

UNDP/UNFPA/WHO/WORLD BANK SPECIAL PROGRAMME OF
RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN
HUMAN REPRODUCTION

Challenges in reproductive health research

Biennial Report 1992–1993

Edited by

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PROGRAMME OF RESEARCH, DEVELOPMENT AND
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**Challenges in Reproductive
Health Research
Biennial Report 1992–1993**

Geneva, World Health Organization, 1994

CORRIGENDUM

1. As a result of an unforeseen incompatibility between the computer programs used by WHO and the printer, "µg" appears as "mg" in this report on the following pages:

page 124, column one, paragraph three, line four;
page 135, column one, paragraph one, line one;
page 144, column two, paragraph one, lines one, two, three,
and eight.

2. In Annex 2, please note the following changes:

- a) page 188, under Kenya, please include:
Population Council, Regional Office, Nairobi
- b) page 195, under India, please insert:
Postgraduate Institute of Medical Education and Research,
Chandigarh.
- c) page 196, under Thailand,
delete: Institute of Health Research, Bangkok
insert: Institute of Health Research, Chulalongkorn
University, Bangkok
- d) page 197, under Malaysia, please insert
International Council on Management of Population
Programmes, Kuala Lumpur

Preface

As the new Director, it gives me great pleasure to present this 1992–1993 Biennial Report of the Programme—the oldest programme of its kind in the United Nations family of organizations. This Programme of great stature is passing through a period of major challenges, most importantly that funding is declining at a time when the expectations of the world for better reproductive health knowledge and technology are continuing to rise. This Report documents the Programme's endeavours towards making sound reproductive health a reality for all.

During the biennium a particularly momentous event was the joint organization of a symposium with the Government of Mexico in Mexico City. Entitled Contraceptive Research and Development for the Year 2000 and Beyond, the Symposium brought together senior managers of all the international and some national public sector agencies that undertake contraceptive research, as well as programme directors and senior staff of certain international and national agencies that support or are otherwise involved in the field of fertility regulation research. The main objective of the Symposium was to review the progress made in the field of contraceptive research since 1984 (when Mexico City hosted the International Conference on Population) and to identify the challenges ahead in preparation for the next International Conference on Population and Development scheduled to be held in Cairo in 1994. The participants in the Symposium prepared a Declaration, which was sent by the WHO Director-General to the Executive Director of the United Nations Population Fund for consideration as a background document during preparatory meetings for the Cairo Conference. This Biennial Report is the Programme's contribution to the ongoing debate on the challenges in reproductive health research in preparation for the Cairo Conference.

Drawing from, and elaborating on, the deliberations of the Mexico Symposium, the first part of the Report highlights the major challenges in reproductive health research as this century draws to a close. On behalf of the Programme, I should like to thank Dr N. J. Alexander, Dr G. Bialy, Ms A. Germain, Dr A. Faundes, and Dr M. F. Fathalla for contributing chapters to this part of the Report.

The second part of the Report presents highlights of the Programme's work during 1992–1993. More detailed technical information on the activities mentioned in this Report can be found in the Programme's Annual Technical Reports.

The third, and final, part contains annexes on the financial situation of the Programme in 1992–1993, a list of institutions that collaborated with the Programme during the biennium, and a list of staff of the Programme.

Giuseppe Benagiano
Director

Executive summary

FROM CONTRACEPTIVE TECHNOLOGY TO REPRODUCTIVE HEALTH

At its inception in 1972, the objectives of the Programme were limited to the development of a variety of safe, acceptable, and effective methods for fertility regulation and the monitoring of the long-term safety and efficacy of existing methods; an additional but important objective was to provide support to institutions in developing countries so that they could conduct research relevant to their own needs. By 1979 the scope of the Programme had been broadened to include research on the acceptability of various contraceptive methods and on the prevention, diagnosis, and treatment of infertility. In 1986 the Programme's Policy

Coordination and Advisory Committee further broadened the scope of activities with the recommendation that the Programme should collaborate closely with the WHO Global Programme on AIDS in conducting research on such issues as the transmission of human immunodeficiency virus (HIV) from mother to infant. And in 1988 the World Health Assembly, endorsing the policy guidelines of the Programme, reaffirmed the close relationship between family planning, health, and development, and the necessity to integrate family planning activities with those of maternal and child health. It was at this stage in the history of the Programme that its mandate was further expanded to include the coordination of the global research effort in the field of reproductive health.

What is reproductive health?

Within the framework of WHO's definition of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity, reproductive health addresses the reproductive processes, functions, and system at all stages of life. Reproductive health therefore implies that people are able to have a responsible, satisfying, and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so. Implicit in this last condition are the right of men and women to be informed of and to have access to safe, effective, affordable, and acceptable methods of fertility regulation of their choice, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.

The concept of reproductive health

The basic elements of reproductive health are: responsible reproductive/sexual behaviour, widely available family planning services, effective maternal care and safe motherhood, effective control of reproductive tract infections (including sexually transmitted diseases (STDs)), prevention and management of infertility, elimination of unsafe abortion, and prevention and treatment of malignancies of reproductive organs. Furthermore, reproductive health affects, and is affected by, other aspects of health, most particularly human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS), nutrition, infant and child health, adolescent health and sexuality, lifestyle, and environmental factors. Pervading and affecting all aspects of reproductive health are vari-

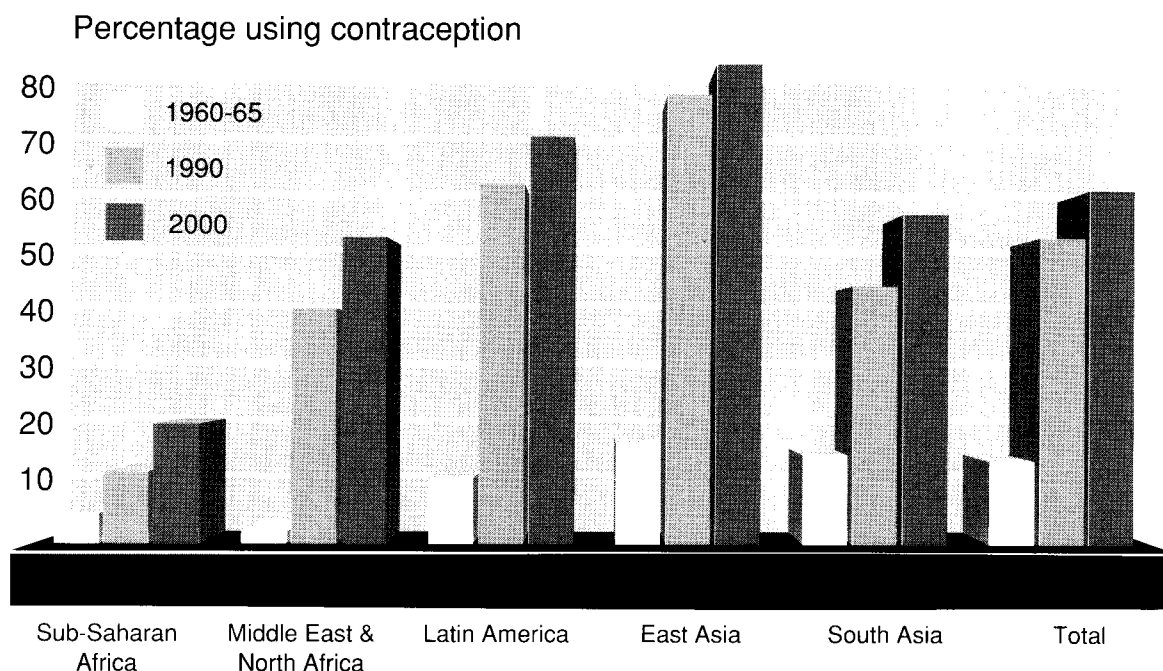
ous social, cultural, and behavioural factors.

The Programme, with its limited resources, cannot involve itself in all areas of reproductive health research. Within WHO, work in the area of reproductive health is shared by various Divisions and Units. Two major players, apart from the Programme, are the Division of Family Health and the Global Programme on AIDS.

CHALLENGES IN FERTILITY REGULATION RESEARCH

Over the last three decades there has been an impressive rise in the use of contraceptives all over the world, which is expected to continue up to the year 2000 (Fig. 1). In 1990 up to 57% of all married

Fig. 1. Trends in contraceptive use in different developing regions of the world



EXECUTIVE SUMMARY

women of reproductive age or their husbands were using a method of contraception. This represents an increase of 6% over the prevalence in 1983 (Table 1).

These figures, however, do not tell the whole story. For example, in the least developed countries, which represent some 540 million people, the total fertility rate was still 6.1 births per woman in 1992, which corresponds to an estimated prevalence of contraceptive use of only 14%.

It is estimated that there are some 120 million women in developing countries who are not practising family planning even though they say that they do not want to become pregnant. The United Nations Population Fund (UNFPA) estimates that during the 1990s the number of married women of reproductive age in developing countries will increase by about 212 million (28%)—from 747 million in 1990 to 959 million in 2000. If the world is to achieve the United Nations medium-variant population projection of 6.2 billion by the year 2000, it is imperative that fertility in developing countries drops to 3.3 births per woman (from 3.9 in 1985–

90) and contraceptive prevalence rises to 59%, from the 1990 figure of 53%. If these levels are to be achieved, the number of contraceptive users in developing countries must increase by 186 million by the year 2000—from 381 million in 1990 to 567 million by the year 2000.

The reproductive health perspective

Among all the factors that influence reproductive health, fertility regulation is undoubtedly one of the most important as it has a bearing on, among others, the prevention of unwanted pregnancy (and its consequences), the prevention of STDs and infertility, sexuality, infant survival and well-being, and safe motherhood.

Unwanted pregnancy and fertility regulation

Half of all pregnancies are unplanned and a quarter certainly unwanted. Unwanted pregnancy is a major public health problem with potentially serious consequences for the health of the girl or woman. Not only is it a denial of a wom-

Table 1. Percentage of couples with wife in reproductive age using a contraceptive method

	World			More developed regions			Less developed regions		
	1983	1987	1990	1983	1987	1990	1983	1987	1990
All methods	51	53	57	70	71	72	45	48	53
Modern methods	42	44	49	46	47	49	40	44	48

Modern methods in this table include: female and male sterilization, oral pills, injectable methods, intrauterine devices, vaginal barrier methods (cervical cap, diaphragm), and the condom.

an's fundamental right to control her fertility, it also exposes her to the hazards of pregnancy and childbirth, or possibly an abortion done under unsafe conditions. In developing countries one in 50 women dies from complications of pregnancy and childbirth, compared to only one in 2700 in developed countries. Also, when a mother dies, the chances of death for her children under five years of age increase by 50%.

Many unwanted pregnancies result in abortion. Around 50 million abortions are performed each year around the world. In developing countries many a pregnancy is terminated in clandestine or otherwise unsafe conditions. This exposes women to a high risk of mortality and morbidity. The estimated annual number of unsafe abortions in the world is 21 million. At least 180 women die every day from unsafe abortions.

Fertility regulation and birth spacing

In many developing countries the traditional practice of prolonged breast-feeding, which helps to achieve longer birth intervals, is gradually eroding. But fortunately contraceptive use is rising and helping to maintain adequate birth intervals. However, where the use of modern contraceptives is not rising as fast as the decline in breast-feeding, many women and their children are being exposed to avoidable health risks, which can lead to death.

With regard to delaying the next birth, two major challenges for policy-makers and scientists are: (a) the maintenance of the practice of prolonged breast-feeding but at the same time promoting the timely

introduction and use of appropriate contraceptives to achieve adequate birth intervals; and (b) the development of suitable and more acceptable methods of birth spacing for lactating women.

The biomedical perspective

Expanding contraceptive choice

Although contraceptive use continues to rise in the world, the currently available methods, however good, do not meet all the different requirements of all the current and potential users. New methods are needed therefore so that the needs of a maximum number of individuals and couples can be satisfied.

Vaginal methods

Vaginal methods include: the barrier methods (condom, diaphragm, and cervical caps) and spermicides (foams, jellies, etc.) or a combination of the two. While other methods have been improved (e.g., oral pills and IUDs), vaginal methods have remained essentially unchanged over the past three decades. Hence, their use-effectiveness and acceptability remain low.

Women's health advocates have been demanding that scientists develop methods of fertility regulation that: (a) are under the control of the user; (b) are not systemic in action; and (c) protect the user against sexually transmitted disease (STD). Many scientists regard this a tall order given the limitations of currently available technology. However, some scientists feel that vaginal methods, which come closer than other methods to meeting these requirements, have not

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received due attention. While the current systemic and service-dependent methods have their own advantages and have proven to be safe and effective, in the coming years improving vaginal methods will be a major challenge.

Male methods

The Programme's own research has demonstrated that, on the one hand, it is possible to suppress spermatogenesis by hormonal means. On the other hand, once spermatogenesis is suppressed and the semen is free of spermatozoa, a high contraceptive efficacy can be maintained for the duration of drug administration (one year in the study conducted by the Programme). Upon withdrawal of the drug, the contraceptive effects are completely reversible. While this represents a major milestone in the history of male contraceptive research, a great amount of further work will be needed to turn this lead into a veritable product.

Fertility regulating vaccines

Fertility regulating vaccines hold the promise of a major breakthrough in contraceptive research. They are expected to be usable by women at all stages of their reproductive life, they would be able to provide long-term, but not permanent, contraceptive protection after a single administration, and they would not produce the disturbances in the menstrual cycle and the metabolic side-effects associated with the hormonal methods. While the whole area of fertility regulating vaccines is full of challenges, one especially formidable challenge would be to develop vaccines for men.

Post-ovulatory contraception

The advent of antiprogestogens has provided some of the most exciting, and sometimes controversial, developments in antifertility research in recent years. Mifepristone (in combination with a low dose of a prostaglandin analogue) has been developed into a non-surgical method of early pregnancy termination. Furthermore, mifepristone is already showing great promise for use as a method of menstrual regulation and in emergency contraception. It may also be possible to use mifepristone (alone or in combination with a prostaglandin) in a once-a-month, menses-inducing pill. Such a pill may prove to be a more attractive alternative to the daily pill. Some scientists regard the developments in this field as a precursor to the development of a post- or peri-coital contraceptive pill.

The epidemiology of contraceptive use

Although the clinical and epidemiological methods currently available for ensuring safety of contraceptives are quite adequate, the "translation" of epidemiological findings into sound advice for consumers is not always easy. A challenge for scientists is to formulate public health advice on the basis of epidemiological studies such that service providers can give the users and potential users of contraceptives reliable and meaningful information on the health implications of the epidemiological findings for them.

Involving the private sector in contraceptive development

Over the last 15 years the pharmaceutical industry has retrenched from the field

of fertility regulation. Originally the industry began to withdraw from the field for reasons such as an unfavourable political climate with regard to contraceptives, problems of liability, and stringent regulatory requirements that prolonged the product development process.

These issues are no longer regarded as the main impediments by industry. Today, the concerns are largely economic. Industrial enterprises see the current profit-making markets, which are mainly in developed countries, already saturated with effective products (Fig 2.). They fear that the cost of developing new products may be too high in relation to the paying capacity of the people in developing countries and thus there may not be sufficient returns on investment.

However, a favourable climate now appears to be emerging for the public and

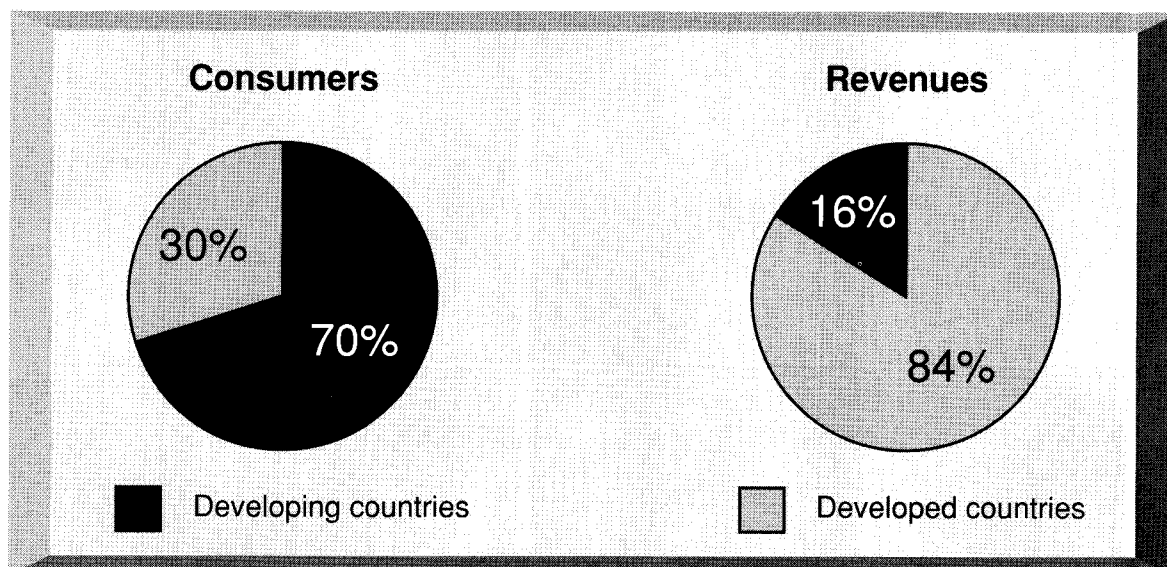
private sectors to work together more closely. It is now believed that the two sectors will need to collaborate in research in order to develop the contraceptives that meet people's needs and expectations beyond this decade.

The social perspective

Contraceptive use behaviour

A question often asked is why women who say they do not want more children do not practice contraception, especially when it is known that in most countries almost all of married women know about contraception. Social science research has generated a wealth of information about the various factors that affect contraceptive use. While there are certain factors that appear to influence contraceptive use in most societies (e.g., women's education, access to services and

Fig. 2. The global contraceptive market



information, and urban residence), it is difficult and unwise to make generalizations. A particularly important challenge is to discover quickly which factors are more important than others in different societies, and to translate this understanding into effective policies and action.

Adolescents and contraceptives

In most developing countries there is a large, and growing, population of adolescents. The last decades have witnessed a changing pattern of sexuality among this population group. It has been found that economic progress and urbanization have been accompanied by a shift in the traditional values associated with sexuality, with the result that many more young people are having sexual relations prior to marriage. In many societies this change has occurred against the backdrop of strict traditional customs, and the society and family planning services are as yet often unprepared in terms of providing information on, and methods of, fertility regulation to the adolescents. Understanding and meeting the information and contraceptive needs of adolescents is a growing area of challenge for scientists and policy-makers.

Sexual behaviour, fertility regulation, and STDs

Sexual behaviour has a bearing on the risk of unwanted pregnancy and of contracting an STD (and possible infertility). It may also influence contraceptive choice. With STDs and unwanted pregnancies on the rise around the world, especially among adolescents, the study of sexual behaviour, particularly in developing countries, has acquired a certain urgency.

A major problem is that sexuality is often surrounded by strict social, moral, and religious beliefs and these make an objective study of the subject difficult. But such knowledge is essential not only in developing sound advice for people but also in deciding which types of contraceptive will most suit people's needs.

The women's perspective

In March 1993 the Government of Mexico and the Programme jointly organized a Symposium in Mexico City entitled Contraceptive Research and Development for the Year 2000 and Beyond. The Declaration of the Symposium (see pages 53–57) calls for the inclusion of women's health advocates and potential users in "all decision-making mechanisms and advisory bodies that are established to guide the research process...". Scientists should welcome this call as the representation of the views of the ultimate users in the contraceptive development process can help to focus scarce resources on methods that are likely to be most acceptable. A major challenge for scientists will be to make adjustments in the current research culture in order to incorporate the viewpoints of potential users and their representatives. On the other hand, the women's health movement will need to be better informed about scientific issues related to fertility regulation research.

The challenge for governments

The importance of the need to continue and expand research on fertility regulation methods cannot be overemphasized. The Mexico Symposium calls on governments in developing countries to "establish programmes for the conduct

of reproductive and sexual health research as a priority component of their national health research agendas, and allocate the funds and develop the human and institutional resources required for carrying out such research". A call was also addressed to donor governments and agencies to: (a) "provide greater financial resources as a priority in order to strengthen further the human and institutional capabilities of developing countries"; and (b) "increase support for basic biomedical, technological, clinical, epidemiological, and social science research to improve existing and to develop new fertility regulation methods that are safe, effective, affordable, suitable for different age groups, and designed in response to users' needs".

LAUNCHING A SECOND CONTRACEPTIVE REVOLUTION

The advances in contraceptive technology over the past few decades can only be described as a revolution. The methods resulting from this revolution have produced a dramatic decline in fertility in many parts of the world. However, the currently available contraceptive "hardware", though still usable, is inadequate to meet the present require-

ments and the rapidly expanding future needs. A second contraceptive revolution is urgently needed, and the agenda for the contraceptives of the 21st century must be set now.

For the successful launching of a second contraceptive technology revolution, the field needs a clear and appealing mission, a strong scientific base, and a private industry ready to seize the opportunity. There are indications that these criteria can now be met. For instance, the mission is now becoming clear and compelling, with women increasingly articulating their unmet needs. Science is again becoming ripe with fascinating advances. New frontiers are opening up with research on cell and molecular biology and with the advent of biotechnology. There are also signs that private industry may be ready to work jointly with public sector programmes to develop new methods of fertility regulation.

THE CHALLENGE OF SEXUALLY TRANSMITTED DISEASES

Sexually transmitted diseases (STDs) are a major public health problem in all countries, but especially so in developing countries. Table 2 shows the global

Table 2. Global incidence of STDs

Disease	Minimum estimates of yearly incidence
Trichomoniasis	120 million
Chlamydial infections	50 million
Human papilloma virus (HPV)	30 million
Gonorrhoea	25 million
Herpes simplex virus (HSV)	20 million
Syphilis	3.5 million

incidence of STDs.

STDs can cause a number of serious clinical conditions and are the most important preventable cause of infertility (see Table 3). The consequences of STDs are particularly severe for women as they are more susceptible to infection and experience symptoms, complications and secondary ascending infection much more often than men.

Genital infection with *Chlamydia trachomatis* is estimated to be the most common bacterial STD with a minimum estimate of 50 million new infections worldwide each year. Chlamydial lower genital tract infection is asymptomatic in the majority of infected men and women.

Only in some countries (such as Sweden) can it be claimed that the public health problem of STDs is diminishing. As more data become available from developing countries, it is clear that reproductive tract infections including STDs and HIV infection are a major concern with substantial social and economic implications. The challenges for the remainder of this century include improved health education for both sexes especially male adolescents, dramatic changes in the status of women and their enfranchisement, and the creation of equal opportunities for adequate reproductive health care and education.

The principal constraints to effective STD control especially in developing

Table 3. Major STD microbial agents and the conditions they produce

Agent	Acute disease	Pregnancy-associated conditions	Chronic conditions
<i>Neisseria gonorrhoeae</i>	Urethritis Cervicitis Salpingitis	Premature birth Septic abortion Ophthalmia of neonate Postpartum endometritis	Infertility Ectopic pregnancy
<i>Chlamydia trachomatis</i>	Urethritis Cervicitis Salpingitis	Septic abortion Ophthalmia of neonate Postpartum endometritis	Infertility Ectopic pregnancy
<i>Treponema pallidum</i>	Primary and secondary syphilis	Spontaneous abortion Stillbirth Congenital syphilis	Neurosyphilis Cardiovascular syphilis Gumma
Human papilloma virus	Genital warts	Neonatal laryngeal papillomatosis	Genital cancer
Herpes simplex virus-2	Genital ulcer	Neonatal herpes Premature birth	Possibly genital cancer

countries include the absence of simple, inexpensive, and accurate diagnostic kits and little or no epidemiological research on the incidence or prevalence of the disease. These deficiencies coupled with the enormous problem of health education and the continued provision of male condoms free of charge or for a nominal cost at all contact points between the subject at risk of STDs and the health care system, pose formidable challenges.

The extent and microbiological nature of reproductive tract infections in developing countries, especially in rural communities with restricted access to health care, need to be quantified. While *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are well established as a cause of salpingitis there remain some 30-40% of cases in which neither organism can be identified. Research is needed on the role of other organisms (including the mycoplasmas) in lower genital tract infection, and on bacterial vaginosis in the genesis of female upper genital tract infection. Vaccines against chlamydial and gonococcal infection have great potential in the long-term for STD control, but much more research and development work is still required. New and continuous advances in immunotherapy have increased the probability of success in this area.

HIGHLIGHTS OF 1992–1993

Epidemiological research

Hormonal contraceptives and cancer

In 1979 the Programme started a major multinational case-control study to

investigate the possible relationship between the use of hormonal contraceptives and neoplastic diseases of the breast, cervix, endometrium, gallbladder, liver, and ovary. An important finding from this study has been that most results from the studies in developed countries of hormonal contraceptives and risk of cancer are also likely to be applicable to women in developing countries. The main results from the study relating to depot-medroxyprogesterone acetate (DMPA) were reviewed in 1993 by a meeting of experts. The participants concluded that among DMPA users there was no evidence for an overall increase in the risk of cancer at any of the four sites reviewed (breast, cervix, endometrium, and ovary). It was also concluded that DMPA had a protective effect with regard to endometrial cancer. Thus, it was recommended not to restrict the use of DMPA as a contraceptive on the grounds of risk of neoplasia.

Vasectomy and cancer

In 1993 two studies were published in the USA which showed an increased risk of prostate cancer 20 years after vasectomy. Although these studies do not establish a causal link between vasectomy and prostate cancer, they may affect the acceptability of vasectomy not only in developed countries but also in developing countries where this method of family planning is quite prevalent. In 1993 the Programme initiated the pilot phase of a multicentre case-control study on the relationship of prostate cancer and vasectomy in four developing countries where this family planning method is common (China, India, Nepal, Republic of Korea).

Hormonal contraception and endemic diseases

Gallstones. The prevalence of gallstone disease varies widely among countries, and women are at a higher risk of being affected than men. Reproductive factors, such as female sex hormones and pregnancy, are considered risk factors for the disease. A study supported by the Programme is in progress in China, in which cases of surgically confirmed gallstone disease are being compared to an equal number of controls to find out if the use of oral contraceptive pills affects the risk of developing the disease. Data collection has been completed and the results are expected in 1994.

Hepatitis B infection. Many family planning programmes recommend that women with a history of jaundice should not be prescribed hormonal contraceptives unless their liver function has been clinically proven to be normal. In developing countries, where hepatitis B infection is common, testing of liver function involves a considerable expense for the potential users of contraceptive pills. There is also a possibility that some family planning programmes may be unnecessarily disqualifying certain women from using hormonal contraceptives. The Programme is supporting a study in China and Thailand in which asymptomatic chronic carriers of hepatitis B virus (HBV) who choose to use low-dose combined oral contraceptives are being investigated. Liver function and replication rates of HBV among the study subjects are being compared to those in a group of chronic carriers of HBV using a

non-hormonal contraceptive method.

Hormonal contraceptives and bone density

Osteoporosis—loss of bone with age—is more pronounced in women than in men. The Programme has started a study in diverse geographic locations to evaluate the relationship between the use of hormonal contraceptives and bone density.

Contraceptive prescribing practices

Recognizing that some of the prescribing practices may hinder access to contraception, the Programme, in collaboration with the WHO Division of Family Health and a number of international agencies, is examining the scientific basis for the eligibility criteria for well established hormonal contraceptive methods and intrauterine devices with the aim of arriving at more rational prescribing practices.

Safety of contraceptives and breast-feeding

Oral contraceptives containing both an estrogen and a progestogen have been shown to affect adversely the quantity and composition of breast milk, whereas progestogen-only pills have little, if any, effect. To establish the safety of progestogen-only methods the Programme conducted a study in which 2466 mother–infant pairs participated. It was concluded that in this study the progestogen-only methods did not adversely affect infant growth or development during the first year of life.

Social dimensions of reproductive health

Dynamics of contraceptive use

During 1992–1993 data from selected countries (Bangladesh, Mexico, Nigeria, and Turkey) that participated in a 10-country study on dynamics of contraceptive use were analysed to see if there were common trends. The analysis revealed that the choice of a particular method is influenced by the perceptions of the individual couple, and of the society at large, regarding different methods, and by the preferences of the family planning programme.

The IUD was the dominant method in Turkey, the pill in Bangladesh, sterilization in Mexico, and abstinence in Nigeria. Most programmes seem to overlook the importance of traditional methods in their settings. These traditional methods account for about one-fourth of all use. In countries such as Nigeria, where the fertility transition has not yet begun, their use may be even higher. Traditional methods do not necessarily give way to modern methods when prevalence increases, as was found in Turkey. A low level of fertility can be achieved even when traditional methods constitute a large proportion of all contraceptive use.

The variation in the patterns of contraceptive use in these four countries highlights the influence of the local, social, and cultural factors in contraceptive use. Strategies to promote family planning and to curtail fertility thus need to be developed carefully, with much attention being paid to local conditions.

Determinants of abortion

United Republic of Tanzania. In Tanzania, a Programme-supported study involving 455 women admitted to four public hospitals in Dar-es-Salaam for complications of induced abortion found that one-third of the sample comprised teenagers. Contraceptive knowledge and use were very low or non-existent. Less than one-fifth of all the women in the study reported using some method at the time of conception and only five women reported that they had used a modern method. A third of the adolescent girls reported that their partner was a man of 45 years or older. The daily cost of treating one woman with abortion complications was estimated to be seven times higher than the per capita budget allocated by the Ministry of Health for all health care during a whole year. As a result of this study, a post-abortion family planning counselling and provision service has been set up on a trial basis for one year in major hospitals of the country.

Mauritius. A study of contraceptive use based on a sample of 475 women admitted to three hospitals with complications due to induced abortion revealed considerable use of unreliable methods (including withdrawal and natural methods), frequent switching from one method to another, and inconsistent use of modern methods. The study found that women seeking abortion were usually under the age of 30 years. One out of every five women with abortion complications was not using any method, and one out of every two was using an unreliable method at the time she became pregnant.

It emerged that with increasing numbers of women employed, their work schedules hindered their going to a family planning clinic and resulted in abortion being used as a back-up to contraceptive failure. Among the women with abortion complications, one-fourth had already had a previous abortion. The results of the study resulted in discussions at the National Assembly, where a motion was tabled to decriminalize abortion.

Dominican Republic. In the Dominican Republic a study was conducted to identify the main factors associated with the occurrence of induced abortion. The results indicated that the majority of women in the study had a low socioeconomic status and a low level of education. Many had migrated to Santo Domingo, the capital, in search of employment. Their average age was about 26 years. Adolescents represented 16% of the total study sample of 350 women. Most of these women were in some sort of union, but only 13% were formally married. Contrary to popular belief that it is only unmarried adolescents who resort to induced abortions, the study showed that the majority were in permanent or semi-permanent unions. In fact, most of them had been in the union for three or more years. The use of contraception was low and unsystematic, with high discontinuation rates. This project has had a significant policy impact. In 1993, a revised Health Code was presented to the Dominican Congress for discussion and approval. The Senator who introduced this legislation had used results from the study.

Mexico. In Mexico the Programme supported a study to understand the

reasons why women resort to induced abortion. Another objective was to assess the opinions of health personnel that provide care for abortion complications. A sample of 300 women hospitalized for abortion complications were interviewed as well as 120 health care workers, including physicians, nurses, social workers, and family planning staff. Abortion complications represented close to 20% of the yearly maternity ward admissions at the hospital. A total of 28% of the women studied were under 20 years of age, 60% had some primary schooling or less, and 68% were single or living in common-law unions. Nearly half of the women (46%) had never used a method of contraception, yet 70% did not want to become pregnant. Some women decided to abort for economic reasons in order to be able to provide adequately for the children they already had; others reported that they could not have the child because they were not married. The methods reportedly used for inducing abortion included injections and falling from heights or down a flight of stairs. The study results have been presented to the Director-General of Maternal and Child Health Care of the Ministry of Health of Mexico, who has used them to seek improvements in the service conditions in public hospitals in the country.

Indonesia. In Indonesia, where abortion is also illegal, a study was conducted to assess the attitudes of health care providers, including general practitioners, gynaecologists, midwives, and traditional birth attendants. The study revealed that in the formal health sector the use of menstrual regulation was apparently increasingly being accepted, though not by everyone and not without many condi-

tions and ambiguities. Traditional birth attendants, on the other hand, were more likely to help women requesting abortion, mainly in order to protect adolescents young women from social ostracism if they were not married. It was clear that for many families the law was less important than the protection of their own reputation and that of the adolescent involved. The National Family Planning Coordinating Board (BKKBN) has given increased attention to the issue of abortion in Indonesia.

Colombia. In Colombia, a project recently completed consisted of the first ever, national survey of induced abortion, using a very innovative methodology. The results were striking: 23% of all women had had at least one abortion in their lifetime, and among ever-pregnant women, the proportion of women who had had at least one abortion reached 30%. The Presidential Counsel for Youth, Women and the Family, of the Office of the President of Colombia, has taken a special interest in the results of this project and consideration is being given to the formulation of reproductive health measures.

Development and assessment of fertility regulation technologies

Long-acting systemic methods

The Programme, in collaboration with the pharmaceutical industry, has developed two combined, once-a-month injectables: Cyclofem and Mesigyna. Both have been shown to be very effective. In 1993 the Programme convened a meeting of experts to review all the data available on these methods and to help iden-

tify further areas of research. The experts concluded that: "Both Cyclofem and Mesigyna are safe and effective products for fertility regulation, which can be added to the existing range of contraceptive methods. They can be used by all potential contraceptive users provided that precautions are taken to assess potential risk factors. They provide high efficacy, and a low incidence of side-effects, and the vaginal bleeding patterns are better than those seen with progestogen-only injectables". Both preparations were registered in 1993 in several countries.

Fertility regulating vaccines

Following the submission and approval of supplementary data requested by regulatory authorities, a Phase II clinical trial of the prototype anti-human chorionic gonadotrophin (hCG) vaccine was initiated in two centres in Sweden in December 1993. Research has continued on an advanced prototype anti-hCG vaccine, which would release the antigen at a steady rate over a period of time. A new company has been identified for the custom formulation of this preparation. A number of vehicles suitable for suspension and delivery of the advanced prototype anti-hCG vaccine were evaluated and several formulations with compositions that may make them acceptable for clinical use are being investigated further. Progress has been made in the basic vaccinology studies aimed at the development of an optimized anti-hCG vaccine which will be simpler, less expensive, and potentially more effective than the existing formulations. Preliminary studies have been carried out to determine the feasibility of developing an orally-active anti-hCG vaccine and further studies

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have been conducted to investigate the possibility of safely reversing the antifertility effect of the vaccine on demand.

Male methods

Hormonal methods. The Programme has conducted studies to find out if testosterone enantate-induced severe oligozoospermia (less than three million spermatozoa per ml of semen) is associated with an acceptable level of contraceptive efficacy. Preliminary results suggest that the contraceptive efficacy is high even when spermatogenesis is not fully suppressed. This preliminary finding, if borne out at the end of the study, has important implications for the development of hormonal methods for men. A multicentre study conducted in Indonesia has shown that DMPA can be used to suppress spermatogenesis to the same degree as testosterone enantate.

No-scalpel vasectomy. In 1993, the Programme, together with the Association for Voluntary Surgical Contraception and the Program for Appropriate Technology in Health (PATH), funded the remaking of an instructional/training video illustrating the no-scalpel vasectomy procedure. Copies of this video are being made available to service providers interested in introducing this method of vasectomy into national family planning programmes.

Intrauterine devices (IUDs)

Long-term studies carried out by the Programme on two copper IUDs, the TCu220C and TCu380A, have provided data on the continuous use of these devices for periods of up to eleven years.

The pregnancy rate for the TCu220C after eleven years of use was 6.3 per 100 woman-years, equivalent to an annual risk of accidental pregnancy with this device of less than 1%. The TCu380A device has an even lower pregnancy rate, 2.3 per 100 woman-years after eleven years of use, equivalent to an annual rate of less than 0.5%. In August 1993, largely as a result of these studies, the United States Food and Drug Administration extended the approved duration of use of the TCu380A from eight to nine years.

The Programme has also carried out a clinical trial to compare the performances of the TCu380A and the Multiload 375. In this study it was found that the pregnancy rate for the Multiload 375 up to three years of use was 2.8 per 100 woman-years, significantly higher than the corresponding rate of 1.4 per 100 woman-years for the TCu380A. Furthermore, at two and three years of use, the Multiload 375 had a higher expulsion rate than the TCu380A. This study will continue in order to collect data on at least six and seven years of use of these two devices.

In 1993 the Programme initiated a six-centre pilot study, involving a total of 55 volunteers, to assess the ease of insertion and the expulsion rate of a new implantable IUD (CuFix PP330) for post-delivery use. Preliminary results show that only one expulsion occurred in this study, whereas at least ten would have been expected with conventional IUDs.

Post-ovulatory methods

In a recently completed multicentre trial coordinated by the Programme, a combination treatment with the

antiprogesterone, mifepristone, plus prostaglandin has been shown to be an efficacious pharmacological approach to menstrual regulation. The overall success rate (97.4%) of the regimen employed in this first trial strongly suggests that the combination is potentially useful for menstrual regulation and probably also as a late luteal, once-a-month contraceptive.

Emergency contraception

To examine if mifepristone could be used as a new method of emergency contraception the Programme supported two randomized trials to compare the efficacy and side-effects of a single dose of 600 mg of mifepristone with those of the standard Yuzpe regimen. The studies confirmed the potential usefulness of antiprogesterones such as mifepristone for emergency contraception. In the two trials combined, 597 women were given mifepristone and none of them became pregnant whereas 35 pregnancies would have been expected among these women if no treatment had been given. Not only was mifepristone more efficacious, the women treated with it also reported less nausea and vomiting, as well as lower rates of other side-effects, than the women treated with the Yuzpe regimen.

Breast-feeding and birth spacing

The duration of lactational infertility is probably influenced by various other factors apart from the breast-feeding practice. However, there are no clear data on which factors are involved and to what degree. In 1989 the Programme launched a large prospective study to

investigate the various possible influences. The study, which included more than 4000 breast-feeding mothers and their infants, was carried out in seven countries: Australia, Chile, China, Guatemala, India, Nigeria, and Sweden. The clinical part of the investigation was completed at the end of 1993 and the data analyses will be carried out during 1994. It is anticipated that this study will provide information on how an individual woman can influence the length of her postpartum amenorrhoea by modifying her pattern of breast-feeding, and how the time of return to fertility may be predicted with reasonable accuracy.

Natural family planning

Scientists in Melbourne, Australia, have developed a home-based assay kit with which women can determine their fertile period by measuring estrone and pregnanediol glucuronides in the urine. A multicentre study conducted by the Programme has compared the efficacy of the kit with the subjective signs and symptoms monitored in conventional natural family planning methods. The study was completed in 1993 and preliminary results indicate difficulties with the kit in ensuring reproducibility of the assays and in identifying the rise in estrone glucuronide and, thus, the start of the fertile period.

Introduction and transfer of technology

During the biennium a new three-stage research strategy for the introduction of contraceptives was developed and begun to be implemented. This strategy is designed to assist decision-making by focusing on users' needs for additional

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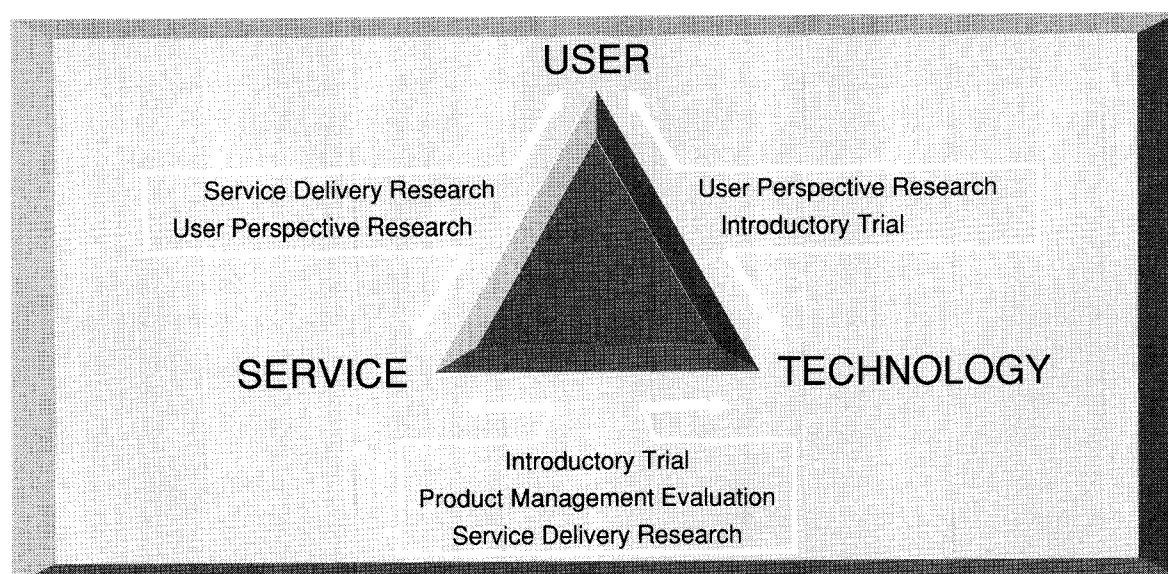
methods and the capability of the services to provide the methods with appropriate quality of care. It addresses the interfaces between the user, the service delivery system, and the technology (Fig. 3).

The first Stage I assessment was conducted in Brazil in late 1993. The assessment was undertaken by a multidisciplinary team which included representatives from the Ministry of Health, women's groups, research scientists, and the Programme. It found that in general family planning services in the public sector were limited. Where services were provided, the range of methods offered was generally less than what could have been made available. Imbalances in the method mix reflect problems of supply and service provision, which in turn has a significant influence on user demand. Of the methods included in the Ministry of Health family planning norms—oral contraceptives, intrauterine devices (IUDs), condoms, spermicides,

diaphragms, and natural methods—few were regularly available in the public sector. The assessment did not identify an immediate need for the introduction of additional methods into the public sector.

Stage II activities have been focused on the introduction of Cycloferm. Introductory trials were carried out on this once-a-month injectable to evaluate whether, under more routine service conditions, the use-effectiveness and reasons for discontinuation were similar to the findings in earlier clinical studies of safety and efficacy. The final analyses of the data from Indonesia, Jamaica, Mexico, Thailand, and Tunisia were reported at a WHO meeting held in Geneva in June 1993. The studies confirmed the high efficacy of Cycloferm but showed (as in the Phase-III clinical trials) major variations between countries in discontinuation on account of amenorrhoea and bleeding-related, or other medical reasons. Other causes of discontinuation were influenced by the limited availability of the

Fig 3. Interfaces between users, services and technologies



method and other service delivery issues.

The third Stage of the strategy involves the development of a strategic plan for ensuring the widespread availability of a method and includes: the preparation of training plans; establishment of necessary infrastructures; provision of information, education, and communication materials; undertaking quality assurance; upgrading logistics systems; and organization of supply sources and possible local production. Stage III studies will be designed and initiated in 1994 in connection with Cycloferm use in Indonesia, Mexico, and Thailand.

The Concept Foundation, Bangkok, Thailand, in collaboration with PATH, has continued to support the transfer of technology relating to the production of Cycloferm in Indonesia, Mexico and Thailand. Indonesia and Mexico are now producing full-scale industrial batches and have obtained registration of the product. In Thailand, the product is awaiting registration. Distribution agreements have been concluded for most Latin American countries.

Mesigyna, the second once-a-month injectable, was licensed to Schering AG, and has been registered in Argentina and Mexico. The company is now making plans to ensure widespread availability of this product in Latin America and Asia.

The Programme is also addressing issues of production and quality assurance of hormonal contraceptives. Work has continued on the development of a number of documents relating to product management. These are: *Considerations for the production of oral and injectable*

hormonal contraceptives; Requirements for the quality assurance of oral and injectable hormonal contraceptives; and A laboratory manual for the quality assurance of oral and injectable hormonal contraception. These documents are being developed in collaboration with PATH, the University of Warwick, UK, and the WHO's Division of Drug Management and Policies.

The document on *Requirements for the quality assurance of oral and injectable hormonal contraceptives* has been prepared to address the question of monitoring of the quality of hormonal contraceptives from the point of import into a country or receipt from a local manufacturing facility, through to the eventual use at the point of service delivery. This document, together with the laboratory manual of analytical and other test procedures, was assessed in mid-1993 at a training course held at the Zimbabwe Regional Drug Control Laboratory with participants from Kenya and Zimbabwe.

Infertility

The Programme is conducting research on subsequent fertility of women admitted to hospital with clinically suspected pelvic infection. Results available so far suggest that fertility up to 24 months after the original hospitalization is adversely affected to a degree which is proportional to the severity of the disease.

During the biennium the Programme made significant progress in its research on the development of a simple diagnostic test which is specific for acute

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chlamydial infection of the genital tract. The test is based on the detection of a secretory immunoglobulin A (SIgA) antibody which is specific to Chlamydia.

A study on condom preference in male sex workers in Bangkok, Thailand, was completed in 1993. Data were collected from 119 men through interviews which included questions on demographic characteristics, knowledge of AIDS and its prevention, condom use, and sexual practices. The study showed that male sex workers have intercourse not only with male clients but also with female clients and girl friends. These sexual networks are likely to exacerbate the rapid spread of STDs and the human immunodeficiency virus (HIV) into the general heterosexual population unless condoms are used regularly. The majority of the men preferred the condoms lubricated with the spermicide nonoxynol-9 as it was considered to have "disinfectant" properties.

A study to assess the acceptability of the female condom (or vaginal sheath) has been completed in Zimbabwe among health care providers and women at high risk of STD transmission. Fifty-five out of 59 women completed the two week trial. The women used an average of 7.3 female condoms in the first week and 7.7 in the second week. Nearly half (26) used the condom with a steady partner, the others with paying clients. After the second week, 51 liked the female condom "very much", although ten experienced some difficulty (mainly with the inner or outer ring of the device). Forty-eight women said they preferred it to the male condom and all would recommend it and use it if it became available. Favourable

responses from steady partners and clients were also reported.

A study of female sex workers in Bangkok, Thailand, was conducted in a massage parlour with approximately 300 masseuses. Among the two types of condom available—one lubricated with silicone oil and the other with nonoxynol—the latter type was chosen by 86%, with only 2% opting for the silicone-lubricated device.

Essential national research

Africa and Eastern Mediterranean

In the African and Eastern Mediterranean regions, the overall objectives remain the strengthening of selected centres and the stimulation of interest in reproductive health research. The principal mechanisms for achieving these goals are long-term support for upgrading research facilities and training in research methodology. During the biennium, 21 institutions in 12 countries in the two WHO regions received grants from the Programme (Table 4). Six of these countries were in the United Nations category of "least developed countries" (LDCs).

The development of regional and national strategic plans for research in reproductive health constitutes an important mechanism for promoting relevant research and research capability strengthening activities. In 1992 an Intercountry Research Needs Assessment Workshop was undertaken for the WHO Eastern Mediterranean Region in Cairo, Egypt, at which common priorities in reproductive health research were identified through the joint efforts of

Table 4. Grants awarded to institutions in the African and Eastern Mediterranean regions during 1992–1993, by objective

Country	Develop ¹ skills		Upgrade ² facilities		Maintain ³ resources	
	1992	1993	1992	1993	1992	1993
Benin	1		1	1		
Cameroon			1	1		
Egypt	1		1	1		1
Ethiopia	1		1	1		
Iran	1	1				
Kenya	3	2	1	1	3	3
Mozambique			1	1		
Nigeria	4		1	1	1	
Pakistan						1
Rwanda			1	1		
Sudan	1		1	1		
Tunisia			1			1
Uganda	1		1	1		
Zambia			1	1		1
Zimbabwe	1		1	1		
Total	14	3	13	12	4	7

¹ Includes Research Training Grants, Re-entry Grants and Grants for workshops and courses.

² Includes Research Needs Assessments, Long-term Institutional Development Grants and Reagent Programme Grants.

³ Includes Capital Grants, Resource Maintenance Grants, Small Grants, and Twinning Grants.

policy-makers, scientists, and the community (including women's health advocates).

In French-speaking Africa, the WHO Regional Centre for Training in Research in Family Health, Kigali, Rwanda, organized two training courses annually for doctors and paramedical staff in various aspects of reproductive health. In 1993 it held a regional training course in epidemiological methods in reproductive health research.

Two inter-country workshops were held in 1993 under the Programme's initiative of Technical Cooperation be-

tween Developing Countries (TCDC). The first, entitled Adolescent Reproductive Health, took place in Nairobi, Kenya, in February 1993 and included 14 participants from eight English-speaking African centres. Two of research projects developed during the workshop were selected for implementation.

The second workshop took place in Kribi, Cameroon, in November 1993 with 11 participants from 6 Francophone African countries. The theme of this workshop was "Constraints to Acceptability of Fertility Regulation Technologies in Africa". The workshop produced three draft research proposals.

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The Americas

The Programme awarded a total of 104 grants to institutions in the Americas (Table 5), representing nearly a threefold increase from 1986–1987. Grants were provided for the implementation of projects, research training, and technical cooperation among developing countries. Roughly two-thirds of the funds were allocated for regional and country activities, including institutional strengthening. Staff development accounted for nearly 22% of the total budget in 1992, decreasing to 11% in 1993.

Two formal training programmes in reproductive epidemiology have recently been developed by institutions in the

region with support from the Programme. A Master's Degree course in reproductive epidemiology was started in Mexico in March 1991, and a one-year tutorial course on the development of randomized clinical trials was initiated in 1992 at the Rosario Centre for Perinatal Studies (CREP), Rosario, Argentina.

The first North-to-South collaboration in the region was established between the Salvador Zubiran National Institute of Nutrition, Mexico, and the National Institute of Environmental Health Sciences in the USA. During the biennium these two institutions established a steering committee for the organization of a workshop on "Environmental Impact on Reproductive Health in Latin America". Planned for

Table 5. Grants awarded to institutions in the region of the Americas during 1992–1993, by objective

Country	Develop ¹ skills		Upgrade ² facilities		Establish ³ training		Maintain ⁴ resources	
	1992	1993	1992	1993	1992	1993	1992	1993
Argentina	8	1	2	1	1	1	1	3
Bolivia							1	
Brazil	3	1	1	1			2	2
Chile	8	1	4	4			3	
Colombia			1				1	1
Costa Rica			1					
Cuba	7	1	2	2	1		3	2
Guatemala		1					1	1
Mexico	3	1	2	2	2	2	3	3
Panama			1	1				
Peru	2	1	1	1				
Venezuela	1	1	1	1				1
Total	32	8	16	13	4	3	15	13

¹ Includes Research Training Grants, Re-entry Grants and Grants for workshops and courses.

² Includes Research Needs Assessments, Long-term Institutional Development Grants and Reagent Programme Grants.

³ Includes Basic Resources for Training Grants and Master's Degree Course Grants.

⁴ Includes Capital Grants, Resource Maintenance Grants, Small Grants and Twinning Grants.

1994, this workshop will serve to define better the research needs in this area.

In 1993 centres in Argentina, Chile, Cuba, Guatemala, and Mexico established, with support from the Programme, a regional network for epidemiological research in reproductive health. The first meeting of the network was held in May 1993. Since then scientists from the network have been assisting in the development of protocols and they are collaborating with the National Perinatal Epidemiological Unit at Oxford, UK, and the WHO Safe Motherhood Initiative. The centres involved plan to conduct multi-centre randomized controlled trials for the evaluation of reproductive health care interventions.

In an effort to increase regional self-reliance in the supply of hormonal assay reagents the Programme has been supporting two regional reagents programme for the past six years. The Cuba–Mexico Regional Reagent Programme is now producing reagent kits for the radioimmunoassay of testosterone, estradiol, progesterone, prolactin, follicle-stimulating hormone, and luteinizing hormone.

In collaboration with the Pan American Health Organization (PAHO) and the Commonwealth Caribbean Medical Research Council (CC-MRC), the Programme has begun to strengthen research capabilities of the English-speaking Caribbean countries. A Research Needs Assessment Workshop was held in Barbados in October 1992 to identify research needs and establish priorities based on reproductive health profiles of the countries, and to recommend actions

to be taken in designing research programmes. Representatives of health ministries and international funding agencies and scientists from 15 countries of the subregion attended the Workshop.

Asia and the Pacific

The strategy for the development of resources in Asia and the Pacific has the following five broad objectives:

- To make the Programme and its institutional development in Asia and the Pacific better known among scientific institutions and governments in the region.
- To encourage countries in the region to establish national priorities in research in reproductive health.
- To encourage intraregional cooperation.
- To generate additional support for the strengthening of research capacities in the region.
- To encourage regional self-reliance in training.

The Programme's support for collaborative activities was considerably expanded in Bangladesh, Myanmar, Nepal, and Viet Nam, and new activities were started in Laos and Mongolia. Altogether, some US\$ 1.7 million were deployed in support of institutional strengthening through the award of 105 grants for training activities and 53 grants for building up or maintenance of resources (Table 6). The grants were provided to 39 institutions in 15 countries, with 14 institutions in nine countries receiving the bulk of the funds. In addition, during the biennium, the Programme managed UNFPA Projects (worth US\$ 1.7 million) in China, the Democratic People's Republic of

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Table 6. Grants awarded to institutions in the Asia and Pacific region during 1992–1993, by objective

Country	Develop ¹ skills		Upgrade ² facilities		Establish ³ training		Maintain ⁴ resources	
	1992	1993	1992	1993	1992	1993	1992	1993
Bangladesh	3			1				
China	17	17	3	3	1	1	9	2
D.P.R. of Korea		6						
India	1	1					4	
Indonesia	4	5					3	2
Malaysia	1							
Mongolia	1	6	1	1				
Myanmar	1	1	1	1				
Nepal	2	3					1	1
Philippines	3	2					1	
Republic of Korea							1	1
Singapore	1		1	1				
Sri Lanka	4		1	2				
Thailand	1	3	1	1	2	2	2	2
Viet Nam	7	5	2	2			1	1
Regional	2	2						
Total	48	51	10	12	3	3	22	9

¹ Includes Research Training Grants, Re-entry Grants and Grants for workshops and courses.

² Includes Research Needs Assessments, Long-term Institutional Development and Reagent Programme Grants.

³ Includes Basic Resources for Training and Master's Degree Course Grants.

⁴ Includes Capital, Resource Maintenance, Small and Twinning Grants.

Korea, Indonesia, Mongolia, and Viet Nam.

As to regional activities, the Programme increased emphasis on regional cooperation through TCDC. The recruitment of experts from developing countries to help their less-developed neighbours was found to very effective, less expensive, and more culture-sensitive.

In order to promote greater awareness about the Programme's activities among professionals in the region, the Programme organized a one-day symposium on reproductive health research as a part

of the 14th Asia and Oceania Congress of Obstetrics and Gynaecology in Manila, the Philippines, which brought together scientists from institutions that have been developed by the Programme in recent years.

The Programme continued to support development of Master's degree programmes in Thailand (Bangkok, and Hat Yai) and China (Beijing). Also, the Programme has extensively used institutions in China, India, Singapore, and Thailand to host visiting scientists and trainees in a variety of research areas from several neighbouring countries.

