shown that success depends on the quality of the service. Isolated studies have shown that output, outcome and sustainability of services depend on the acceptance of the programme, not only by the community in general and women in particular, but also by the health care delivery team. More work should be done to explore the development of culturally specific information, education and communication (IEC) materials, teaching methods, referral systems, guidelines on audit, and feedback mechanisms.

In order to achieve best results, the different components of a safe motherhood programme will have to be delivered as one package which includes upgraded services at the community level, proper and clear procedures for referral, and improved district hospitals. The other components of reproductive health care need to be delivered through the same channels in the same way. From the point of view of operational efficiency and client convenience, ways to integrate the various components of reproductive health care at the district level should be tested and evaluated by research studies.

In spite of the great strides made by modern medicine, the

pregnant woman continues to pose a few enigmas that challenge the wisdom of modern obstetricians. The treatments for certain conditions, such as pregnancy-induced hypertension, serve to alleviate the symptoms and signs but they do not address the root of the problem. Without knowing the cause of the condition, it is not possible to find the most direct way of prevention and cure. Thus, basic research in the pathophysiology of such conditions is warranted.

The research agenda

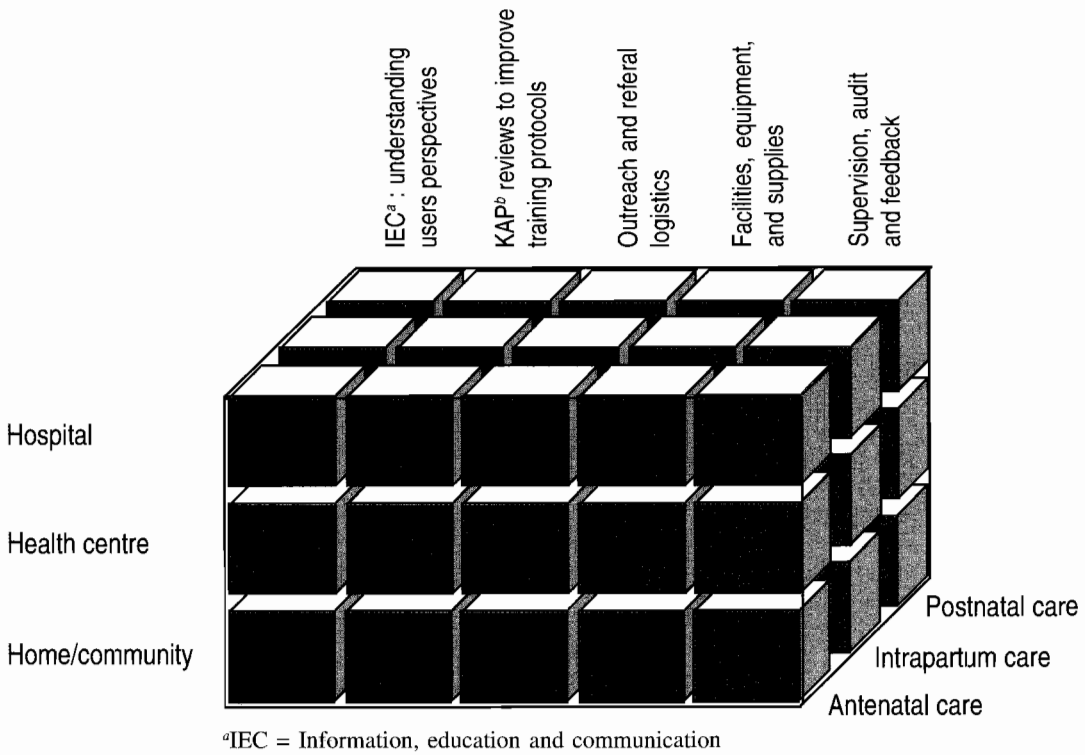
In its assessment of the research needs and priorities in sexual and reproductive health, WHO (*3*) has identified the following five strategies which essentially answer the questions posed in the first part of this chapter and can be used to guide the research agenda:

1. Identify, promote and adapt the best practices for maternal care.
2. Make programmatic strategies, such as the WHO *Mother-baby package*, operational in countries.
3. Improve quality of services for mothers.
4. Integrate maternal health activities in countries' overall reproductive health strategies.
5. Stimulate fundamental research on outstanding obstetric problems of global importance.

Conceptual framework for safe motherhood programmes and research

For a systematic approach to the determination of the research and programme priorities, the conceptual framework for a safe motherhood programme and research (Fig. 2) is a useful tool. The figure shows the inter-relationships between the three lev-

Fig. 2. Conceptual framework for Safe Motherhood programmes and research



[a]IEC = Information, education and communication
[b]KAP = Knowledge, attitude and practice

els of health care provision, the three periods of maternity and the five main programme components as building blocks. Experience from the past decade has shown that continued development of programmes with regard to all of the eleven elements on the three axes is of paramount importance for improving maternal health care.

Maternity care and reproductive health care are delivered at one, two or all three levels of care (home, health centre or hospital) in different parts of a country depending on the local facilities and practice. Thus, for each locality the emphasis placed on each of these levels of care may vary. Graphically this may be represented by increasing the height of the respective series of blocks. Similarly, some areas may provide antenatal care at the community level and delivery services in hospital, thus the depth of the row of blocks representing antenatal and intrapartum care for the community and hospital would vary accordingly.

Research and programme development could use this three-dimensional matrix system for situation analysis and management. It is postulated that all 45 blocks need to be in place for programmes to function efficiently. Most health systems have most of the blocks in place. However, relative weakness in one or more blocks within a layer would destabilize the whole structure. That is to say, for each level of care, the programme would be most cost-effective if the five columns of IEC, training, referral logistics, equipment and supplies, and audit are in place. In conducting needs assessment for planning purposes, it is important to identify which block(s) is (are) the weakest and require(s) attention soonest.

Research priorities and benefits

The lack of knowledge in a particular block or level should be identified as a topic for research under "best practice" or "quality of care" (see WHO strategies Nos.1 and 3). The development of standards for cost-effective practices could help health service planners to compare what they have with what they should have as a needs assessment exercise. Weakness in a row or column at whichever level of care would indicate the need for health service research on programme management (see WHO strategies Nos. 2 and 4). Results of these studies will help health care planners to allocate resources in the most cost-efficient manner.

Best practice

The multicentre controlled trial of a new model of antenatal care, currently being conducted by WHO, is an initiative worthy of note (see page 55). The trial aims to evaluate the effectiveness, acceptability and cost of a simple package of interventions that have been scientifically demonstrated to be effective in improving maternal and newborn health. The success of the trial could form the basis for exploring ways to improve antenatal care in different settings. For example, a follow-up trial could be done in areas where deliveries are arranged at home instead of in hospital. The

sites selected for such a trial should define the minimum logistical standard required to organize effective outreach and referral services.

For the prevention and treatment of obstructed labour, postpartum haemorrhage and infection, standard protocols should be developed for each level of care. In this regard, priority should be given to the needs of the community health worker. Systematic reviews of recent literature should be conducted periodicallly, and experience gained in research projects should be reviewed and documented by technical working groups, such as those convened by WHO. A case for consideration is the partogram in the prevention of obstructed labour, which was successfully tested by WHO. Could a birth attendant without adequate asepsis implement this safely at home? Sytematic reviews of research findings may come up with simpler alternatives. Similarly, the reviews could find simpler alternatives to oxytocic drugs in the prevention of primary postpartum haemorrhage at the community level.

Quality of care

To improve the use of services, acceptance and compliance, the quality of care will need to be improved. In this regard, socioculturally appropriate IEC materials will need to be developed, backed up by communication research, in order to promote maternal care in the community, especially among women. The development or adaptation of existing teaching manuals and tools to improve the quality of interaction between health care providers and their clients has to be preceded by anthropological and behavioural research for specific settings. In this context the specific areas that need attention pertain to people's perception of risks and danger signs during pregnancy and barriers to the use of health care facilities.

The knowledge, attitude and practice (KAP) of the mothers and the providers also need to be studied in order to develop the IEC materials mentioned above as well as new training curricula and methodologies for health care providers. Clinical protocols developed for specific purposes such as the management of the major causes of death—e.g. eclampsia in the local setting—should form the backbone of the training manual. Any new protocols, tools or methodologies developed would need to be tested prior to inclusion in training manuals.

Access to care may be improved by arranging affordable services through outreach midwives provided there are in place effective communication and procedures for referral to hospital. Innovative methods of financing essential obstetric care, fail-safe transport and communication have been introduced in different parts of the world. An evaluation of such projects could form the basis for the development of guidelines for strengthening maternal referral systems.

Training and guidelines cannot be expected to improve the quality of care if the hardware for delivery of care is not upgraded

accordingly. This, however, does not necessarily mean that when services are being improved, heavy expenditure needs to be incurred on hardware. By reviewing the whole programme and by taking into consideration all the existing facilities and equipment it may be possible to redistribute the workload and equipment, thus avoiding heavy capital expenditure. Standard lists of basic requirements for maternal care facilities, including equipment, drugs and consumables, are available, but guidelines are needed on the maintenance of equipment and supplies, as well as on how best to recover investment costs. For donor- or credit-supported programmes, sustainability depends on a reliable source of recurrent income. Studies in this aspect are urgently needed.

Compliance to guidelines and protocols is the essence of successful training. The concept of teacher-cum-supervisor may not need testing but methods for effective monitoring, audit and feedback should be evaluated. Should monitoring be done by regular on-site testing and checking? Is clinical review of critical incidents adequate? What is the best way of getting client opinion? Can the impact analysis on output and outcome be used as an assessment of quality of care?

Programme strategies

The five programme components shown in Fig. 2 are essential but each has its own associated difficulties in implementation. Lessons could be learnt from family planning and child health programmes, especially in the areas of IEC, KAP and social marketing. Given limited resources, should the programme components be implemented sequentially, and, if so, in what order? Which component will yield the greatest gain with the smallest resource input? Should the hypothesis be tested that this is an "all-or-none" activity—that all the components should be implemented simultaneously for maximum result? What management and technical tools could be used effectively for each of these programme components? In short, how do we revitalise the district health care system to integrate different components of reproductive health care with net gain in productivity and outcome? The Mother-baby package (*1*) is a complete guideline that should be operationalized. The research programme outlined above would help to fill in the details of the programmes and to improve them.

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Reducing the impact of reproductive tract and sexually transmitted infections

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Reproductive tract infections (RTIs), including sexually transmitted infections (STIs), remain a global public health problem. In recent years, concerns about the spread of the human immunodeficiency virus (HIV) and recognition of the role STIs play in the transmission of HIV, as well as heightened awareness of the severe consequences of STIs for women and infants, have provided considerable impetus to efforts to prevent and treat STIs. At the same time, a number of community-based epidemiological studies conducted in developing countries have drawn attention to the burden of RTIs that are not usually sexually transmitted (such as bacterial vaginosis and candidiasis) and their impact on women's sexual and reproductive lives. Efforts to prevent and treat these infections have been initiated and have taken on more salience in view of preliminary findings that some common RTIs, such as bacterial vaginosis, may facilitate the transmission of HIV. Thus, in order to both contribute to the prevention of HIV/AIDS and to protect women's reproductive health, there is a need to intensify and expand programmes for the control of RTIs, including STIs. However, more research is urgently needed to answer key questions that arise as interventions are designed and applied on a large scale.

Assessing the scope and magnitude of the problem

RTIs include STIs, iatrogenic infections (including postabortion and postpartum sepsis), and endogenous infections that result from overgrowth of organisms normally present in the reproductive tract (e.g. those that cause bacterial vaginosis and candidiasis).

Although some STIs have long been recognized as a public health problem in many parts of the world, it is only in recent years that information has emerged on the extensive spread of RTIs in developing countries. Data sources remain limited and considerable variation has been found between studies in the prevalence and patterns of RTIs. This variation surely reflects differences in the epidemiology of RTIs in the populations studied. On the other hand, some of these variations may also be related to fundamental differences that exist across studies with respect to study designs, diagnostic criteria and measurement techniques. In some studies, laboratory investigations were incomplete, and self-reported symptoms or clinical findings were emphasized, even though there is little concordance between these different approaches to the assessment of RTIs.

Few studies in developing

countries have measured the prevalence of chlamydial, gonococcal and human papillomavirus (HPV) genital tract infections. There is a need for more information on the epidemiology of RTIs in selected populations, including adolescents, who may be particularly vulnerable to infection, and family planning and antenatal clinic clients, who are in contact with the health services but among whom RTI diagnosis and treatment are often overlooked. Whenever possible, these studies should investigate potential social and behavioural risk factors for RTIs, and their consequences for sexual and reproductive health. The experience from epidemiological studies should lead to the development of indicators and practical methods for estimating the burden of infection at the local level. This information is required for the identification of needs, setting of priorities, and design and evaluation of control programmes.

In addition, tracking the antimicrobial susceptibility of major infectious agents is important because susceptibility patterns tend to be highly variable. Laboratory-based surveillance systems or intermittent surveys can contribute information on antimicrobial susceptibilities to guide local policy and practice on treatment of RTIs.

Understanding people's perspectives on RTIs

There is evidence that people commonly delay or fail to seek appropriate treatment for RTIs. This allows complications to set in and, in the case of STIs, leads to continued spread of infection. Studies are required to explore how people recognize and interpret RTIs and to understand the decision-making process that people go through in assessing and using sources of advice and care available to them. People's perceptions of illness shape the prevention practices they adopt, trigger health-seeking behaviours, and determine satisfaction with services.

Research on perceptions and behaviour should be sensitive to the broader context of people's lives. It should explore the critical linkages between perceptions and health-care seeking behaviour, on the one hand, and other significant concerns such as sexuality, sexual behaviour and gender power relations, on the other. For example, there is a need to understand how gender roles affect decision-making related to sex and its consequences and how they restrict women's access to resources and services.

The above studies are required in order to design programmes that are responsive to clients' needs and remove barriers to access and improve quality of care. Yet, such studies are too often neglected. They would be particularly valuable for populations that suffer high rates of infection but remain under-served by reproductive health programmes. Adolescents in particular are especially vulnerable to STIs, including HIV, but face many obstacles in accessing information and services for prevention and care. More research is needed to understand better the needs and concerns of adolescents in order to meet their information needs and to develop

new, or to improve existing, services for them.

Strengthening primary prevention approaches

Approaches to the prevention of acquisition of infection vary according to the type of infection. The main approach to prevention of STIs is through the adoption of safer sexual behaviour, including the use of condoms whenever there is a risk of infection. The prevention of endogenous infections, in principle, requires behaviour change with respect to a range of hygiene (including personal, sexual and menstrual hygiene) and health-seeking behaviours. In the case of iatrogenic infections, prevention is achieved through improvements in the quality of care, including technical competence of providers and adherence to infection-control procedures. However, it is not known what proportion of all RTIs are endogenous or iatrogenic. Also, there is as yet no experience with assessment of the impact of any intervention that seeks to prevent these infections through changes in individual or provider behaviour. On the other hand, available evidence indicates that various forms of interventions are effective in changing risk-related sexual behaviours and in reducing the risk of STIs, including HIV, in certain population groups. Further research is required to identify effective and sustainable approaches to STI prevention among vulnerable groups, such as adolescents, migrant workers, and the military.

Of interest to reproductive health providers is the finding that women have limited opportunities to protect themselves from the two possible negative consequences of sexual intercourse: unwanted pregnancy and infection. To date, the only contraceptive methods that can also prevent the transmission of STIs, and can therefore offer "dual protection", are the male and female condoms. Such dual protection can also be achieved through a "dual method" approach, in which a highly effective method is used to prevent pregnancy and condoms are used during any act of intercourse with a risk of STI transmission. This may place a greater burden on women and men, however, and studies have shown that, in general, the more effective the primary contraceptive is in preventing pregnancy, the lower is the level of consistent condom use. Alternative approaches to dual protection include the provision of emergency contraception as a backup to barrier methods. Research is needed to develop and test these and other modalities for dual protection in different settings.

The reality is, however, that condom use often remains low even in high-risk sexual encounters, in spite of intensive and sustained education and promotion efforts. In part, this is because men are not always willing to protect themselves or their partner. There is some urgency to develop and test new or modified infection protection technologies (with or without contraceptive effects) that can expand the range of options for protection against STIs. There is particular interest in methods that a woman can use

with or without her partner's knowledge or consent, such as vaginal microbicides. Research to develop suitable microbicidal products and to test them for acceptability, safety and efficacy in the prevention of lower genital tract infections and HIV infection is of highest priority.

Finally, basic research must continue to develop vaccines against common and serious STI pathogens, including *Chlamydia trachomatis* and HPV, which hold promise as further tools for prevention in the longer term.

Improving case management

The identification and treatment of established RTIs is crucial as it has important effects at both the individual and community levels. Case management includes proper diagnosis and clinical management, client counselling and, when appropriate, partner management. These efforts relieve symptoms, prevent prolonged infections that can result in serious complications and sometimes in death, and (for some STI organisms) limit the duration of infectiousness—a critical determinant in the sustained spread of STIs in the community.

Case management is also important for reducing the risk of HIV transmission. The results from a recent community trial in Mwanza, United Republic of Tanzania, showed that improved case management at the primary health care level could reduce HIV incidence at the community level by 42% (*1*); the effect on the incidence and prevalence of STIs was less pronounced.

A number of technical challenges regarding the diagnosis and management of RTIs, including STIs, still need to be addressed in order to improve further the feasibility and cost-effectiveness of case management activities. Simple, affordable and accurate diagnostic tests are still not available for most RTIs. Until they become available, the syndromic approach to case management is recommended, especially in resource-poor settings. This approach uses flow charts that rationalize and standardize clinical decision-making for common conditions with easily recognizable signs and symptoms, such as genital ulcer and urethral and vaginal discharge.

Studies indicate that genital ulcer and urethral discharge can be managed effectively with this approach. But flow charts for the syndromic management of vaginal discharge do not perform as well in discriminating between vaginal infections (frequently associated with non-sexually transmitted RTIs) and cervical infections (usually associated with STIs, such as chlamydial and gonococcal infections). Most flow charts successfully deal with vaginal infections, but they do not pick up cervical infections, particularly in settings where the prevalence of STIs is low, such as in family planning and antenatal clinics. Further research is needed to improve and refine the flow charts for vaginal discharge, and, more generally, to develop methodologies to adapt the syndromic approach to the local epidemiological context and service delivery conditions.

Another issue in case management is that most RTIs are

often asymptomatic in both men and women. Hence people do not seek treatment early. This limits the utility of approaches that deal only with symptomatic infections. A more systematic effort is required to develop cost-effective approaches for the detection of asymptomatic infections, through screening or case finding. But this may be difficult to achieve until new, simple, robust and low-cost technologies are available to identify major infectious agents. Research to develop simplified RTI diagnostic kits and test their use under field conditions is of highest priority. Until then, one of the most effective means of reaching asymptomatic persons with STIs is to notify the partners of symptomatic cases. There is a need for more studies to develop and test strategies for partner notification, referral and management; these strategies should be practical and affordable in developing countries.

Assessing and improving health services

Further research on many aspects of service organization and delivery is also required to support the introduction, upgrading or expansion of services for the control of RTIs. This should include situation analyses to describe current activities and resources and identify critical gaps with respect to RTI prevention and treatment services, in both the public and the private sectors. These assessments should not only investigate policies and norms, but also strive to understand what actually happens at the community level. For example, syphilis screening in pregnant women, which has long been recognized as a feasible and cost-effective public health intervention and is widely recommended, is not usually practised in resource-poor settings. Constraints in the way of such interventions need to be identified. This should lead to the definition of a core set of field-tested indicators suitable for planning, monitoring and evaluating RTI control activities within reproductive health programmes.

Intervention studies that assess the feasibility, acceptability, effectiveness and cost of alternative approaches to delivering services for the prevention and treatment of RTIs are also needed. At the present time health services are moving away from the concept of dedicated STI centres (which have tended to cater mainly to men and become stigmatized) towards integration of services for the diagnosis and management of a broader array of reproductive health problems (including RTIs) into existing health services for women and men.

Approaches to determine the appropriate mix of services will clearly vary in different settings, at different levels of the health system, and according to the prevalence of RTIs and the amount of available resources. Demonstration projects and operations research are required for defining strategic approaches to integration and for assessing their cost-effectiveness. Research is also urgently needed to evaluate service delivery models that reach out to vulnerable or marginalized groups, such as

Critical research needs related to RTIs

1. Assessment of the scope and magnitude of the problem

•Document the prevalence of key RTIs (including gonococcal, chlamydial and HPV infections) in selected populations.

•Identify key social and behavioural risk factors for RTIs , and their consequences for people's sexual and reproductive health.

•Develop indicators and methods for rapid assessments of the prevalence of infectious agents.

•Track antimicrobial susceptibility of major infectious agents.

2. Understanding community perspectives on RTIs

•Investigate community perspectives on RTIs and care-seeking behaviours, especially among under-served groups, such as adolescents.

3. Strengthening primary prevention approaches

•Identify effective and sustainable approaches to STI prevention among vulnerable groups.

•Develop and test modalities for dual protection in different settings.

•Develop and test the acceptability, safety and efficacy of new or modified infection protection technologies, such as microbicides.

•Develop vaccines against *Chlamydia trachomatis* and HPV.

4. Improvement of case management

•Improve and refine the syndromic approach for use in different settings and under different service delivery conditions.

• Investigate approaches to screening or case finding of asymptomatic infections.

•Develop simplified RTI diagnostic kits and test their use under field conditions.

•Develop and test strategies for partner notification, referral and management in different settings.

5. Assessment and improvement of health services

•Conduct situation analyses of RTI control services within the health system.

•Develop and test methodologies for the planning, monitoring and evaluation of RTI control services.

•Test modalities for the integration of RTI control services within the existing health system.

•Evaluate service delivery models that reach out to vulnerable or marginalized groups, such as adolescents.

adolescents, who are currently out of the ambit of most reproductive health programmes.

Conclusions

Sexual relations and reproductive events should be free from infection (*2*). In order to reach this goal, further research is needed: (*a*) to understand better the problem of RTIs and people's responses in different settings, and (*b*) to develop improved tools and approaches for prevention and management. This chapter has identified a number of critical research needs (see box on facing page) that must be addressed through a concerted programme of biomedical, epidemiological, behavioural and operations research.

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The role of men in improving reproductive health: the direction research should take

One of the fundamental changes that has taken place as a result of the International Conference on Population and Development (ICPD), held in Cairo, Egypt, in 1994, is the shift in the focus of population policy away from a long-standing preoccupation with macrodemographic issues toward a concern with the well-being of individual men and women. While the ICPD recommendations are directed primarily toward improving the condition of women—by addressing in particular their sexual and reproductive health needs and rights—they also stress that to achieve these goals the role of men must be considered. The international agreement reached at ICPD, better known as the Programme of Action states:

> *"Changes in both men's and women's knowledge, attitudes and behaviours are necessary conditions for achieving the harmonious partnership of men and women. Men play a key role in bringing about gender equality since, in most societies, men exercise preponderant power in nearly every sphere of life, ranging from personal decisions regarding the size of families to the policy and programme decisions taken at all levels of Government."*
> (*1, paragraph 4.24*)

ICPD's impact on population policies is leading to changes in the provision of family planning programmes and restructuring of health delivery systems. An important aspect of this change has been the involvement of community groups and non-governmental organizations (NGOs) in co-operative research to test how elements of the Cairo agreement can be incorporated into community services. Cairo represents a major watershed for the women's health movement, especially for the NGOs that have been working towards the empowerment of women to enable them to achieve self-determination in matters concerning their reproductive and sexual lives. As a result, women are increasingly being brought into discussions of health programme planning and a public debate has ensued on how best to attain reproductive health goals. While the processes of involving men and women vary from region to region and from country to country, family planning and other action programmes have had to reconsider the way in which they approach their clients, recognizing that gender is a critical variable that can no longer be ignored.

Male involvement: the dilemma

The ICPD Programme of Action repeatedly emphasizes the importance of achieving

greater male involvement in reproductive health. Such involvement is needed in order to improve and protect the sexual and reproductive well-being of both men and women. Achieving this objective means that men would have greater participation in roles traditionally assigned by society to women: child care and socialization, prenatal and postpartum care, contraception, disease prevention (especially of sexually transmitted diseases, STDs), and general household work and support.

While there is general agreement that greater male involvement in these activities is desirable, there is concern among some feminist groups that increasing men's involvement in reproductive matters may hinder a woman's position within the household, undermining efforts to reinforce female empowerment and self-determination. It is not well known what women want with respect to male involvement and what their perceptions are of the extent they would like their partners being involved. The lack of information on some of these issues may hinder or delay the implementation of the Cairo recommendations with respect to male involvement and improved gender equity. In many instances women's groups are still not quite sure what the right approach to male involvement should be or what coalitions or alliances should be formed so that agreements can be reached that do not hinder women's power or status. To resolve this impasse there is an urgent need to conduct social science and behavioural research that applies a "gender lens" to the understanding of sexual and reproductive processes and decisions. Such information is also essential for planning and designing appropriate reproductive health care interventions. As a UNFPA report (*2*) on male involvement in reproductive health states:

> *"The first reason to involve men in reproductive health stems from the need to promote observance of human rights and the need to enforce equity, i.e., an obligation from the gender and reproductive rights perspective."*

Gender: the new lens

While the Programme of Action is clear in its commitment to reducing gender inequality, the term "gender" often leads to confusion. First, a gender perspective does not (and should not) mean a "feminist" perspective. Secondly, a gender perspective in research is an attempt to include the perceptions and behaviours of both men and women in order to understand a particular issue or behavioural process. The Programme of Action's support for "responsible sexual behaviour, sensitivity and equity in gender relations" (*1, paragraph 7.34*), represents a revolution in thinking and a challenge to the research community dedicated to the advancement of sexual and reproductive health. A gender lens applied to sexuality and reproductive issues implies probing into the ways men and women interact, and explaining existing differences, both in meaning and in intent. The study of these

issues requires the examination of the attitudes and behaviour of both men and women from various perspectives, including social, economic, cultural, political, psychological and health.

In the field of population studies, most research conducted in the past fifty years—especially fertility studies—has focused on women with the assumption that men and women have complementary roles which render women exclusively responsible for fertility. Hence, information could be collected from women alone and their views would completely represent those of their male partners. The rationale for this emphasis has to do with the fact that women have a well-defined reproductive life span, while men's is open-ended; women bear children while the role of men is biologically restricted to the initial phase of the reproductive process. There may also be a more practical explanation. For the purposes of survey research, women are generally easier to reach as most are usually at home and can be more easily approached to talk about issues such as pregnancy, birth, fetal and infant loss, and so on. On the other hand, men are often perceived as being difficult to find, and less willing to discuss or report accurately on reproductive events.

Analytic models have also been devised to work with only one gender, which has made statistical analysis easier but the comprehension of family dynamics, particularly the way in which reproductive decisions are made, more difficult if not impossible. Thus, advocating a gender approach to research simply recognizes, as Dixon-Mueller (*3*) remarks, that:

> "*Gender forms a basis in all societies for the division of labour and the social allocation of rights and responsibilities.*"

Furthermore, because in many societies the division of labour includes greater benefits for men, including legal rights, social protection, insurance and access to resources (e.g. to education and training), this inequality between men and women is also extended to other realms, most importantly to sexuality and reproductive rights.

The neglect of sexuality

Another important aspect that has been neglected by population studies is sexuality. Ideally, sexuality should be expressed through a series of emotions that include love and caring, and when sexual acts take place, their joy should be shared equally by both the man and the woman. But sexuality can also involve anger and violence, coercion, abuse and rape. Looking through a gender lens, sexuality can be seen to be expressed differently by men and women. These differences can have important consequences for third parties, such as on children conceived as a result of rape or on family members during other types of sexual violence.

In men the roots of sexual violence may lie in individual personality traits, often reinforced by culturally entrenched represen-

tations of masculinity. The well known machismo stereotype, conveying an image of physical strength, sexual prowess and superiority, is an example of how a false idea of what a man should be is projected. When such stereotypical images are acted out, women become the victims.

Social norms make it easier for men to express their sexuality, act on their sexual instincts, and explore sex before marriage. In general, men enjoy considerably more sexual freedom than women. The way in which men protect and help define social norms, especially those that concern household power allocation, sexual behaviours and fertility decisions, including contraceptive use, often lead to institutionalization of inequity. These are important, albeit difficult areas for research, but necessary if gender inequity is to be reversed.

Reproductive health services for men

Perhaps one of the greatest challenges for researchers and health planners alike is finding appropriate models for including men in reproductive health services. Family planning and, more generally reproductive care, have traditionally been women's unquestioned domain. Men have been called "the new clients" of family planning clinics and certainly they will be so in the new reproductive health services being planned by governments around the world. Figueroa (*4*) has cautioned that, while attempts are being made to set up services for men, "these are often based on interpretations in terms of prototypical patterns of reproductive behaviour among women, and fail to develop a prototype that takes into account the reproductive behaviour of couples as a process of interaction and negotiation between men and women".

There is also the question of motivating men to come to reproductive health services. A recent survey of publicly funded family planning clinics in the USA showed that in only 13% of the clinics male clients represented more than 10% of the total clientele. The situation is much worse in developing countries, even though in these countries men are often the ones who make decisions with regard to contraception and having another child. Data for Burkina Faso, Ghana, Zambia and Zimbabwe indicate the difficulties of bringing men into reproductive and family planning services, ranging from men's opposition to using family planning to fear of contraceptive drugs and devices (*5*). Findings from these African countries clearly indicate that men are "involved" in fertility-related decisions, in some cases acting as facilitators, in others as barriers to action by their wives. The challenge there is to find ways to improve men's awareness of women's reproductive health needs, including contraception, and to increase their trust in modern medical approaches. With HIV/AIDS rampant in Africa, the relationship between contraception and health prevention measures based on condom use needs to be explored in greater detail. The lack of a simple female contraceptive that serves also to prevent STDs adds

to this complex issue.

The next question is, what should services for men include? Reproductive health services for women usually provide some or all of the following: (*a*) education and counselling on sexuality, contraception, abortion, childbearing, hygiene, infection, and disease; (*b*) screening and treatment of reproductive tract infections (including STDs), cervical cancer, and other gynaecological problems; (*c*) means to make informed choices about contraceptive methods, with systematic attention to contraceptive safety; (*d*) safe early abortion in the case of contraceptive failure or non-use; (*e*) prevention and treatment of infertility; (*f*) prenatal care, supervised delivery, and postpartum care; and (*g*) infant and child health services (*3*). Of these seven elements, the first three apply equally to men (with the exception of cervical cancer and gynaecological problems) and (*d*) and (*e*) should involve both partners in the decision to seek the appropriate services. Men should also become supportive of their wives seeking proper health care during pregnancy, delivery and while the child is still an infant. From these seven elements a series of important research questions emerge:

- How a community reproductive health service that includes specialized care for both women and men should be organized?
- Which services should be joint and which separated?
- Should male clients be seen by male providers?
- How do men behave if women are also around in the waiting room?
- Should men and women be served at different times?
- Should women be encouraged to bring their husbands along?
- Should the approach to counselling men be different from that used for women or should services be designed for couples?
- What types of problem should the counselling cover?

Male participation in services raises many more questions and the answers will not be in the form of universal service norms. In some cultures (e.g. the Muslim world) it may not be acceptable for men to receive services from women providers (and vice versa) while this may be possible in Africa and Latin America. Service research is needed to assess various models of community reproductive health service delivery and the challenge is to find solutions that work for both women and men.

Men and contraception

Another deterrent to greater involvement of men in reproductive health is the lack of contraceptive options for men. There are essentially three male methods, the condom, withdrawal and vasectomy. Today, the male and female condoms are the only barrier contraceptives that also protect against STDs, including HIV/AIDS. In spite of this specific advantage, both men and women are not inclined to use condoms for contraception. There are mixed perceptions about condoms and their use tends to be sporadic and continuation rates low. For example, in the Philippines, where 25% of the women

use modern methods, barrier methods are among the least popular and condom (male) use is very low (1%) despite special efforts to encourage their use; 60% of condom users discontinue using the method within a year.

The reality is that the use of male methods remains low in most places. Moreover, condom use tends to be primarily associated with commercial sex and often programmes downplay their effectiveness for pregnancy prevention. Given this situation, it has been suggested (*6*) that involving men might mean increasing men's use of one or more male-dependent methods, or alternatively, promoting men's encouragement of their women partners to use female methods. But condom use among adolescents requires special attention. For example, in Latin America, adolescents enter into sexual relationships fairly early and an important proportion of adolescent sexual activity takes place without any contraceptive protection.

There is ample evidence—even in contexts where family planning is widespread, such as Bangladesh—that men often oppose the use of contraception by their spouses or partners. Therefore, research to identify culturally sensitive ways of reversing these negative attitudes without undermining female control over contraceptive choice is important.

In other contexts, e.g. Africa, where family planning efforts are weaker, the role of the male head of household tends to be even more authoritative. This is the case among the main Nigerian ethnic groups in which men completely dominate family and social relations, including decisions on reproduction. But men's dominant role in decisions on matters of reproduction does not translate into greater responsibility for contraception. Condom use by couples in Africa remains low: current use reported by husbands

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in the Central African Republic was 2.4%; in Ghana 8.4%; in Kenya 5.6%; and in Zimbabwe, 4.3%. When these same men were asked whether they had ever used this method in the past, the results were also indicative of low patterns of use: in the Central African Republic, 46% of the men had ever used a condom; in Ghana 32%; and in Zimbabwe 66% (data on this aspect were not available from Kenya).

The wives of these men reported much lower ever-use of the condom than the men, usually half the rates reported by men, which indicates low rates of condom use in marital relationships. Although extramarital relations and the presence of other people during interviews do not make substantial contributions to the observed gender gap in these countries, they do have the potential to affect reporting. Wives usually show a greater reluctance to acknowledge condom use because of its association with extramarital relations. It has been suggested (*7*) that the condom gap might be "due to the differential purpose of its use by men and women rather than to its use by men for extramarital relations". This implies that men are more likely to have used condoms before marriage for disease protection while women use them within marriage in combination with other methods for contraceptive purposes. This issue needs further exploration. Unquestionably, the acceptability of contraception by men and the dynamics of decision processes, including method choice, within the family unit remain important areas for research.

Conclusion

To develop new approaches for increasing men's involvement in improving reproductive health, research planners will need to adopt a gender-sensitive research agenda that addresses the roles of both men and women. In this regard, research will need to focus on how men and women interact within sexual unions, including the way in which sexuality and reproductive processes are viewed, and how family building decisions are reached and contraceptive choice made. Increased male involvement in reproductive health implies that men need to adopt safer sex practices, practise effective contraception and/or support their partners in doing so, seek and use reproductive health services, assist their partners in the processes that surround reproduction, and respect their sexual and reproductive rights. For men in many cultures this will require major shifts in perception and in disposition in matters of sexuality and reproduction. To develop strategies for achieving this shift, policy-makers and planners will need sound data on the perceptions of men and women on all these issues. Research will also be needed to test the strategies developed to change men's perspectives.

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Research needs in adolescent sexual and reproductive health

Facing up to adolescent sexuality remains a challenge in most societies, and governments in both developed and developing countries are reluctant to tackle adolescent sexual and reproductive health issues in case this earns the disapproval of parents and other adults. Providing information and services for young people is still controversial, despite the fact that people in many parts of the world now recognize that population policies and family planning programmes have in the past neglected the needs of the young.

The current world population of young people aged between 10 and 19 years is over one billion (*1*). They are all experiencing life in many different ways. Some are in education, some in work, and some are out of work and living on the streets. But they share many common experiences. With marriage taking place later nearly everywhere, more and more adolescents are starting sexual activity before marriage. Despite huge cultural variations influencing the onset of sexual activity, by age 20 the level of sexual experience is high in most countries (*2*).

In the last few years, interest in offering services to adolescents has grown and a number of different approaches have been adopted. This is important because the setting in which adolescents experience their first, and later, sexual experiences bears heavily on the services they need. In order to provide appropriate services, however, more systematic information is needed about the proportion of adolescents who are sexually active at different ages as well as about their patterns of sexual behaviour, including the number of relationships they usually have before the first long-standing one. There is also not enough information about the context in which sexual activity of adolescents occurs, nor about the current reproductive and sexual health status of adolescents. Another area where more research is required is in the effectiveness of interventions employed to improve adolescent sexual and reproductive health.

Patterns of sexual activity

Clearly, the first research need, is for better data. More and more surveys are now being carried out which give some idea of young people's sexual behaviour—e.g. Youth Behaviour Surveys and certain Demographic and Health Surveys. These do not usually allow crosscultural comparisons, however, because there is no one definition of what constitutes sexual activity or sexual experience. Better methods and more situational analyses to discover patterns of sexual relationships and behaviour, and how they change through the adoles-

cent years, are required. How much of sexual activity is unprotected, which adolescents protect themselves against pregnancy and disease, and how and what makes them take these measures are other questions that need answering.

The next research requirement is to identify a set of indicators to measure the sexual and reproductive health of adolescents, with the development of appropriate tools and methodologies. This includes collecting data about the levels of unintended pregnancies, childbirth, abortion, sexual violence and coercion, and sexually transmissible diseases. Estimates exist but usually cover a wide range. For example, abortions among adolescents are believed to number anywhere between one million and 4.4 million a year (*3*). At least 111 million of the new cases of curable sexually transmitted diseases (STDs) that occur in the world each year affect young people under the age of 25 years. More than half of all new HIV infections occur among those aged 15–24 (*4*). More accurate and more country- and situation-specific statistics are needed.

Data on fertility are more detailed and are nearly always aggregated by age groups. Hence, the number of births to young women aged 15–19 is known. But it would be more useful to know fertility rates by single years, as the risks of childbearing are vastly different for the youngest and oldest members of the 15–19 years age group. There is also a need for more information about childbearing below age 15. Moreover, in order to assess their needs for education or other interventions, information is needed on the attitudes and emotional development of children before they reach their teenage years. Clearly, these data are needed by sex. Moreover, for different settings, the relationship between gender roles and reproductive health should be examined.

The social setting of adolescent sexual behaviour

Many adolescents have poor knowledge about sexual matters and about how to protect themselves against pregnancy and STDs. When they do have information, they are not always able to act upon it or they do not have access to the means to protect themselves (such as contraception and condoms).

Young people's needs in the area of sexual and reproductive health vary widely, even among those of similar age and same sex. The social situations in which adolescents find themselves have a strong influence on their sexual behaviour. Many young people need support in delaying sexual intercourse; others are sporadically sexually active and need to know how to protect themselves from pregnancy and disease. Others are unmarried but they are having sex regularly, in some cases with members of their own sex, and need comprehensive services. Many young women are married early and so pushed into early childbearing. They need the same services as older married women, including maternal health services. Unlike adolescent childbearing, which can be charted, the amount of abuse experienced

by adolescents is much harder to gauge, but where it exists there is a need for treatment and protection.

Little research has been carried out into how adolescents, and adults, view adolescent sexuality, and whether there are differences in values between adolescents and adults and disagreements about autonomy. What are the best ways to help young people disclose problems with sexual abuse, sexual orientation and sexual dysfunction, for example? What are the barriers, in particular settings, to communication among adolescents and between young people and adults? Even when parents or other adults such as teachers or health workers have a favourable attitude towards sexuality education for adolescents, there is often the problem that they may have neither the appropriate knowledge nor skills to impart the knowledge. How do young people feel their needs for information are currently being met by the information provided?

Other influences on adolescent sexual activity that need more research concern official policies and laws relating to adolescent reproductive health. Studies are also needed on the views of professionals and adolescents on such policies and laws and which of these are believed to be implemented. It is also important to monitor the impact of changes in laws and policies.

The best way of delivering services

Another research need is to find the best ways to deliver programmes for young people, programmes that meet their needs and promote healthy sexuality. In some countries, adolescent programmes are part of health services and in others not. A first step would be analytic research into how adolescents use reproductive health services, including family planning, maternal and child health services, and services related to prevention and treatment of STDs. Young people in different settings should be asked what they think of existing services and what improvements can be made to create a more positive environment so that they find them more accessible and convenient.

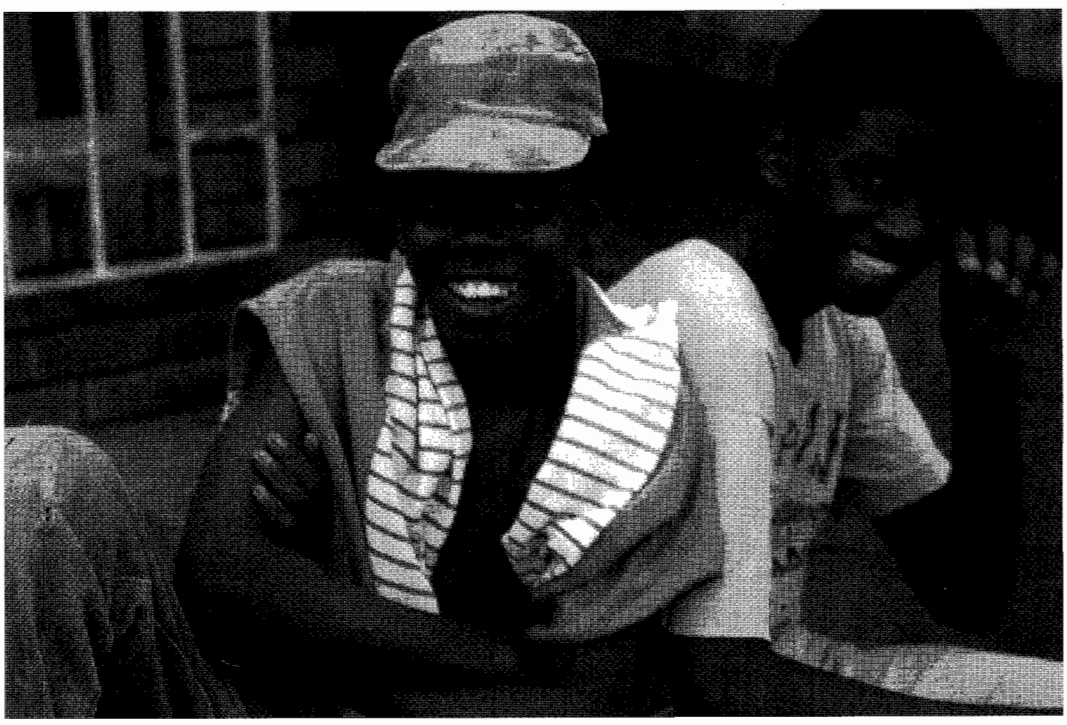
During recent years, many countries have introduced programmes for youth using a variety of different approaches. However, more research is needed into the types of youth programmes in various countries, particularly research that will contribute more to improving programme design and implementation. For example, it is not clear which elements of a programme are most important in reaching programme goals, or which are the best training and teaching methods. The level of participation or exposure required by young people in order to increase knowledge, change attitudes and influence behaviour also needs investigating, as does the level of skills and knowledge that providers need to have.

Some programmes have successfully increased knowledge about reproductive health and fostered positive attitudes towards health behaviour among young people. But these programmes

need to go further and actually reduce unsafe behaviour. They need to train young people in how to protect themselves and in identifying and resisting pressures to be sexually active, where possible by helping them to rehearse negotiations to avoid sex or at least achieve safer sexual behaviour. Young people are increasingly looking for training in such skills and counselling as well as access to contraceptive services. The most appropriate links between information services and those providing supplies, counselling or treatment therefore need to be developed and established.

Funding, cost–effectiveness, and sustainability of programmes are other areas which have been little researched. Many of the programmes or projects that have been initiated to help young people, especially in developing countries, have been short-term and small-scale. And there are few examples of projects where mechanisms were established at the outset to ensure their progression, if successful, to full-scale programmes. Donors have usually given funds for fixed periods, and unless the success of these project is well documented and monitored, programmes have found it hard to find support to continue and expand. Specific operational research is needed to look at programme and service sustainability and overcome current problems.

Though the benefits of particular approaches are often put forward, there is no firm evidence to support such claims. Peer education programmes, for example, have been heralded as models, because they provide the "context" for sexuality information—i.e. information is presented by peers who are trusted, in language and style young people understand. Apart from raising awareness and distributing condoms, however, it is not know how effective peer education pro-



WHO PHOTO BY CARLOS GAGGERO

grammes are in bringing about behaviour change.

Measuring the effectiveness and impact of programmes

There is a broad consensus on the key interventions needed to improve young people's sexual and reproductive health, and much has been written about the importance of including young people in the design, implementation and evaluation of projects. Yet little is known about the effectiveness of such strategies. This is because, although there are numerous case studies, there are few studies that have attempted impact evaluations of such programmes. And the available evaluation studies have generally produced inconclusive and unreliable results owing to their poor design. Hence they cannot be used to guide the development of new programmes. This is especially true with respect to the impact of interventions on behaviour; assessments have shown positive improvements in adolescents' knowledge and understanding following a particular intervention, but it is not known whether long-term changes in practice result. No comprehensive body of evidence has been built up on this. In fact, a recent review of the evaluation studies which measured behavioural change found that only four programmes had led to significant improvements in safe sexual behaviour.

To monitor the impact of programmes effectively there is a need to develop appropriate reproductive and sexual health indicators. These will allow changes to be measured in the health status of adolescents and thus help in the evaluation of interventions to improve sexual and reproductive health. As yet, however, it is not know which indicators best measure the impact of programmes and which are most suited for measuring the extent of use of health services by those who need the services.

It is generally easier to show the impact of programmes to improve young people's knowledge than to show the impact of outreach or condom distribution programmes. This is partly because it is more difficult and expensive to conduct surveys of clients. Thus, evaluations have focused on measuring inputs such as the quality of peer counselling, or outputs such as numbers of condoms distributed. Only a few programmes have been able to demonstrate an increase in the use of contraception. There is, therefore, an urgent to need to develop suitable cost-effective methodologies for evaluation studies.

Evaluations of programmes that have been set up with the involvement of young people themselves should concentrate on identifying the relationship between the participation of young people at all levels of the programme and success of the intervention in terms of improvements in the sexual and reproductive health of youth. There is a need to find the best practice and the best way of involving young people in health programmes.

Research methods need to be developed for assessing policy and programme changes, especially where changes are made to make the policies and pro-

grammes more "youth-friendly" or to improve access or links with other services. This also applies to programmes in which staff have been trained in youth-friendly skills: the impact of the training needs to be assessed. Services also need to be evaluated from the perspective of the users (the youth), and tools developed for young people to use themselves in evaluating their programmes.

Other research issues

There are also a few particular situations in which young people find themselves to which further attention needs to be given. These include: research into the influence of drugs and alcohol on the sexual risk behaviour of young people; the needs of young gay/lesbian and bisexual people and how they can be addressed; the special needs of, and interventions for, young people in high-risk situations—for example, street children, young people in refugee camps, and orphans.

In addition, further research is required into: the possible long-term effects of the use of hormonal contraception which was initiated during adolescence; the relationship between knowledge, attitudes and practice of natural family planning by young people; study of the physiological vulnerability of an immature cervix and vaginal membranes and susceptibility to STDs, including HIV infection; and investigation into the need for smaller condoms for use by sexually active adolescents.

Conclusion

Young people represent the future of our world. Investing in their well-being must be one of the best and most important actions that can be taken today. Part of this investment, possibly the most urgent, is to carry out the research necessary to identify their precise needs, find effective ways of meeting them, and continuously test and monitor interventions.

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Implications of domestic violence for women's reproductive health: what we know and what we need to know

Violence against women is defined as "any act of gender-based violence that results in, or is likely to result in, physical, sexual or psychological harm or suffering to women..." (*1*). Violence against women, whether wife-beating, rape, or sexual abuse, is increasingly recognized as a major social and public health problem. A disturbing profile has begun to emerge, globally, of the prevalence and health consequences of violence against women. For example, rape and domestic violence together are estimated to account for 5% of the healthy years of life lost to a woman of reproductive age in developing countries (*2*).

At the root of violence against women lie unequal power relations and unequal control over resources between women and men. Power dynamics strongly influence or constrain women's ability to exercise choices in their own lives, including choices that would enable them to resist abuse. Societal norms about gender relations often reinforce this lack of choice. The consequences of violence for women's health and lives are huge, but remain poorly documented.

There is a growing recognition that violence against women takes place largely within the confines of the home and family. Sexual abuse, rape, battering, and wife burning are among the most pervasive manifestations of violence faced by women, and the major proportion of these episodes tends to be perpetrated by the husband or partner (*3, 4*). Hence, this paper reviews what is known about this one dimension, namely domestic violence against adolescent and adult women, and about the association between violence and women's reproductive health. It also highlights research needs in this area.

This focus on domestic, rather than all forms of violence against adolescent and adult women means that other dimensions of violence against women that have implications for their reproductive health are not considered here. These include: acts of violence perpetrated against children; sex-selective abortion; forced sex by dating partners; sexual assault by strangers; female genital mutilation; violence perpetrated against women in situations of conflict and among refugee populations; trafficking in women and forced prostitution; and indeed, all acts of violence against women, sexual and other, that are perpetrated by non-family members.

I begin with a word of caution. Information on violence against women and its consequences for women's lives and health is by and large sparse and fragmented. Much of what is available, particularly on reproductive health consequences, comes, moreover,

from the developed world (*5*). Available studies span a variety of definitions, designs, and samples covered. Thus, the findings may not be comparable between studies or necessarily represent the situation in the population at large.

Evidence of domestic violence in women's lives

Reports of domestic violence involving women are available from all regions of the world. These suggest that between one-fifth and one-half of women interviewed have experienced physical abuse by their husband or partner. For example:

- Community-based surveys suggest that domestic violence by husband or partner is experienced by 15–20% of women in Colombia (*6*) and 26% and 33% of women in Chile and Mexico, respectively(*1*).
- A study in Kenya found that 42% of women were beaten "regularly", another in Zambia reported that 40% had been beaten by their partners, and a third in Uganda found that 46% were physically abused by a partner (*1*).
- A survey in Egypt found that 35% of ever-married women had been beaten at least once since marriage: almost half of them suffered beating in the year prior to the survey as well (*7*).
- Wife abuse has been reported by 39% of women in Malaysia (*8*) and 42% of women in the Republic of Korea (*1*).
- Wife beating has been reported by: 45% and 37% of women in Uttar Pradesh and Tamil Nadu, respectively, in India (*9*); 47% in Bangladesh (*10*); and 35% in rural Pakistan (*11*).
- Data from developed countries suggest a similar situation. Domestic violence is reported by 29% of women in Canada (*12*), 25% in Norway and 28% in the USA (*1*).

Abuse apparently begins early in marriage when women are most vulnerable. A study of battered women in Malaysia found that for 35%, the first incident of abuse occurred within the first year of marriage, and for 55% in the second or third year (*8*).

Less information exists on sexual abuse. Data suggest that marital rape (or rape by partner) is experienced by between 5% and 10% of all women. In Colombia, for example, 7% of rural women and 9% of urban women reported having being raped by their husband after marriage (*6*). In Mexico, 6% reported marital rape(*13*). In Central America the figure was12% (*13*) and in India 10% (L. Visaria, personal communication).

In many societies wife beating appears to be justified by societal norms. For example, studies from as diverse settings as Bangladesh (*10*), India (*9*), Malaysia (*8*), Mexico (*14*), Papua New Guinea (*15*), Zambia (*1*) and Zimbabwe (*16*) show that wife abuse is perceived as acceptable behaviour and justified as a normal and acceptable part of married life. In contrast, studies pointing to the perceived unacceptability of such behaviour are rare (*17*).

Impact on women's reproductive health

Not only is domestic violence a violation of women's human rights, it is also a major public

health problem and a significant cause (both direct and indirect) of female ill-health. For example, in Lima, Peru, one-third of women treated in an emergency ward in hospital were found to be victims of domestic violence (*5*). A study of emergency room records in a public hospital in Mumbai, India, found that 23% of its female patients were victims of domestic violence, in which the perpetrator was identified as a family member (A. Daga et al., personal communication).

Data from community-based studies are rare, but also point to the public health problem posed by domestic violence. Up to 6% of serious injuries and deaths among women in Shanghai, China, are due to domestic violence (*5*). In another study, 18% of wives in a survey in urban Papua New Guinea had received hospital treatment for injuries inflicted by their husbands (*5*). And 7% of all deaths among women aged 15–44 years in Matlab, Bangladesh, during the years 1976–1986 resulted from suicide (5%) or homicide (2%) (*18*).

Women who have suffered domestic violence are also observed to experience health problems other than physical injury, such as chronic headaches and sleep and eating disorders. Moreover, victims of violence are more likely than non-victims to be heavy users of alcohol or psychotropic substances (*19*). The psychological impact of abuse is commonly perceived as more damaging than the physical, and mental health problems among abused women are not uncommon (*20*).

The consequences of violence for reproductive and sexual health are acute. In particular, domestic violence affects women's ability to engage in safe sexual relations free from coercion or disease, make choices regarding pregnancy and fertility regulation, go through pregnancy and childbearing safely, and seek appropriate care for themselves and their infants. In spite of a paucity of data, the following profile emerges.

Threat to safe sexual relations free from coercion or disease

Several studies report women's ignorance about sex at marriage and the coercive and painful nature of early sexual relations with their husband. In studies in India, for example, women have described early sexual experiences with their husband as traumatic, distasteful and painful. The use of force is frequently mentioned: "It was a terrifying experience, when I tried to resist, he pinned my arms above my head. It must have been so painful and suffocating that I fainted..." (*21*). Moreover, lack of choice is frequently expressed: "This man has brought you here; if not for this, why has he brought you? You have to do it..." (*22*). Similarly, violent early sexual experiences have also been reported by Iranian women living in the USA (*23*).

Although in surveys between 5% and 10% of women report having experienced marital rape, qualitative research suggests that this may be an underestimate. A study in rural Gujarat, India, found that out of 98 women who had sought abortions, and who responded fully to questions on

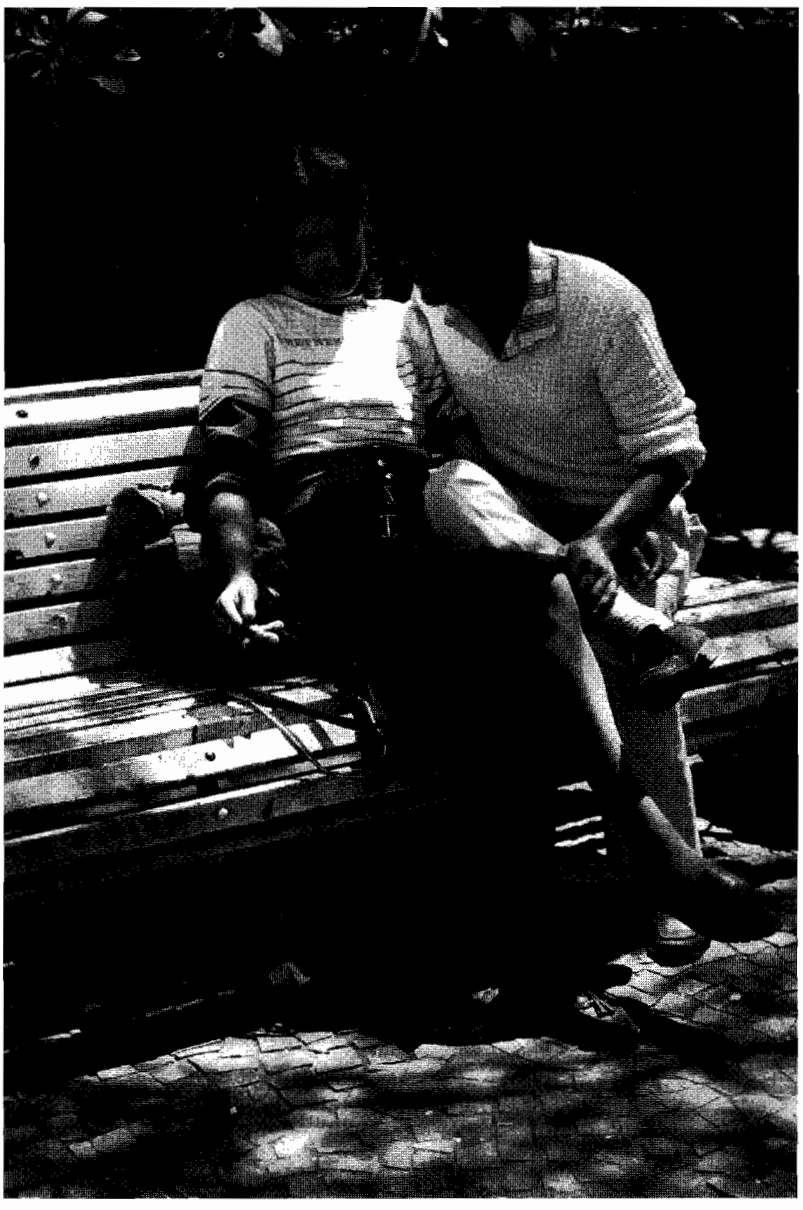
sexual relations, 67 said they had experienced sexual coercion, 21 reported physical violence, 14 reported verbal abuse, and the remaining 32 did not elaborate. Predictably, the typical response to violence was acquiescence (*21*).

Battering and sexual abuse go together. Large proportions of women with physically abusive partners have also experienced sexual abuse: e.g. over 50% of women in studies in Puerto Rico and Colombia (*20*), 30–58% in studies in Central America (*13*), and 68% in a study in Trondheim, Norway (*24*).

Where the threat of violence pervades sexual relationships, it is unlikely that women are able to exert choices that ensure protection against sexually transmitted disease (STD). Sexual violence during adolescence has particularly far reaching psychological and behavioural consequences (*25*). It invokes a sense of vulnerability and powerlessness as well as shame, guilt and fear of sex, and an inability to distinguish affection from sexual exploitation. It is also associated with early onset of regular sexual activity, a greater risk of unprotected sex, inability to negotiate condom use and increased risk of STD and pregnancy.

Few studies have directly addressed the links between women's experience of domestic violence and their ability to insist on condom use, or their vulnerability to STDs or other gynaecological conditions. One study in Rwanda observed that HIV-positive women were found to be more likely than other women to report coercive sex (*26*). Another, in Chiapas, Mexico, found that women who suffered violence were also likely to suffer illness, unwanted fertility and infections, including STDs (*14*). A third, in Norway, reported that 12% of women in the general community, compared with 58% of battered women, reported pelvic inflammatory disease (*24*). A study in Zimbabwe found that fear of violence inhibited women from negotiating sexual relations, including insisting on condom use or treatment for partners with symptoms of STDs (*16*).

WHO PHOTO BY CARLOS GAGGERO



Risk of unwanted pregnancy and constrained contraceptive choice

The threat of violence also limits women's ability to make reproductive choices in terms of whether or when to become pregnant, whether and what steps to take to control fertility, or which method of contraception to adopt. It also exposes them to unwanted pregnancy and related health consequences. Moreover, in patriarchal societies in which the husband has the ultimate say in all issues—including the number of children to have and whether and which fertility regulation method should be used—women who suffer violence are more likely than other women to experience unwanted pregnancy and constrained contraceptive choices. Women are often either reluctant to use contraception for fear of abuse from their husbands, or have indeed suffered severe beating after their contraceptive behaviour was discovered by their partners (*27*). At the same time, childlessness can exacerbate the chances of abuse (*16*).

There is some evidence to suggest that women who have suffered violence are more likely than non-abused women to undergo abortion if they become pregnant: 42% of women in one study at an abortion clinic in Canada had suffered physical violence by their current partner and 17% had suffered sexual abuse (*28*). At the same time, women whose pregnancies are unwanted or mistimed appear to be at considerably greater risk of abuse than women whose pregnancies are wanted (four times higher in one study in the USA, *29*).

Adolescents (and young women) are particularly vulnerable to violence and forced sex since women in this age group tend to be particularly disadvantaged in gender power dynamics and find it difficult to negotiate sexual relations. The deleterious consequences of forced sex are often compounded by the additional trauma of pregnancy. In a maternity hospital in Lima, Peru, for example, 90% of young mothers aged 12–16 years were victims of rape—the majority by a relative (*23*).

Threat to safe pregnancy and childbearing

Evidence from many countries suggests that pregnant women are no less—and some suggest that they are more—vulnerable to violence than are other women. In the USA, for example, one study reports that the main predictor of violence during pregnancy was violence prior to pregnancy: 88% of women battered during pregnancy were also battered prior to becoming pregnant (*30*). A qualitative study in Zimbabwe reports that violence that is ongoing before pregnancy may increase in intensity during pregnancy and contribute significantly to maternal and fetal mortality (*16*).

Irrespective of whether or not the experience of violence changes during pregnancy, evidence suggests that pregnant women face considerable risk. In Egypt, one in three women is reported to have been beaten during pregnancy (*7*). Studies in the USA suggest rates ranging from 7% to 19% (*19, 30, 31, 32*).

Battering during pregnancy commonly occurs on the abdomen, as studies in Zimbabwe (*16*), India (L. Visaria, personal communication), Malaysia (*8*) and Canada (*33*) reveal. This has obvious adverse implications for obstetric and infant morbidity. In Malaysia, 40 of 60 battered women interviewed had been beaten on their abdomen during pregnancy: 3% required hospitalization (*8*).

Battering during pregnancy can result not only in obstetric complications, it can also have serious implications for the health and well-being of the fetus or infant. Such battering is known to cause: fetal fractures; placental separation; rupture of the uterus, liver, or spleen; haemorrhage; premature labour or birth; miscarriage; low birth weight infants; as well as maternal and infant mortality.

The association between battering during pregnancy and premature delivery, miscarriage, and low birth weight infants is best documented. Studies of pregnant women in the USA find that even after controlling for a host of risk factors, victims of violence during pregnancy were over twice as likely to experience preterm labour than non-abused women (*34*); twice as likely to miscarry (*35*); and four times as likely to give birth to a low birth weight baby (*36*). Studies in Malaysia document that 3% of women battered during pregnancy suffered a miscarriage as a result of the beating (*8*).

Barriers to seeking health care

The threat of violence also appears to have a more indirect bearing on reproductive ill-health. Battered women are frequently the most powerless and least likely to have the decision-making authority, mobility or control over resources needed to seek appropriate and timely health care, whether for themselves or for their infants. Evidence from the USA suggests, for example, that no more than one-third of battered women seek care for injuries sustained (*30*). In a study in rural India, although 90% of battered women reported that their injuries were serious enough to warrant medical care, only 38% did indeed seek treatment and few admitted the cause of their injuries to care providers (L. Visaria, personal communication).

Battered women are also more likely than other women to delay seeking of reproductive health care. Studies from the USA find that battered women are more likely to delay attending for antenatal care until the third trimester (*31, 37, 38*). Likewise, in the slums of Mumbai, India, battered women are constrained from making decisions regarding nutrition or health care for themselves or their infants (*39*).

Deficiencies in health care systems also make it difficult for battered women to seek care. While theoretically well placed to identify and care for victims of violence, gaps remain in health services in terms of: the insight needed by providers to deliver care to battered women; inhibitions on the part of providers in dealing with victims of violence; assurance of confidentiality to victims; and training needed to provide counselling, referral and other services. Studies in the United Kingdom and the USA report that

battered women typically prefer to conceal their experiences of abuse from providers because they fear retaliation from their partners and because they perceive providers as indifferent and uninterested in their situation beyond their immediate physical injuries (*40, 41*).

The research agenda

The gaps in understanding about domestic violence and its consequences for reproductive health are numerous and formidable. Community- and health facility-based and behavioural research is needed in developing countries on the context and health consequences of domestic violence.

Also needed are appropriate study methodologies and designs. Research on violence against women often provides the victims a rare opportunity to discuss their experiences. But it also makes them recall some of their most traumatic times. Thus, methodologies and research approaches need to be especially sensitive in eliciting such information. They must ensure confidentiality and must be equipped to offer referrals for counselling, treatment, or legal recourse. Moreover, methodologies must enable women to overcome their reluctance to discuss this issue and this may require greater reliance on qualitative methods. Also, research findings must go beyond simple descriptions of data and analyse behavioural relationships, health consequences, and the social and cultural factors that compromise women's ability to remain free from violence.

Priority areas for research are listed below.

Domestic violence and underlying gender power imbalances

Research is needed to document the prevalence and nature of domestic violence, the situations and context in which it occurs, and perceptions of domestic violence as an acceptable behaviour. The role of family power dynamics and gender relations in influencing domestic violence need special attention. Related questions include: What are women's and men's perspectives regarding the acceptability of domestic violence? How do constraints on women's ability to exercise choices in their own lives affect their ability to protect themselves from violence? What strategies do women adopt to free themselves from violence?

The consequences of domestic violence for safe pregnancy and childbearing

Violence does not apparently abate during pregnancy. Research is needed in developing-country settings on how domestic violence impairs the health of women and their infants. Are women victims of violence more likely to be anaemic or experience other danger signals of ill-health? Are they less likely to seek care for the danger signals if they experience them? Are they less likely to use maternal health services? Are they more likely to experience adverse outcomes in terms of obstetric morbidity, fetal and neonatal mortality, or low birth weight infants?

Domestic violence, unwanted pregnancy, and constrained con-

traceptive choices

Another likely reproductive health consequence of domestic violence is unwanted pregnancy and constraints on contraceptive choice. However, these links have rarely been explored empirically. Research questions include: To what extent are women with an unmet need for fertility regulation inhibited from practising contraception by the threat of violence? How much of unwanted pregnancy can be traced back to the threat of violence or a non-consensual sexual encounter?

The prevalence and consequences of sexual violence

Women tend to under-report sexual violence both because forced sex by husbands or intimate partners is not perceived as violence and because shame and other factors inhibit them from admitting the experience. Studies are needed that examine women's experiences of sexual violence in order to bring out the linkages between violence, in general, but coercive or non-consensual sexual relations, in particular, on the one hand, and women's ability to negotiate safe sex as well as their exposure to STDs on the other. Possible links between early experience of violence and sexual abuse and subsequent risk-taking behaviour also need to be explored.

The vulnerability of adolescents to sexual abuse

Adolescent women are particularly vulnerable to violence, sexual abuse and coercion. Yet little is known about their life skills, ability to negotiate consensual sexual relations, or the short- and long-term consequences of these experiences on their lives. Little is also known about socialization processes that teach young women to tolerate violence, and young men to inflict it. Research is needed that provides insights into the expectations and experiences of adolescents with regard to violence (including sexual violence), the consequences this violence has for their reproductive health (and health more generally), as well as their ability to make reproductive choices.

The role of men

A greater insight is needed into the perceptions, attitudes and experiences of men and, in some settings, of other powerful family members. Little is known about how men who perpetrate violence and those who have more egalitarian relationships perceive their own role and responsibilities in relationships. Do men perceive wife (or partner) abuse as their prerogative? Do men (and other powerful family members) recognize the links between the violence they perpetrate and women's reproductive ill-health, poor pregnancy outcomes, or inability to exercise reproductive choices?

The role of the health sector

The role of the health sector in identifying and treating victims and preventing violence needs to be studied. To what extent, for example, has the public health sector played a role in highlighting the extent of the problem or in providing the evidence that can enable women to seek a legal

recourse to their situation? How do service providers perceive battered women and what is the nature and quality of the interaction between them?

Strategies for combatting violence

The above research is needed in order to ensure that policies and programmes are reoriented to incorporate strategies to combat violence. The preliminary evidence reviewed here suggests that strategies must address not only the immediate health needs of battered women, but also the root causes of violence—unequal gender relations and the way these relations reinforce women's powerlessness. This undoubtedly will require the health sector to interact actively with other sectors—including women's organizations—in raising awareness of the extent of the problem as well as in promoting behavioural changes and negotiation skills of women.

Studies linking domestic violence with reproductive ill-health argue compellingly for the integration of services in order to identify, refer and prevent domestic violence in primary or reproductive health programmes. They argue also for health programmes to be vigilant, sensitive and responsive to the conditions of battered women, by way of services, counselling, and referrals to appropriate legal agencies. At the same time, community education efforts, directed towards adolescents, women, men and family elders, must forcefully convey the need for gender equity and respect for women's rights generally, including their right to be free from violence. Moreover, people need be made aware of the various means (legal, social support, health care, etc.) available to women for protecting themselves against violence. There is also a need to highlight the likely consequences of domestic violence on women's lives and health and on the lives of the infants they bear. The aim should be to reverse social attitudes and beliefs that legitimise male violence, with promotion of responsible sexual and gender attitudes among men. Above all, the efforts must promote women's understanding of their strategic needs and empower them to resist abuse.

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Annex 1

Funding during 1996–1997

In June 1995 the Programme's Policy and Coordination Committee approved a budget of some US$ 42.5 million for the biennium 1996–1997. However, as it became clear during the course of the biennium that contributions to the Programme would not reach that level, a revised budget was prepared at US$ 37.5 million. The actual contributions during the biennium reached US$ 37.2 million. This represented a decrease of about US$ 4.0 million compared to the amount available in 1994–1995.

Fig. 1 compares the actual contributions received by the Programme in relation to approved budgets since 1988. The contributions received are also represented as a percentage of the approved budget for each biennium. In terms of trend, the actual contributions for each biennium were close to 90% of the approved budgets during the period 1988-1991. During the last three biennia, the percentage reached 78%, 79% and 88%, respectively. In absolute terms, however, there has been a worrying decline in Programme income since the biennium 1992–1993, when contributions received reached the highest level in the Programme's history at US$ 46.5 million.

Contributions

The sources of contributions received by the Programme during the last biennium and the total since 1970 are shown in Table 1. In 1996–1997, 25 governments and agencies contributed US$ 37 198 600 (US$ 16 908 200 in 1996 and US$ 20 290 400 in 1997). The donors included 13 developed countries, four developing countries, and five agencies/organizations in addition to three of the four cosponsors.

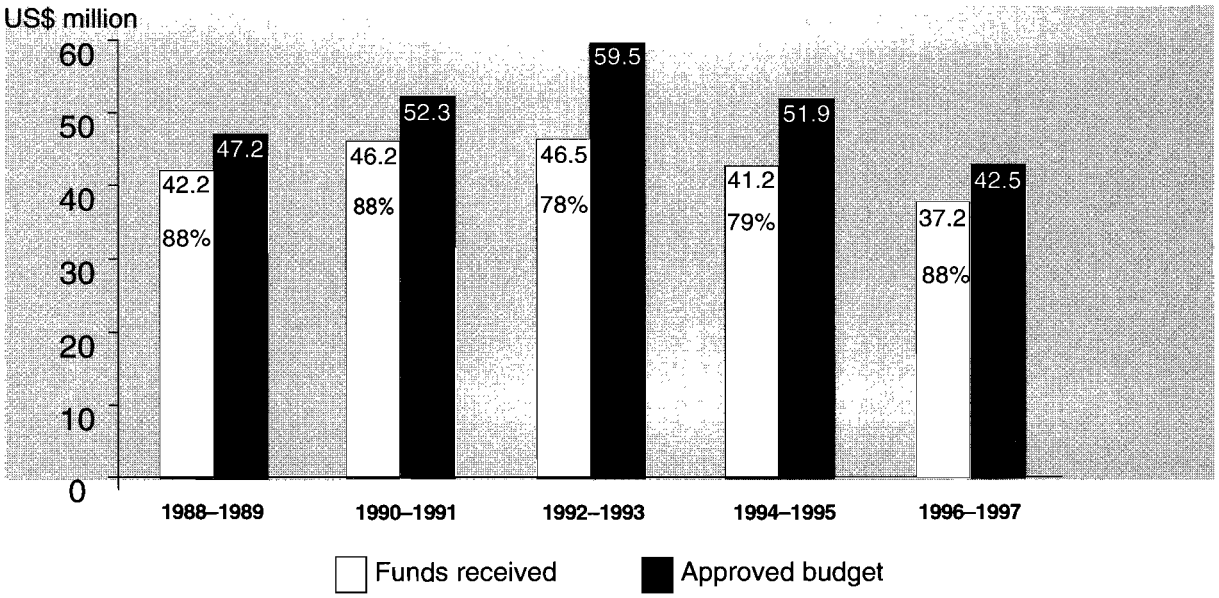
As can be seen from Table 1, the Programme remains heavily dependent on a relatively small number of "core contributors". In 1996–1997, the four largest donors were the United Kingdom, UNFPA, the World Bank and the USA, together providing some 64% of the total income.

The contributions made by the developing countries, though small, are an important sign of those countries' continued interest in the work of the Programme. In fact, the developing countries contribute more than the amounts shown in Table 1. For instance, in order to maintain certain research institutions the developing countries make "counterpart contributions". Since funds made available to the institutions by the Programme often do not cover all the costs, the institutions frequently pay for some of the staff time spent on, and materials used in, Programme projects. These contributions are difficult to quantify, but are certainly substantial in many cases.

Table 1. Income for 1996 and 1997 and for the period 1970-1997 (in US$ thousands)

Source of funds	1996	1997	1970–1997
I. Developed countries			
Australia	564.1	-	4108.1
Canada	253.6	294.1	9828.3
Denmark	-	-	29 514.5
Finland	480.4	166.9	3473.1
France	-	-	6.5
Germany	1288.2	896.0	15 328.0
Italy	-	100.0	654.9
Japan	200.0	100.0	300.0
Netherlands	660.1	532.8	6290.6
New Zealand	13.9	-	27.1
Norway	1187.2	1286.8	45 864.5
Russian Federation (in kind)	-	-	99.5
Sweden	746.9	916.2	93 742.1
Switzerland	-	178.6	2906.7
United Kingdom	3867.3	3979.2	68 538.6
United States of America	-	4000.0	15 220.6
II. Developing countries			
Argentina	-	-	45.1
Bangladesh	-	-	5.0
Chile	-	-	35.0
China	55.0	55.0	820.0
Cuba	-	-	24.6
India	32.3	70.7	729.1
Kenya	-	-	0.5
Malaysia	-	-	1.1
Mexico	-	6.6	97.2
Nigeria	-	-	60.8
Pakistan	-	-	5.0
Thailand	20.0	19.7	161.3
III. Cosponsors, foundations, etc.			
Family Health International	-	-	205.0
Ford Foundation	-	-	1084.0
IDRC (Canada)	-	-	716.5
Mellon Foundation	200.0	160.0	360.0
Packard Foundation	-	20.0	20.0
PATH	87.1	36.8	123.9
Rockefeller Foundation	65.0	205.0	3517.9
UNDP	-	-	1695.0
UNFPA	3500.0	3500.0	55 040.0
UNFPA funds for country and inter-country projects	66.4	(4.1)	22 650.8
Wellcome Trust	20.5	-	20.5
World Bank	2500.0	2500.0	24 258.3
IV. WHO and miscellaneous			
WHO	828.9	828.9	14 475.2
Interest	215.1	266.2	11 556.0
Handling charge for reagents and miscellaneous	5.1	0.9	1 286.2
Patents	51.1	174.1	294.1
Total income	**16 908.2**	**20 290.4**	**435 191.2**

Fig. 1. Funds received in relation to approved budgets during 1988–1997



Annex 2

Centres collaborating with the Programme during 1996–1997

WHO African Region

Benin
National University of Benin, Cotonou
National University Hospital Centre, Cotonou

Cameroon
Hospital and University Centre of Yaoundé, Yaoundé
Faculty of Medicine and Biological Sciences WHO Centre for Research in Human Reproduction, Yaoundé

Cote d'Ivoire
Ministry of Public Health and Social Affairs, Abidjan

Democratic Republic of the Congo
National Cell for Research in Human Reproductive Health, Kinshasa
Technical Information and Research Centre for Development, Kinshasa

Ethiopia
Addis Ababa University, Addis Ababa

Guinea
Donka University Hospital Centre, Conakry

Kenya
Institute of Primate Research, Karen, Nairobi
Kenya Medical Research Institute, Nairobi
Kenyatta National Hospital, Nairobi
National Museums of Kenya, Institute of Primate Research, Nairobi
Population Council, Nairobi
University of Nairobi, Nairobi

Mozambique
Maputo Central Hospital, School of Medicine, Maputo

Nigeria
Ministry of Health, Ibadan
Nigerian Institute of Medical Research, Lagos
Ogun State University Teaching Hospital, Sagamu
University of Benin, Benin City
University of Benin Teaching Hospital, Benin City
University of Ibadan College of Medicine, Ibadan
University of Lagos College of Medicine, Lagos
University of Jos, Jos

Niger
University of Benin, Benin

Senegal
Learning and Research Centre for Reproductive Health, Dakar
Le Dantec University Hospital Centre, Dakar

Ministry of Public Health and Social Welfare, Dakar
Research Network in Reproductive Health, Dakar
University of Dakar, Faculty of Medicine and Pharmacy, Dakar

South Africa
Baragwanath Hospital and Greater Johannesburg, Bertsham
Pan African Federation for Mother and Child Health (Pafmach), Rivonia
Tygerberg Hospital, Tygerber
University of Natal, Durban
University of the Witwatersrand, Johannesburg

Uganda
Makerere Institute of Social Research, Kampala
Makerere University Medical School, Mulago Hospital, Kampala

United Republic of Tanzania
Ministry of Health, Dar-es-Salaam

Zambia
Ministry of Health, Lusaka
University of Zambia, Lusaka
University of Zambia School of Medicine, Lusaka

Zimbabwe
University of Zimbabwe, Harare
University of Zimbabwe Godfrey Huggins School of Medicine, Harare

WHO Region of the Americas

Argentina
Centre for Endocrinological Investigations (CEDIE), Buenos Aires
Centre for Medical Education and Clinical Research, Buenos Aires
Centre for Population Studies (CENEP), Buenos Aires
Centre for Studies of the State and Society (CEDES), Buenos Aires
Institute of Biology and Experimental Medicine, Buenos Aires
Laboratory for Investigation in Growth and Development, Buenos Aires
National University of La Plata, Faculty of Medical Sciences, La Plata
Norberto Quirno Centre for Medical Education and Clinical Investigations (CEMIC), Buenos Aires
Provincial Hospital of Rosario National University, Rosario
Rosario Centre of Perinatal Studies (CREP), Rosario
University of Buenos Aires, Faculty of Medicine, Buenos Aires

Bolivia
Ministry of Human Development, National Secretariat for Health, La Paz

Brazil
Campinas Research Centre for the Control of Maternal and Childhood Diseases (CEMICAMP), Campinas
Federal University of Juiz de Fora, Centre for Reproductive Biology, Juiz de Fora
Tropical Institute of Applied Cultural Concepts, Fortaleza
Nucleus for the Study of Population (NEPO), University of Campinas, Campinas

Canada
Maisonneuve-Rosemont Hospital, Montreal
McMaster University, Hamilton

Chile
Catholic University of Chile, Santiago

Chilean Institute of Reproductive Medicine (ICMER), Santiago
Education for Improvement of Quality of Life (EDUK), Santiago
Frontier University, Medical Faculty, Temuco
Institute for Mother and Child (IDIMI), University of Chile, Santiago
Jose Joaquin Aguirre Hospital, Santiago
Ramon Barros Luco-Trudeau Hospital, Santiago
University of Concepcion, Concepcion

Colombia

Colombian Institute for the Study of Family and Population, Santa Fe de Bogota
Foundation for Higher Education, Cali
University of Valle, Cali

Cuba
Cmdte. Fajardo Hospital, Havana
Institute of Endocrinology, Havana

Dominican Republic
Dominican Association for Family Welfare (Profamilia), Santo Domingo

Guatemala
General San Juan de Dios Hospital, Guatemala City

Jamaica
Ministry of Health, Kingston
University of the West Indies, Kingston

Mexico
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College of Mexico, Mexico City
Latin American Programme of Cooperation and Research in Human Reproduction, Mexico City
Mexican Institute of Social Security, Mexico City
National Institute of Public Health, Cuernavaca
Population Council, Mexico City
Salvador Zubiran National Institute of Nutrition, Mexico City
University of Juarez of the State of Durango, Durango

Panama
Center for Research in Human Reproduction (CRHR), Ministry of Health, Panama

Paraguay
Centre for Rural Interdisciplinary Studies (CERI), Ascension

Peru
Cayetano Heredia National Hospital, Lima
Cayetano Heredia National University, Lima
Latin American Association for Research in Human Reproduction (ALIRH), Lima

United States of America
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Boston Collaborative Drug Surveillance Program, Lexington, MA
Center for Health Promotion and Education, Atlanta, GA
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Tactyl Technologies Inc, Vista
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Venezuela
Foundation for Mother and Infant Studies (FUNDAMATIN), San Martin
Simon Bolivar University, Caracas
Venezuelan Institute for Scientific Research. Caracas

WHO Eastern Mediterranean Region

Egypt
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Egyptian Fertility Care Society, Cairo
Shatby Maternity Hospital, Alexandria
University of Alexandria, Alexandria

Islamic Republic of Iran
Institute for Research in Planning and Development, Teheran
Ministry of Health and Medical Education, Teheran

Pakistan
Aga Khan University, Faculty of Health Sciences Medical College, Karachi
National Research Institute of Fertility Control, Karachi
Quaid-E-Azam University, Islamabad

Sudan
University of Khartoum, Faculty of Medicine, Khartoum

Tunisia
National Office for Family Planning and Population, Tunis
The Ariana Centre for Research in Human Reproduction, New Ariana
Tunisian Endocrinology Society, Tunis

WHO European Region

Armenia
Armenian Research Centre for Maternal and Child Health Protection, Yerevan

Austria
Salzburg General Hospital, Salzburg

Belgium
International Institute of Cellular and Molecular Pathology, Brussels
International Union for the Scientific Study of Population (IUSSP), Brussels
Free University of Brussels, School of Public Health, Brussels

Denmark
Danish Cancer Registry, Danish Cancer Society, Copenhagen

Finland
University of Helsinki, Children's Hospital, Helsinki
Family Federation of Finland, Sexual Health Clinic, Helsinki

France
University Hospital Centre, Le Kremlin-Bicêtre, Paris

Georgia
Zhordania Institute of Human Reproduction, Tbilisi

Hungary
Albert Szent-Györgyi Medical University, Szeged
Institute of Microbiology, University Medical School, Pecs

Israel
Beilinson Medical Center Sackler School of Medicine, Petah-Tiqva
Chaim Sheba Medical Centre, Tel Aviv
Soroka University Hospital, Beer Sheva

Italy
Ambrosian Centre for Natural Methods (CAMEN), Milan
Rome University of Studies, Rome
University of Milan, Faculty of Medicine, Milan
University of Turin, Turin

Norway
Ulleval Hospital Clinic for Families and Children, Oslo

Romania
Center for Public Health, Targu-Mures

Slovenia
University Gynaecology Clinic, Ljubljana
University of Ljubljana Medical Centre, Ljubljana

Sweden
Karolinska Hospital, Stockholm
Karolinska Institute, Stockholm
Umea University, Umea
University of Lund, Lund
Uppsala University, Unit of International Child Health Care, Uppsala

Switzerland
Cantonal Hospital, University of Geneva, Geneva
Global Knowledge Network, Geneva
University Medical Centre for Research and Training in Immunology, Geneva

Turkey
Marmara University, Medical Faculty, Istanbul
University of Istanbul, School of Medicine, Istanbul

Ukraine
Kiev Research Institute of Endocrinology and Metabolism, Kiev

United Kingdom of Great Britain and Northern Ireland
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Chelsea Hospital for Women, London
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London School of Hygiene and Tropical Medicine, London
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Queen Charlotte's and Chelsea Hospital, London
Reproductive Health Matters, London
UK Cochrane Centre, Oxford
University Hospital of South Manchester, Manchester
University of Edinburgh Centre for Reproductive Biology, Edinburgh

University of Manchester, Manchester
University of Warwick, Coventry

Yugoslavia
University of Belgrade, Clinical Centre of the School of Medicine, Belgrade

WHO South-East Asia Region

Bangladesh
International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), Dhaka

Democratic People's Republic of Korea
Pyongyang Maternity Hospital, Pyongyang

India
All India Institute of Medical Sciences, New Delhi
Belaku, Bangalore
Institute for Research in Reproduction, Mumbai
Indian Society for the Study of Reproduction and Fertility, Mumbai
Jawaharlal Institute of Post-Graduate Medical Education and Research, Pondicherry
Ministry of Health and Family Welfare, New Delhi
Punjab University, Chandigarh
Postgraduate Institute of Medical Education and Research, Chandigarh

Indonesia
Airlangga University, Dr Soetomo Hospital, Surabaya
Raden Saleh Clinic, Jakarta
Sriwijaya University, Faculty of Medicine, Palembang
University of Indonesia, Jakarta
University of North Sumatra, Western Indonesian Reproductive Health Development Centre, Medan
Yayasan Kusuma Buana, Jakarta

Myanmar
Ministry of Health, Department of Medical Research, Yangon

Nepal
Center for Research on Environmental Health and Population Activities, Kathmandu
Tribhuvan University, Institute of Medicine, Kathmandu

Sri Lanka
University of Colombo, Colombo
University of Ruhuna, Matara

Thailand
Chiang Mai University Research Institute for Health, Chiang Mai
Chulalongkorn Hospital Medical School, Bangkok
Institute of Health Research, Bangkok
Institute of Population and Social Research, Nakhon Pathom
Khon Kaen University, Faculty of Medicine, Khon Kaen
Mahidol University, Siriraj Hospital, Bangkok
Mahidol University Family Planning Research Unit, Bangkok
Population Council, Bangkok
Prince of Songkla University, Faculty of Medicine, Hat Yai

WHO Western Pacific Region

Australia
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Prince Henry's Institute of Medical Research, Melbourne
Royal Prince Alfred Hospital, Sydney
University of Melbourne, Carlton

China
Beijing Municipal Maternal Health Institute, Beijing
Chinese University of Hong Kong, Faculty of Medicine, Hong Kong SAR
Family Planning Research Institute of Guangdong, Guangzhou
Family Planning Research Institute of Sichuan, Chengdu
Family Planning Research Institute, Tong Ji Medical University, Wuhan
First Teaching Hospital, Beijing Medical University, Beijing
Guizhou Institute of Family Planning Research, Guiyang
Hebei Family Planning Institute, Shijiazhuang
Henan Research Institute for Family Planning, Zhendhzou
Harbin University of Medical Sciences, Harbin
Institute of Population Research, Peking University, Beijing
International Peace MCH Hospital, Shanghai
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Tianjin Medical College, Tianjin
University of Hong Kong, Queen Mary Hospital, Hong Kong SAR
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Xuan-Wu Hospital, Capital Institute of Medicine, Beijing
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Malaysia
International Council on Management of Population Programmes, Kuala Lumpur
University of Malaya Faculty of Medicine, Kuala Lumpur

Mongolia
State Research Centre on Human Reproduction and Maternal and Child Health, Ulaanbaator

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Annex 3

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The Special Programme of Research, Development and Research Training in Human Reproduction was established by the World Health Organization (WHO) in 1972 to coordinate, promote, conduct and evaluate international research in human reproduction. The United Nations Development Programme, the United Nations Population Fund and the World Bank joined WHO as cosponsors of the Programme in 1988 when the World Health Assembly endorsed the role of the Programme in *"coordination of the global research effort in the field of reproductive health"*. As the main instrument within the United Nations system for research in human reproduction, the Programme brings together health care providers, policy-makers, scientists, clinicians and consumer and community representatives to identify and address priorities for research aimed at improving reproductive health.

The Programme investigates the extent and nature of reproductive health problems, their determinants and the interventions needed for their alleviation or resolution. While fertility regulation has remained the core area of the Programme's research, the research agenda in recent years has been broadened to address other challenges in reproductive health. This reflects the Programme's response to the wide range of issues in reproductive health identified in recent international fora, particularly the International Conference on Population and Development in 1994 and the International Conference on Women in 1995. The Programme also carries out activities to strengthen the capabilities of developing countries to meet their own research needs and to enable them to participate in the global effort in reproductive health research.

The Programme promotes the use of research results in policy-making and planning at national and international levels and contributes to the setting of norms, standards and guidelines, including ethical guidelines, in the field of reproductive health research. The Programme works to ensure that gender issues, and particularly the perspectives of women, are reflected in both its research and research capability strengthening activities to foster the achievement of greater equity and sexual and reproductive rights.

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